



Precautionary Statement (01-50-1443)

Biomet Biologics, Inc.

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01-50-1443

Date: 03/07

GPS® III Mini 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 Mini Platelet Concentrate Separation Kit with ACD-A

The GPS® III Mini 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 Mini 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.

Graft Delivery System

The GPS® III Mini Platelet Concentrate Separation Kit with ACD-A includes syringes comprising the Graft Delivery System. The Graft Delivery System is comprised of disposable piston syringes intended for delivery of allograft and autograft bone materials to an orthopedic surgical site.

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 kit 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 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 kit is only for use with the GPS® III Mini Platelet Concentrate Separation Kit.

INDICATIONS FOR USE

GPS® III Mini Platelet Concentrate Separation Kit with ACD-A

The GPS® III Mini 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.

Graft Delivery System

The Graft Delivery System is designed for use in delivery of allograft and autograft bone materials to an orthopedic surgical site, and to facilitate pre-mixing of bone graft materials with I.V. fluids, blood, plasma, PRP, bone marrow or other specific blood components as deemed necessary by the clinical use requirements.

WARNINGS 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 (GPS® - IEC centrifuge or 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 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.

STERILITY

The GPS® III Mini Platelet Concentrate Separation Kit platelet separator is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. All other GPS® III Mini Platelet Concentrate Separation Kit components are sterilized by the respective suppliers using irradiation or ethylene oxide gas. Do not re-sterilize. Do not use after expiration date.

INSTRUCTIONS FOR USE

NOTE: Use standard aseptic technique throughout the following procedures.

1. **DRAW** 3ml of ACD-A into 30ml syringe, attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 15 to 27ml of patient's own blood into the 30ml 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 30ml syringe (3ml of ACD-A mixed with 15 to 27ml 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 purple GPS® Mini counterbalance tube (800-0505) with 18-30ml 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 GPS® III Mini platelet separators with equal amounts of whole blood plus ACD-A. Place filled platelet separators directly opposite from each other into 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 sterile 30ml syringe to port #2, invert platelet separator, and extract platelet-poor-plasma (PPP). Remove 30ml 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 10ml syringe to port #3. Extract 1ml of PRP into the 10ml 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 10ml syringe. Remove 10ml syringe from port #3, and cap with a sterile syringe cap.

Caution: Federal Law (USA) limits this device to sale 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.