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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® technology

**Improves Haemostasis/Graft Handling**
- Three-fold increase in fibrinogen concentration

**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 needed\(^1\)
- Polyacrylamide beads, which remove excess water from the platelet poor plasma, resulting in a plasma concentrate with a three-fold increase in fibrinogen concentration\(^2\)

**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

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.
Step Two: Spin

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

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

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.
Step Five: Spin

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

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

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<th>Product</th>
<th>Description</th>
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<tr>
<td>Plasmax Plus With GPS III Single &amp; 30 ml ACD-A</td>
<td>800-0517</td>
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## Plasmax Hardware

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<td>7433</td>
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<td>Centrifuge 115V 50/60 HZ Drucker with Cord</td>
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<td>755VES</td>
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<tr>
<td>Aerosol Regulator</td>
<td></td>
<td>800-0211</td>
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<tr>
<td>Plasmax® Plus Concentrator</td>
<td>Counterbalance</td>
<td>800–0512</td>
</tr>
<tr>
<td>GPS® Non-Sterile Counterbalance (Blue)</td>
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# Ordering Information

## Plasmax Disposables

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<td>Applicator Tip</td>
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<tr>
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<td>Malleable Dual Cannula Tip 20 Gauge x 4 inch Length</td>
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<td></td>
<td>Malleable Dual Cannula Tip 20 Gauge x 7 inch Length</td>
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<td>Blending Connector Tip Single Cannula</td>
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<td></td>
<td>Malleable Dual Lumen Endoscopic Tip 5 mm x 12 inch Length</td>
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<td>Aerosol Spray Kit with Two Tips</td>
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<td></td>
<td>12 inch Aerosol Endoscopic Rigid Tip 1 to 1 Ratio (Tubing included)</td>
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<tr>
<td></td>
<td>16 inch Aerosol Endoscopic Rigid Tip 1 to 1 Ratio (Tubing included)</td>
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<td></td>
<td>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</td>
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## Clotalyst Autologous Thrombin Collection System

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<td>Clotalyst/GPS III Single Kit &amp; Reagent</td>
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<td>Clotalyst Heater Cord</td>
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<td>Centrifuge 115V 50/60 HZ Drucker with Cord</td>
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References


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. UNLOCK 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 syringes (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 (800-0558) 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 syringes from port #3, and cap with a sterile syringe cap.

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

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. Place mixed PPP in the platelet separator.
3. BALANCE: Place the green Plasmax™ Plus counterbalance tube (800-0512) directly opposite from the Plasmax™ Plus Plasma Concentrator's upper chamber to saturate the beads. There should be no white beads visible. Place into 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 PPP: Unscrew red cap on port #2, and extract PPP using a sterile 10ml syringe. Remove 10ml syringes 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.

These devices are only approved for distribution outside the United States.

GPS is a registered trademark in the United States.

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