**Biomet Biologics**
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

**01-50-1474**
**Revision B**
Date: 2012-08

**Clotalyst Kit with GPS III Separator**

**ATTENTION OPERATING SURGEON**

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

**DESCRIPTION**
The Clotalyst Kit with GPS III Separator(s) contains Clotalyst and GPS III Separator(s), Clotalyst Reagent, ACD-A anticoagulant and blood draw accessories. The system produces autologous serum and autologous platelet-rich plasma (PRP).

**MATERIALS**
**Clotalyst Separator**
The Clotalyst Separator consists of medical grade polymers, silicone, acrylic, polyester and borosilicate (glass beads) suitable for use in medical devices.

**Clotalyst Reagent (66% v/v ethyl alcohol, U.S.P./25mM Calcium Chloride, U.S.P.)**
Clotalyst Reagent is supplied and manufactured by ThermoGenesis Corp., Rancho Cordova, CA, for Biomet Biologics, Warsaw, IN. Please contact ThermoGenesis Corp., Rancho Cordova, CA, at 1-800-783-8357 for further information regarding the reagent.

**The GPS III Separators and blood draw components**
The materials used for syringes, needles, tubing and GPS III Separators consist of medical grade polymers, elastomers and stainless steel suitable for use in medical devices. Blood-draw components, when supplied in this kit, are packaged, labeled and sterilized as indicated by the manufacturer's labeling.

**ACD-A (Anticoagulant Citrate Dextrose Solution, Solution A. U.S.P.)**
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.

All Components in this Kit are latex-free

Please note: the ACD-A anticoagulant and Clotalyst Reagent included in this kit are only for use with the Clotalyst Kit with GPS III Separators. NOT FOR DIRECT INTRAVENOUS INFUSION.

**INDICATIONS**
The GPS III 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 or allograft bone prior to application to an orthopedic surgical site as deemed necessary by clinical use requirements.

The Clotalyst Kit is designed for the preparation of autologous serum that is to be mixed with the PRP and autograft or allograft for bone graft handling prior to application to the orthopedic surgical site.

**CONTRAINDICATIONS**
1. Use as a dialyzer or for dialysis with a dialysate.
2. Direct connection to patient's vascular system of circulating blood volume.

**WARNING AND PRECAUTIONS**
1. Do not use sterile components of this kit if package is opened or damaged.
2. Clotalyst serum can be stored at 18 $^{o}$ C -26$^{o}$ C (64.4 $^{o}$ F -78.8$^{o}$ F) for up to 4 hours prior to use. Discard remaining serum if not used within the provided time frames.
3. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
4. The patient is to be made aware of the general risks associated with the treatment and possible adverse effects.
5. The autologous serum exhibits thrombin activity and therefore must not be injected into or otherwise allowed to enter the patient's vascular system.
6. The safety and effectiveness of the device for bone healing and hemostasis has not been established.
7. Follow manufacturer instructions when using the centrifuge. Use only a Biomet Biologics centrifuge. Outcomes using centrifuges from other manufacturers are unknown.
8. Do not use after expiration date.
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.
10. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

**POSSIBLE ADVERSE EFFECTS FROM BLOOD DRAW**
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 Clotalyst and GPS III Separators are terminally sterilized by exposure to a minimum dose of 25 kGy of gamma irradiation. All other components supplied in this system are sterilized by their respective suppliers as indicated on their labeling. Do not use any component from an opened or damaged package. Do not re-sterilize. Do not use after expiration date.

**INSTRUCTIONS FOR USE**
**Use standard aseptic technique throughout the following procedures.**

**PRP PREPARATION GPS III standard size separator (Figure 1) produces 6ml of PRP**
1. **DRAW:** Draw 8ml ACD-A into 60ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 52ml of the patient's blood into the 60ml 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 DISPOSABLE, and that the GPS III Separator remains upright.** Unscrew cap connected on center port #1. Remove and discard cap

and green packaging post. Slowly load blood filled 60ml syringe (8ml ACD-A mixed with 52ml of the patient's whole blood) into center port #1. Unscrew and discard protective inner piece from white cap tethered to port #1. Screw white cap onto port #1. Place GPS III Separator filled with anticoagulated blood in a Biomet Biologics centrifuge.

3. **BALANCE:** Fill blue GPS counterbalance tube (800-0508) with 35ml -60ml of sterile saline/water (equal to amount of whole blood plus ACD-A dispensed in the GPS III Separator). Place filled counterbalance directly opposite from the GPS III Separator in the centrifuge.
4. **SPIN:** Close centrifuge lid. Set RPM to 3.2 (x1000) and the time to 15 minutes. Press the start button. Once cycle is complete, open the centrifuge and remove the GPS III Separator.
5. **EXTRACT PPP:** Unscrew and save yellow cap on port #2. Connect 30ml syringe to port #2, invert GPS III 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. **SUSPEND PRP:** Holding GPS III Separator in the upright position, unscrew red cap on port #3. Attach sterile 10ml syringe to port #3. Extract 2ml of PRP into the 10ml syringe. Leave the syringe attached. Shake GPS III Separator gently for 30 seconds.
7. **EXTRACT PRP:** Immediately after suspending the platelets, extract the remaining PRP into the attached 10ml syringe. Remove 10ml syringe from port #3 and cap with a sterile syringe cap.

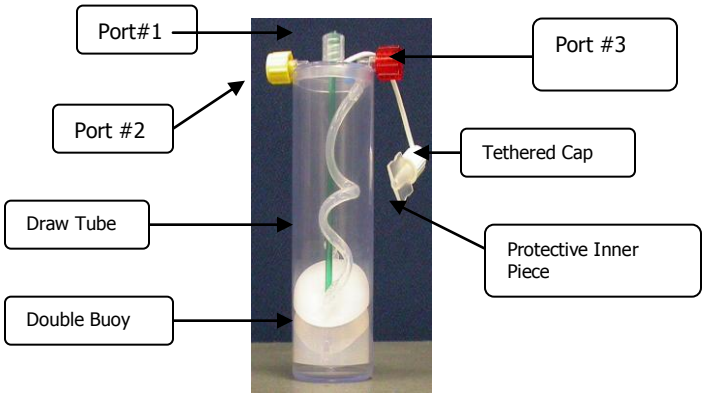


Figure 1
GPS III Separator

**PRP PREPARATION: GPS III Mini Separator (Figure 1), produces 3ml of PRP**

1. **DRAW:** Draw 4ml ACD-A into 30ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 26ml of the patient's blood into the 30ml 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 DISPOSABLE, and that the GPS III Mini Separator remains upright.** Unscrew cap connected on center port #1. Remove and discard cap and green packaging post. Slowly load blood filled 30ml syringe (4ml ACD-A mixed with 26ml of the patient's whole blood) into center port #1. Unscrew and discard protective inner piece from white cap tethered to port #1. Screw white cap onto port #1. Place GPS III Mini Separator filled with anticoagulated blood in a Biomet Biologics centrifuge.
3. **BALANCE:** Fill blue GPS counterbalance tube (800-0505) with 30ml of sterile saline/water (equal to amount of whole blood plus ACD-A dispensed in the GPS III Mini Separator). Place filled counterbalance directly opposite from the GPS III Mini Separator in the centrifuge.
4. **SPIN:** Close centrifuge lid. Set RPM to 3.2 (x1000) and the time to 15 minutes. Press the start button. Once cycle is complete, open the centrifuge and remove the GPS III Mini Separator.
5. **EXTRACT PPP:** Unscrew and save yellow cap on port #2. Connect 30ml syringe to port #2, invert GPS III Mini 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. **SUSPEND PRP:** Holding GPS III Mini Separator in the upright position, unscrew red cap on port #3. Attach sterile 10ml syringe to port #3. Extract 1ml of PRP into the 10ml syringe. Leave the syringe attached. Shake GPS III Mini Separator gently for 30 seconds.
7. **EXTRACT PRP:** Immediately after suspending the platelets, extract the remaining PRP into the attached 10ml syringe. Remove 10ml syringe from port #3 and cap with a sterile syringe cap.

**AUTOLOGOUS SERUM PREPARATION: Clotalyst Separator (Figure 2) produces 6ml of autologous serum**

1. **DRAW:** Draw 1ml ACD-A anticoagulant into a sterile 20ml syringe. Attach to the 18-gauge apheresis needle and prime with anticoagulant. Slowly draw 11ml of the patient's blood into the 20ml syringe primed with anticoagulant. Gently, but thoroughly mix the whole blood and anticoagulant upon collection to prevent coagulation.

   **NOTE: The 20ml syringe provided has graduation markings to aid in the accurate retrieval of 12ml of anticoagulated whole blood.**
2. **LOAD DEVICE: ENSURE BLOOD FROM ONLY ONE PATIENT IS PROCESSED.** Unscrew and discard blue cap on port # 1 and the red cap on port #2. Attach the Clotalyst Reagent syringe to port #1 and attach the 20ml syringe with anticoagulated blood to port #2. By depressing the plunger of the Clotalyst reagent syringe, transfer the entire volume through port #1 and into the 20ml syringe with anti-coagulated blood through port #2. By depressing the plunger of the 20ml syringe, transfer the 16ml mixture into the separator through port #2. Unscrew and discard the Clotalyst reagent syringe and the empty 20ml syringe. Unscrew and discard protective inner piece from white caps tethered to ports #1 and #2. Screw white caps onto ports #1 and #2.

   **NOTE: The Clotalyst Separator tube has a 16ml fill line to aid in the transfer of the proper volume into the tube.**
3. **MIX:** After securing the white caps to ports #1 and #2, vigorously shake the Clotalyst Separator for 15 seconds to thoroughly activate the mixture. This process should produce foam on top of the mixture. .
4. **INCUBATE:** Holding the preparation tube on its side, insure the glass beads are distributed evenly. Place the preparation tube on table top for a 15 minute incubation period at 18°C- 26°C. Orient the tube so that the 16ml graduation is facing upwards during incubation.
5. **SHAKE/ CLOT DISRUPTION:** Following the 15 minute incubation, shake the separator vigorously for 5 seconds. Dislodging and breaking up any coagulum that may be present in the tube.

6. **EXTRACT OUTPUT** Holding Clotalyst Separator upright, unscrew and remove the yellow cap on center port # 3. Pump the plunger on sterile 10ml syringe once to reduce friction and then attach the syringe to port # 3 Continue by steadily extracting 8ml-10ml output. Remove the 10ml syringe from port # 3 and cap with a sterile syringe tip.
   **NOTE: Product should be aspirated from the Clotalyst Separator immediately after step 5.**
7. **STORAGE:** The serum may be stored at 18° C -26° C (64.4°F -78.8°F) for up to 4 hours prior to use. Discard remaining output if not used within the provided time frames.

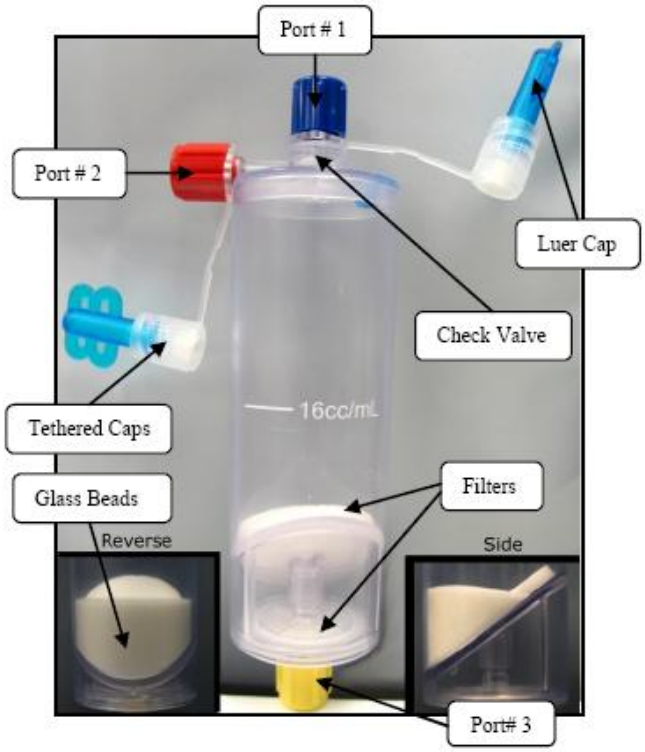


Figure 2
Clotalyst Separator

**CAUTION:** Federal law (USA) limits 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.



**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

STERILE EO — Sterilized using ethylene oxide

STERILE R — Sterilized using irradiation

STERILE — Sterile

STERILE A — Sterilized using aseptic processing techniques

STERILE — Sterilized using steam or dry heat

Use by date

WEEE device

REF — Catalogue number

LOT — Batch code

FLAMMABLE — Flammable

EC REP — Authorized representative in the European Community