**Biomet Biologics**
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**01-50-1465**
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**BioCUE™ Platelet Concentration System**

**ATTENTION OPERATING SURGEON**

**NOTE: DEVICE IS FOR SINGLE USE ONLY. Discard the entire disposable system after one use, using an acceptable disposal method for products potentially contaminated with blood.**

## DESCRIPTION

The BioCUE™ Platelet Concentration System consists of a standard (containing 60 ml separator) or a mini (containing 30 ml separator) kit. The kit separates a mixture of the patient's blood and bone marrow components by density through the use of the BioCUE™ Separator and a Biomet Biologics centrifuge. The system contains syringes, blood draw components, a separator, and bone marrow aspiration (BMA) needle.

The BioCUE™ Separator permits platelet poor plasma (PPP) and platelet rich plasma (PRP) to be rapidly prepared from a small volume of a mixture of the patient's blood and bone marrow that is drawn at the time of treatment.

## MATERIALS

The materials used for syringes, needles, tubing, connectors, and separators consist of medical grade polymers, elastomers and stainless steel that are suitable for use in medical devices. All components in this system are packaged, labeled and sterilized as indicated by the manufacturer's labeling. All components in this system 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 Anticoagulant, please contact the supplier at 1-800-299-3411.

The ACD-A included in this system is only for use with the BioCUE™ Platelet Concentration System.

## INDICATIONS

The BioCUE™ Platelet Concentration System is designed to be used in the clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet poor plasma (PPP) and platelet rich plasma (PRP) from a small sample of a mixture of blood and bone marrow. The plasma and concentrated platelets produced can be used for diagnostic tests. Additionally, the PRP can be mixed with autograft and/or allograft bone prior to application to an orthopedic site.

## WARNING AND PRECAUTIONS

1. Use proper safety precautions to guard against needle sticks.
2. Follow manufacturer instructions when using centrifuge. Use only a Biomet Biologics centrifuge (Thermo International Equipment Company (IEC) centrifuge or The Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
3. When using the bone marrow aspiration needle, follow manufacturer's instructions for use.
4. Do not use sterile components of this system if package is opened or damaged.
5. Single use device. Do not reuse.
6. Do not use after expiration date.
7. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
8. Use prepared PPP or PRP within 4 hours after drawing blood and marrow from the patient, according to current AABB guidelines.
9. 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.
10. The safety and effectiveness of this device for *in vivo* indications for use, such as bone healing and hemostasis, have not been established.
11. The PRP prepared by this device has not been evaluated for any clinical indications.
12. PRP prepared from a mixture of whole blood and bone marrow may contain higher levels of plasma free hemoglobin than PRP prepared from whole blood.
13. The PRP prepared by this device is NOT indicated for delivery to the patient's circulatory system.
14. Device is single use only. Do not attempt to clean or re-sterilize this product. After use, this product may be a potential biohazard.

## POSSIBLE ADVERSE EFFECTS

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

## STERILITY

The BioCUE™ Separator is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. All other BioCUE™ Platelet Concentration System components are sterilized by their respective suppliers as indicated on their labeling. Do not use any component from an opened or damaged package. Do not resterilize. Single Use Only. Do not use past the expiration date.

## INSTRUCTIONS FOR USE

**NOTE: Use standard aseptic technique throughout the following procedure.**

**BioCUE™ Platelet Concentration System**

1. **WHOLE BLOOD DRAW:**
   **Draw** 10 ml of ACD-A into 60 ml syringe, attach to apheresis needle and prime with ACD-A ensuring the ACD-A coats the entire inner surface of the syringe. Flush the syringe with the excess ACD-A ensuring a 1:9 ratio of ACD-A to whole blood is achieved after the blood draw. Slowly draw blood from the patient into the 60 ml syringe primed with ACD-A. Gently, but thoroughly mix the blood and ACD-A upon collection to prevent coagulation.
2. **BONE MARROW ASPIRATION:**
   a) **Remove** BMA needle from its sterile package. Remove the inner trocar from the BMA needle and set aside.
   b) **Draw** 10 ml ACD-A into a sterile 30 ml syringe; ensure the ACD-A coats the entire inner surface of the syringe. Attach 30ml syringe to BMA needle and prime with ACD-A. Flush the syringe with the excess ACD-A ensuring a 1:5 ratio of ACD-A to bone marrow is achieved after aspiration. Remove BMA needle and replace the trocar. Follow the BMA needle manufacturer's package insert to obtain marrow aspirate in the 30 ml syringe primed with ACD-A. Gently, but thoroughly mix the marrow and ACD-A upon collection to prevent coagulation.
3. **LOAD:** Ensure Blood and Bone Marrow from only one patient is processed, and that the separator remains upright. Unscrew cap on center port #1. Remove and discard cap and green packaging post. Attach and slowly add one at a time the anticoagulated Blood contained in a 60 ml syringe and the anticoagulated Bone Marrow contained in a 30 ml syringe into center port #1 of the separator. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap onto port #1. Place loaded separator into the Biomet Biologics centrifuge.
4. **BALANCE:** Fill blue counterbalance tube (800-0508) with 60 ml sterile saline/water (equal to the amount of the anticoagulated blood/marrow mixture dispensed in the BioCUE™ Separator). Place the counterbalance directly opposite from the separator in the centrifuge.
5. **SPIN:** Close centrifuge lid. Set RPM to 3.2 (x1000) and the time to 15 minutes. Press the start button. Once the centrifuge processing is complete, open centrifuge and remove BioCUE™ Separator.
6. **EXTRACT PPP:** Unscrew yellow cap on port #2, and save yellow cap. Connect sterile 30 ml syringe, tilt separator toward port #2, and extract the PPP. Remove the 30 ml syringe from port #2, cap with sterile syringe cap, and set aside. Replace yellow cap on port #2.
7. **SUSPEND PRP:** Holding the separator in the upright position, shake vigorously for 30 seconds.

8. **EXTRACT PRP:** Immediately after suspending the PRP, unscrew the red cap on port #3. Attach sterile 10 ml syringe to port #3, and extract the PRP. Remove the 10 ml syringe, and cap with a sterile syringe cap.

**BioCUE™ Mini Platelet Concentration System**
**WHOLE BLOOD DRAW:**

1. a) **Draw** 5 ml of ACD-A into 30 ml syringe, attach to apheresis needle and prime with ACD-A ensuring the ACD-A coats the entire inner surface of the syringe. Flush the syringe with the excess ACD-A ensuring a 1:9 ratio of ACD-A to whole blood is achieved after the blood draw. Slowly draw blood from the patient into the 30 ml syringe primed with ACD-A. Gently, but thoroughly mix the blood and ACD-A upon collection to prevent coagulation.
2. **BONE MARROW ASPIRATION:**
   a) **Remove** BMA needle from its sterile package. Remove the inner trocar from the BMA needle and set aside.
   b) **Draw** 10 ml ACD-A into a sterile 30 ml syringe; ensure the ACD-A coats the entire inner surface of the syringe. Attach 30ml syringe to BMA needle and prime with ACD-A. Flush the syringe with the excess ACD-A ensuring a 1:5 ratio of ACD-A to bone marrow is achieved after aspiration. Remove BMA needle and replace the trocar. Follow the BMA needle manufacturer's package insert to obtain bone marrow aspirate in the 30 ml syringe primed with ACD-A. Gently, but thoroughly mix the marrow and ACD-A upon collection to prevent coagulation.
3. **LOAD:** Ensure Blood and Bone Marrow from only one patient is processed, and that the separator remains upright. Unscrew cap on center port #1. Remove and discard cap and green packaging post. Attach and slowly add one at a time the anticoagulated Blood contained in a 30 ml syringe and the anticoagulated Bone Marrow contained in a 30 ml syringe into center port #1 of the separator. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap onto port #1. Place loaded separator into the Biomet Biologics centrifuge.
4. **BALANCE:** Fill blue counterbalance tube (800-0508) with 30 ml sterile saline/water (equal to the amount of the anticoagulated blood/marrow mixture dispensed in the BioCUE™ Separator). Place the counterbalance directly opposite from the separator in the centrifuge.
5. **SPIN:** Close centrifuge lid. Set RPM to 3.2 (x1000) and the time to 15 minutes. Press the start button. Once the centrifuge processing is complete, open centrifuge and remove BioCUE™ Mini **S**eparator.
6. **EXTRACT PPP:** Unscrew yellow cap on port #2, and save yellow cap. Connect sterile 30 ml syringe, tilt separator toward port #2, and extract the PPP. Remove the 30 ml syringe from port #2, cap with sterile syringe cap, and set aside. Replace yellow cap on port #2.
7. **SUSPEND PRP:** Holding the separator in the upright position, shake vigorously for 30 seconds.
8. **EXTRACT PRP:** Immediately after suspending the PRP, unscrew the red cap on port #3. Attach sterile 10 ml syringe to port #3, and extract the PRP. Remove the 10 ml syringe, and cap with a sterile syringe cap.

**Caution:** Federal Law (USA) restricts this device to sale 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: 574-372-3968.



Symbol Legend

 Manufacturer

 Date of Manufacture

 Do Not Reuse

 Caution

 Sterilized using Ethylene Oxide

 Sterilized using Irradiation

 Sterile

 Sterilized using Aseptic Processing Techniques

 Sterilized using Steam or Dry Heat

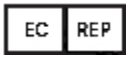
 Use By

 WEEE Device

 Catalogue Number

 Batch Code

 Flammable

 Authorized Representative in the European Community