

**01-50-1453**  
**Revision C**  
**Date: 2014-08**



## GPS III or GPS III Mini Platelet Separation Tube Only

### ATTENTION OPERATING SURGEON

#### Other components required but not included:

**GPS III:** (1ea.) 60 ml luer-lock syringe; (1ea.) 30 ml luer-lock syringe; (1ea.) 10 ml luer-lock syringe; (1ea.) 18 gauge apheresis needle; 8 ml citrate-based anticoagulant (ACD-A)\*  
**GPS III Mini:** (1ea.) 30 ml luer-lock syringe; (1ea.) 10 ml luer-lock syringe; (1ea.) 18 gauge apheresis needle; 4 ml citrate-based anticoagulant (ACD-A)\*

*\*GPS III Separators have not been tested with heparin or other anticoagulants and therefore mixing ratios and output are unknown.*

**NOTE: FOR SINGLE USE ONLY. Discard the entire platelet separation tube after one use by an acceptable disposal method for devices potentially contaminated with blood products.**

#### DESCRIPTION

The GPS III or GPS III Mini Platelet Separation tube aids separation of the patient's own blood components by density through the use of a Biomet Biologics centrifuge.

The GPS III or GPS III Mini Platelet 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 consist of medical grade polymers and elastomers suitable for use in medical devices. Neither the GPS III nor the GPS III Mini Platelet Separation tube contains latex.

#### INDICATIONS FOR USE

The GPS III or GPS III Mini Platelet 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 the clinical use requirements.

#### 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 a Biomet Biologics centrifuge (GPS – IEC centrifuge or the Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
3. Do not use sterilized device 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. In advance, 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. Users should exercise caution when handling surgical needles to minimize the risk of inadvertent needle sticks. Discard used needles in "sharps" containers.
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 III and GPS III Mini Platelet Separation tube are sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. Single use only. Do not re-sterilize. Do not use after expiration date. Do not use any component from an opened or damaged package.

#### INSTRUCTIONS FOR USE

**NOTE: Use standard aseptic technique throughout the following procedures.**

#### GPS III Platelet Separation tube:

1. **DRAW:** Draw 8 ml of citrate-based anticoagulant into 60 ml luer-lock syringe. Attach to 18 gauge apheresis needle and prime with anticoagulant. Slowly draw 30 ml to 52 ml of patient's own blood into the 60 ml luer-lock syringe primed with anticoagulant. Gently, but thoroughly, mix the whole blood and anticoagulant upon collection to prevent coagulation.
2. **LOAD: ENSURE BLOOD FROM ONLY ONE PATIENT IS PROCESSED PER SPIN, and that the platelet separation tube remains upright.** Unscrew cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 60 ml luer-lock syringe (8 ml of citrate-based anticoagulant mixed with 30 ml to 52 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 back onto port #1. Place separation tube filled with anticoagulated blood in Biomet Biologics centrifuge.
3. **BALANCE:**  
**Processing One Platelet Separation tube**  
Fill blue GPS counterbalance tube (800-0508) with 35 ml to 60 ml of sterile saline/water (equal to amount of whole blood plus anticoagulant dispensed in the platelet separation tube). Place filled counterbalance directly opposite from the platelet separation tube in the centrifuge.  
**Processing Two Platelet Separation tubes**  
Fill both platelet separation tubes with equal amounts of whole blood plus anticoagulant. Place filled platelet separation tubes directly opposite from each other 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 luer-lock syringe to port #2. Slowly tilt the platelet separation tube while withdrawing the platelet-poor-plasma (PPP). Remove 30 ml luer-lock 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 separation tube in the upright position, unscrew red cap on port #3. Attach 10 ml luer-lock syringe to port #3. Extract 2 ml of PRP into the 10 ml syringe. Leave the syringe attached. Shake platelet separation tube gently for 30 seconds.
8. **EXTRACT PRP:** Immediately after suspending the platelets, extract remaining PRP into the attached 10ml luer-lock syringe. Remove 10 ml luer-lock syringe from port #3, and cap with a sterile syringe cap.

#### GPS III Mini Platelet Separation tube:

1. **DRAW:** Draw 4 ml of citrate-based anticoagulant into 30 ml luer-lock syringe. Attach to apheresis needle and prime with anticoagulant. Slowly draw 15 ml to 26 ml of patient's own blood into the 30 ml luer-lock syringe primed with anticoagulant. Gently, but thoroughly, mix the whole blood and anticoagulant upon collection to prevent coagulation.
2. **LOAD: ENSURE BLOOD FROM ONLY ONE PATIENT IS PROCESSED PER SPIN, and that the platelet separation tube remains upright.** Unscrew cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 30ml luer-lock syringe (4 ml of anticoagulant mixed with 15 ml to 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 back onto port #1. Place separation tube filled with anticoagulated blood in Biomet Biologics centrifuge.

3. **BALANCE:**

**Processing One Platelet Separation tube**

Fill purple GPS Mini counterbalance tube (800-0505) with 18 ml to 30 ml of sterile saline/water (equal to amount of whole blood plus anticoagulant dispensed in the platelet separation tube). Place filled counterbalance directly opposite from the platelet separation tube in the centrifuge.

**Processing Two Platelet Separation tubes**

Fill both platelet separation tubes with equal amounts of whole blood plus anticoagulant. Place filled platelet separation tubes directly opposite from each other in the centrifuge.

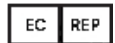
4. **SPIN:** Close centrifuge lid. Set RPM to 3.2 (x 1,000) and the time to 15 minutes. Press the start button. Once spin is complete, open centrifuge.
5. **EXTRACT PPP:** Unscrew yellow cap on port #2, and save yellow cap. Connect sterile 30 ml luer-lock syringe to port #2. Slowly tilt the platelet separation tube while withdrawing the platelet-poor-plasma (PPP). Remove 30 ml luer-lock 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 separation tube in the upright position, unscrew red cap on port #3. Attach 10 ml luer-lock syringe to port #3. Extract 1 ml of PRP into the 10 ml luer-lock syringe. Leave the syringe attached. Shake platelet separation tube gently for 30 seconds.
8. **EXTRACT PRP:** Immediately after suspending the platelets, extract remaining PRP into the attached 10 ml luer-lock syringe. Remove 10 ml luer-lock syringe from port #3, 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, 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.  
Waterton Industrial Estate  
Bridgend, South Wales  
CF31 3XA UK



Symbol Legend



Manufacturer



Date of manufacture



Do not reuse



Do not resterilize



Caution, see instructions for use



Sterilized using ethylene oxide



Sterilized using irradiation



Sterile



Sterilized using aseptic processing techniques



Sterilized using steam or dry heat



Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.



Do not use if package is damaged (Pack Damaged)



Use by date



WEEE device



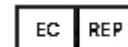
Catalogue number



Batch code



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