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Revision A
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Clotalyst Kit with GPS III Separator

FOR INTERNATIONAL USE ONLY

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

DESCRIPTION

The Clotalyst Kit with GPS III Separator(s) permits the rapid preparation of autologous platelet-rich plasma (PRP) and clotting factors from a small volume of the patient's blood that is drawn and mixed with a citrate-based anticoagulant at the time of aspiration.

The Clotalyst Kit with GPS III Separator(s) contains Clotalyst and GPS III Separator(s), Clotalyst Reagent, and ACD-A anticoagulant.

MATERIALS

Clotalyst Separator (Fig. 1)

The Clotalyst Separator consists of medical grade polymers, silicone, acrylic, polyester and borosilicate suitable for use in medical devices.

The GPS III Separator (Fig. 2)

GPS III Separators consist of medical grade polymers, elastomers and stainless steel suitable for use in medical devices.

Clotalyst Reagent (Fig. 1)

Clotalyst Reagent is supplied and manufactured by ThermoGenesis Corp., Rancho Cordova, CA, for Biomet Biologics, Warsaw, IN. Please contact ThermoGenesis Corp. at 1-800-783-8357 for additional information.

ACD-A (Fig. 2)

ACD-A (Anticoagulant Citrate Dextrose Solution, Solution A, USP) is manufactured and supplied by Citra Labs LLC Braintree, MA. For further information please contact the supplier at 1-800-299-3411.

Notes

The ACD-A and Clotalyst Reagent included in this kit are for use exclusively with the Clotalyst Kit with GPS III Separators. All components in this kit are latex-free. NOT FOR DIRECT INTRAVENOUS INFUSION.

INDICATIONS

The GPS III Separator is designed to be used for the safe and rapid preparation of autologous PRP from a small sample of the patient's blood at the point of care. The PRP can be applied to the surgical site as deemed necessary by clinical use requirements.

The Clotalyst Separator is designed to be used for the safe and rapid preparation of autologous serum rich in clotting factors from a small

sample of anticoagulated blood at the patient's point of care. The output can be used to activate PRP, PPP or plasma concentrate.

CONTRAINDICATIONS

1. Use as a dialyzer or for dialysis with a dialysate.
2. Direct connection to patient's vascular system

WARNINGS AND PRECAUTIONS

1. Single use device. Do not reuse.
2. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.
3. Do not use components of this kit if package is opened or damaged.
4. Follow manufacturer instructions when using centrifuge. Use only a Biomet Biologics centrifuge.
5. After preparation, store output at 18 - 26 ° C for up to 4 hours. If output is not used within 4 hours of preparation, discard output.
6. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
7. The patient is to be made aware of general risks associated with the treatment and the possible adverse effects.
8. Patient blood and blood fractions are to be drawn and handled according to applicable established institutional guidelines.
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. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

POSSIBLE ADVERSE EFFECTS

(Associated with surgery & 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 Separator(s) are sterilized by exposure to a minimum dose of 25 kGy gamma radiation. All other components supplied in this system are sterilized by their respective suppliers using radiation or steam heat. Do not re-sterilize. Single Use Only. Do Not Reuse. Do not use any component from an opened or damaged product. Do not use any component past expiration date.

Comments regarding these devices 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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Intended for international use only. Indications for use of products and/or therapies contained herein may not be cleared or approved for marketing for use by the United States Food and Drug Administration.

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



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

INSTRUCTIONS FOR USE

Autologous Thrombin Preparation

- DRAW**

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

Unscrew and discard the blue cap on port # 2. Attach the Clotalyst reagent syringe. Unscrew and discard the red cap on port # 1. Attach the 20 ml syringe with anticoagulated blood. Depress the plunger of the Clotalyst reagent syringe to transfer the entire volume through port # 2 and into the 20 ml syringe with anticoagulated blood at port # 1. Depress the plunger of the 20 ml syringe to transfer the 16 ml mixture into the Clotalyst Separator. Unscrew and discard empty Clotalyst reagent and 20 ml syringes. Unscrew and discard blue sterile caps from tethered port caps at ports #1 and #2. Screw tethered caps onto ports # 1 and # 2.
- MIX**

After securing the tethered 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.
- INCUBATE**

Place the Clotalyst Separator table top for 15 minutes at room temperature. Ensure glass beads are evenly distributed. Orient the tube so that the 16 ml fill line is facing upwards during incubation.
- SHAKE**

Shake the Clotalyst Separator vigorously for 5 seconds to dislodge any coagulum that may be present from the Clotalyst Separator walls.
- EXTRACT OUTPUT**

Holding Clotalyst Separator upright, unscrew and remove the yellow cap from port # 3. Pump the plunger on sterile 10 ml syringe once to reduce friction and then attach the syringe to port # 3. Steadily extract 4-10 ml of output. Remove the 10 ml syringe from port # 3 and cap with sterile luer cap.
- STORAGE**

The output may be stored at 18-26°C for up to 4 hours prior to use. Discard output if not used within 4 hours

PRP Preparation (Standard)

- DRAW**

Draw 5-8 ml ACD-A into sterile 60 ml syringe. Attach an 18-gauge apheresis needle and prime with ACD-A. Slowly draw 52-55 ml of the patient's blood into the 60 ml syringe primed with ACD-A. Gently mix the whole blood and ACD-A upon collection to prevent coagulation.
- LOAD**

Unscrew cap connected on center port # 2. Remove and discard cap and green packaging post. Slowly load citrated blood from 60 ml syringe into center port # 2. Unscrew and discard blue luer cap from tethered sterile cap attached to port #1. Screw sterile tethered cap onto port #1. Place loaded GPS III Separator in Biomet Biologics centrifuge.
- BALANCE**

Fill blue GPS counterbalance tube (800-0508) with 35-60 ml of sterile saline/water (equal to amount of whole blood plus ACD-A loaded into GPS III). Place filled counterbalance directly opposite from the GPS III Separator in the centrifuge.
- SPIN**

Close centrifuge lid. Set RPM to 3200 and the time to 15 minutes. Press the start button. Once spin is complete, open the centrifuge and remove the GPS III Separator.
- EXTRACT PPP**

Unscrew and save yellow cap on port # 1. Connect 30 ml syringe to port # 1, invert GPS III Separator, and aspirate PPP. Remove 30 ml syringe from port # 1, cap with a sterile syringe cap and set aside. Replace yellow cap on port # 1.
- SUSPEND PRP**

Holding GPS III Separator in the upright position, unscrew red cap on port # 3. Attach sterile 10ml syringe to port # 3. Extract 2 ml of PRP into the 10 ml syringe. Leave the syringe attached. Shake GPS III Separator gently for 30 seconds.
- EXTRACT PRP**

Immediately after suspending the platelets, extract the remaining PRP into the attached 10 ml syringe. Remove 10 ml syringe from port # 3 and cap with a sterile luer cap.

PRP Preparation (Mini)

- DRAW**

Draw 3-4 ml ACD-A into sterile 30 ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 26-27 ml of the patient's blood into the 30 ml syringe primed with ACD-A. Gently mix the whole blood and ACD-A upon collection to prevent coagulation.
- LOAD**

Unscrew cap connected on center port # 2. Remove and discard cap and green packaging post. Slowly load citrated blood from 30 ml syringe into center port # 2. Unscrew and discard blue luer cap from tethered sterile cap attached to port # 2. Screw sterile tethered cap onto port # 2. Place loaded GPS III Mini Separator in Biomet Biologics centrifuge.
- BALANCE**

Fill blue GPS counterbalance tube (800-0505) with 30 ml of sterile saline/water (equal to amount of whole blood plus ACD-A loaded into GPS III). Place filled counterbalance directly opposite from the GPS III Mini Separator in the centrifuge.
- SPIN**

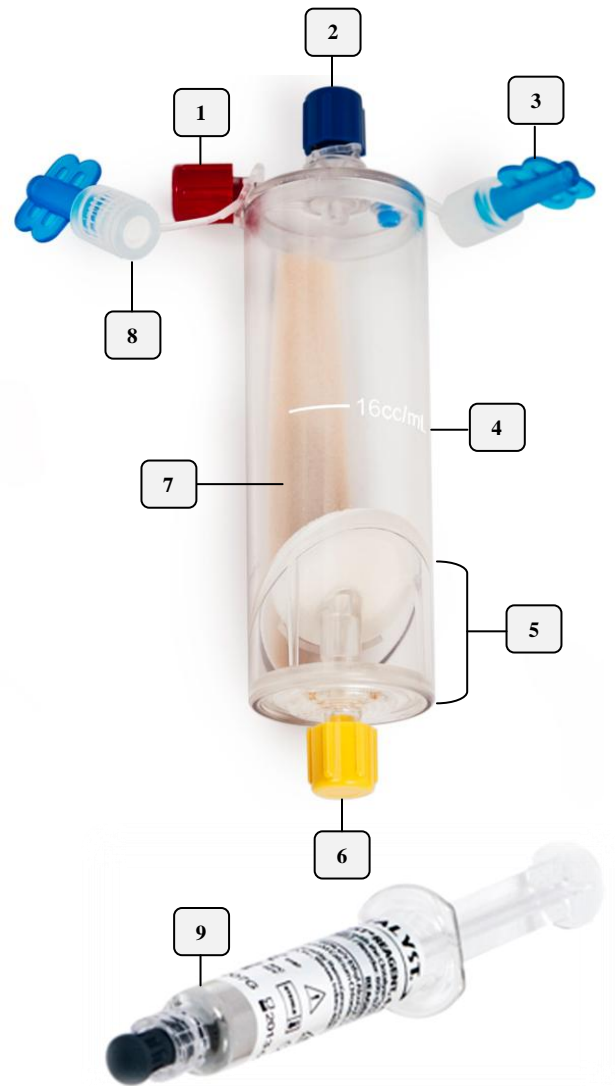
Close centrifuge lid. Set RPM to 3200 and the time to 15 minutes. Press the start button. Once spin is complete, open the centrifuge and remove the GPS III Mini Separator.
- EXTRACT PPP**

Unscrew and save yellow cap on port # 1. Connect 30 ml syringe to port # 1, invert GPS III Mini Separator, and aspirate PPP. Remove 30 ml syringe from port # 1, cap with a sterile syringe cap and set aside. Replace yellow cap on port # 1.
- 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 1 ml of PRP into the 10 ml syringe. Leave the syringe attached. Shake GPS III Mini Separator gently for 30 seconds.
- EXTRACT PRP**

Immediately after suspending the platelets, extract the remaining PRP into the attached 10 ml syringe. Remove 10 ml syringe from port # 3 and cap with a sterile luer cap.

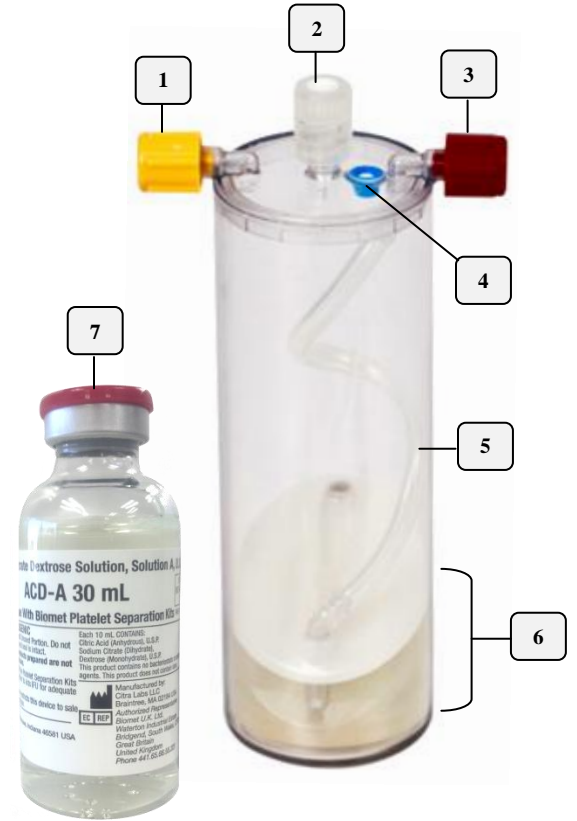
(Figure 1)
Clotalyst Separator & Reagent



(66% v/v ethyl alcohol, U.S.P. / 25 mM Calcium Chloride, U.S.P.)

ID	Description
1	Port # 1 – Blood Port
2	Port # 2 – Reagent Port
3	Luer Cap
4	Fill Line Guide
5	Filters
6	Port # 3 – Product Port
7	Glass Beads
8	Tethered Caps
9	Clotalyst Reagent

(Figure 2)
GPS III Separator



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

ID	Description
1	Port # 2 – PPP Aspiration Port
2	Port # 1 – Blood Loading Port
3	Port # 3 – PRP Aspiration Port
4	Hydrophobic Vent
5	PRP Aspiration Tube
6	Double Buoy System
7	ACD-A Anticoagulant