Precautionary Statement (01-50-1431)

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

01-50-1431
Date: 09/07

Vortech™ Concentration System

ATTENTION OPERATING SURGEON

NOTE: FOR SINGLE USE ONLY. Discard all disposable components of this system after one use by an acceptable disposal method for devices potentially contaminated with blood products.

DESCRIPTION

The Vortech™ Concentration System contains a plasma concentrator that is used to produce autologous platelet-poor plasma concentrate (PPPc) by centrifugation utilizing the Vortech™ base unit and desalting beads. The plasma concentrator has a side access port with a red cap for loading the anticoagulated whole blood and a center port with a blue cap to extract the PPPc. See Figure 1 for a labeled diagram.

Anticoagulated whole blood is added to the top chamber of the device where the red blood cells pass through medical grade felt and are collected in the top chamber during the initial processing cycle. The plasma then passes into the next chamber, where it mixes with desalting beads to remove excess water during the second cycle. During the final cycle, the desalting beads and PPPc are separated, and the PPPc collects in the lower chamber, where it is extracted using a sterile 30ml syringe.

MATERIALS

The Vortech™ plasma concentrator consists of medical grade polymers and porous polyacrylamide desalting beads suitable for use in medical devices.

The materials used for syringes, needles, tubing, and connectors consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices.

Blood draw kit components in this system are packaged, labeled and sterilized as indicated by the manufacturer's labeling.

All components in this system are latex-free.

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, please contact the supplier at 1-800-299-3411.

The ACD-A included in this system is only for use with the Vortech™ Concentration System.

INDICATIONS
The Vortech™ Concentration System is designed to be used for the safe and rapid preparation of autologous platelet-poor-plasma concentrate (PPPc) from a small volume of patient's blood at the point of care. The PPPc can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- Single-use device. Do not reuse.
- Use proper safety precautions to guard against needle sticks.
- Do not use sterile components of this system if package is opened or damaged.
- Use only the Vortech™ base unit with the Vortech™ plasma concentrator.
- Follow Operator's Manual, 01-50-1433, when using the base unit.
- Use prepared PPPc within 4 hours after drawing blood from the patient, according to current AABB guidelines.
- The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
- The patient is to be made aware of the general risks associated with treatment and possible adverse effects.
- Use of this device requires collection of a potentially clinically significant volume of blood from the patient. The impact of this blood loss on the health status of the patient should be considered.
- The safety and effectiveness of platelet-poor plasma concentrate (PPPc) for bone healing and hemostasis have 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 Vortech™ Concentration System plasma concentrator is 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 gas plasma, radiation or ethylene oxide gas (ETO). Do not re-sterilize. Do not use after expiration date has passed.

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

1. **DRAW:** Draw 5ml of ACD-A into both (2) 60ml sterile syringes and 3ml of ACD-A into the sterile 30ml syringe. Attach sterile syringe caps to one 60ml syringe and the 30ml syringe. Attach the other 60ml syringe to the 18-gauge apheresis needle and prime with ACD-A. Slowly draw 55ml of the patient's blood into each 60ml syringe, and 27ml of blood into the 30ml syringe, then remove and cap each syringe with sterile syringe caps. There will be a

total of 137ml of whole blood mixed with 13ml ACD-A. Gently, but thoroughly mix each syringe containing the anticoagulated whole blood upon collection to prevent coagulation.

2. **ATTACH:** Align the two notches on the plasma concentrator with the two pegs found on the base unit. Rotate the plasma concentrator clockwise until it locks into place and the red indicator light has turned to green on the base unit.
3. **LOAD: ENSURE BLOOD FROM ONLY ONE PATIENT IS PROCESSED, and that the plasma concentrator remains upright.** Unscrew and discard red cap on side access port. Attach and slowly load blood-filled syringes (two 60ml syringes, each with 5ml of ACD-A mixed with 55ml of patient's whole blood, and one 30ml syringe containing 3ml of ACD-A mixed with 27ml of patient's whole blood) one at a time into the plasma concentrator using the side access port.
4. **REMOVE: Unscrew and discard the side access port.**
5. **SPIN:** Press the green start button on the front of the base unit to begin processing. An audible beep and flashing red light will alert the user that the process is complete.
6. **EXTRACT PPPc:** Leaving plasma concentrator attached to the base unit, unscrew and remove the blue cap on the center port. Add 5ml of air to a sterile 30ml syringe, and attach syringe to the center port. Inject the 5ml of air to aid in extraction of the PPPc. Slowly withdraw the PPPc, then remove the 30ml syringe from the center port and cap with a sterile syringe cap.

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.

Figure 1 – Vortech™ Concentration System