Plasmax® Plasma Concentration System

Are you looking for your patient’s own derived fibrin sealant?

Intended for international use only. Indications for use of products and/or therapies contained herein may not be cleared/approved for use by the U.S. Food and Drug Administration.
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 utilising...

- 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

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Step One: Load

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

Remove protective cover on white cap and discard. Screw white cap onto centre 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.
**Technique (continued)**

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.
Technique (continued)

Step Five: Spin

Place Plasmax® Plus 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 RPMs.

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.
The Plasmax® Plus System creates a plasma concentrate that can be used as an autologous alternative to commercially available fibrin sealants in wound closure and for haemostasis.

Maxillo-Facial Surgery
- Mandibular reconstruction\(^3,4\)
- Maxillary sinus lift\(^5,6\)

Cardiothoracic Surgery
- Thoracic surgery\(^7\)
- Sternal closure\(^8\)

General Surgery
- Rectal fistula repair\(^4,10\)
- Perilymphatic fistula repair\(^11\)
- Endoscopic sinus surgery\(^12\)
- Partial nephrectomy\(^13\)
- Abdominal surgery\(^14\)

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- Abdominal surgery\(^14\)

Oral Surgery
- Tonsillectomy\(^15\)
- Tooth extractions\(^16\)

Ocular Surgery
- Glaucoma filtering surgery\(^17\)

Otology
- Tympanoplasty\(^18\)

Plastic Surgery
- Skin graft fixation\(^19,20\)
- Skin transplantation\(^21\)
- Cosmetic surgery\(^22,23\)
- Burn wounds\(^24\)
- Mastectomy\(^25\)
- Blepharoplasty\(^26,27\)

Obstetrics
- C-section\(^28\)
- Hysterectomy\(^28\)

Orthopedic Surgery
- Total joint arthroplasty\(^29\)
- Spine surgery\(^30\)
Clotalyst® Autologous Clotting Factor.
The key to effective sealing with Plasmax® Plus Concentration System

Clotalyst® Autologous Clotting Factor, when used in conjunction with plasma concentrate derived from the Plasmax® Plus System, activates the clotting cascade, ensuring a fully autologous fibrin sealant.

Clotalyst® System produces approximately 6ml of autologous thrombin from only 12ml of patients’ own citrated blood. The thrombin output can be used to activate plasma concentrate and platelet rich plasma (PRP) produced by the Plasmax® Plus System. The Clotalyst® System provides rapid clotting (under 15 seconds) of plasma and platelet derived products, giving the surgeon a unique product that is safe for the patients in a variety of procedures.

Plasma concentrate derived from the Plasmax® Plus System in combination with Clotalyst® Autologous Clotting Factor.

For more detailed information, refer to Clotalyst brochure BBI0004.0
For optimal clotting with plasma concentrate and PRP, use of the ATM100 and ST-3 tips are recommended.

**ATM100 TIP:** The ATM100 tip has a blending channel that mixes the plasma concentrate portion with the thrombin before being sent through a sheath for precise delivery.

**ST-3 TIP:** The ST-3 TIP is used in conjunction with a blending connector (800-0204). It blends the plasma concentrate and thrombin portions before passing through the tip, which produces a fanned out spray.

These tips provide the optimal conversion of plasma concentrate to fibrin glue and platelet rich plasma to platelet gel.
Ordering Information

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<table>
<thead>
<tr>
<th>Description</th>
<th>Catalog Number</th>
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<tbody>
<tr>
<td>Plasmax® Plus Disposable Kit</td>
<td>800-0560A</td>
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</tbody>
</table>

Contents:
- One Plasmax® Plus Concentrator Canister
- One Disposable GPS® III Canister
- One 60ml syringe
- One 30ml syringe
- Two 10ml syringes
- One 18 gauge needle set w/clamp
- One 18 gauge 1 ½” needle
- One 30ml bottle of ACD-A
- One non-latex tourniquet
- One roll of adhesive tape
- Two gauze sponges
- Five syringe tips

*Denotes Blood Draw Kit Items
## Plasmax® Hardware Ordering Information

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<table>
<thead>
<tr>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>GPS® Spare Bucket Kit (Drucker Centrifuge; 2 Blue Buckets)</td>
<td>7431</td>
</tr>
<tr>
<td>Drucker 230 Volt 50-60 Hz Centrifuge</td>
<td>755VES-230V</td>
</tr>
<tr>
<td>Aerosol Regulator without Vent</td>
<td>800-0211</td>
</tr>
<tr>
<td>Plasmax® Plus Concentrator Counterbalance</td>
<td>800–0512</td>
</tr>
<tr>
<td>GPS® Non-Sterile Counterbalance (Blue)</td>
<td>800-0508</td>
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### Plasmax® Disposable Ordering Information

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<table>
<thead>
<tr>
<th>Description</th>
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<tbody>
<tr>
<td>Dual Spray Applicator Tip</td>
<td>800-0201</td>
</tr>
<tr>
<td>Malleable Dual Cannula Tip 20 Gauge x 4 inch Length</td>
<td>800-0202</td>
</tr>
<tr>
<td>Malleable Dual Cannula Tip 20 Gauge x 7 inch Length</td>
<td>800-0203</td>
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<tr>
<td>Blending Connector Tip Single Cannula</td>
<td>800-0204</td>
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<tr>
<td>Malleable Dual Cannula Tip 20 Gauge x 10 inch Length</td>
<td>800-0206</td>
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<tr>
<td>Malleable Dual Lumen Endoscopic Tip 5mm x 12 inch Length</td>
<td>800-0207</td>
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<tr>
<td>Aerosol Spray Kit with Two Tips</td>
<td>800–0260</td>
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<tr>
<td>12 inch Aerosol Endoscopic Rigid Tip 1 to 1 Ratio</td>
<td>800-0216</td>
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<tr>
<td>(Tubing included)</td>
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<tr>
<td>16 inch Aerosol Endoscopic Rigid Tip 1 to 1 Ratio</td>
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<tr>
<td>(Tubing included)</td>
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<tr>
<td>Biomet Biologics Manual Spray Applicator Kit (Tip not included)</td>
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<tr>
<td>Contents include: Two 12ml Syringes, Two 1ml Syringes,</td>
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<tr>
<td>Two Syringe Assembly Sets, Three Liquid Transfer Cups</td>
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<tr>
<td>and Lids, One Plastic Tray</td>
<td>800-0250</td>
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<td>Description</td>
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<tr>
<td>Graft Preparation System</td>
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<tr>
<td>ATM100 Autologous Thrombin Mixer Tip</td>
<td>ATM100</td>
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<tr>
<td>ST-3 Tip (Ten Pack) to be used with 800-0204</td>
<td>ST-3 TIP</td>
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### Clotalyst® Autologous Thrombin Collection System

<table>
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<tr>
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<tr>
<td>Clotalyst® Disposable</td>
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<tr>
<td>Clotalyst® Heater (Heater Cord included)</td>
<td>800-0755</td>
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<tr>
<td>Clotalyst® Heater Cord</td>
<td>800-0757</td>
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<tr>
<td>Clotalyst® Non-Sterile Counterbalance</td>
<td>800-0760</td>
</tr>
<tr>
<td>Drucker 230 Volt 50-60Hz Centrifuge</td>
<td>755VES-230V</td>
</tr>
<tr>
<td>TPD™ Thrombin Reagent (10 pack)</td>
<td>TPDRS100T</td>
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</table>
References


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