



**Plasmax® Plasma
Concentration
System**

BIOMET[®]
BIOLOGICS

Plasmax® Plasma Concentration System

Plasmax® Plasma Concentrate System Contains

- Plasmax® concentrator
- GPS® III separator

Provides

- 16ml of autologous output, 6ml of PRP and 10ml of autologous plasma concentrate
- Rapidly polymerizing autologous plasma concentrate
- GPS® III generated PRP has nine times more platelets and 5 times more white blood cells than whole blood¹

Consistent/Reproducible Results

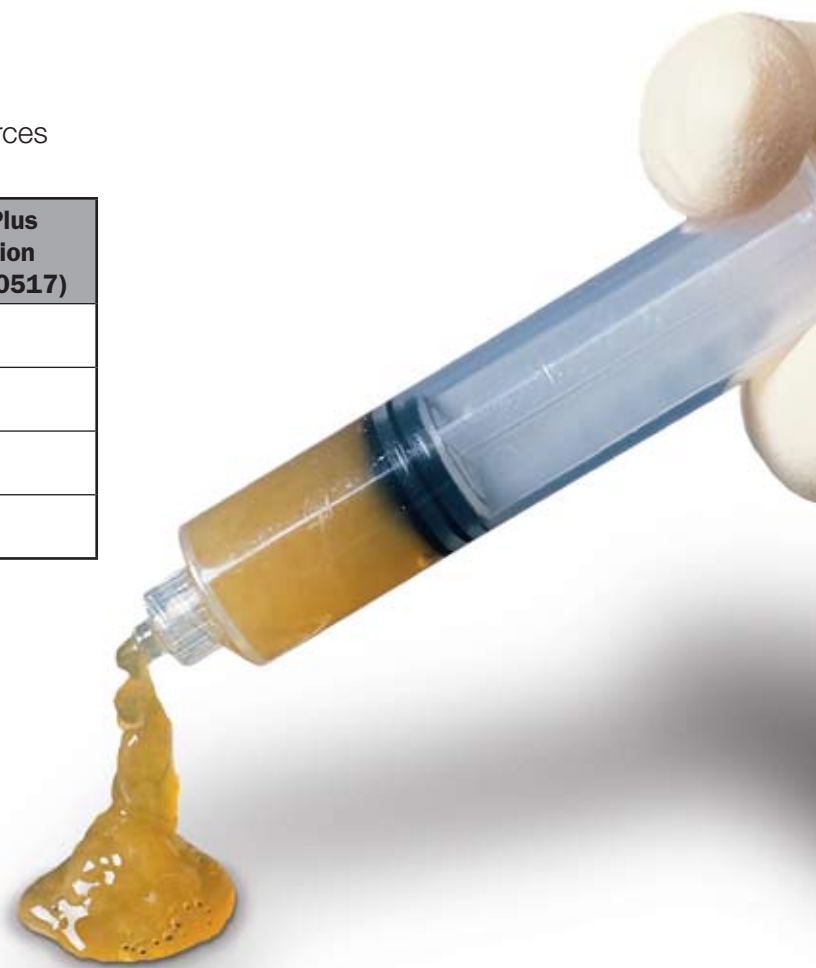
- Utilizes GPS® III technology to produce platelet rich plasma
- Polyacrylamide beads remove excess water from plasma in two minutes

Safe

- Autologous end products
- Eliminates concerns regarding pooled blood sources

	Plasmax® Concentration System (800-0516)	Plasmax® Plus Concentration System (800-0517)
Whole Blood Input	30ml	60ml
Platelet Rich Plasma Output	3ml	6ml
Platelet Poor Plasma Input	15ml	25ml
Plasma Concentrate Output	6ml	10ml

Note: Refer to package inserts for more detailed descriptions



Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) Preparation with GPS® III System

Technique describes Plasmax® Plus Concentration System (800-0517)

Step One: Load

Remove discard cap and green packaging post on center port (No 1). Slowly load blood-filled 60ml syringe (5ml of citrate anticoagulant and 55ml of blood) into the center port (No 1) of the GPS® III separator.



Remove and discard protective cover on tethered white cap. Screw white cap onto center port (No 1).



Place GPS® III separator into centrifuge. Fill the blue GPS® III counterbalance (800-0508) with 60–65ml of sterile saline and place into the opposite side of the centrifuge.



Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) Preparation with GPS® III System

Technique describes Plasmax® Plus Concentration System (800-0517)

Step Two: Spin

Close the lid and set speed for 3200 RPM and timer to 15 minutes. Press green button to start spin.



Step Three: PPP and PRP Extraction

Once spin is complete, remove yellow cap (No. 2). Invert the tube and withdraw 25ml of PPP (No. 2) with a sterile 30ml syringe. Replace yellow cap.



Remove red cap on side port No. 3 and connect sterile 10ml syringe. Withdraw 2ml.



Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) Preparation with GPS® III System

Technique describes Plasmax® Plus Concentration System (800-0517)

Step Three: PPP and PRP Extraction (Continued)

With 10ml syringe attached, suspend the platelets by gently shaking the tube for 30 seconds.



Extract the remaining platelet rich plasma (PRP) into the attached 10ml syringe.



Platelet Poor Plasma (PPP) Concentration with Plasmax® Concentrator

Technique describes Plasmax® Plus Concentration System (800-0517)

Step Four: Load Plasma

Unscrew yellow cap on port No. 1 of Plasmax® Plus concentrator and fill with 25ml of PPP. Replace cap (800-0517). Remove and discard protective cover on tethered white cap. Screw white cap onto port No 1.



Spin paddle by hand until plasma is fully mixed into beads. Mixing is complete when the white beads are completely saturated with plasma.



Note: While spinning, piston the paddle, be sure to push it firmly against the bottom to ensure adequate mixing.



Platelet Poor Plasma (PPP) Concentration with Plasmax® Concentrator

Technique describes Plasmax® Plus Concentration System (800-0517)

Step Five: Spin

Place Plasmax® Plus (800-0517) concentrator into centrifuge with the empty Plasmax® Plus counterbalance (800-0512). They should be placed on opposite sides in the centrifuge. Spin for 2 minutes at 2000 RPM.



Step Six: Extraction of Plasmax®

After the spin, the Plasmax® Plus concentrator contains approximately 10ml of autologous plasma concentrate.



Unscrew red cap on port No. 2. Connect sterile 10ml syringe on port No. 2 and extract approximately 10ml of concentrated plasma.



GPS® III Platelet Concentrate

Quality Platelet Concentrate

- From a small volume of a patient's blood, the GPS® III System provides a high quality platelet concentrate in an efficient manor.

Ease of Use

- Load blood, spin, extract platelet concentrate.
- Kits contain all components needed to process platelet concentrate—no searching for individual items.

Safety

- Patient's own blood is used.
- Blood taken at point-of-care.
- Small volume of blood required (27–110ml).



Ordering Information

Part No.	Description
800-0516	Plasmax® Plasma Concentrate Kit
800-0517	Plasmax® Plus Plasma Concentrate Kit
755VES	Centrifuge 115 volt 50–60 Hz (Table Top)
800-0508	GPS® Counterbalance (Blue)
800-0512	Plasmax® Plus Concentrator Counterbalance
800-0510	Plasmax® Concentrator Counterbalance
800-0250	Spray Applicator Kit (Tip not included)
800-0201	Dual Spray Applicator Tip
800-0202	Malleable Dual Cannula Tip 20 Gauge x 4" Length
800-0203	Malleable Dual Cannula Tip 20 Gauge x 7" Length
800-0206	Malleable Dual Cannula Tip 20 Gauge x 10" Length
800-0204	Blending Connector Tip Single Cannula
800-0260	Aerosol Spray Kit with Tip
800-0211	Aerosol Regulator w/o vent
800-0215	Endoscopic Aerosol Venting Regulator
800-0208	Rigid Dual Cannula Aerosol Tip 5mm dia. x 16" Length (Tubing Included)
800-0216	Rigid Dual Cannula Tip 5mm dia x 12" Length
800-0207	Malleable Dual Lumen Endoscopic Tip 5mm dia. x 12" Length

Biomet Biologics, Inc.
P.O. Box 587
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01-50-1448
Date: 03/07

**Plasmax™ Plasma Concentrator Accessory used with GPS® III
Mini Platelet Concentrate Separation Kit with ACD-A**

ATTENTION OPERATING SURGEON

NOTE: FOR SINGLE USE ONLY. Discard the entire disposable kit after one use, using acceptable disposal method for potentially contaminated blood products.

DESCRIPTIONS

Plasmax™ Plasma Concentrator Accessory

The Plasmax™ Plasma Concentrator Accessory aids in the concentration of the patient's own plasma proteins by centrifugation utilizing a Biomet Biologics centrifuge. Excess water is removed from the platelet-poor-plasma (PPP) with desalting beads.

GPS® III Mini Platelet Concentrate Separation Kit with ACD-A

The GPS® III Mini 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.

MATERIALS

The Plasmax™ Plasma Concentrator Accessory consists of medical grade polymers suitable for the use in medical devices, and contains porous polyacrylamide desalting beads.

The GPS® III Mini Platelet Separation Kit with ACD-A includes syringes, needles, tubing, connectors, and platelet separators which also consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices.

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

All components in this kit 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 kit is only for use with the Plasmax™ Plasma Concentrator Accessory used with GPS® III Mini Platelet Concentrate Separation Kit.

INDICATIONS

The Plasmax™ Plasma Concentrator with GPS® III Mini Platelet Concentrate Separation Kit with ACD-A is designed to be used for the safe and rapid preparation of concentrated platelet-poor-plasma (PPPc) and autologous platelet- rich-plasma (PRP) from a small sample of blood at the patient's point of care. The PPPc and PRP 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

1. Use proper safety precautions to guard against needle sticks.
2. Follow manufacturer instructions when using the centrifuge. Use only Biomet Biologics centrifuges (GPS® – IEC centrifuge or Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
3. Do not use sterile 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 the general risks associated with treatment and possible adverse effects.
7. Use prepared PPPc and PRP within 4 hours after drawing blood from patient, according to current AABB guidelines.
8. The safety and effectiveness 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 Plasmax™ Plasma Concentrator Accessory and the GPS® III Mini Platelet Separator are sterilized by exposure to a minimum dose of 25 kGy gamma radiation. All other components supplied in this kit are sterilized by the respective suppliers using radiation 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.

PROCEDURE ONE: Use the GPS® III Mini Platelet Concentrate Separation Kit with ACD-A to prepare platelet-poor-plasma (PPP) and PRP.

1. **DRAW:** Draw 3ml of ACD-A into 30ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 27ml of patient's own 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 platelet separator remains upright.** Unscrew clear cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 30ml

syringe (3ml of ACD-A mixed with 27ml 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 a Biomet Biologics centrifuge.

3. **BALANCE:** Fill purple GPS® Mini counterbalance tube (800-0505) with 30ml of sterile saline/water (equal to the amount of whole blood plus ACD-A dispensed in the platelet separator). Place filled counterbalance directly opposite from the platelet separator 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 exactly 15ml of 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 a 10ml syringe to port #3. Extract 1ml of PRP in the 10ml syringe. Leave the 10ml syringe attached to port #3. 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.

PROCEDURE TWO: Use the Plasmax™ Plasma Concentrator Accessory to prepare PPPc.

1. **LOAD:** Unscrew cap on port #1. Slowly load the 15ml PPP collected in 30ml syringe into port #1. Unscrew and discard clear, protective inner piece from white cap tethered to port #1. Screw white cap onto port #1.
2. **MIX:** Twist and piston the mixing paddle for 30 seconds. Be sure to push and twist the paddle to the floor of the Plasmax™ Plasma Concentrator Accessory's upper chamber to saturate the beads. There should be no white beads visible. Place into centrifuge.
3. **BALANCE:** Place the green Plasmax™ counterbalance (800-0510) directly opposite from the Plasmax™ Plasma Concentrator Accessory in the centrifuge.
4. **SPIN:** Close centrifuge lid and set RPM to 2.0 (x 1,000) and the time to 2 minutes. Press the start button. Once spin is complete, open centrifuge.
5. **EXTRACT PPPc:** Unscrew red cap on port #2 and extract PPPc using a sterile 10ml syringe. Remove 10ml syringe from port #2, and cap with a sterile syringe cap.

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, P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-1683.

GPS is a registered trademark of Biomet Manufacturing Corp. in the United States.

Biomet Biologics, Inc.
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Warsaw, Indiana 46581 USA

01-50-1456
Date: 03/07

**Plasmax™ Plus Plasma Concentrator Accessory used with
GPS® III Platelet Concentrate Separation Kit with ACD-A**

ATTENTION OPERATING SURGEON

NOTE: FOR SINGLE USE ONLY. Discard the entire disposable kit after one use, using acceptable disposal method for potentially contaminated blood products.

DESCRIPTION

Plasmax™ Plus Plasma Concentrator Accessory

The Plasmax™ Plus Plasma Concentrator Accessory aids in the concentration of the patient's own plasma proteins by centrifugation, utilizing a Biomet Biologics centrifuge. Excess water is removed from the platelet-poor-plasma (PPP) when mixed with desalting beads.

GPS® III Platelet Concentrate Separation Kit with ACD-A

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.

MATERIALS

The Plasmax™ Plus Plasma Concentrator Accessory consists of medical grade polymers suitable for the use in medical devices, and contains porous polyacrylamide desalting beads.

The GPS® III Platelet Concentrate Separation Kit with ACD-A includes syringes, needles, tubing, connectors, and platelet separators which consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices.

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

All components in this kit 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 kit is only for use with the Plasmax™ Plus Plasma Concentrator Accessory used with GPS® III Platelet Concentrate Separation Kit.

INDICATIONS

The Plasmax™ Plus Plasma Concentrator Accessory used with GPS® III Platelet Concentrate Separation Kit with ACD-A is designed to be used for the safe and rapid preparation of concentrated platelet-poor-plasma (PPPc) and autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient's point of care. The PPPc and PRP 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

1. Use proper safety precautions to guard against needle sticks.
2. Follow manufacturer instructions when using the centrifuge. Use only a Biomet Biologics centrifuge (GPS® – IEC centrifuge or Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
3. Do not use sterile 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 the general risks associated with treatment and possible adverse effects.
7. Use prepared PPPc and PRP within 4 hours after drawing blood from patient, according to AABB guidelines.
8. The safety and effectiveness 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 Plasmax™ Plus Plasma Concentrator Accessory and the GPS® III platelet separator are sterilized by exposure to a minimum dose of 25 kGy gamma radiation. All other components are sterilized by the respective suppliers using radiation 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.

PROCEDURE ONE: Use the GPS® III Platelet Concentrate Separation Kit with ACD-A to prepare platelet-poor-plasma (PPP) and PRP.

1. **DRAW:** Draw 5ml of ACD-A into 60ml syringe, attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 55ml 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 clear cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 60ml syringe (5ml of ACD-A mixed with 55ml 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 a Biomet Biologics centrifuge.

3. **BALANCE:** Fill blue GPS® counterbalance tube (800-0508) with 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 blood-filled platelet separator 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 exactly 25ml of 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 a 10ml syringe to port #3. Extract 2ml of PRP in the 10ml syringe. Leave the 10ml syringe attached to port #3. 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.

PROCEDURE TWO: Use the Plasmax™ Plus Plasma Concentrator Accessory to prepare PPPc.

1. **LOAD:** Unscrew cap on port #1. Slowly load the 25ml PPP collected in 30ml syringe into port #1. Unscrew and discard clear, protective inner piece from white cap tethered to port #1. Screw white cap onto port #1.
2. **MIX:** Twist and piston the mixing paddle for 30 seconds. Be sure to push and twist the paddle to the floor of the Plasmax™ Plus Plasma Concentrator Accessory's upper chamber to saturate the beads. There should be no white beads visible. Place into centrifuge.
3. **BALANCE:** Place the green Plasmax™ Plus counterbalance (800-0512) directly opposite from the Plasmax™ Plus Plasma Concentrator Accessory in the centrifuge.
4. **SPIN:** Close centrifuge lid and set RPM to 2.0 (x 1,000) and the time to 2 minutes. Press the start button. Once spin is complete, open centrifuge.
5. **EXTRACT PPPc:** Unscrew red cap on port #2 and extract PPPc using a sterile 10ml syringe. Remove 10ml syringe from port #2, and cap with a sterile syringe cap.

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References

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

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