Biomet Biologics
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Warsaw, Indiana 46581 USA

01-50-1436
Revision C
Date: 2014-10

BioCUE and BioCUE Mini Concentration Systems

ATTENTION OPERATING SURGEON

Not for Sale in the U.S.A.

DESCRIPTION

BioCUE Concentration System

The BioCUE Concentration System separates up to 60 ml of the patient's bone marrow components by density through the use of the BioCUE cell separator.

BioCUE Mini Concentration System

The BioCUE Mini Concentration System separates up to 30 ml of the patient's bone marrow components by density through the use of the BioCUE Mini cell separator.

Heparin, utilized in the anticoagulation step of the Instructions for Use, is not supplied in these systems.

MATERIALS

Blood-draw and bone marrow aspiration components supplied with single kits are packaged, labeled and sterilized as indicated by the manufacturer's labeling**.** All components in these systems are latex-free.

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

ACD-A (Anticoagulant Citrate Dextrose Solution, Solution A, USP) is manufactured and supplied by Citra Labs LLC, Braintree, MA. For further information regarding ACD-A, please contact the supplier at +1-800-299-3411.

The ACD-A included in this kit is only for use with the BioCUE Concentration Systems. **Not for direct intravenous infusion.**

INDICATIONS FOR USE

The BioCUE and BioCUE Mini Concentration Systems with ACD-A are designed to be used for the safe and rapid preparation of autologous concentrated bone marrow aspirate (cBMA) from a small sample of bone marrow aspirate at the patient's point of care. The cBMA can be applied to a surgical site or can be mixed with graft material prior to application to a surgical site as deemed necessary by the clinical use requirements.

WARNINGS

- FOR AUTOLOGOUS USE ONLY. cBMA should only be applied to the patient from whom the cBMA was derived. Process only one patient's bone marrow aspirate per disposable.
- Only use prepared cBMA as directed. NOT FOR DIRECT INTRAVENOUS INFUSION.
- STERILE CONTENTS. Single use device. Do not reuse. Use contents of BioCUE Concentration Systems immediately after its packaging is opened. **Do not attempt to re-sterilize this product. After use, this product may be a potential biohazard.**
- Do not use sterile components in BioCUE Concentration Systems if package is open or damaged.
- Use proper safety precautions to minimize the risk of inadvertent needle sticks. Discard used needles in "sharps" containers.
- Patient is to be made aware of general risks associated with treatment and possible adverse effects.
- The administering personnel are to be thoroughly familiar with the equipment and the procedure prior to using this device. Strict aseptic administration technique must be followed.

PRECAUTIONS

- Use Biomet Biologics centrifuge only as outcomes using centrifuges from other manufacturers are unknown.

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 BioCUE and BioCUE Mini cell separators are sterilized by exposure to a minimum dose of 25kGy gamma irradiation. ACD-A is sterilized by the supplier using steam sterilization. All other BioCUE and BioCUE Mini Concentration System components are sterilized by their respective suppliers as indicated on their labeling. Do not resterilize. Do not use any component from an open or damaged package or after expiration date. Single Use Only.

INSTRUCTIONS FOR USE

Store in original packaging. Discard the entire disposable kit after one use, using acceptable disposal methods for products potentially contaminated with blood.

Discard any unused cBMA. Use strict aseptic technique throughout processing and ensure blood from only one patient is processed per centrifugation cycle.

BioCUE Concentration System

1. **REMOVE:** Remove BMA needle from its sterilized package. Remove the inner trocar from the BMA needle, and set aside.
2. **ANTICOAGULATION: Perform ONE of the following techniques.**
   METHOD 1 (Heparin technique):
   Draw 3 ml heparin solution (1000 U/ml) into a sterilized 30 ml syringe; ensure the heparin coats the entire inner surface of the syringe and set aside. Draw 10 ml heparin solution into a second sterilized 30 ml syringe; ensure the heparin coats the entire inner surface of the syringe. Attach the second 30 ml syringe to the BMA needle and prime with heparin, ensuring 3 ml heparin remains in the 30 ml syringe. Remove BMA needle and replace the trocar.
   METHOD 2 (ACD-A technique):
   Draw 5 ml into a sterilized 30 ml syringe. Pull syringe plunger back completely, ensuring the ACD-A coats the entire inner surface of the syringe and set aside. Draw 10 ml ACD-A solution into a second sterilized 30 ml syringe. Pull syringe plunger back completely, ensuring the ACD-A coats the entire inner surface of the syringe. Attach the second 30 ml syringe to the BMA needle and prime with ACD-A, ensuring 5 ml ACD-A remains in the 30 ml syringe. Remove BMA needle and replace the trocar.
3. **ASPIRATION:** Follow the BMA needle manufacturer package insert to obtain a total of 60 ml anticoagulated BMA (3 ml heparin mixed with 27 ml BMA per 30 ml syringe **OR** 5 ml ACD-A mixed with 25 ml BMA per 30 ml syringe), using the syringes prepared in the previous step.
4. **LOAD: Ensuring 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 30 ml anticoagulated, BMA-filled syringes one at a time into center port #1. 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 centrifuge.
5. **BALANCE**: Fill blue counterbalance (800-0508) with an amount of sterilized saline/water equal to that of BMA plus anticoagulant dispensed in the cell separator. Place counterbalance directly opposite from aspirate-filled separator in centrifuge.
6. **SPIN:** Close centrifuge lid. Set speed for 3.2 (x 1,000 rpm) and set the time to 15 minutes. Press the start button. Once cycle is complete, open centrifuge and remove cell separator.
7. **EXTRACT PLASMA:** Unscrew yellow cap on port #2, and save cap. Connect sterilized 30 ml syringe, tilt cell separator toward port #2, and extract plasma. Remove the 30 ml syringe from port #2, cap with a sterilized syringe cap, and set aside. Replace yellow cap on port #2.
8. **SUSPEND cBMA:** Holding the cell separator in the upright position, shake tube vigorously for 30 seconds.

9. **EXTRACT cBMA:** Immediately after suspending the cBMA, unscrew the red cap on port #3. Attach sterilized 10 ml syringe to port #3, and extract the cBMA. Remove the 10 ml syringe, and cap with a sterilized syringe cap.
10. **APPLY**: Apply cBMA to surgical site, with or without graft material as required.

BioCUE Mini Concentration System

1. **REMOVE:** Remove BMA needle from its sterilized package. Remove the inner trocar from the BMA needle, and set aside.
2. **ANTICOAGULATION: Perform ONE of the following techniques.**
   METHOD 1 (Heparin technique):
   Draw 10 ml heparin solution (1000 U/ml) into a sterilized 30 ml syringe; ensure the heparin coats the entire inner surface of the syringe. Attach the syringe to the BMA needle and prime with heparin, ensuring 3 ml heparin remains in the 30 ml syringe. Remove BMA needle and replace the trocar.
   METHOD 2 (ACD-A technique):
   Draw 10 ml ACD-A into a sterilized 30 ml syringe. Pull syringe plunger back completely, ensuring the ACD-A coats the entire inner surface of the syringe. Attach the 30 ml syringe to the BMA needle and prime with ACD-A, ensuring 5 ml ACD-A remains in the 30 ml syringe. Remove BMA needle and replace the trocar.
3. **ASPIRATION:** Follow the BMA needle manufacturer package insert to obtain 30 ml of anticoagulated BMA (3 ml heparin mixed with 27 ml BMA **OR** 5 ml ACD-A mixed with 25 ml BMA) using the syringe prepared in the previous step.
4. **LOAD: Ensuring that the cell separator remains upright,** unscrew cap on center port #1 on the cell separator. Remove and discard cap and green packaging post. Attach and slowly load the 30 ml anticoagulated, BMA-filled syringe into center port #1. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap onto port #1. Place cell separator into the centrifuge.
5. **BALANCE**: Fill purple counterbalance (800-0505) with an amount of sterilized saline/water equal to that of BMA plus anticoagulant dispensed in the cell separator. Place counterbalance directly opposite from aspirate-filled separator in centrifuge.
6. **SPIN:** Close centrifuge lid. Set speed for 3.2 (x 1,000 rpm) and set the time to 15 minutes. Press the start button. Once cycle is complete, open centrifuge and remove cell separator.
7. **EXTRACT PLASMA:** Unscrew yellow cap on port #2, and save cap. Connect sterilized 30 ml syringe, tilt cell separator toward port #2, and extract plasma. Replace yellow cap on port #2.
8. **SUSPEND cBMA:** Holding the cell separator in the upright position, shake tube vigorously for 30 seconds.
9. **EXTRACT cBMA:** Immediately after suspending the cBMA, unscrew the red cap on port #3. Attach sterilized 10 ml syringe to port #3, and extract the cBMA. Remove the 10 ml syringe, and cap with a sterilized syringe cap.
10. **APPLY**: Apply cBMA to surgical site, with or without graft material as required.

CAUTION: These devices are only approved for distribution outside of the United States.

Comments regarding these devices can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-3968.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

EC REP Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend
CF31 3XA UK

CE 0086

Symbol Legend
Manufacturer

Date of Manufacture

Do Not Reuse

Do not resterilize

Caution, see instructions for use

STERILE EO Sterilized using Ethylene Oxide

STERILE R Sterilized using Irradiation

STERILE Sterile

STERILE A Sterilized using Aseptic Processing Techniques

STERILE Sterilized using Steam or Dry Heat

Rx Only Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Do not use if package is damaged (Pack Damaged)

Use By

WEEE Device

REF Catalogue Number

LOT Batch Code

FLAMMABLE Flammable

EC REP Authorized Representative in the European Community