



Precautionary Statement (01-50-1438)

Biomet Biologics, Inc. **01-50-1438**

P.O. Box 587

Date: 06/07

56 East Bell Drive

Warsaw, Indiana 46581 USA

MarrowStim™ Concentration Kit or MarrowStim™ Mini Concentration Kit

ATTENTION OPERATING SURGEON

NOTE: FOR SINGLE USE ONLY. Discard the entire disposable kit after one use, using acceptable method for potentially contaminated blood products.

DESCRIPTION

MarrowStim™ Concentration Kit

The MarrowStim™ Concentration Kit separates 60ml of the patient's blood or bone marrow components by density through the use of the MarrowStim™ cell separator.

MarrowStim™ Mini Concentration Kit

The MarrowStim™ Mini Concentration Kit separates 30ml of the patient's blood or bone marrow components by density through the use of the MarrowStim™ Mini cell separator.

The above listed kits are to be used with a centrifuge distributed by Biomet Biologics, Inc. ("BBI").

MATERIALS

The materials used for syringes, needles, tubing, connectors, and cell separators consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices.

All components in these kits are packaged, labeled and sterilized as indicated by the manufacturer's labeling.

All components in these kits are latex-free.

ACD-A is an anticoagulant supplied by Citra Anticoagulants, Inc., Braintree, MA, and manufactured by Cytosol Laboratories, Inc., Braintree, MA. For further information regarding ACD-A, please contact the supplier at 1-800-299-3411.

The ACD-A provided is only for use with the MarrowStim™ and MarrowStim™ Mini Concentration Kits.

INDICATIONS

The MarrowStim™ Concentration Kit and MarrowStim™ Mini Concentration Kit are intended to be used in the clinical laboratory or intra-operatively at point-of-care for the safe and rapid

preparation of platelet-poor-plasma and platelet concentrate from a small sample of blood and for preparation of a cell concentrate from bone marrow.

WARNINGS AND PRECAUTIONS

- Single use device. Do not reuse.
- Use proper safety precautions to guard against needle sticks.
- Do not use sterile components of these kits if package is opened or damaged.
- Use prepared platelet-poor-plasma, platelet concentrate or concentrated bone marrow aspirate (cBMA) within 4 hours after drawing blood or marrow from the patient, according to current AABB guidelines.
- The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
- The patient is to be made aware of the general risks associated with bone marrow aspiration. These risks include, but are not limited to hemorrhage, seroma formation, infection and/or persistent pain at the site of aspiration.
- Follow manufacturer's instructions when using a BBI centrifuge (IEC centrifuge or The Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
- The safety and effectiveness of this device for in vivo indications for use has not been established.

POSSIBLE ADVERSE EFFECTS

1. Damage to blood vessels, hematoma, delayed wound healing and/or infection.
2. Temporary or permanent nerve damage that may result in pain or numbness.
3. Early or late postoperative infection.
4. Pain at bone marrow harvest site.

STERILITY

The MarrowStim™ and MarrowStim™ Mini cell separators are sterilized by exposure to a minimum dose of 25 kGy gamma radiation. All other components supplied in these kits are sterilized by their respective suppliers as indicated on their labeling. Do not re-sterilize. Do not use past expiration date.

INSTRUCTIONS FOR USE

NOTE 1: Use standard aseptic technique throughout the following procedures.

NOTE 2: For the preparation of platelet-poor-plasma and platelet concentrate from whole blood, obtain the appropriate blood-draw components (not supplied in these kits), and follow the Instructions for Use found in the appropriate package inserts for the GPS® II and GPS® Mini Kits, available online at www.BiometBiologics.com.

MarrowStim™ Concentration Kit

1. **REMOVE:** Remove BMA needle from its sterile package. Remove the inner trocar from the BMA needle, and set aside.
2. **ANTICOAGULATION: Perform ONE of the following techniques.**
METHOD 1 (preferred method):

Heparin (not supplied in these kits): Draw 3ml heparin solution (1000 U/ml) into a sterile 30ml syringe; ensure the heparin coats the entire inner surface of the

syringe and set aside. Draw 10ml heparin solution into a second sterile 30ml syringe; ensure the heparin coats the entire inner surface of the syringe. Attach the second 30ml syringe to the BMA needle and prime with heparin, ensuring 3ml heparin remains in the 30ml syringe. Remove BMA needle and replace the trocar.

METHOD 2:

ACD-A: Draw 5ml ACD-A into a sterile 30ml syringe; ensure the ACD-A coats the entire inner surface of the syringe and set aside. Draw 10ml ACD-A into a second sterile 30ml syringe; ensure the ACD-A coats the entire inner surface of the syringe. Attach the second 30ml syringe to the BMA needle and prime with ACD-A, ensuring 5ml ACD-A remains in the 30ml syringe. Remove BMA needle and replace the trocar.

3. **ASPIRATION:** Follow the BMA needle manufacturer package insert to obtain a total of 60ml anticoagulated bone marrow aspirate (3ml heparin mixed with 27ml BMA per 30ml syringe **OR** 5ml ACD-A mixed with 25ml BMA per 30ml syringe).
4. **LOAD: ENSURE BMA FROM ONLY ONE PATIENT IS PROCESSED, and that the cell separator remains upright.** Unscrew cap on center port #1. Remove and discard cap and green packaging post. Attach and slowly load both 30ml anticoagulated BMA-filled syringes one at a time into center port #1 of the cell separator. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap onto port #1. Place cell separator filled with anticoagulated BMA into the BBI centrifuge.
5. **BALANCE:** Fill blue counterbalance tube (800-0508) with 60ml sterile saline/water (equal to the amount of BMA plus anticoagulant dispensed in the cell separator). Place the counterbalance directly opposite from the cell separator in the centrifuge.
6. **SPIN:** Close centrifuge lid. Set RPM to 3.2 (x1000) and the time to 15 minutes. Press the start button. Once the spin is complete, open centrifuge and remove cell separator.
7. **EXTRACT PLASMA:** Unscrew yellow cap on port #2, and save yellow cap. Connect sterile 30ml syringe, tilt cell separator toward port #2, and extract the plasma. Remove the 30ml syringe from port #2, cap with sterile syringe cap, and set aside. Replace yellow cap on port #2.
8. **SUSPEND cBMA:** Holding the cell separator in the upright position, shake vigorously for 30 seconds.
9. **EXTRACT cBMA:** Immediately after suspending the cBMA, unscrew the red cap on port #3. Attach sterile 10ml syringe to port #3, and extract the cBMA. Remove the 10ml syringe, and cap with a sterile syringe cap.

MarrowStim™ Mini Concentration Kit

1. **REMOVE:** Remove BMA needle from its sterile package. Remove the inner trocar from the BMA needle, and set aside.
2. **ANTICOAGULATION: Perform ONE of the following techniques.**
METHOD 1 (preferred method):

Heparin (not supplied in these kits): Draw 10ml heparin solution (1000 U/ml) into a sterile 30ml syringe; ensure the heparin coats the entire inner surface of the syringe. Attach the 30ml syringe to the BMA needle and prime with heparin, ensuring 3ml heparin remains in the 30ml syringe. Remove BMA needle and replace the trocar.

METHOD 2:

ACD-A: Draw 10ml ACD-A into a sterile 30ml syringe; ensure the ACD-A coats the entire inner surface of the syringe. Attach the 30ml syringe to the BMA needle and prime with ACD-A, ensuring 5ml ACD-A remains in the 30ml syringe. Remove BMA needle and replace the trocar.

3. **ASPIRATION:** Follow the BMA needle manufacturer package insert to obtain a total of 30ml anticoagulated BMA in the 30ml syringe (3ml heparin mixed with 27ml BMA **OR** 5ml ACD-A mixed with 25ml BMA).
4. **LOAD: ENSURE BMA FROM ONLY ONE PATIENT IS PROCESSED, and that the cell separator remains upright.** Unscrew cap on center port #1. Remove and discard cap and green packaging post. Attach and slowly load the 30ml anticoagulated BMA-filled syringe into center port #1 of the cell separator. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap onto port #1. Place cell separator filled with anticoagulated BMA into the BBI centrifuge.
5. **BALANCE:** Fill purple counterbalance tube (800-0505) with 30ml sterile saline/water (equal to the amount of BMA plus anticoagulant dispensed in the cell separator). Place the counterbalance directly opposite from the cell separator in the centrifuge.
6. **SPIN:** Close centrifuge lid. Set RPM to 3.2 (x1000) and the time to 15 minutes. Press the start button. Once the spin is complete, open centrifuge and remove cell separator.
7. **EXTRACT PLASMA:** Unscrew yellow cap on port #2, and save yellow cap. Connect sterile 30ml syringe, tilt cell separator toward port #2, and extract the plasma. Remove the 30ml syringe from port #2, cap with sterile syringe cap, and set aside. Replace yellow cap on port #2.
8. **SUSPEND cBMA:** Holding the cell separator in the upright position, shake vigorously for 30 seconds.
9. **EXTRACT cBMA:** Immediately after suspending the cBMA, unscrew the red cap on port #3. Attach sterile 10ml syringe to port #3, and extract the cBMA. Remove the 10ml syringe, and cap with a sterile syringe cap.

Caution: Federal law (USA) limits this device to sale, distribution, or use by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-1683.

GPS is a registered trademark of Biomet Manufacturing Corp. in the United States.