

SmartPReP[®] PRP Procedure Pack (PRP-1, PRP-1J & PRP-2)

Instructions for Use



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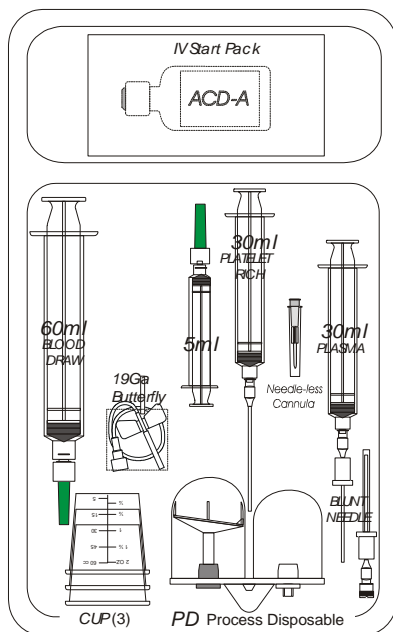
Indications for Use: The SmartPReP Procedure Pack is intended for use with the SmartPReP Platelet Concentrate System. The PRP-1 provides components for a single 60ml process, the PRP-2 provides components for a double 120ml process.

Contraindications: The use of the Harvest SmartPReP System may be contraindicated when there is clinical or laboratory evidence of septicemia; and for patients who have taken aspirin, or other medications that alter platelet function within 3 days prior to surgery, or patients with disorders associated with platelet dysfunction.

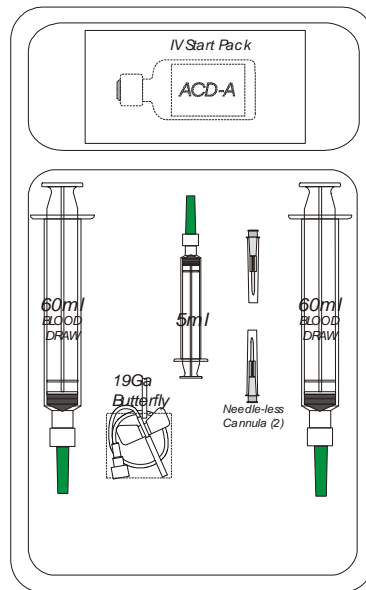
Warnings: 1) Federal law (USA) restricts this device to sale by, or on the order of a physician. The physician is solely responsible for the use of this device; 2) Plasma and platelets prepared with this system are not intended for transfusion.

Cautions: 1) Refer to SmartPReP Operator's Manual for additional information concerning centrifuge operation and maintenance; warnings and cautions; 2) Inspect product prior to use, do not use if tray pack is damaged or opened; 3) Always follow aseptic technique whenever entering a sterile container; wipe ACD-A and PD chamber access sites with alcohol pad prior to entry; 4) Aseptic technique, proper skin preparation, and continued protection of the venipuncture site are essential; 5) Dispose of blood contaminated disposable following hospital policy and procedures for biological waste, use Universal Precautions; 6) After processing, maintain PD upright. Tilting may spill fluids from one chamber to the other, affecting process results; 7) Separated blood products should be used within 4 hours of collection. 8) Do not resterilize, disposable is for single use only, discard all unused components at the end of the procedure.

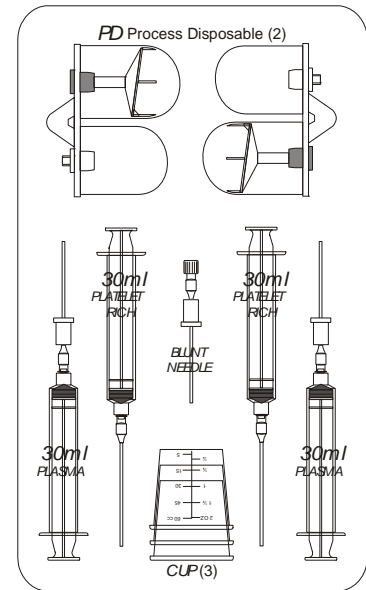
Procedure Pack components:



SINGLE PROCESS/PRP-1



BLOOD DRAW



DOUBLE PROCESS

PRP-1/Single Process Pack includes:

- 1-IV Start Pack
- 1-19 Ga Butterfly
- 1-5mL Syringe Assembly
- 1-60 mL Syringe Assembly
- 1-ACD-A anticoagulant, USP
- 1-Process Disposable (PD)
- 1-Needle-less Cannula
- 2- 30 mL Syringes
- 3-Blunt Needle Cannula
- 2 sets-3mL and 7mL Spacers
- 3-Sterile Plastic Cups

PRP-2/Double Process Pack includes:

- Blood Draw Kit
- 1-IV Start Pack
- 1-19 Ga Butterfly
- 1-5mL Syringe Assembly
- 2-60 mL Syringe Assemblies
- 2- Needle-less Cannula
- 1-ACD-A anticoagulant, USP

Double Process Kit

- 2-Process Disposable (PD)
- 4-30 mL Syringes
- 5-Blunt Needle Cannula
- 3 sets-3mL and 7mL Spacers
- 3-sterile Plastic Cups

NOTE: PRP-1J Procedure Pack do not contain the IV Start Pack, 19 Ga Butterfly, 5ml Syringe Assembly, 60ml Syringe Assembly, ACD-A Anticoagulant and Needle-less Cannula.

INSTRUCTIONS FOR USE:

Preparation of the Venipuncture Site

CAUTION: The health care professional responsible for blood collection should be trained in the practice of venipuncture and the inherent risks. Aseptic technique, proper skin preparation and continued protection of the venipuncture site are essential.

The following steps provide general guidelines for preparing the venipuncture site for blood collection:

1. Use the intravenous IV (19 Ga Butterfly) access catheter and IV Start Pack provided or other appropriate venous access (19 gauge or larger) to withdraw blood.

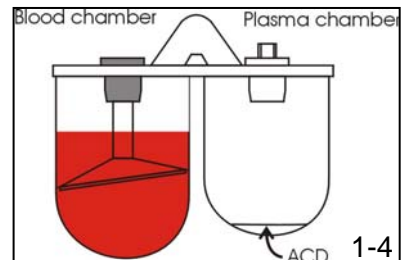
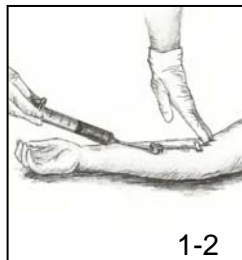
NOTE: A suitably large peripheral vein free of lesions should be selected, typically the antecubital or cephalic vein. A central venous line (preferably ≥ 19 gauge) may also be used. DO NOT USE ARTERIAL LINE FOR BLOOD DRAW.

2. Apply tourniquet or blood pressure cuff; identify venipuncture site and release tourniquet/cuff.
3. Scrub area at least 4 cm (1.5 inches) in all directions from the intended site of venipuncture for a minimum of 30 seconds with an aqueous solution of iodophor compound. Excess foam may be removed, but the arm need not be dry before the next step.
4. Starting at the intended site of venipuncture and moving outward in a concentric spiral apply 10% PVP-iodine solution; let stand for 30 seconds.
5. Cover the area with dry, sterile gauze until the time of venipuncture. After the skin has been prepared, it must not be touched again. Do not repalpate the vein at the intended venipuncture site.
6. Perform venipuncture, clamp IV access catheter and secure catheter to skin.

Drawing Patient Blood

NOTES: (1) Patient's blood should be drawn prior to the start of the procedure and before administration of any fluids (particularly systemic anticoagulants). (2) For PRP-1J Packs, the following items identified in the Blood Draw Instructions below are not included and must be provided separately: ACD-A Anticoagulant USP, 60ml Blood Draw Syringe and Needle-less Cannula.

1. Remove Processing Disposable(s) (PD) from packaging and place on an appropriate workspace.
2. Draw 9 mL of citrate anticoagulant into the 60 mL syringe(s). (Illustration 1-1)
3. Place 2 mL of citrate anticoagulant (ACD-A) into plasma chamber of the PD. (Illustration 1-4)
4. Connect syringe to IV access catheter (or alternative access site). Release clamp.
5. **GENTLY** draw blood from the patient (Illustration 1-2). **CAUTION:** excessive force may activate platelets and hemolyze red blood cells. The total volume in the syringe for female patients is **60 mL** (53 mL whole blood & 7 mL ACD-A). The total volume in the syringe for male patients is **55 mL** (48 mL whole blood & 7 mL ACD-A). Total syringe volume should be within ± 0.5 mL of volume specified. Close clamp on IV access catheter.
6. Invert the syringe several times to ensure **adequate mixing of the blood and anticoagulant**; **CAUTION:** inadequate mixing may cause the blood to clot in the syringe and/or may result in suboptimal process results.
7. Attach Needle-less cannula to the blood filled 60 mL syringe and dispense contents into the blood chamber of the PD (side with **RED** access site) (Illustration 1-3). If required, repeat steps 1 through 7 to fill a second PD.



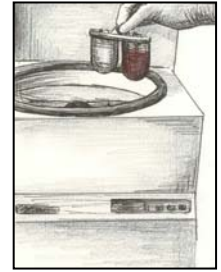
PROCESS VOLUMES: Whole blood volumes to be drawn into the 60 mL syringe to maximize platelet yields are as follows:

	Anticoagulant Vol.	Whole Blood Vol.	Total Syringe Vol.
Male Patients	7 mL	48 mL	55 mL
Female Patients	7 mL	53 mL	60 mL

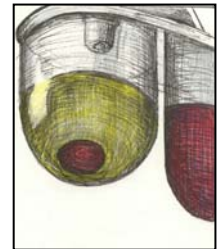
Blood Processing

1. **Load Centrifuge:** Place the PD into the SmartPReP System. To prevent system imbalance, be sure that equal volumes have been dispensed into each PD. Only (1) PD is available with the PRP-1 kit. **CAUTION:** Use appropriate Balance Weight when running one PD (PDR-1 or AT-Adapter). Without Balance Weight, resulting imbalance will shutdown centrifuge.

CAUTION: Do not force Processing Disposable into Rotor Trunnion. The Processing Disposable should fit snugly but should not require excessive force to install. If resistance is experienced, check for obstructions in the Rotor and/or debris on the Process Disposable.



2. Close lid on machine and press **GREEN** button to start the process.
3. Remove PD(s) when cycle is complete.
4. **Platelet Resuspension:** Typical plasma volumes used for platelet resuspension are 7-10 mL. Using the 30 mL syringe with blunt cannula and two white spacers, withdraw plasma volume from plasma chamber of PD until air enters the syringe. If BOTH white spacers are attached to the blunt needle, this will leave approximately 10 mL of PPP in the PD, if the small spacer is removed, this will leave approximately 7 mL of PPP in the PD. **NOTE:** the spacer on the blunt needle determines the volume of concentrated platelet product produced in the PD.
5. Transfer PPP to the yellow specimen cup located in sterile field.



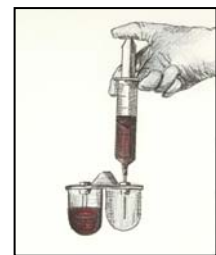
FINAL Volume in PD	Approx. VOL
Two Spacer Attached (Large & Small)	10 mL
One Spacer Attached (Large)	7 mL

6. To resuspend the platelets into a concentrated platelet rich plasma (PRP):
 - Withdraw remaining PPP into new 30 mL syringe with blunt needle (NO SPACERS) and gently inject back into the plasma chamber.
 - Repeat above step 2-3 times (until platelets are visibly resuspended in the plasma) and withdraw total volume into syringe.
 - Observe base of plasma chamber to confirm all platelets have been withdrawn into 30 mL syringe.
7. Transfer concentrated platelets to the red specimen cup located on sterile field.



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

CAUTION: Excess blood products should be disposed of in accordance with policies for disposal of biohazardous waste.



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Developing technologies for accelerating healing, naturally®

Harvest Technologies Corp
40 Grissom Road, Suite 100
Plymouth, MA 02360
Phone (508) 732-7500 Fax (508) 732-0400
www.harvesttech.com

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