



INSTRUCTIONS FOR USE

Autologous Platelet Integrated Concentrate (APIC™) Processing Kit for the APIC PRP System

ATTENTION OPERATING SURGEON

**FOR SINGLE USE ONLY. Discard the entire disposable kit after one use.
Use an appropriate disposal method for potentially contaminated blood products.**

Description & Materials

The APIC Processing Kit is composed of materials to aid in the process of preparing APIC concentrated plasma from a patient's blood, including 1) Blood Collection, 2) Centrifugation, and 3) Concentration. The APIC Processing Kit disposables are made of medical grade polymers and other materials suitable for use in medical devices. All components in this kit are packaged, labeled, and sterilized as indicated and are latex-free.

ACD-A is not supplied as part of the APIC Processing Kit. ACD-A is an anticoagulant supplied by Fenwal, Inc., Lake Zurich, IL, and manufactured by Baxter Healthcare Corporation, Deerfield, IL.

This product may be protected under one or more of the following: U.S. patents #7,709,215 and #8,338,572, along with patents pending PCT/US09/58976 and PCT/US2013/027159, and other US and international patents pending.

Intended Use

The Autologous Platelet Integrated Concentration (APIC) System is indicated for the rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The platelet rich plasma is mixed with autograft and/or allograft bone prior to application to a bony defect for improving bone graft handling characteristics.

Contraindications

1. The APIC System is not for use as a dialyzer or for dialysis with a dialysate.
2. The APIC System is not for direct connection to a patient's vascular system.

Warnings and Precautions

1. Use proper safety precautions to guard against needle sticks.
2. Follow manufacturer instructions when using the APIC System Centrifuge. Use only Cytonics Corporation APIC™ System Centrifuge. Outcomes using a centrifuge from other manufacturers are unknown.
3. Follow manufacturer instructions when using the APIC System Pump. Use only Cytonics Corporation APIC™ System Pump. Outcomes using a pump system from other manufacturers are unknown.
4. Do not use sterile components in the APIC Processing Kit if the package is opened or damaged.
5. The APIC Processing Kit components are for single use only. Do not reuse.
6. The surgeon should be thoroughly familiar with the equipment and the procedure prior to using this device.
7. The patient should be made aware of the general risks associated with treatment and possible adverse effects.
8. Use prepared APIC concentrated plasma within 4 hours after drawing blood in accordance with AABB guidelines.
9. The safety and effectiveness for bone healing and hemostasis have not been established.
10. **Caution:** US Federal law limits this device to sale or use by or on the order of a physician.
11. Comments regarding this device can be directed to Attn: Regulatory Affairs Department, Cytonics Corporation, 555 Heritage Drive, Jupiter, FL 33458 USA, Email: Info@Cytonics.com Fax: 561-257-0782.

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 APIC Centrifugation Kit and Concentration Kit components are sterilized by exposure to a minimum dose of 25 kGy gamma radiation. All other components supplied in this kit are prepackaged and pre-sterilized by their respective suppliers using gamma radiation or ethylene oxide gas (ETO). **WARNING: Do not re-sterilize. Do not use after expiration date.**

Instructions For Use: APIC Processing Kit

STEP 1: APIC Blood Collection Kit

1. Connect a blunt fill needle to each of the three provided 60ml syringes
2. Alcohol wipe the septum of the ACD-A bag
3. Remove the cap from blunt fill needle and insert the needle into the septum of the ACD-A bag
4. Draw 7ml of ACD-A into the syringe then remove the blunt fill needle from ACD-A bag
5. Carefully recap the blunt fill needle and set the syringe aside. Repeat so that each syringe contains 7ml ACD-A
6. Using the provided IV Start Pack, prepare the patient for venipuncture, then perform venipuncture
7. Note: To minimize exposure, place the provided gauze sponge under the IV site
8. Disconnect the capped needle from the syringe containing ACD-A and attach the syringe to the IV access port
9. Carefully draw blood into syringe to reach a total volume of 45ml
10. Disconnect syringe and carefully pass off to a 2nd technician, maintaining upright position to avoid leak or spill
11. Repeat previous steps so that each syringe contains a total volume of 45ml anti-coagulated blood

STEP 2: APIC Centrifugation Kit

1. Connect a blunt plastic cannula to each of the blood filled syringes
2. With cap secured, invert each syringe several times to achieve adequate mixing of blood and anticoagulant
3. Remove APIC Centrifuge Tubes from sterile packaging
4. Remove the cap from the blunt plastic cannula and insert the cannula into the septum of the first centrifuge tube
5. Dispense 45ml of anti-coagulated blood from each syringe into the centrifuge tube then dispose of each syringe
6. Note: Do not invert or tilt the centrifuge tube because fluid may leak from the septum
7. Load centrifuge tubes into the APIC Centrifuge, using balanced technique, then close and lock the centrifuge lid
8. Select the "PRP Cycle" and press "START"
9. After the 4 minute spin cycle is complete, open the centrifuge and carefully remove each centrifuge tube
10. Connect the 60ml syringe to the plasma collection needle
11. Alcohol wipe the septum for each of the centrifuge tubes
12. Insert the plasma collection needle into the first centrifuge tube to a level 1cm above the buffy coat
13. Slowly collect 15 ml of plasma into the syringe, maintaining the position of the needle tip 1cm above the buffy coat. **Do not disturb the surface of the buffy coat.**
14. Remove the plasma collection needle from the first centrifuge tube
15. Collect 15ml plasma from the second centrifuge tube into the syringe with the needle tip 1cm above the buffy coat
 - a. After this collection the total volume in the syringe should be at the 30ml graduation
16. Collect 15ml of plasma from the third centrifuge tube into the syringe with the needle tip 1cm above the buffy coat
 - a. After this collection the total volume in the syringe should be at the 45ml graduation
17. Secure the syringe contents during transfer to the Concentration Kit

STEP 3: APIC Concentration Kit

1. Remove the APIC Concentration Kit from the sterile packaging
2. Place the Concentration Kit onto the pump platform and press "Enter" on the pump keypad
3. Remove the plasma collection needle from the syringe containing 45ml of plasma and immediately connect the syringe to the blue port of the concentration bag
4. Inject the plasma into the concentration bag and press "Enter" on the pump keypad
5. Disconnect and discard the empty 60ml syringe
6. Load the tube into the pump head, lock the pump head lever, and press "Start" on the pump keypad
7. After the 20 minute concentration process is complete the keypad will read "APIC Ready"
8. Immediately following the cycle completion, engage the white clamp on the waste bag tubing to prevent dilution
9. Using an alcohol pad, wipe the blue port of the APIC Concentration Bag
10. Connect a syringe to the blue port of APIC Concentration Bag and draw the concentrated plasma into the syringe
11. Disconnect the syringe containing the concentrated plasma
12. Mix the concentrated plasma with autograft or allograft bone as required
13. Unlock lever to remove tubing from the pump head, remove and discard all components of the APIC Concentration Kit

For more information, please visit www.Cytonics.com or contact us by
Phone: 561-575-4451 Fax: 561-257-0782 Email: Info@Cytonics.com