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Revision C

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GPS II or MINI PLATELET CONCENTRATE SEPARATION TUBE ONLY

ATTENTION OPERATING SURGEON

DESCRIPTION

GPS II or Mini Platelet Separation Tube

The GPS II or Mini Platelet Concentrate Separation Tube 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.

The GPS II or Mini Platelet Concentrate Separation Tube 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 the tubes consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices. The GPS II or Mini Platelet Concentrate Separation Tube does not contain latex.

INDICATIONS FOR USE

GPS II or Mini Platelet Concentrate Separation Tube

The GPS II or Mini Platelet Concentrate Separation Tube 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.

INTENDED USE

GPS II or Mini Platelet Concentrate Separation Tube

Blood is drawn from the patient. The blood is then spun in a Thermo IEC or Drucker Company centrifuge in accordance with centrifuge operating directions. The platelet concentrate is then collected with a syringe. Certain syringe components are intended for use in the delivery of allograft and autograft bone materials to an orthopedic surgical site.

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 GPS - IEC centrifuge or the Drucker Company centrifuge. Outcomes using centrifuges from other manufacturers are unknown.
3. Do not use sterile component 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 general risks associated with treatment and the possible adverse effects.
7. Use prepared platelet concentrate material within 4 hours after drawing blood from patient.
8. The safety and effectiveness of this device for in vivo indications for use has not been established.
9. Device is single use only. Do not attempt to clean or re-sterilize this product. After use, this product may be a potential biohazard.

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 II or Mini Platelet Concentrate Separation Tube unit is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. 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

1. **DRAW** 30 to 52 ml of blood from patient. Draw blood using standard aseptic practice.
2. **LOAD:** Unscrew cap on center blood port #1 and remove cap and green packaging post. Discard both. Slowly load blood-filled 60 ml syringe (8 ml of citrate anticoagulant and 52 ml of whole blood) for GPS II or a 30ml syringe (4 ml of citrate anticoagulant and 26-ml of whole blood) for GPS Mini into center blood port #1. Unscrew clear protective inner piece from white tethered cap and screw white tethered cap onto center blood port #1. Place separator in centrifuge.
3. **BALANCE:** If processing one disposable, fill GPS II blue counterbalance tube (800-0508) with 30-60ml of sterile saline (equal to amount of whole blood +ACD-A dispensed in the GPS II disposable). With the GPS Mini disposable, use the purple counterbalance tube (800-0505) with 20 to 30 ml of sterile saline equal to the amount of whole blood + ACD-A dispensed in the GPS Mini disposable. Place into opposite sides of centrifuge.

If processing two GPS disposables, fill both tubes with equal amounts of whole blood +ACD-A. Place into opposite sides of centrifuge.
4. **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.
5. **PPP EXTRACTION:** If platelet poor plasma (PPP) is desired, unscrew yellow cap on port #2. Connect a 30ml or larger syringe (not supplied) and extract PPP.
6. **SUSPEND:** Shake tube vigorously for 30 seconds to suspend the platelets.
7. **PRP EXTRACTION:** Unscrew red cap on port #3. Connect a 10ml or larger syringe (not supplied) and extract Platelet Rich Plasma (PRP)

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: 574-372-3968.

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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.

Authorized Representative: Biomet U.K., Ltd.
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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

Flammable



Authorized representative in the European Community