Do you want a sticky gel to improve the handling of your bone graft?

Platelet Rich Plasma Concentrate

High Volume in 5 Minutes

This brochure is for International use only. It is not for distribution in the United States.
The Vortech™ Concentration System produces 30 ml of platelet rich plasma concentrate from only 150 ml of patients’ own citrated blood. Total operating time will be approximately 5 minutes from the introduction of the blood into the Vortech™ disposable. When combined with autologous thrombin, the end product is a sticky, platelet rich plasma gel that can be utilised to accelerate soft tissue and bone healing in a variety of surgical procedures. The Vortech™ System consists of a base unit and a disposable.

Only the Vortech™ Concentration System can give you the following benefits.
• Simple and quick preparation
• High volume platelet rich plasma concentrate derived from the patients’ own blood
• High fibrinogen concentration
**Vortech™ Concentration System**

**Why Platelets?**

Utilising the Vortech™ Concentration System, the patient's own blood is taken and spun down to create a highly concentrated formula. This high volume formula contains a mixture of concentrated fibrin and platelets. When the platelets become activated, growth factors are released and initiate the body's natural healing response.

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### Platelet Derived Growth Factor (PDGF-aa, PDGF-ab, PDGF-bb)
- Stimulates cell replication
- Promotes angiogenesis
- Promotes epithelialisation
- Promotes granulation tissue formation

### Vascular Endothelial Growth Factor (VEGF)
- Promotes angiogenesis

### Epidermal Growth Factor (EGF)
- Promotes cell differentiation
- Stimulates re-epithelialisation, angiogenesis and collagenase activity

### Transforming Growth Factor (TGF-β1, TGF-β2)
- Promotes formation of extracellular matrix
- Regulates bone cell metabolism

### Fibroblast Growth Factor (FGF)
- Promotes proliferation of endothelial cells and fibroblasts
- Stimulation of angiogenesis
Why an Elevated Concentration in Fibrinogen?

Fibrin is the naturally optimised carrier for delivery of haematogenic tissue growth factors. During the process of wound repair, platelets and the coagulation proteins, including fibrinogen, combine to form a fibrin gel. Tissue growth factors and other active wound healing and signalling cytokines are released by the platelets throughout the forming fibrin gel, within which they are encapsulated. Upon contraction of the fibrin gel these growth factors are released into the surrounding tissues.

A moderate elevated concentration in fibrinogen, as seen in Vortech™ Concentration System (5 to 15 mg/ml), creates a fibrin gel that is safely below the densities seen to inhibit wound repair, while strong enough to firmly bind bone graft particles and retain them securely in place throughout the revascularisation period. A Vortech™ coagulum will be resorbed in a physiological way during the tissue healing process. The graft material may be tightly bound together by the fibrin gel and fixed in place by the formation of new vascular tissue.²
Simple and Quick Preparation

• User friendly twist on disposable locks onto base unit with ease
• 5 simple steps to produce platelet rich plasma concentrate in approximately 5 minutes

High Volume Platelet Concentrate

• Vortech™ Concentration System quickly produces 30 ml of platelet rich plasma concentrate from 150 ml of the patients’ own citrated blood
• Provides full array of autologous growth factors

High Fibrinogen Concentration

• Optimal gel strength
• Helps to prevent graft migration
• Retains growth factors at desired site
• Improves handling when mixed with graft materials due to the 3x concentration of fibrinogen
• Useful as an adjunct to sutures and staples
• Provides haemostasis
• Optimal fibrinogen concentration allows cellular infiltration, providing additional nourishment
**Vortech™ Concentration System Preparation**

**Step One:**

Attach disposable onto base by aligning the tabs and twist clockwise until locked. Once disposable is locked into the proper position, the Ready/Run light turns from red to green.

**Step Four:**

Push green button on the base to start cycle. Total spin time is 5 minutes.
Step Two:

Unscrew red cap on Port “1” and discard. Slowly load blood filled syringes (a total of 150 ml of citrated blood; 137 ml of patients’ blood mixed with 13 ml of ACD-A anticoagulant) into port “1”.

Step Three:

Unscrew port “1” and discard. This will release the rotor and allow it to spin freely.

Step Five:

Once spin is complete, remove blue cap on port “2”. Use 30 ml syringe to extract platelet rich plasma concentrate.
How to use TPD™ Thrombin Processing Device with Whole Blood

Step One: Preparing TPD™ Thrombin Processing Device for introducing reagent/blood

Remove plastic protectors from both stopcock valves and attach plunger to reagent syringe.

While holding TPD™ Thrombin Processing Device at a 45° angle, completely inject reagent. **NOTE:** When injecting reagent, ensure internal beads are submerged in fluid. Remove reagent syringe and replace blue cap.

Remove yellow luer cap over blood injection port and attach syringe with 11 ml of anticoagulated blood.

While holding the TPD™ Thrombin Processing Device upright, slowly inject approximately 11 ml of anticoagulated blood into TPD™ Thrombin Processing Device. **Note:** Fluid level needs to be at MAX line to ensure proper functioning of TPD™ Thrombin Processing Device. DO NOT OVERFILL. Blood cannot be drawn back after entering TPD™ Thrombin Processing Device.

Turn stopcock A 90° counterclockwise so the “OFF” knob points down. Turn stopcock B 180° counterclockwise so the “OFF” knob points to the left. Detach blood syringe and re-attach yellow luer cap to blood port.
Step Two: Processing TPD™ Thrombin Processing Device

Gently invert TPD™ Thrombin Processing Device at least seven times. Ensure beads fully mix with fluid.

Place TPD™ Thrombin Processing Device horizontally on a flat surface, with beads distributed evenly. Allow TPD™ Thrombin Processing Device to rest at 18°C – 26°C for 20 minutes. Note: Do not disturb the TPD™ Thrombin Processing Device during this 20-minute incubation period.

After 20 minutes has passed, shake TPD™ Thrombin Processing Device vigorously to break up any gel that may be present and evenly re-distribute beads. Place horizontally on a flat surface for an additional 5 minutes. Note: Do not disturb TPD™ Thrombin Processing Device during this 5-minute incubation period. After time has elapsed, shake TPD™ Thrombin Processing Device vigorously to dislodge gel. The thrombin is ready to harvest.

Step Three: Harvesting Thrombin

Remove white luer cap and attach 20 ml syringe to thrombin collection port. Turn stopcock A 90° clockwise so the “OFF” knob points to the left.

Hold TPD™ Thrombin Processing Device upright. Pull syringe plunger back past 20 ml mark. In a few seconds the thrombin solution will begin to flow into collection syringe. Continue harvesting the solution until bubbles are observed in the tubing, which indicates harvest is complete. Volume of thrombin produced is at least 7 ml. Note: A slight resistance will be felt when thrombin solution is pulled through internal filters.

Storage Requirements

<table>
<thead>
<tr>
<th>Anticoagulant</th>
<th>8 –12% ACD-A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage Requirements</td>
<td>When used immediately or within one hour: Store at 18 –26°C  When used after one hour: Store at 2 –6°C (up to 4 hours)</td>
</tr>
</tbody>
</table>
## Ordering Information

<table>
<thead>
<tr>
<th>Description</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vortech™ Disposable Kit</td>
<td>800-7600A</td>
</tr>
<tr>
<td>Contents:</td>
<td></td>
</tr>
<tr>
<td>Vortech™ Disposable</td>
<td></td>
</tr>
<tr>
<td>Two Gauze Sponges</td>
<td></td>
</tr>
<tr>
<td>Adhesive Tape</td>
<td></td>
</tr>
<tr>
<td>One 18 Gauge Needle</td>
<td></td>
</tr>
<tr>
<td>30ml Bottle of ACD-A</td>
<td></td>
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<tr>
<td>Two 30 ml Syringes</td>
<td></td>
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<tr>
<td>Two 60 ml Syringes</td>
<td></td>
</tr>
<tr>
<td>Tourniquet</td>
<td></td>
</tr>
<tr>
<td>One 18 Gauge Needle Set</td>
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<tbody>
<tr>
<td>Vortech™ Base</td>
<td>7600</td>
</tr>
<tr>
<td>Biomet Biologics Manual Spray Applicator Kit (Tip not included)</td>
<td>800-0250V</td>
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<tr>
<td>Two 12 ml Syringes</td>
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<tr>
<td>Two Syringe Assembly Sets</td>
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<tr>
<td>One Plastic Tray</td>
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<tr>
<td>Vortech™ Malleable Dual Cannula Tip 20 Gauge x 4 inch Length</td>
<td>800-0202V</td>
</tr>
<tr>
<td>Vortech™ Blending Connector Tip Single Cannula</td>
<td>800-0204V</td>
</tr>
<tr>
<td>Vortech™ Graft Preparation System</td>
<td>800-0300V</td>
</tr>
<tr>
<td>Autologous Thrombin Mixer (Pack of 10 Applicator Tips)</td>
<td>ATM100T</td>
</tr>
<tr>
<td>Autologous Thrombin Spray Tip (Pack of 10; To be used with 800–0204V)</td>
<td>ST–3 TIP</td>
</tr>
</tbody>
</table>

![Vortech™ Base — power cord included (7600)](image1)

![Spray Applicator Kit — Tip not included (800–0250V)](image2)

![Malleable Dual Cannula Tip 20 Gauge x 4 inch Length (800–0202V)](image3)

![Blending Connector Tip Single Cannula (Includes Two Flexible Sheaths) (800–0204V)](image4)

![Vortech™ Graft Preparation System (800–0300V)](image5)

![Autologous Thrombin Mixer (ATM100T)](image6)

![Autologous Thrombin Spray Tip (2) (ST–3 TIP)](image7)
## Ordering Information

<table>
<thead>
<tr>
<th>TPD™ Thrombin Processing Device</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TPD™ Device and Syringes (Box of 10 devices/syringes)</td>
<td>TPD100T</td>
</tr>
<tr>
<td></td>
<td>Thrombin Reagent (Box of 10 reagents)</td>
<td>TPDRS100T</td>
</tr>
</tbody>
</table>
References
STERILITY
Vortech™ Concentration System components are sterilized by exposure to a minimum dose of 25 kGy gamma radiation. All other Vortech™ components are sterilized by the respective suppliers using gas plasma radiation or ethylene oxide gas (ETO). Do not re-sterilize. Do not use after expiration date.

INSTRUCTIONS FOR USE
USING THE VORTECH™ CONCENTRATION SYSTEM
1. ATTACH to base unit by orienting the notches on the side of the disposable to the pins on the top of the base and while pressing down turn clockwise until locked into place.
2. DRAW at least 5ml of anticoagulant into two 60ml syringes and 3ml of anticoagulant into one 30ml syringe. Attach to apheresis needle and prime with anticoagulant. Draw blood using standard aseptic practice. Draw 55ml of blood from patient into each 60ml syringe and 27ml of blood from patient into the 30ml syringe. Gently, but thoroughly mix the whole blood and anticoagulant upon collection to prevent coagulation.
3. LOAD: Slowly load both blood-filled 60ml syringes (5ml of citrate anticoagulant and 55ml of whole blood) into port number one. Slowly load the 30ml of whole (3ml of citrate anticoagulant and 27ml of whole blood) into port number one.
4. REMOVE access port.
5. SPIN: Press green button on front of base unit to start the blood separation process.
6. EXTRACTION: After the process is complete attach a 30ml syringe to the center port of disposable and extract the concentrate.
7. Dispose of the Vortech™ container in the appropriate biohazard container.

Comments regarding this device can be directed to Attn: Regulatory Dept, Biomet. P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-1683.

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