Biomet Biologics
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01-50-1440
Revision D
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GPS III Platelet Concentrate Separation Kit with ACD-A

ATTENTION OPERATING SURGEON

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

DESCRIPTION

GPS III Platelet Concentrate Separation Kit with ACD-A
The GPS III Platelet Concentrate Separation Kit with ACD-A aids separation of the patient's own blood components by density through the use of a Biomet Biologics centrifuge.

The GPS III Platelet Concentrate Separation Kit with ACD-A permits platelet concentrate to be rapidly prepared from a small volume of the patient's blood that is drawn at the time of treatment.

MATERIALS

The materials used for syringes, needles, tubing, connectors, and platelet separators consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices. Blood-draw components, when supplied in this kit, are packaged, labeled and sterilized as indicated by the manufacturer's labeling**.** All components in this kit are latex free.

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 Anticoagulant, please contact the supplier at 1-800-299-3411.

The ACD-A included in this kit is only for use with the GPS III Platelet Concentrate Separation Kit. NOT FOR DIRECT INTRAVENOUS INFUSION.

INDICATIONS FOR USE

GPS III Platelet Concentrate Separation Kit with ACD-A
The GPS III Platelet Concentrate Separation Kit with ACD-A is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient's point of care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by clinical use requirements.

WARNINGS AND PRECAUTIONS

1. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.
2. Follow manufacturer instructions when using centrifuge. Use only a Biomet Biologics centrifuge (GPS – IEC centrifuge or The Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
3. Do not use sterile components in this kit if package is opened or damaged.
4. Single use device. Do not reuse.
5. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
6. The patient is to be made aware of general risks associated with treatment and the possible adverse effects.
7. Use prepared platelet concentrate material within 4 hours after drawing blood from patient, according to current AABB guidelines.
8. The safety and effectiveness of the autogolous output 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 and/or allergic reaction.

STERILITY

The GPS III Platelet Concentrate Separation Kit platelet separator is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. All other components supplied in this kit are sterilized by the respective suppliers using irradiation or ethylene oxide gas (ETO). Do not re-sterilize. Do not use after expiration date. Do not use any component from an opened or damaged package. Single Use Only.

INSTRUCTIONS FOR USE

NOTE: Use standard aseptic technique throughout the following procedures.

1. **DRAW:** Draw 8 ml of ACD-A into 60 ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 30 ml to 52 ml of patient's own blood into the 60 ml syringe primed with ACD-A. Gently, but thoroughly, mix the whole blood and ACD-A upon collection to prevent coagulation.
2. **LOAD: ENSURE BLOOD FROM ONLY ONE PATIENT IS PROCESSED PER SPIN, and that the platelet separator remains upright.** Unscrew cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 60 ml syringe (8 ml of ACD-A mixed with 30 ml to 52ml of patient's whole blood) into center blood port #1. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap onto port #1. Place platelet separator filled with anticoagulated blood in Biomet Biologics centrifuge.
3. **BALANCE:**
   Processing One Platelet Separator
   Fill blue GPS counterbalance tube (800-0508) with 35 ml to 60 ml of sterile saline/water (equal to amount of whole blood plus ACD-A dispensed in the platelet separator). Place filled counterbalance directly opposite from the platelet separator in the centrifuge.
   Processing Two Platelet Separators
   Fill both platelet separators with equal amounts of whole blood plus ACD-A. Place filled platelet separators directly opposite from each other in the centrifuge.
4. **SPIN:** Close centrifuge lid. Set RPM to 3.2 (x 1,000) and the time to 15 minutes. Press the start button. Once spin is complete, open centrifuge.
5. **EXTRACT PPP:** Unscrew yellow cap on port #2, and save yellow cap. Connect 30 ml syringe to port #2. Slowly tilt the platelet separator, and while withdrawing the platelet-poor-plasma PPP. Remove 30 ml syringe from port #2, cap with a sterile syringe cap, and set aside. Replace yellow cap on port #2.
6. **If PRP is desired, follow steps 7 – 8.**
7. **SUSPEND PRP:** Holding platelet separator in the upright position, unscrew red cap on port #3. Attach sterile 10 ml syringe to port #3. Extract 2 ml of PRP into the 10 ml syringe. Leave the syringe attached. Shake platelet separator gently for 30 seconds.
8. **EXTRACT PRP:** Immediately after suspending the platelets, extract remaining PRP into the attached 10 ml syringe. Remove 10 ml syringe from port #3, 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.

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

Symbol Legend
 Manufacturer

 Date of manufacture

 Do not reuse

 Caution, see instructions for use

Sterilized using ethylene oxide

Sterilized using irradiation

Sterile

Sterilized using aseptic processing techniques

Sterilized using steam or dry heat

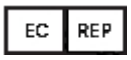
 Use by date

 WEEE device

Catalogue number

Batch code

Flammable



Authorized representative in the European Community