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Revision C

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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 (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 Plasmax Plasma Concentrator Accessory used with GPS III Mini Platelet Concentrate Separation Kit. NOT FOR DIRECT INTRAVENOUS INFUSION.

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

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 the centrifuge. Use only Biomet Biologics centrifuges (GPS – IEC centrifuge or Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
3. Do not use sterile components of 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 the general risks associated with treatment and possible adverse effects.
7. Use prepared PPPc and PRP within 4 hours after drawing blood from patient, according to current AABB guidelines.
8. 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 and/or allergic reaction.

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. 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.

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

1. **DRAW:** Draw 4 ml of ACD-A into 30 ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 26 ml of patient's own blood into the 30 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 clear cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 30 ml syringe (4 ml of ACD-A mixed with 26 ml 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.
3. **BALANCE:** Fill purple GPS Mini counterbalance tube (800-0505) with 30 ml 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.
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 while withdrawing the exactly 15 ml of 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 a 10 ml syringe to port #3. Extract 1 ml of PRP in the 10 ml syringe. Leave the 10 ml syringe attached to port #3. 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.

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















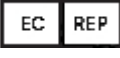
1. **LOAD:** Unscrew cap on port #1. Slowly load the 15 ml PPP collected in 30 ml syringe into port #1. Unscrew and discard clear, protective inner piece from white cap tethered to port #1. Screw white cap onto port #1.
2. **MIX:** Twist and piston the mixing paddle for 30 seconds. Be sure to push and 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 10 ml syringe. Remove 10 ml syringe from port #2, 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, P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372- 3968.

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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