Precautionary Statement (01-50-1426)

Biomet Biologics, Inc. **01-50-1426**
A Subsidiary of Biomet, Inc. **Date: 04/06**
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GPS® II Platelet Concentrate Separation Kit Accessory

PLASMAX™ PLUS PLASMA CONCENTRATOR, GPS® II WITH 50ml ACD-AANTICOAGULANT

ATTENTION OPERATING SURGEON

DESCRIPTION

The GPS® II Platelet Concentrate Separation Kit with the Plasmax™ Plus Plasma Concentrator accessory aids in the concentration of the patient's own plasma proteins by centrifugation, utilizing the Thermo International Equipment Company (IEC) centrifuge or The Drucker Company centrifuge. Excess water is removed by mixing plasma concentrate with desalting beads.

GPS® II Platelet Separation Kit

The GPS® II Platelet Concentrate Separation Kit aids separation of the patient's own blood components by density through the use of the GPS® - Thermo International Equipment Company (IEC) centrifuge or The Drucker Company centrifuge.
GPS® II Platelet Concentrate Separation Kit 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 in the Plasmax™ Plus Plasma Concentrator consist of medical grade polymers, suitable for the use in medical devices. Desalting beads are porous polyacrylamide beads. 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 the Plasmax™ Plus Plasma Concentrator Kit, are packaged, labeled and sterilized as indicated by their individual labeling. The Plasmax™ Plus Plasma Concentrator components do not contain Latex.

ACD-A Anticoagulant is supplied by Citra Anticoagulants, Inc. Braintree, MA manufactured by Cytosol Laboratories, Inc. Braintree, MA. The ACD-A Anticoagulant in the 50ml container is cleared for marketing in the U.S.

INDICATIONS

The GPS® II Platelet Concentrate Separation Kit w/Plasmax™ Plus Plasma Concentrator Accessory is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) and concentrated platelet-poor-plasma (PPPc) from a small sample of blood at the patient's point of

care. The PRP and PPPc 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

- Use as a dialyzer or for dialysis with a dialysate.
- 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 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 plasma concentrate material within 4 hours after drawing blood from patient.
- Follow manufacturer package insert for ACD-A Anticoagulant.
- 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™ Plus Plasma Concentrator components are sterilized by exposure to a minimum dose of 25 kGy gamma radiation. All other components 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 USING THE GPS® II KIT

- **DRAW** at least 5ml of anticoagulant into 60ml syringe, attach to apheresis needle and prime with anticoagulant. Draw blood using standard aseptic practice. Draw 55ml of blood from patient. Gently, but thoroughly mix the whole blood and anticoagulant upon collection to prevent coagulation.
- **LOAD:** Unscrew cap on center blood port #1and remove cap and green packaging post. Discard both. Slowly load blood-filled 60ml syringe (5ml of citrate anticoagulant and 55ml of whole blood) into center blood port #1. Unscrew clear protective inner piece from white tethered cap and attach onto center blood port #1. Place separator in centrifuge.
- **BALANCE:** Fill GPS® II blue counterbalance tube (800-0508) with 60 ml of sterile saline (equal to amount of whole blood +ACD-A dispensed in the GPS® II disposable). Place into opposite bucket from the disposable that was inserted into the centrifuge during Step 2.
- **SPIN:** Close lid and set speed for 3.2 (x 1,000) and time to 15 minutes. Press green button to start spin. Once spin is complete, press red button to open lid.
- **PPP EXTRACTION:** To remove platelet poor plasma (PPP), unscrew yellow cap on port #2. Connect 30ml syringe and extract PPP.

- If platelet rich plasma (PRP) is desired, follow steps 7 - 8.
- **SUSPEND:** Shake tube vigorously for 30 seconds to suspend the platelets.
- **PRP EXTRACTION:** Unscrew red cap on port #3. Connect 10ml syringe and extract Platelet Rich Plasma (PRP).

USING PLASMAX™ PLUS PLASMA CONCENTRATOR:

- **LOAD:** Unscrew cap on port #1. Slowly load 25ml plasma into port #1. Unscrew clear, protective inner piece from white tethered cap and screw back onto blood port #1.
- **MIX:** Twist mixing stem until no white beads are visible.
- Place into centrifuge.
- **BALANCE:** Place counterbalance (800-0510) into opposite side of centrifuge.
- **SPIN:** Close lid and set speed for 2.0 (x 1,000) and time to 2 minutes. Press green button to start spin. Once spin is complete, press red button to open lid.
- **PLASMA CONCENTRATE EXTRACTION:** Extract plasma concentrate by connecting a 10cc syringe to port #2 and extract contents.

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.