

HARVEST[®]

SmartPReP[®] 2 Bone Marrow Procedure Pack

Instructions for Use

MARROW TRANSFER



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Indications for Use: The SmartPREP 2 Bone Marrow Processing Pack used in conjunction with the SmartPREP2 Centrifuge System is intended to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of a cell concentrate from bone marrow.

Warnings: 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

Precautions: 1) Refer to SmartPREP2 Operator's Manual for additional information concerning centrifuge operation and maintenance; contraindications, warnings and cautions; 2) Inspect product prior to use, do not use if procedure 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 and proper skin preparation during collection of bone marrow aspirate are essential; 5) The safety and effectiveness of this device for in vivo indications for use has not been established; 6) Dispose of contaminated disposable following hospital policy and procedures for biological waste, use Universal Precautions; 7) After processing, maintain PD upright. Tilting may spill fluids from one chamber to the other, affecting process results; 8) Do not resterilize, disposable is for single use only; discard all unused components at the end of the procedure.

BONE MARROW ASPIRATION PACK			BONE MARROW PROCEDURE PACK		
BMAC 60	BMAC 120	Sterile Field Components	BMAC 60	BMAC 120	Bone Marrow Aspirate Processing Components
1	1	Blood Transfer Bag	1	2	Process Disposable (PD)
1	1	Bag Spike Assy	1	1	10 mL Anticoagulant Syringe/Needle Assy
		Aspiration Syringe Kit	1	2	30 mL Plasma Syringe w/Blunt Cannula & Spacer
2	4	60 mL BMA Transfer Syringe w/Fem/Fem	1	0	20 mL BMAC Syringe w/Blunt Cannula
1	1	Blunt Fill Needle	0	2	30 mL BMAC Syringe w/Blunt Cannula
2	4	Blunt Plastic Cannula			
2	2	20 mL BMAC Receive Syringe w/Fem/Fem	1	1*	Blood Filter
			1	1*	ACD-A Kit
2	4	30 mL BMA Aspiration Syringe		*	30 mL ACD-A Vial Packed with 20 mL Transfer Syringe
1	1	Needless Injection Site			and Blunt Fill Needle
1	2	BMA Aspiration Needle			DO NOT PASS VIAL or BLOOD FILTER INTO STERILE FIELD
					● Kits are available w/o Aspiration Needles

INSTRUCTIONS FOR USE:

Draw Bone Marrow Aspirate

NOTE: Bone Marrow should be collected only by qualified medical professionals using proper anticoagulation (i.e., ACD-A) and sterile techniques. Dilution with peripheral blood can be minimized and bone marrow-derived cell concentration maximized by limiting the aspiration volume per puncture. A minimum of **55 to 60mL** of anticoagulated bone marrow is required per process disposable. For best results, bone marrow should be collected in heparin-coated syringes. **Heparin / sodium chloride bath consisting of a minimum of 25 mL of heparin / sodium chloride in a concentration of 2000 µ/mL.** Refer to the Instructions for Use accompanying the aspiration needles for additional instructions and information.

Prepare Aspiration Syringes and Blood Transfer Bag

Pass contents of Bone Marrow Aspiration Pack to sterile field (Circulator Nurse).

1. Pass Sterile Field Wrapped Blood Bag and BMA Aspiration Needle(s) to sterile field.
 - a. Close Blue Tubing Clamp
 - b. Slide needle cover over Blood Bag Needle
2. Transfer minimum of 25 mL **Heparin / Sodium Chloride solution (2000 µ/mL)** to labeled beaker/basin in sterile field.
3. Replace Injection site on Bag Spike with Needless Injection Site.
4. Rinse aspiration & transfer syringes & Needless Injection /Bag Spike with heparin solution (2000 µ/mL). Ensure heparin solution has coated the entire marrow contacting surfaces.
5. Rinse Aspiration Needles and Stylets with heparin solution so that all marrow-contacting (including needle lumen) surfaces are coated.
6. Return any remaining heparin from the syringe to the beaker/basin.
7. Insert Needless Injection/Bag Spike into the blood transfer bag (Scrub Nurse).
8. Transfer the ACD-A solution (4 mL for 60 mL marrow collection; 8 mL for 120 mL marrow collection) using the 20 mL syringe to the scrub tech/nurse holding the 20 mL ACD-A Receiving syringe w/Fem/Fem
9. Place 4 mL of ACD-A into blood transfer bag for every 60 mL Bone Marrow to be collected. Ensure ACD-A coats entire inside surface of the Blood Bag.

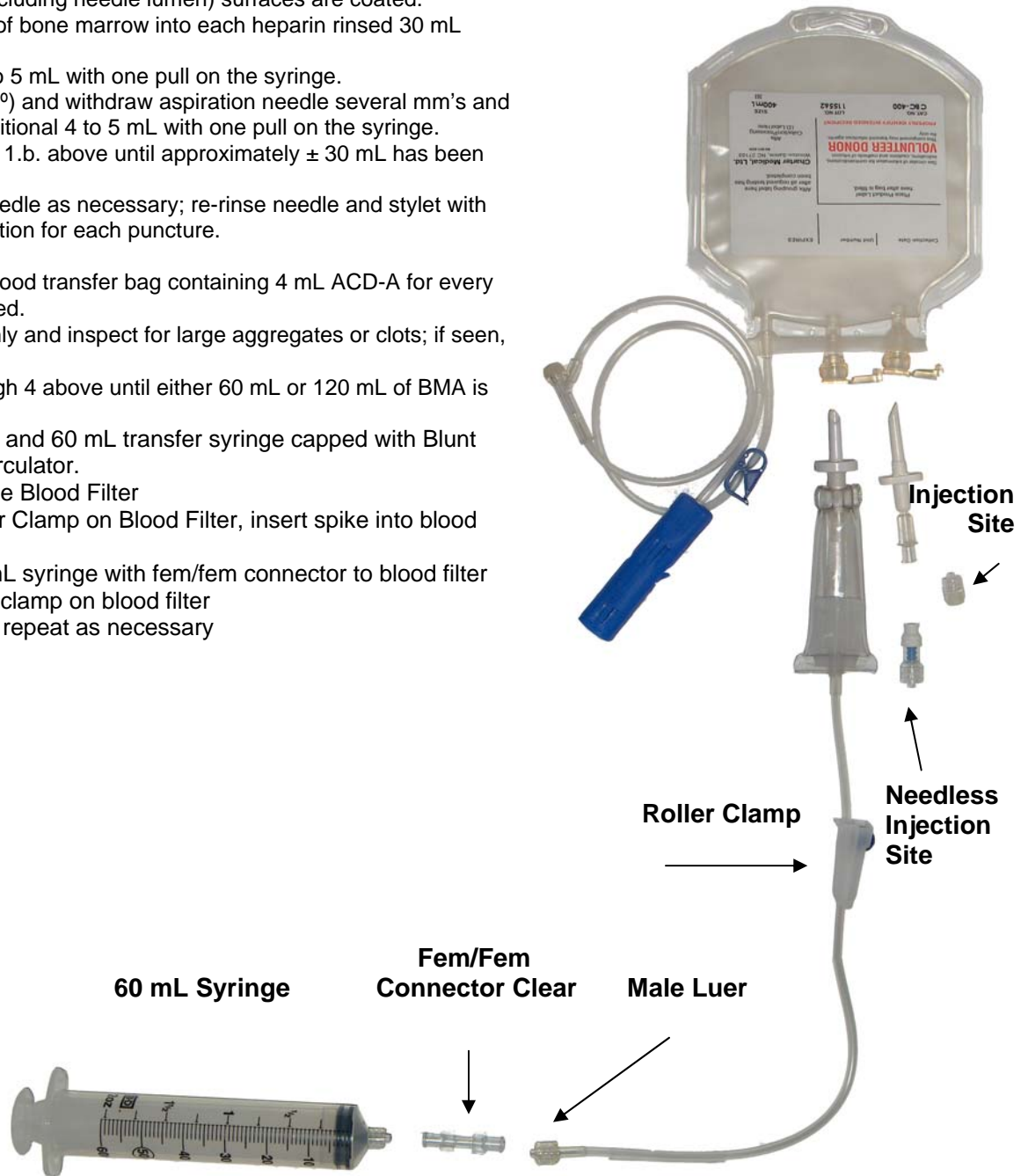
BMA Blood Bag

Collect and Inspect Aspirate (Recommendations)

1. Rinse Aspiration Needles and Stylets with heparin solution so that all marrow-contacting (including needle lumen) surfaces are coated.
2. Aspirate up to 30 mL of bone marrow into each heparin rinsed 30 mL aspiration syringe.
 - a. Draw up 4 to 5 mL with one pull on the syringe.
 - b. Rotate ($\pm 90^\circ$) and withdraw aspiration needle several mm's and draw an additional 4 to 5 mL with one pull on the syringe.
 - c. Repeat step 1.b. above until approximately ± 30 mL has been collected.
 - d. Re-direct needle as necessary; re-rinse needle and stylet with heparin solution for each puncture.

Marrow Transfer Bag

3. Transfer aspirate to blood transfer bag containing 4 mL ACD-A for every 60 mL marrow collected.
4. Mix contents thoroughly and inspect for large aggregates or clots; if seen, record on run sheet.
5. Repeat Steps 1 through 4 above until either 60 mL or 120 mL of BMA is collected.
6. Pass filled blood bag and 60 mL transfer syringe capped with Blunt Plastic Cannula to circulator.
7. Spike the bag with the Blood Filter
 - a. Close Roller Clamp on Blood Filter, insert spike into blood bag
 - b. Attach 60 mL syringe with fem/fem connector to blood filter
 - c. Open roller clamp on blood filter
 - d. Fill syringe, repeat as necessary



Transferring Bone Marrow Aspirate to Processing Disposable

1. Remove Processing Disposable(s) (PD) from packaging and place on an appropriate workspace.
2. Slowly dispense 60 mL BMA into the marrow chamber of the PD through the RED access site (Ref. Figures 1 and 2).



Fig 1



Fig 2

Bone Marrow Aspirate Processing

1. **Load Centrifuge:** Place the PD (or PD's) into the SmartPReP2 System. Insert the appropriate reusable Balance Weight (BW) into the opposite bucket; BW-60 for the 60 mL PD if centrifuging only one PD. **Note:** Align the white dots on the PD and balance weight to the white dot on the rotor for proper alignment.

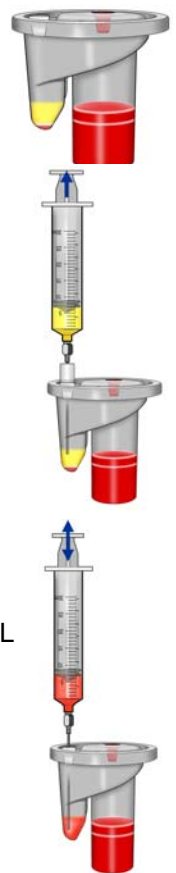
CAUTION: Use appropriate Balance Weight when running one PD. Without Balance Weight, the resulting imbalance will shutdown centrifuge.

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. **Cell Resuspension, 60 mL PD:** The plasma volume used for cell resuspension is based on user discretion. The syringe with blunt cannula and white spacers is used to withdraw unwanted plasma from the plasma chamber of PD by being careful not to disturb the lower cell layer and drawing until bubbles are observed. (**Note:** Using both spacers will leave approximately 10 mL in the plasma chamber while removing one spacer will leave approximately 7 mL. It is not advised to remove any more spacers as removal of the plasma will then tend to disturb the cell layer at the base of the plasma chamber.) Using the gradations on the syringe a known volume of plasma may be dispensed back into the plasma chamber to adjust the final volume of desired concentrate.



5. To resuspend the bone marrow cells into the plasma:
 - Withdraw remaining plasma into 30mL (20 mL in the BMAC 60 Kit) BAMC syringe with blunt needle (NO SPACER) and gently inject back and forth into the plasma chamber.
 - Repeat above step 2-3 times (until cells are visibly resuspended in the plasma) and withdraw total volume into syringe.
 - Observe base of plasma chamber to confirm all cells have been withdrawn into BAMC syringe.
6. Transfer back into sterile field by connecting BAMC syringe to sterile luer lock connector on 20 mL sterile BAMC Receiving syringe held by the scrub nurse in the sterile field.

