Platelet Concentrate
in Total Knees
Total Knee Arthroplasty
Total knee arthroplasty is performed to replace a damaged or diseased joint with an artificial prosthesis. This damage can result from arthritis, trauma, or other destructive diseases of the knee resulting in severe pain, stiffness, instability and deformity.

About Platelet Concentrate
From a small volume of the patient’s blood, the GPS® III Platelet Separation System will produce a highly concentrated mixture of platelets, which contain growth factors, and white blood cells. The system will collect over 90% of the available platelets and provide a 5x concentration of white blood cells.¹

This high level is made possible by the buoys within the GPS® III disposable. They are tuned to the density between platelets and red blood cells. Regardless of the hematocrit of the patient, the automated buoy system will float to the precise level capturing the platelet rich layer.

The Surgical Technique
The surgeon will resect the damaged surfaces of the femur, tibia and patella. These surfaces are then replaced with artificial implants (Figure 1).
Platelet Concentrate in Total Knees

Manual Spray Application

Figure 2-Once all components are in place and after routine irrigation, carefully aspirate all fluids and dry the surfaces. Carefully spray the platelet concentrate on high-risk areas such as medial anterior tibial release, patellar tendon and any lateral release. After spraying the above areas, the exposed cut bone surfaces, synovia areas, tendons, ligaments and joint capsule should be sprayed.

Aerosol Spray Application

Figure 4-The aerosol applicator can also be used to apply the platelet concentrate in the same fashion as above. This applicator provides an “air painting” effect creating a fine mist of platelet concentrate.

Figure 3-Just prior to closure, the subcuticular surface is also sprayed. If dealing with a large wound, consider spraying the platelet poor plasma (PPP) on the subcutaneous tissues to enhance wound closure.

Figure 5-Aerosol spray application of retinacular closure and subcutaneous tissues prior to closure.
Clinical Results
Platelet-Rich Plasma Application during closure following Total Knee Arthroplasty²

PRP Application 81 Knees
Controls 72 Knees

Transfusions (Units per patient)
55% more units of blood had to be given to control group

Range of Motion
All days statistically significant except for day 3
Clinical Results
Platelet Gel and Fibrin Sealant reduce Allogeneic blood transfusions in Total Knee Arthroplasty

PRP Application  85 Knees  
Controls     80 Knees

Transfusions (Units per patient)
67% more units given per patient in control group

Hemoglobin Level
Post-op Day 1

Superficial Wound Infection

Wound Leakage and Healing
GPS™ III Platelet Concentrate Separation Kit with ACD-A

ATTENTION OPERATING SURGEON

FOR INTERNATIONAL USE ONLY

NOTE: FOR SINGLE USE ONLY. Discard the entire disposable kit after one use by an acceptable disposal method for devices potentially contaminated with blood products.

DESCRIPTION
The GPS™ III Platelet Concentrate Separation Kit with ACD-A aids separation of the patient’s own blood components by density through the use of a Biomet Biologics centrifuge.

The GPS™ III Platelet Concentrate Separation Kit with ACD-A permits platelet concentrate to be rapidly prepared from a small volume of the patient’s blood that is drawn at the time of treatment.

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 this kit, are packaged, labeled and sterilized as indicated by their individual labeling. All components in this kit are latex free.

ACD-A is an anticoagulant supplied by Citra Anticoagulants, Inc., Braintree, MA, and manufactured by Cyotosol Laboratories, Inc., Braintree, MA. For further information regarding ACD-A Anticoagulant, please contact the supplier at 1-800-299-3411.

The ACD-A included in this kit is only for use with the GPS™ III Platelet Concentrate Separation Kit.

INDICATIONS FOR USE
The GPS™ III Platelet Concentrate Separation Kit with ACD-A 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 applied to the surgical site as deemed necessary by clinical use requirements. In addition, it may be used to improve bone graft handling.

WARNINGS AND PRECAUTIONS
1. Use proper safety precautions to guard against needle sticks.
2. Follow manufacturer instructions when using centrifuge. Use only a Biomet Biologics centrifuge (GPS™ – IEC centrifuge or the Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
3. Do not use sterilized components of this kit if package is opened or damaged.
4. Single use device. Do not reuse.
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 general risks associated with treatment and the possible adverse effects.
7. Use prepared platelet concentrate material within 4 hours after drawing blood from patient.
8. 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.

STERILITY
GPS™ III Platelet Concentrate Separation Kit platelet separator is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. All other GPS™ III Platelet Concentrate Separation Kit components are sterilized by the respective suppliers using irradiation or ethylene oxide gas (ETO). Do not re-sterilize. Do not use after expiration date.

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

1. DRAW: Draw 6ml of ACD-A into 60ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 30 to 54ml of patient’s own 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 platelet separator remains upright. Unscrew cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 60ml syringe (6ml of ACD-A mixed with 30 to 54ml of patient’s whole blood) into center blood port #1. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap onto port #1. Place platelet separator filled with anticoagulated blood in Biomet Biologics centrifuge.

3. BALANCE:
   Processing One Platelet Separator
   Fill blue GPS™ counterbalance tube (800-0508) with 36-60ml of sterile saline/water (equal to amount of whole blood plus ACD-A dispensed in the platelet separator). Place filled counterbalance directly opposite from the platelet separator in the centrifuge.
   Processing Two Platelet Separators
   Fill both platelet separators with equal amounts of whole blood plus ACD-A. Place filled platelet separators directly opposite from each other in the centrifuge.

4. SPIN: Close centrifuge lid. Set RPM to 3.2 (x 1,000) and the time to 15 minutes. Press the start button. Once spin is complete, open centrifuge.

5. EXTRACT PPP: Unscrew yellow cap on port #2, and save yellow cap. Connect 30ml syringe to port #2, invert platelet 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. IF PRP is desired, follow steps 7 – 8.

7. SUSPEND PRP: Holding platelet separator in the upright position, unscrew red cap on port #3. Attach 10ml syringe to port #3. Extract 2 ml of PRP into the 10ml syringe. Leave the syringe attached. Shake platelet separator gently for 30 seconds.

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

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.

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References:

1. Data on file at Biomet Inc. Bench test results are not necessarily indicative of clinical performance


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This brochure describes the surgical technique used by Mark Klaassen, M.D.

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