



Precautionary Statement (01-50-1448)

Biomet Biologics, Inc. **01-50-1448**

P.O. Box 587

Date: 03/07

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Warsaw, Indiana 46581 USA

Plasmax™ Plasma Concentrator Accessory used with 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.

DESCRIPTIONS

Plasmax™ Plasma Concentrator Accessory

The Plasmax™ Plasma Concentrator Accessory aids in the concentration of the patient's own plasma proteins by centrifugation utilizing a Biomet Biologics centrifuge. Excess water is removed from the platelet-poor-plasma (PPP) with desalting beads.

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.

MATERIALS

The Plasmax™ Plasma Concentrator Accessory consists of medical grade polymers suitable for the use in medical devices, and contains porous polyacrylamide desalting beads.

The GPS® III Mini Platelet Separation Kit with ACD-A includes syringes, needles, tubing, connectors, and platelet separators which also consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices.

Blood-draw components 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, please contact the supplier at 1-800-299-3411.

The ACD-A included in this kit is only for use with the Plasmax™ Plasma Concentrator Accessory used with GPS® III Mini Platelet Concentrate Separation Kit.

INDICATIONS

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

CONTRAINDICATIONS

1. Use as a dialyzer or for dialysis with a dialysate.
2. Direct connection to patient's vascular system of circulating blood volume.

WARNINGS AND PRECAUTIONS

- Use proper safety precautions to guard against needle sticks.
- Follow manufacturer instructions when using the centrifuge. Use only Biomet Biologics centrifuges (GPS® - IEC centrifuge or Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
- Do not use sterile components of this kit if package is opened or damaged.
- Single use device. Do not reuse.
- 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 treatment and possible adverse effects.
- Use prepared PPPc and PRP within 4 hours after drawing blood from patient, according to current AABB guidelines.
- The safety and effectiveness for bone healing and hemostasis have 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 Plasmax™ Plasma Concentrator Accessory and the GPS® III Mini Platelet Separator are sterilized by exposure to a minimum dose of 25 kGy gamma radiation. All other components supplied in this kit are sterilized by the respective suppliers using radiation or ethylene oxide gas (ETO). Do not re-sterilize. Do not use after expiration date.

INSTRUCTIONS FOR USE

NOTE: Use standard aseptic technique throughout the following procedures.

PROCEDURE ONE: Use the GPS® III Mini Platelet Concentrate Separation Kit with ACD-A to prepare platelet-poor-plasma (PPP) and PRP.

- **DRAW:** Draw 3ml of ACD-A into 30ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 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.
- **LOAD: ENSURE BLOOD FROM ONLY ONE PATIENT IS PROCESSED PER SPIN, and that the platelet separator remains upright.** Unscrew clear 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 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 a Biomet Biologics centrifuge.

- **BALANCE:** Fill purple GPS® Mini counterbalance tube (800-0505) with 30ml of sterile saline/water (equal to the amount of whole blood plus ACD-A dispensed in the platelet separator). Place filled counterbalance directly opposite from the platelet separator in the centrifuge.
- **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.
- **EXTRACT PPP:** Unscrew yellow cap on port #2, and save yellow cap. Connect 30ml syringe to port #2, invert platelet separator, and extract exactly 15ml of PPP. Remove 30ml syringe from port #2, cap with a sterile syringe cap, and set aside. Replace yellow cap on port #2.
- **If PRP is desired, follow steps 7 - 8.**
- **SUSPEND PRP:** Holding platelet separator in the upright position, unscrew red cap on port #3. Attach a 10ml syringe to port #3. Extract 1ml of PRP in the 10ml syringe. Leave the 10ml syringe attached to port #3. Shake platelet separator gently for 30 seconds.
- **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.

PROCEDURE TWO: Use the Plasmax™ Plasma Concentrator Accessory to prepare PPPc.

1. **LOAD:** Unscrew cap on port #1. Slowly load the 15ml PPP collected in 30ml syringe into port #1. Unscrew and discard clear, protective inner piece from white cap tethered to port #1. Screw white cap onto port #1.
2. **MIX:** Twist and piston the mixing paddle for 30 seconds. Be sure to push and twist the paddle to the floor of the Plasmax™ Plasma Concentrator Accessory's upper chamber to saturate the beads. There should be no white beads visible. Place into centrifuge.
3. **BALANCE:** Place the green Plasmax™ counterbalance (800-0510) directly opposite from the Plasmax™ Plasma Concentrator Accessory in the centrifuge.
4. **SPIN:** Close centrifuge lid and set RPM to 2.0 (x 1,000) and the time to 2 minutes. Press the start button. Once spin is complete, open centrifuge.
5. **EXTRACT PPPc:** Unscrew red cap on port #2 and extract PPPc using a sterile 10ml syringe. Remove 10ml syringe from port #2, 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, 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.