

**Biomet Biologics**

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**01-50-1451**

Date: 02/09

## **GPS™ III or GPS™ III Mini Platelet Separator**

### **ATTENTION OPERATING SURGEON**

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

#### **DESCRIPTION**

The GPS™ III or GPS™ III Mini Platelet Separator 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 Separator 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 Separator contain latex.

#### **INDICATIONS FOR USE**

The GPS™ III or GPS™ III Mini Platelet Separator 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. Use proper safety precautions to guard against needle sticks.
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. 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.

#### **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 GPS™ III and GPS™ III Mini Platelet Separators are sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. Do not re-sterilize. Do not use after expiration date.

#### **INSTRUCTIONS FOR USE**

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

##### **GPS™ III Platelet Separator:**

1. **DRAW:** Draw 6ml of citrate-based anticoagulant into 60ml syringe. Attach to apheresis needle and prime with anticoagulant. Slowly draw 30ml to 54ml of patient's own blood into the 60ml 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 separator remains upright.** Unscrew cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 60ml syringe (6ml of anticoagulant mixed with 30ml to 54ml 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 separator filled with anticoagulated blood in Biomet Biologics centrifuge.
3. **BALANCE:**  
**Processing One Platelet Separator**  
Fill blue GPS™ counterbalance tube (800-0508) with 36ml to 60ml of sterile saline/water (equal to amount of whole blood plus anticoagulant dispensed in the platelet separator). Place filled counterbalance directly opposite from the platelet separator in the centrifuge.  
**Processing Two Platelet Separators**  
Fill both platelet separators with equal amounts of whole blood plus anticoagulant. Place filled platelet separators 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 30ml syringe to port #2, invert platelet separator, and extract platelet-poor-plasma (PPP). Remove 30ml 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 10ml syringe to port #3. Extract 2ml of PRP into the 10ml syringe. Leave the syringe attached. Shake platelet separator gently for 30 seconds.
8. **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.

##### **GPS™ III Mini Platelet Separator:**

1. **DRAW:** Draw 3ml of citrate-based anticoagulant into 30ml syringe. Attach to apheresis needle and prime with anticoagulant. Slowly draw 15ml to 27ml of patient's own blood into the 30ml 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 separator remains upright.** Unscrew cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 30ml syringe (3ml of anticoagulant mixed with 15ml to 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 back onto port #1. Place separator filled with anticoagulated blood in Biomet Biologics centrifuge.
3. **BALANCE:**  
**Processing One Platelet Separator**  
Fill purple GPS™ Mini counterbalance tube (800-0505) with 18ml to 30ml of sterile saline/water (equal to amount of whole blood plus anticoagulant dispensed in the platelet separator). Place filled counterbalance directly opposite from the platelet separator in the centrifuge.  
**Processing Two Platelet Separators**  
Fill both platelet separators with equal amounts of whole blood plus anticoagulant. Place filled platelet separators 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 30ml syringe to port #2, invert platelet separator, and extract platelet-poor-plasma (PPP). Remove 30ml 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 10ml syringe to port #3. Extract 1ml of PRP into the 10ml syringe. Leave the syringe attached. Shake platelet separator gently for 30 seconds.
8. **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.

**CAUTION:** Federal law (USA) restricts this device to sale, distribution, 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.

Some devices may or may not be approved for sale in Canada, consult the following website for the most current device license listing: [www.healthcanada.gc.ca/medical devices](http://www.healthcanada.gc.ca/medical devices).

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