Biomet Biologics
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01-50-1439
Date: 01/09

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 and blood draw accessories. The system produces autologous serum and autologous platelet-rich plasma (PRP). Additional equipment used in the processing are the Clotalyst™ Heater and Biomet Biologics™ centrifuge.

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 is an anticoagulant supplied by Citra Anticoagulants, Inc., Braintree, MA, and manufactured by Cytosol Laboratories, Inc., 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 and Clotalyst™ Reagent included in this kit are only for use with the Clotalyst™ Kit with GPS™ III Separators.

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. Single use device. Do not reuse.
2. Use proper safety precautions to guard against needle sticks.
3. Do not use sterile components of this kit if package is opened or damaged.
4. Store Clotalyst™ serum at 18-26° C (64.4-78.8° F) for up to 4 hours prior to use. Discard remaining serum if not used within the provided time frames.
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 the general risks associated with the treatment and possible adverse effects.
7. The autologous serum exhibits thrombin activity and therefore must not be injected into or otherwise allowed to enter the patient's vascular system.
8. The safety and effectiveness of the device for bone healing and hemostasis has not been established.
9. Follow manufacturers' instructions when using a Biomet Biologics™ centrifuge (IEC centrifuge or the Drucker company centrifuge) and the Clotalyst™ Heater. Outcomes utilizing centrifuges or heaters from other manufactures are unknown.

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.

STERILITY

The Clotalyst™ and GPS™ III Separators are terminally sterilized by exposure to a minimum dose of 25 kGy gamma radiations. All other components supplied in this system are sterilized by their respective suppliers using radiation or ethylene oxide gas (ETO). Do not re-sterilize. Do not use after expiration date.

INSTRUCTIONS FOR USE

Store serum at 18-26° C (64.4-78.8° F) for up to 4 hours prior to use.
Use standard aseptic technique throughout the following procedures.

PROCEDURE ONE: Use of GPS™ III Separator (standard size) to prepare platelet-rich plasma (PRP)(Figure 1)

1. **DRAW:** Draw 6ml ACD-A into 60ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 54ml 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 SPIN, 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 (6ml ACD-A mixed with 54ml 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 35-60ml of sterile saline/water (equal to amount of whole blood plus ACD-A dispensed in the platelet concentrator). 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 spin 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 form port #3 and cap with a sterile syringe cap.

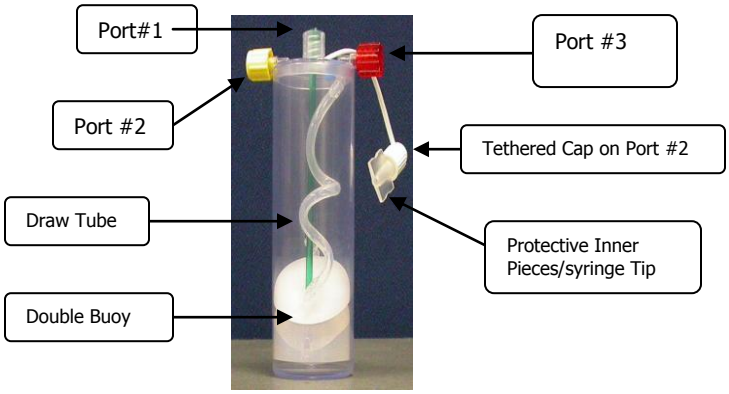

Figure 1
GPS™ III Separator

PROCEDURE ONE: <u>Use of GPS™ III Mini Separator to prepare platelet-rich plasma (PRP)(Figure 1)</u>

1. **DRAW:** Draw 3ml ACD-A into 30ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 27ml 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 SPIN, 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 (3ml ACD-A mixed with 27ml 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 spin 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 form port #3 and cap with a sterile syringe cap.

PROCEDURE TWO: Use the Clotalyst™ Separator to prepare the autologous serum (Figure 2)

1. **TURN ON:** The Clotalyst™ Heater to achieve the appropriate operating temperature 25°C (77°F).

2. **DRAW:** Draw 1ml ACD-A into a sterile 10ml syringe. Attach to the 18-gauge apheresis needle. Slowly draw 11ml of the patient's blood into the 10ml syringe primed with ACD-A. Gently, but thoroughly mix the whole blood and ACD-A upon collection to prevent coagulation.

   NOTE: The 10ml syringe provided has graduation markings to 12ml.

3. **LOAD Clotalyst™ REAGENT: Ensure the Clotalyst™ Separator remains upright.** Unscrew and discard blue cap on port #2, attach Clotalyst™ Reagent syringe and **completely** transfer contents (4 ml) through port #2. Remove and discard reagent syringe. Unscrew and discard protective inner piece from white cap tethered to port #2. Screw white cap onto port #2.

   NOTE: Dislodging duckbill valves attached to ports #2 and #3 of the Clotalyst™ Separator during steps 3 and 4 can occur. This is NOT detrimental to the procedure.

4. **LOAD BLOOD: ENSURE BLOOD FROM ONLY ONE PATIENT IS PROCESSED** Unscrew and discard red cap on port #3. Attach and slowly transfer contents of anticoagulated blood-filled syringe (1ml ACD-A mixed with 11ml of patient's whole blood) through port #3. Unscrew and discard protective inner piece from white cap tethered to port #3. Screw white cap onto port #3.
5. **MIX:** Without producing foam gently invert Clotalyst™ Separator 12 times to thoroughly mix the anticoagulated blood with the Clotalyst™ reagent and glass beads.
6. **INCUBATE:** Holding the Clotalyst™ Separator on its side ensures the glass beads are distributed evenly. Place the Clotalyst™ Separator in the heater and begin the incubation cycle (25 minutes at 25°C).
7. **SHAKE:** Remove Clotalyst™ Separator from the heater and shake vigorously for 5 second, thus dislodging and braking up any coagulum that may be present in the separator. Place the Clotalyst™ Separator in a Biomet Biologics™ centrifuge.
8. **BALANCE:** Place the orange Clotalyst™ counterbalance (800-0760) directly opposite from the Clotalyst™ Separator in the centrifuge.
9. **SPIN:** Close centrifuge lid. Set RPM to 3.2 (x 1,000) and the time to 5 minutes. Press the start button. Once the spin is completed, open the centrifuge.
10. **EXTRACT SERUM:** Gently remove the Clotalyst™ Separator without disturbing the stratified layers. Holding Clotalyst™ Separator upright unscrew and remove the yellow cap on center port #1. Attach a sterile 10ml syringe to center port # 1. To maximize serum volume output gently tilt Clotalyst™ Separator toward port #3 while slowly extracting 5-6ml serum Remove the 10ml syringe from center port #1 and attach sterile syringe cap

    NOTE: If the extraction tube becomes plugged prior to achieving 5-6ml of output, the Clotalyst™ Separator can be placed back in the centrifuge for one minute at 3200 RPMs to dislodge the clot, allowing the remaining serum to be extracted.

11. **STORAGE:** Store serum at 18-26° C (64.4-78.8°F) for up to 4 hours prior to use. Discard remaining serum if not used within the provided time frames.

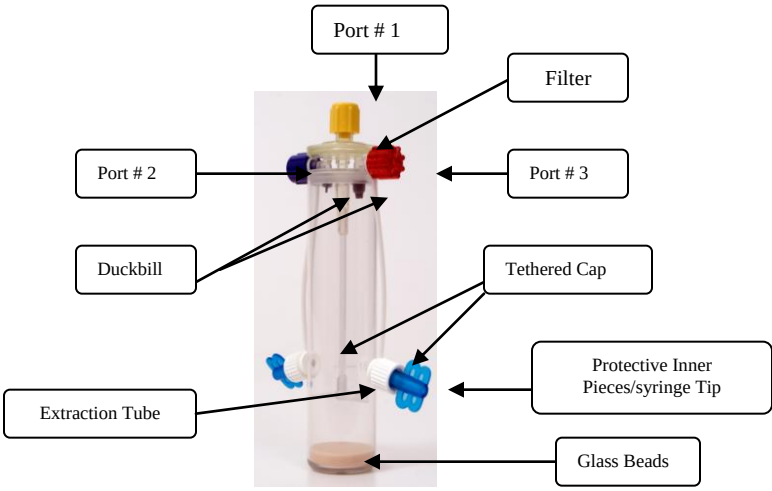

Figure 2
Clotalyst™ Separator

Caution: Federal law (USA) limits 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.

 Manufacturer

 Date of Manufacture

 Do Not Reuse

 Caution, Consult Accompanying Documents

Sterilized using Ethylene Oxide

Sterilized using Irradiation

Sterile

Sterilized using Aseptic Technique

Sterilized using Steam or Dry Heat

 Use By

 WEEE Device

Catalogue Number

Batch Code

Flammable