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**GPS II Platelet Concentrate Separation Kit
with ACD-A Anticoagulant**

ATTENTION OPERATING SURGEON

DESCRIPTION

GPS II Platelet Separation Kit

The GPS II Platelet Concentrate Separation Kit aids separation of the patient's own blood components by density through the use of the GPS centrifuge.

The GPS II Platelet Concentrate Separation Kit permits platelet concentrate to be rapidly prepared from a small volume of the patient's blood that is drawn at the time of treatment.

Graft Delivery System

The GPS II Platelet Concentrate Separation Kit includes syringes comprising the Graft Delivery System. The Graft Delivery System is comprised of disposable piston syringes intended for delivery of allograft and autograft bone materials to an orthopedic surgical site.

MATERIALS

The materials used for syringes, needles, tubing, connectors, and platelet separators consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices. Blood draw kit components, when supplied in GPS II Platelet Concentrate Separation Kits, are packaged, labeled and sterilized as indicated by their individual labeling. The GPS II Platelet Concentrate Separation Kit and blood draw kit components do not contain latex.

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.

INDICATIONS FOR USE

GPS II Platelet Concentrate Separation Kit

The GPS II Platelet Concentrate Separation Kit 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 and allograft bone prior to application to an orthopedic surgical site as deemed necessary by clinical use requirements.

Graft Delivery System

The Graft Delivery System is designed for use in delivery of allograft and autograft bone materials to an orthopedic surgical site, and to facilitate pre-mixing of bone graft materials with I.V. fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood components as deemed necessary by the clinical use requirements.

INTENDED USE

GPS II Platelet Concentrate Separation Kit

Blood is drawn from the patient. The blood is then spun in a centrifuge in accordance with centrifuge operating directions. The platelet concentrate is then collected with a syringe. Certain syringe components are intended for use in the delivery of allograft and autograft bone materials to an orthopedic surgical site.

The ACD-A Anticoagulant is for use only with the GPS II Platelet Concentrate Separation Kit. NOT FOR DIRECT INTRAVENOUS INFUSION.

WARNINGS AND PRECAUTIONS

1. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.
2. Follow manufacturer instructions when using centrifuge. Use only GPS – IEC centrifuge. Outcomes using centrifuges from other manufacturers are unknown.
3. Follow manufacturer package insert for ACD-A Anticoagulant.
4. Do not use sterile component of this kit if package is opened or damaged.
5. Single use device, do not reuse.
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 treatment and the possible adverse effects.
8. Use prepared platelet concentrate material within 4 hours after drawing blood from patient.
9. The safety and effectiveness of this device for in vivo indications for use has 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 and/or allergic reaction.

STERILITY

The GPS II Platelet Concentrator is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. All other GPS II Platelet Concentrate Separation Kit components are sterilized by the respective suppliers using irradiation or ethylene oxide gas. Do not re-sterilize. Do not use after expiration date. Do not use any component from an opened or damaged package. Single Use Only.

INSTRUCTIONS FOR USE

1. **DRAW** 8 ml of anticoagulant into 60 ml syringe, attach to apheresis needle and prime with anticoagulant. Draw blood using standard aseptic practice. Draw 30 to 52 ml of blood from patient. Gently, but thoroughly mix the whole blood and anticoagulant upon collection to prevent coagulation.
2. **LOAD:** Unscrew cap on center blood port #1 and remove cap and green packaging post. Discard both. Slowly load blood-filled 60 ml syringe (8 ml of citrate anticoagulant and 52 ml of whole blood) into center blood port #1. Unscrew clear protective inner piece from white tethered cap and screw back onto center blood port #1. Place separator in centrifuge.
3. **BALANCE:** If processing one disposable, fill GPS blue counterbalance tube (800-0508) with 30-60ml of sterile saline (equal to amount of whole blood +ACD-A dispensed in the GPS disposable). Place into opposite sides of centrifuge. If processing two GPS disposables, fill both tubes with equal amounts of whole blood +ACD-A. Place into opposite sides of centrifuge.
4. **SPIN:** Close lid and set speed for 3.2 (x 1,000) and time to 15 minutes. Press green button to start spin. Once spin is complete, press red button to open lid.















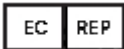
5. **PPP EXTRACTION:** If platelet poor plasma (PPP) is desired, unscrew yellow cap on port #2. Connect 30ml syringe and extract PPP.
6. **SUSPEND:** Shake tube vigorously for 30 seconds to suspend the platelets.
7. **PRP EXTRACTION:** Unscrew red cap on port #3. Connect 10ml syringe and extract platelet rich plasma (PRP)

CAUTION: Federal Law (USA) limits this device to sale 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.

All trademarks herein are the property of Biomet, Inc., or its subsidiaries unless otherwise indicated.

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
	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
	Authorized representative in the European Community