

Plasmax[®] Plasma Concentration System

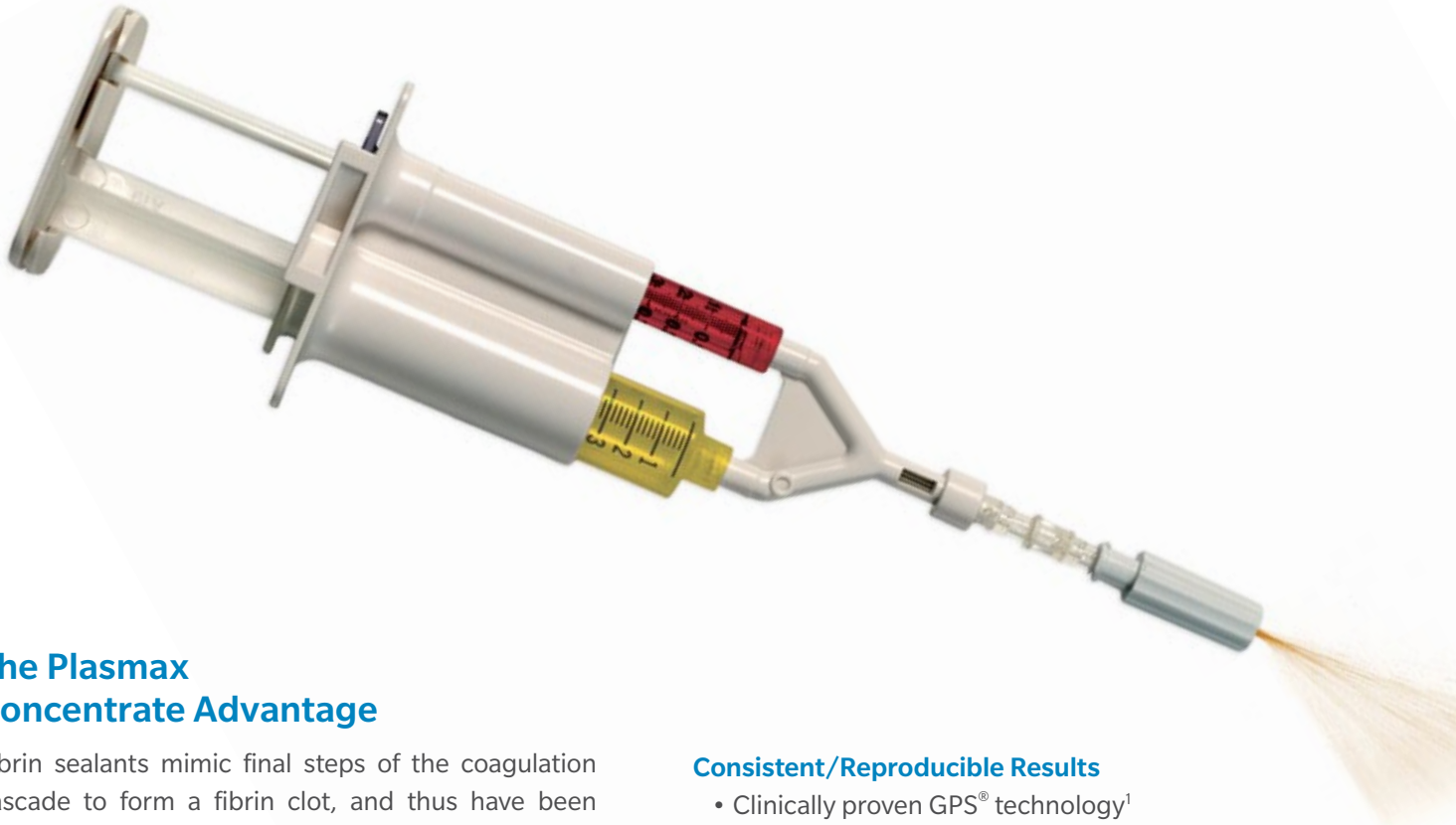
Processing Guide



Table of Contents

Product Overview.....	1-2
Processing Technique.....	3-6
Ordering Information.....	7-9
References	10
Indication	11

Plasmax Plus Plasma Concentration System



The Plasmax Concentrate Advantage

Fibrin sealants mimic final steps of the coagulation cascade to form a fibrin clot, and thus have been used as haemostatic agents in many different surgical procedures. However, many commercially available fibrin sealants are derived from pooled sources or contain proteins of bovine origin. Potential disease transmission and the possibility of a patient developing an immunogenic response are two potential risks associated with these sources.

The Plasmax Plus Concentration System, which produces a totally autologous plasma concentrate, eliminates the concern of disease transmission through fibrin sealants derived from pooled sources. Plasmax concentrate is a quality plasma concentrate that is safe, simple to process, and has an elevated fibrinogen concentration that is optimal for haemostasis and improved bone graft handling in a variety of surgical procedures.

Consistent/Reproducible Results

- Clinically proven GPS® technology¹

Improves Haemostasis/Graft Handling

- Three-fold increase in fibrinogen concentration²

Safe

- 100% autologous plasma concentrate

Simple

- Quality plasma concentrate in two minutes

Consistent and Reproducible Results

The Plasmax Plus Plasma Concentrate System provides a quality end product by utilizing.

- Clinically proven GPS technology, which will provide platelet poor plasma (PPP) and also a platelet concentrate, if needed¹
- Polyacrylamide beads, which remove excess water from the platelet poor plasma, resulting in a plasma concentrate with a three-fold increase in fibrinogen concentration²



Improves Haemostasis and Graft Handling

- Useful as an adjunct to sutures and staples
- Optimal gel strength
- Increase in fibrinogen concentration is vital for graft containment



Safe

- 100% autologous plasma concentrate
- Provides a natural haemostatic alternative
- Eliminates concerns of fibrin sealants derived from pooled blood sources or from bovine origin



Simple

- Load blood, spin, extract plasma, load plasma, spin, extract plasma concentrate
- The Plasmax Plus Plasma Concentrate System contains all components needed to process a plasma (and a platelet) concentrate—no searching for individual items



Preparation of Platelet Poor Plasma (PPP) with GPS III System

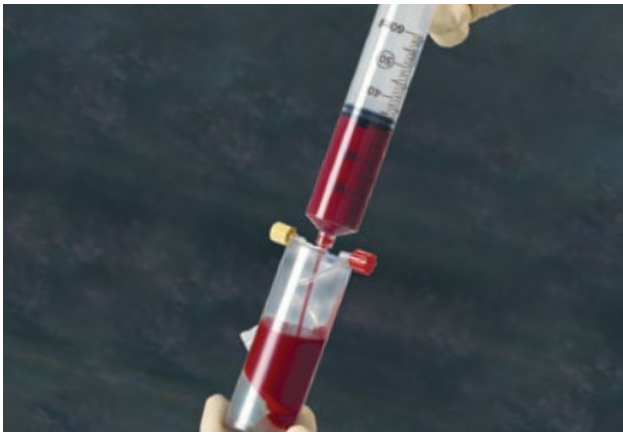


Figure 1



Figure 3



Figure 2

Step One: Load

Slowly load blood-filled 60ml syringe (6ml of citrate anticoagulant and 54ml of blood) into the center port of GPS® III canister.

Remove protective cover on white cap and discard. Screw white cap onto center port.

Place GPS III canister into centrifuge. Fill the blue GPS counterbalance with 60ml of sterile saline and place into the opposite side of the centrifuge.



Figure 4

Step Two: Spin

Close lid. Set speed at 3200 RPM and time at 15 minutes. Press green button to start spin.



Figure 5



Figure 6

Step Three: PPP Extraction

Once spin is complete, press red button to open lid. Remove yellow cap on side port No. 2 of GPS III canister and withdraw approximately 25ml of PPP with a 30ml syringe. Replace yellow cap.

ⓘ **Note:** If Platelet Rich Plasma (PRP) is desired, take out the remaining PPP from the tube, if necessary. Remove red cap on side port No. 3 and connect 10ml syringe. Withdraw 2ml. With 10ml syringe attached, suspend the platelets by shaking the tube for 30 seconds. If the pellet between the buoys is not suspended completely, shake tube vigorously. Extract the remaining platelet rich plasma (PRP) into the attached 10ml syringe.

Concentration of Platelet Poor Plasma (PPP) with Plasmax® Plus Concentrator



Figure 10



Figure 12



Figure 11

Step Four: Load Plasma

Unscrew cap on port No. 1 of Plasmax Plus Concentrator and fill with 25ml of PPP. Replace cap.

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 the paddle, be sure to push it firmly against the bottom to ensure adequate mixing.



Figure 13

Step Five: Spin

Close lid. Set speed at 2000 RPM and time at 2 minutes. Press green button to start spin.



Figure 14




Figure 15

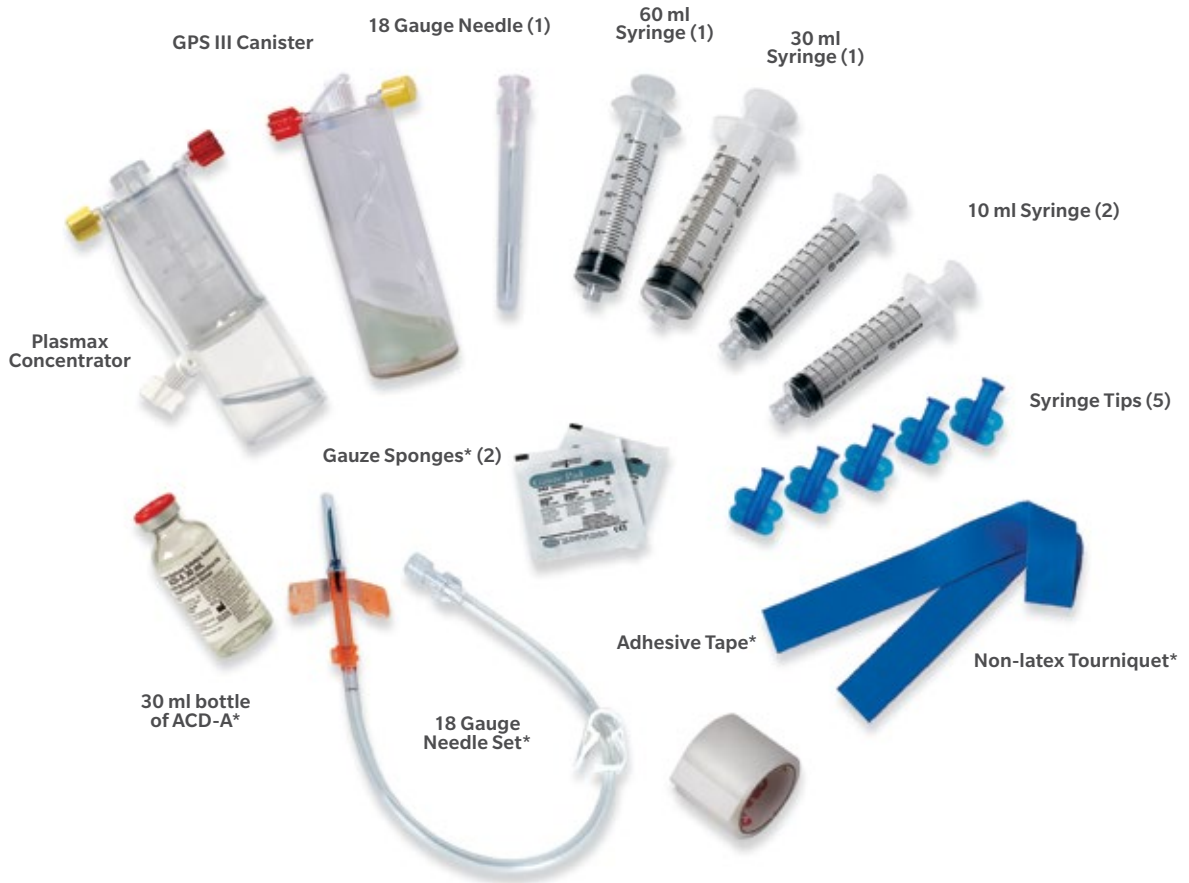
Step Six: Plasma Concentrate Extraction

After the spin, the Plasmax Plus Concentrator contains 10ml of autologous plasma concentrate.

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

Ordering Information

Product	Description	Part Number
	Plasmax Plus With GPS III Single & 30 ml ACD-A	800-0517



*Denotes Blood Draw Kit Items

Plasmax Hardware

Product	Description	Part Number
	Universal GPS Spare Bucket Kit for 755VES 60mL (2 Green Buckets)	7433
	Centrifuge 115V 50/60 HZ Drucker with Cord	755VES
	Aerosol Regulator	800-0211
	Plasmax® Plus Concentrator Counterbalance	800-0512
	GPS® Non-Sterile Counterbalance (Blue)	800-0508

Ordering Information

Plasmax Disposables

Product	Description	Part Number
	Applicator Tip	800-0201
	Malleable Dual Cannula Tip 20 Gauge x 4 inch Length	800-0202
	Malleable Dual Cannula Tip 20 Gauge x 7 inch Length	800-0203
	Blending Connector Tip Single Cannula	800-0204
	Malleable Dual Lumen Endoscopic Tip 5 mm x 12 inch Length	800-0207
	Aerosol Spray Kit with Two Tips	800-0260
	12 inch Aerosol Endoscopic Rigid Tip 1 to 1 Ratio (Tubing included)	800-0208
	16 inch Aerosol Endoscopic Rigid Tip 1 to 1 Ratio (Tubing included)	800-0217
	Biomet Biologics Manual Spray Applicator Kit (Tip not included) Contents include: Two 12ml Syringes, Two 1ml Syringes, Two Syringe Assembly Sets, Three Liquid Transfer Cups and Lids, One Plastic Tray Spray Applicator Tip	800-0250

References

1. B.L. Eppley *et al.*: "Platelet Quantification and Growth Factor Analysis from Platelet-Rich Plasma (PRP): Implications for Wound Healing." *Plast. Reconstr. Surgery*, 114: 1502–1508, November 2004.
2. Data on File at Biomet. Bench test results are not necessarily indicative of clinical performance.
3. Dimonte M, *et al.*: Maxillary sinus lift in conjunction with endosseous implants. A long-term follow-up scintigraphic study. *Minerva Stomatol*, 51(5):161–5, 2002.
4. Tayapongsak P, *et al.*: Inferior border titanium cribs in mandibular reconstruction. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod*, 79(1):10–17, 1995.
5. Tayapongsak P, *et al.*: Autologous fibrin adhesive in mandibular reconstruction with particulate cancellous bone and marrow. *J Oral Maxillofac Surg*, 52:161–5, 1994.
6. Vachiramon A, *et al.*: Delayed immediate single-step maxillary sinus lift using autologous fibrin adhesive in less than 4-millimeter residual alveolar bone: case report. *J Oral Implantol*, 28(4):189–93, 2002.
7. Kjaergard HK, *et al.*: Autologous fibrin glue-preparation and clinical use in thoracic surgery. *Eur J Cardiothorac Surg*, 6(1):52–4, 1992.
8. Kjaergard HK, *et al.*: Bleeding from the sternal marrow can be stopped using Vivostat patient-derived fibrin sealant. *Ann Thorac Surg*, 69(4):1173–5, 2000.
9. Cintron JR, *et al.*: Repair of fistulas using fibrin adhesive: long term follow-up. *Dis Colon Rectum*, 43(7):944–49, 2000.
10. Sentovich SM.: Fibrin glue for all anal fistulas. *J Gastrointest Surg*, 5(2):158–61, 2001.
11. Black FO, *et al.*: Surgical management of perilymphatic fistulas: a Portland experience. *Am J Otol*, 13(3):254–62, 1992.
12. Gleich LL, *et al.*: Autologous fibrin tissue adhesive in endoscopic sinus surgery. *Otolaryngol Head Neck Surg*, 112(2):238–41, 1995.
13. Levinson AK, *et al.*: Fibrin glue for partial nephrectomy. *Urology*, 38(4):314–6, 1991.
14. Bulajic P, *et al.*: Role of autologous fibrin tissue adhesive in abdominal surgery. *Achta Chir Jugosl*, 46(1–2):43–45, 1999.
15. Gross CW, *et al.*: Autologous fibrin sealant reduces pain after tonsillectomy. *Laryngoscope*, 111(2):259–63, 2001.
16. Leuthold, B. *et al.*: Autologous fibrin glue—a local hemostatic agent following dental surgical interventions in patients undergoing anticoagulant therapy. *Zahn Mund Kieferheilkd Zentralbl*, 77(3):268–72, 1989.
17. Yieh FS, *et al.*: The use of autologous fibrinogen concentrate in treating ocular hypotony after glaucoma filtration surgery. *J Ocul Pharmacol Ther*, 17(5):443–448, 2001.
18. Park MS, *et al.*: Autologous fibrin glue for tympanoplasty. *Am J Otol*, 15(5):687–9, 1994.
19. Chakravy RC, *et al.*: Autologous fibrin glue in full-thickness skin grafting. *Ann Plast Surg*, 23(6):488–91, 1989.
20. Buckley RC, *et al.*: A simple preparation of autologous fibrin glue for skin-graft fixation. *Plast Reconstr Surg*, 103(1):202–6, 1999.
21. Dahlstrom KK, *et al.*: The use of autologous fibrin adhesive in skin transplantation. *Plast Reconstr Surg*, 89(5):968–72, 1992.
22. de Moraes AM, *et al.*: Use of autologous fibrin glue in dermatologic surgery: application of skin graft and second intention healing. *Sao Paulo Med J*, 116(4):1747–52, 1998.
23. Man D, *et al.*: The use of autologous platelet-rich-plasma (platelet gel) and autologous platelet-poor-plasma (fibrin glue) in cosmetic surgery. *Plast Recon Surg*, 107:229–237, 2001.
24. Saltz R, *et al.*: Application of autologous fibrin glue in burn wounds. *J Burn Care Rehabil*, 10:504–7, 1989.
25. Moore MM, *et al.*: Fibrin sealant reduces serous drainage and allows for earlier drain removal after axillary dissection: a randomized prospective trial. *Am Surg*, 63(1):97–102, 1997.
26. Mandel MA: Closure of blepharoplasty incisions with autologous fibrin glue. *Arch Ophthalmol*, 108(6):842–4, 1990.
27. Mandel MA.: Minimal suture blepharoplasty: closure of incisions with autologous fibrin glue. *Aesthetic Plast Surg*, 16(3):269–72, 1992.
28. Adamyan LV, *et al.*: Use of fibrin glue in obstetrics and gynecology: a review of the literature. *Int J Fertil*, 36:76–8, 1991.
29. Levy, O *et al.*: The use of fibrin tissue adhesive to reduce blood loss and the need for blood transfusion after total knee arthroplasty. *J Bone Joint Surg Am*, 81–A:1580–8, 1999.
30. Ono K, *et al.*: Bone-fibrin mixture in spinal surgery. *Clin Orthop Relat Res*, (275):133–9, 1992.

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

01-50-1457
Date: 03/07

PLASMAX™ PLUS PLASMA CONCENTRATOR
USED WITH 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, using acceptable disposal method for potentially contaminated blood products.

DESCRIPTION

Plasmax™ Plus Plasma Concentrator
Plasmax™ Plus Plasma Concentrator 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 using a Biomet Biologics centrifuge.

MATERIALS

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

GPS® III Platelet Concentrate 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 kit 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 used with GPS® III Platelet Concentrate Separation Kit.

INDICATIONS

Plasma from the Plasmax™ Plus Plasma Concentrator may be used as an autologous alternative to wound closure and hemostasis, and it may be used to improve bone graft handling.

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 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 the general risks associated with treatment and possible adverse effects.
7. Use prepared plasma concentrate material within 4 hours after drawing blood from patient.

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

Plasmax™ Plus Plasma Concentrator and the GPS® III 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 Platelet Concentrate Separation Kit with ACD-A to prepare PPP and platelet-rich-plasma (PRP).

1. DRAW: Draw 6ml of anticoagulant into 60ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 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 clear 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 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 back 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 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 sterile 10ml syringe to port #3. Extract 2ml 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.

PROCEDURE TWO: Use the Plasmax™ Plus Plasma Concentrator to prepare platelet-poor-plasma concentrate (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'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 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.

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 in the United States.


All content herein is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to Zimmer Biomet or its affiliates unless otherwise indicated, and must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of Zimmer Biomet.

This material is intended for healthcare professionals. Distribution to any other recipient is prohibited.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

©2021 Zimmer Biomet



 **Responsible Manufacturer**
Biomet Biologics
A Subsidiary of Biomet
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
USA

Tel.: +1 574 267 6639