

SmartPREP2 APC+[®] Procedure Pack

Instructions for Use



HARVEST[®]

Developing technologies for **accelerating healing, naturally**[™]

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Indications for Use: The SmartPReP2 Procedure Pack is intended for use with the SmartPReP2 Platelet Concentrate System. The system is provided in three sizes for low, medium, and large volume procedures; APC-20, APC-60 and APC-120, respectively.

Contraindications: The use of the Harvest SmartPReP2 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 SmartPReP2 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:

APC-20/Single Process Pack includes:

- 1-IV Start Pack
- 1-19 G IV Fistula
- 1-3 mL Anticoagulant Syringe Assembly
- 1-20 mL Blood Draw Syringe Assembly
- 1-ACD-A anticoagulant, USP
- 1-20 mL Process Disposable (PD)
- 1-20 mL Plasma Syringe with Blunt Cannula and Spacer (s)
- 1-10 mL PC Syringe with Cannula
- 1-10 ml Syringe (spare)
- 1-Blunt Plastic Cannula
- 3-Sterile Plastic Cups

APC-60/Single Process Pack includes:

- 1-IV Start Pack
- 1-19 G IV Fistula
- 1-3 mL Anticoagulant Syringe Assembly
- 1-60 mL Blood Draw Syringe Assembly
- 1-ACD-A anticoagulant, USP
- 1-60 mL Process Disposable (PD)
- 1-30 mL Plasma Syringe with Blunt Cannula and 2 Spacers
- 1-20 mL PC Syringe with Blunt Cannula
- 1-10 ml Syringe (spare)
- 1-Blunt Plastic Cannula
- 3-Sterile Plastic Cups

APC-120/Double Process Pack includes:

- 1-IV Start Pack
- 1-19 G IV Fistula
- 1-5 mL Anticoagulant Syringe Assembly
- 2-60 mL Blood Draw Syringe Assemblies
- 1-ACD-A anticoagulant, USP
- 2-60 mL Process Disposable (PD)
- 1-30 mL Plasma Syringes with Blunt Cannula and Spacers
- 2-20 mL PC Syringe with Cannulae
- 1-10 ml Syringe (spare)
- 1-Blunt Plastic Cannula
- 3-Sterile Plastic Cups

Note: APC-20i, APC-60i and APC-120i products do not include an IV Start Pack

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(Fistula) 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 1% 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

NOTE: Patient's blood should be drawn prior to the start of the procedure and before administration of any fluids (particularly systemic anticoagulants).

1. Remove Processing Disposable(s) (PD) from packaging and place on an appropriate workspace.
- 2a. Draw the appropriate amount of anticoagulant (ACD-A) into the blood draw syringe per Table 1. Draw the appropriate amount of ACD-A into the anticoagulant syringe assembly (Ref. Table 1) and transfer ACD-A into the plasma chamber (white port) of the PD. (Ref. III. 1-2)

Table 1 – Anticoagulant Dispensing

PD Size	Plasma Side of PD	Blood Draw Syringe
20 ml	1 ml	2 ml
60 ml	2 ml	6 ml

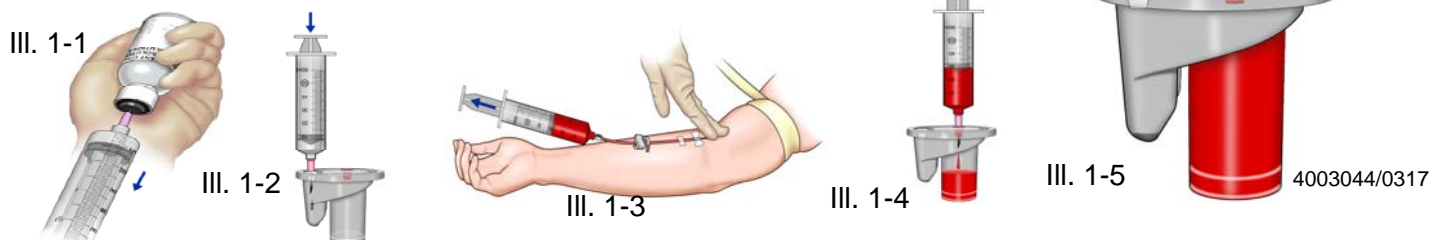
- 2b (Alternate Office Protocol) Draw 3 ml of ACD-A (APC-20) or 8 ml ACD-A (APC-60) into the appropriate blood draw syringe. Transfer 1 ml ACD-A from the 20 ml syringe or 2 ml ACD-A from the 60 ml syringe into the plasma chamber (white port) of the PD. (ref. III. 1-2)
3. Connect the blood draw syringe to IV access catheter (or alternative access site). Release clamp.
4. **GENTLY** draw blood from the patient (III. 1-3). For the 20 ml PD, fill the syringe to the 3/4 oz. mark (approximately 22 ml volume). For the 60 ml PD, fill the syringe to 60 ml total volume. Close IV access catheter clamp and disconnect the syringe.

CAUTION: Excessive force may activate platelets and hemolyze red blood cells.

5. 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.

6. Attach a Blunt Needle cannula to the blood filled syringe and dispense contents into the blood chamber of the PD through the **RED** access site (III. 1-4, 1-5).



Blood Processing

1. **Load Centrifuge:** Place the PD into the SmartPReP2 System. Insert the appropriate reusable Balance Weight into the opposite bucket; BW-20 for the 20 ml PD, BW-60 for the 60 ml PD.

CAUTION: Use appropriate Balance Weight when running one PD. Without Balance Weight, the resulting imbalance will shutdown centrifuge.

CAUTION: Do not force the PD or BW into Rotor Trunnion. The PD and BW 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 PD and/or BW.



2. Close lid on machine, the AMBER "LID OPEN" light must be off. Press GREEN "START" button to start the process. Total processing time is approximately 14 minutes.

3. Remove PD (s) when cycle is complete.

- 4.a. **Platelet Resuspension, 20 ml PD:** The plasma volume used for platelet resuspension is 3 mL*. Using the plasma syringe with blunt cannula and white spacer, withdraw plasma volume from plasma chamber of PD until air enters the syringe. Approximately 3 mL of PPP and platelet concentrate (PC) will be left in the PD

* For 2.5mL of PC, remove the optional thin spacer and repeat the procedural steps in 4a.

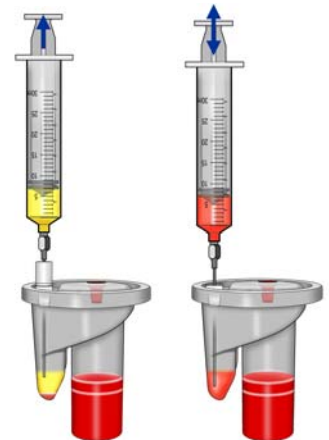


- 4.b. **Platelet Resuspension, 60 ml PD:** The plasma volume used for platelet resuspension is 10 mL. Using the plasma syringe with blunt cannula and two white spacers, withdraw plasma volume from plasma chamber of PD until air enters the syringe. Approximately 10 mL of PPP and PC will be left in the PD. By first removing the smaller of the two spacers, 7 ml of PPP and PC will remain in the PD.

5. Transfer the recovered PPP to the yellow cup located in sterile field.

6. To resuspend the platelets into a concentrated platelet rich plasma (PRP):

- Withdraw remaining PPP into new PC syringe with blunt needle (NO SPACER) 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 PC syringe.



7. Transfer concentrated platelets to the red specimen cup located in 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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