1000031832
(REV. A)

HARVEST® BONE MARROW ASPIRATE CONCENTRATE (BMAC®2) PROCEDURE PACK

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IMPORTANT INFORMATION ON HARVEST® BONE MARROW ASPIRATE CONCENTRATE (BMAC®2) PROCEDURE PACK
51416 (BMAC2-30-07), 51417(BMAC2-60-07), 51418 (BMAC2-120-07)
GLOBUS MEDICAL 1000031832
RX ONLY

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WITHIN THE UNITED STATES ONLY

ENGLISH

IMPORTANT INFORMATION ON HARVEST® BONE MARROW ASPIRATE CONCENTRATE (BMAC®2) PROCEDURE PACK

INDICATIONS
The SmartPrep® Bone Marrow Procedure Pack used in conjunction with the SmartPrep® Centrifuge System is intended to be used in the clinical laboratory or intra-operatively at the point of care for the safe and rapid preparation of a cell concentrate from bone marrow.

CONTRAINDICATIONS
Heparin sodium should not be used in patients in the following situations:

- If the patient has a hypersensitivity to heparin.
- If the patient has an uncontrollable active bleeding state, except when this is due to disseminated intravascular coagulation.
- If there is an inability to perform suitable blood coagulation testing, such as whole blood clotting time, partial thromboplastin time, etc., at the required intervals.

There is usually no need to monitor the effect of low-dose heparin in patients with normal coagulation parameters.

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. For bone marrow aspirate concentrate (BMAC) processing, the safety and effectiveness of this device for in vivo indications for use has not been established.
4. This device is only intended for use on a single patient during a single procedure, and it should not be used for multiple patients.
5. **Do Not Reuse/Not for Reuse**: Globus Medical products bearing the "Do Not Reuse" 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. Do not pass the packaging of the sterile components into the sterile field.
6. All bone marrow 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.
7. Disposables that have come in contact with bone marrow 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 bone marrow samples and bone marrow products.
8. Separated bone marrow products should be used within four (4) hours of collection.
9. 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.
10. 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.
11. If the system is not loaded properly, an imbalance will occur, and the system will stop the processing cycle.
12. 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.
13. To ensure proper device operation, allow the procedure pack or kit to come to room temperature before use.
14. 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.
15. The BMAC® Procedure Packs should only be used with the SmartPrep Centrifuge System.

PROCEDURE PACK COMPONENTS

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Caution: Follow sterile technique whenever you are passing components into the sterile field.
Caution: Do not pass the packaging of the sterile components into the sterile field.
Caution: Ensure all required components from the table below are present in the applicable procedure pack before you begin the procedure.

BMAC® Aspiration Kit

51416 (BMAC2-30-07)	51417 (BMAC2-60-07)	51418 (BMAC2-120-07)	Component
–	–	2	60 mL BMA Vacuum Pressure Aspiration Syringe
–	–	4	30 mL BMA Vacuum Pressure Aspiration Syringe
–	–	2	20 mL ACD-A Receive Syringe with Female-Female Luer Lock Connector
–	–	2	20 mL BMAC® Receive Syringe with Female-Female Luer Lock Connector

BMA Process Kit

51416 (BMAC2-30-07)	51417 (BMAC2-60-07)	51418 (BMAC2-120-07)	Component
–	1	2	60 mL Process Disposable
1	–	–	30 mL Process Disposable
–	1	2	30 mL Plasma Syringe with Blunt Cannula and Spacers
1	–	–	20 mL Plasma Syringe with Blunt Cannula and Spacers
1	–	–	10 mL BMAC® Syringe with Blunt Cannula
–	1	–	20 mL BMAC® Syringe with Blunt Cannula
–	–	2	30 mL BMAC® Syringe with Blunt Cannula

BMAC® Sterile Field Components

51416 (BMAC2-30-07)	51417 (BMAC2-60-07)	51418 (BMAC2-120-07)	Component
1	1	1	10 mL ACD-A Transfer Syringe
2	2	1	Blunt Fill Needle (red, used with ACD- A Syringe)
–	–	2	60 mL BMA Transfer Syringe
–	–	2	Blunt Plastic Cannula (used with BMA Transfer Syringe)
1	1	1	Patient Label Sheet (6 labels)
1	1	2	Bone Marrow Aspiration (BMA) Needle 11 G (Blunt and Sharp Stylets)
1	1	1	300 mL MarrowPrep® Filter Bag
1	1	1	ACD-A, 30 mL
2	2	–	Alcohol Pad
1	1	–	20 mL Syringe
1	1	–	Sterile Convenience Kit

MarrowPrep® Filter Bag Diagram

1. Needleless access input valve (referred to throughout these instructions as the input valve)
2. Needleless access output valve (referred to throughout these instructions as the output valve)

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

Bone marrow should be collected only by qualified medical professionals using aseptic technique and an appropriate anticoagulant, such as Anticoagulant Citrate Dextrose Solution A (ACD-A). To maximize the bone marrow-derived cell concentration and minimize the dilution of the bone marrow with peripheral blood, limit the aspiration volume per puncture.

For best results, collect the bone marrow in syringes coated with heparin. The heparin/sodium chloride solution referred to in the following instructions consists of a minimum of 25 mL of heparin/sodium chloride in a concentration of 2000 IU/mL. Refer to the Instructions for Use accompanying the aspiration needles for additional instructions and information.

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.

PREPARING THE ASPIRATION SYRINGES AND THE ASPIRATION NEEDLES
1. Remove all outer component packaging.
2. Pass the contents of the BMAC® Procedure Pack into the sterile field.
3. Transfer a minimum of 25 mL of heparin/sodium chloride solution to a suitable container.
4. Rinse the BMA aspiration syringes with the heparin/sodium chloride solution.
5. Ensure that the heparin/sodium chloride solution has coated all surfaces of the syringes that will contact the bone marrow.
6. Rinse both the sharp and blunt BMA aspiration needles with the heparin/sodium chloride solution.
7. Ensure that the heparin/sodium chloride solution has coated all surfaces of the needles that will contact the bone marrow, including the lumens.
8. Return any remaining heparin/sodium chloride solution to a suitable container.

COATING THE MARROWPREP® FILTER BAG WITH ACD-A
1. Transfer the ACD-A solution to the scrub tech/nurse.
2. Close the white slide clamp between the filter and the MarrowPrep® filter bag.
3. Remove and discard the red cap from the input valve on the MarrowPrep® filter bag.
4. Inject 2 mL of ACD-A into the MarrowPrep® filter bag for every 30 mL of bone marrow to be collected, as shown in Figure 1.

Figure 1: Injecting ACD-A into the MarrowPrep® filter bag

5. Mix the contents of the MarrowPrep® filter bag thoroughly to ensure that ACD-A coats the entire inside surface of the bag.

COLLECTING THE BONE MARROW ASPIRATE (RECOMMENDATIONS)
1. Use a sharp BMA aspiration needle to gain initial entry into the bone marrow space (approximately 2 cm), as shown in Figure 2.

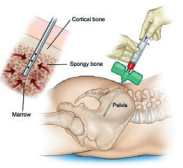

Figure 2: Gaining entry into the bone marrow space

2. Replace the sharp stylet with the blunt stylet (11 G needle only) if necessary, and advance the needle further into the bone marrow space.
3. Remove the stylet from the BMA aspiration needle, and attach one of the BMA aspiration syringes that was rinsed with the heparin/sodium chloride solution.
4. Complete the following steps to aspirate the bone marrow into the BMA aspiration syringe:
   a. Draw up a small volume with one pull on the BMA aspiration syringe; rotating the plunger allows small vacuum steps to ease aspiration.

b. Rotate 90° and withdraw the BMA aspiration needle several millimeters, and draw an additional small volume with one pull on the syringe.

c. After the BMA aspiration syringe is filled, remove it from the BMA aspiration needle and attach an empty BMA aspiration syringe to the needle.

d. Repeat steps a through c until each BMA aspiration syringe is filled.

Note: Redirect the aspiration needle as necessary. Rinse the BMA aspiration needle and the stylet with the heparin/sodium chloride solution before each attempt at puncture and re-entry.

FILTERING THE BONE MARROW ASPIRATE

1. Attach the BMA aspiration syringe to the input valve on the MarrowPrep® filter bag, and inject the bone marrow aspirate into the bag, as shown in Figure 3.

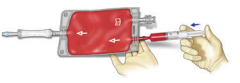

Figure 3: Injecting the BMA into the MarrowPrep® filter bag

2. Mix the contents of the MarrowPrep® filter bag thoroughly and inspect for large aggregates or clots. If you observe any large aggregates or clots, record the observation per your institution's standard operating procedure.
3. Repeat steps 1 and 2 until the MarrowPrep® filter bag contains the desired volume of bone marrow aspirate.
4. Open the white slide clamp and gently squeeze the filter chamber to allow the bone marrow aspirate to enter the filter chamber.
5. Mix the contents of the MarrowPrep® filter bag thoroughly.
6. Attach a BMA transfer syringe to the output valve on the MarrowPrep® filter bag, and fill the syringe, as shown in Figure 4.

Figure 4: Filling the BMA transfer syringe

7. Attach a blunt plastic cannula to the BMA transfer syringe that you have filled with bone marrow aspirate; repeat steps 6 and 7 as necessary.
8. Pass the BMA transfer syringe(s) out of the sterile field for processing.

PREPARING THE PROCESS DISPOSABLE

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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.

1. Remove the process disposable(s) from the packaging and place it on an appropriate workspace.
2. Insert the BMA transfer syringe into the red port on the process disposable, as shown in Figure 5, and dispense the contents into the marrow 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 bone marrow aspirate.

Figure 5: Dispensing the bone marrow aspirate into the marrow chamber

PROCESSING THE BONE MARROW ASPIRATE 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.

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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.
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 BMAC® 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 Figure 6.

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

RESUSPENDING THE CELLS

To adjust the volume of plasma used for resuspending the cells, you can remove a syringe/cannula spacer from the plasma syringe. The spacers determine the volume of fluid that is withdrawn from the plasma chamber. Use the information in the following table to determine how many spacers to remove to achieve a certain volume of fluid in the plasma chamber.

Adjusting the volume of plasma for resuspending cells

	Volume of fluid in the plasma chamber for resuspension	Number of spacers to remove
30 mL Process Disposable	10 mL	None (use 2 spacers that remain)
	3 mL	1 (use 1 spacer that remains)
60 mL Process Disposable	10 mL	None (use 2 spacers that remain)
	7 mL	1 (use 1 spacer that remains)

If you remove more spacers than recommended, you could disturb the cell layer at the base of the plasma chamber. Using the gradations on the plasma syringe, you can dispense a known volume of plasma back into the plasma chamber to adjust the final volume of the concentrate.

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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.

1. If necessary, remove a spacer from the plasma syringe without touching the cannula.
2. Use an alcohol pad to wipe the white port of the process disposable with a circular motion prior to entry.
3. Insert the plasma syringe with the blunt cannula and spacers into the white port on the process disposable.
4. Withdraw the supernatant from the plasma chamber of the process disposable without disturbing the lower cell layer, as shown in Figure 7. Withdraw the supernatant until you observe bubbles in the syringe.

Figure 7: Withdrawing the supernatant

5. Withdraw the remaining plasma into the BMAC® syringe with a blunt cannula and no spacer.
6. Gently inject the fluid into and withdraw it out of the plasma chamber, as shown in Figure 8. Repeat this 2 to 3 times until the cells are visibly suspended in the plasma.

Figure 8: Gently injecting and withdrawing the fluid

7. Once the cells are suspended, draw the total volume into the BMAC® syringe.
8. Observe the base and walls of the plasma chamber to confirm that all cells have been drawn into the BMAC® syringe.
9. Transfer the BMAC® into the sterile field by connecting the BMAC® syringe to the luer lock connector on the BMAC® receiving syringe, as shown in Figure 9.

Figure 9: Transferring the BMAC® into the sterile field

STORAGE CONDITIONS

Long-term Storage Range: 15 °C to 25 °C (59 °F to 77 °F)

Permitted Excursions: –20 °C to 20 °C (–4 °F to 68 °F) for up to 72 hours, Up to 50 °C (122 °F) for 1 week

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)
	DO NOT RESTERILIZE		TEMPERATURE RANGE
	PRODUCT QUANTITY		DO NOT USE IF PACKAGE IS DAMAGED
Rx ONLY	PRESCRIPTION ONLY		