Would you like to have an autologous thrombin for rapid clotting and haemostasis?

Clotalyst®
Autologous Clotting Factor
Autologous = Safe for the Patient
- Eliminates possible hypersensitivity reactions
- Eliminates risk of bovine spongiform encephalopathy (BSE)
- Eliminates possible future coagulopathies (i.e. acquired Factor V inhibitors)
- No pooled or bovine sources

User Friendly
- Minimal steps required to produce autologous thrombin
- Procedural steps on Clotalyst® heater

Reliable
- Consistently produces 5 to 6ml of thrombin
- Stable up to 4 hours after preparation

Convenient Design
- Single use disposable
- Aids in separation of patient's own blood components utilising glass beads and centrifugation
- Clots in less than 15 seconds
The Clotalyst® Autologous Thrombin Collection System produces approximately 6ml of autologous thrombin from only 12ml of patients’ own citrated blood. The thrombin output can be used to activate platelet rich plasma (PRP) and platelet poor plasma (PPP) produced by the GPS® III system, along with plasma concentrate produced by the Plasmax® Plus Plasma Concentration System. The Clotalyst® Autologous Thrombin Collection System provides autologous clotting factors which rapidly convert GPS® III platelet concentrate into platelet gel and PPP and Plasmax® Plus fibrinogen to fibrin. The Clotalyst® Autologous Thrombin Collection System provides rapid clotting (approximately 15 seconds) of platelet and plasma derived products, giving the surgeon a unique product that is safe for the patient in a variety of procedures.
Preparation of the Clotalyst® Autologous Clotting Factor

This brochure is for International use only. It is not for distribution in the United States.

Step 1: Draw

Draw 12ml of citrated blood in a 12ml syringe (1ml of anticoagulant and 11ml of blood).

Gently mix the whole blood and anticoagulant upon collection to prevent coagulation.

Step 2: Load

Remove reagent syringe from sterile pouch and attach plunger.

**Note:** Leave grey stopper on opposite end of reagent syringe when attaching plunger.

Remove grey stopper on reagent syringe. Unscrew blue cap on port No. 2 of disposable and attach reagent syringe. While holding the Clotalyst® disposable vertically, completely inject 4ml of reagent. Remove the reagent syringe from the disposable. Remove protective cover on white cap and discard. Screw the white cap onto port No. 2.
Step 2: Load (continued)

Unscrew red cap on port No. 3 and attach syringe that contains 12ml of citrated blood.

While holding disposable vertically, inject blood until syringe is empty.

Remove the empty syringe. Remove protective cover on the white cap and discard. Screw white cap onto port No. 3.
Technique (continued)

Step 3: Incubate

Mix by inverting disposable at least 12 times (gently without producing foam).

Place disposable into Clotalyst® Heater. The glass beads inside the disposable should be distributed evenly when it is placed into the heater. Press the incubation button to start cycle. When the incubation cycle is complete (25 minutes), the heater will beep four times.

Step 4: Balance

At the end of the 25-minute incubation period, shake the Clotalyst® disposable enough to dislodge and break up any gel that may be present.
Step 4: Balance (continued)

Place Clotalyst® disposable in the centrifuge with the empty Clotalyst® orange counterbalance (800-0760) in the opposite side of the centrifuge.

Step 5: Spin

Close centrifuge lid and set speed to 3200 RPM’s and time to 5 minutes. Press green button to start centrifuge cycle. Once cycle is complete, press red button to open lid.

Step 6: Thrombin Extraction

Gently remove the disposable from the centrifuge without disturbing the stratified layers. Unscrew the yellow cap from the center port while holding the disposable vertically. Connect sterile 12ml syringe to the center port and extract 5 to 6ml of thrombin.
Step 6: Thrombin Extraction (continued)

To maximize harvest volume, the disposable may be tilted towards port No. 3 as thrombin is extracted.

Step 7: Storage

Place cap supplied onto syringe and store between 2–6°C if thrombin is not used within 1 hour.

Storage Requirements

<table>
<thead>
<tr>
<th>Anticoagulant</th>
<th>Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>8–12% ACD-A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storage Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>When used immediately or within one hour: Store between 18–26°C</td>
</tr>
<tr>
<td>When used after one hour: Store between 2–6°C (up to 4 hours)</td>
</tr>
</tbody>
</table>
## Clotalyst® System

<table>
<thead>
<tr>
<th>Description</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotalyst® Disposable</td>
<td>800-0750</td>
</tr>
<tr>
<td>Clotalyst® Heater (Heater Cord included)</td>
<td>800-0755</td>
</tr>
<tr>
<td>Clotalyst® Heater Cord</td>
<td>800-0757</td>
</tr>
<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>
</tr>
</tbody>
</table>
## Gravitational Platelet Separation System

**(GPS® III System)**

Produces a 9x concentration of platelets, 5x concentration of white blood cells, and concentrated growth factors from a small amount of the patient’s own blood (27-108ml).

<table>
<thead>
<tr>
<th>Description</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>GPS® III Mini Disposable Kit</td>
<td>800-0670A</td>
</tr>
<tr>
<td>GPS® III Single Disposable Kit</td>
<td>800-0675A</td>
</tr>
<tr>
<td>GPS® III Double Disposable Kit</td>
<td>800-0680A</td>
</tr>
</tbody>
</table>

## Plasmmax® Plus Plasma Concentrate System

Takes GPS® technology one step further by concentrating the platelet poor fraction, giving the surgeon plasma concentrate (3x concentration of fibrinogen) and platelet concentrate if desired.

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

## Hardware

<table>
<thead>
<tr>
<th>Description</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>GPS® Spare Bucket Kit (Drucker Centrifuge; 2 Blue Buckets)</td>
<td>7431</td>
</tr>
<tr>
<td>GPS® Mini Spare Bucket Kit (Drucker Centrifuge; 2 Purple Buckets)</td>
<td>7433</td>
</tr>
<tr>
<td>Drucker 230 Volt 50-60 Hz Centrifuge (comes with set of 7431 and 7433)</td>
<td>755VES-230V</td>
</tr>
<tr>
<td>Aerosol Regulator without Vent</td>
<td>800-0211</td>
</tr>
<tr>
<td>Plasmmax® Plus Concentrator Counterbalance</td>
<td>800-0512</td>
</tr>
<tr>
<td>GPS® Non-Sterile Counterbalance (Blue)</td>
<td>800-0508</td>
</tr>
<tr>
<td>GPS® Mini Non-Sterile Counterbalance (Purple)</td>
<td>800-0505</td>
</tr>
</tbody>
</table>
## Accessories

<table>
<thead>
<tr>
<th>Description</th>
<th>Catalog Number</th>
</tr>
</thead>
<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>
</tr>
<tr>
<td>Blending Connector Tip Single Cannula</td>
<td>800-0204</td>
</tr>
<tr>
<td>Malleable Dual Cannula Tip 20 Gauge x 10 inch Length</td>
<td>800-0206</td>
</tr>
<tr>
<td>Malleable Dual Lumen Endoscopic Tip 5mm x 12 inch Length</td>
<td>800-0207</td>
</tr>
<tr>
<td>16 inch Manual Endoscopic Rigid Tip 1 to 1 Ratio</td>
<td>800-0208</td>
</tr>
<tr>
<td>12 inch Aerosol Endoscopic Rigid Tip 1 to 1 Ratio (Tubing included)</td>
<td>800-0216</td>
</tr>
<tr>
<td>16 inch Aerosol Endoscopic Rigid Tip 1 to 1 Ratio (Tubing included)</td>
<td>800-0217</td>
</tr>
<tr>
<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</td>
<td>800-0250</td>
</tr>
</tbody>
</table>
## Accessories Continued

<table>
<thead>
<tr>
<th>Description</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerosol Spray Kit with Two Sets of Syringes and Two Tips</td>
<td>800-0260</td>
</tr>
<tr>
<td>Graft Preparation System</td>
<td>800-0300</td>
</tr>
<tr>
<td>ATM100 Autologous Thrombin Mixer Tip</td>
<td>ATM100</td>
</tr>
<tr>
<td>ST-3 Tip (Ten Pack) to be used with 800-0204</td>
<td>ST-3 TIP</td>
</tr>
</tbody>
</table>
Biomet Biologics, Inc. 01-50-1434
P.O. Box 587  Date: 01/07
56 E. Bell Drive
Warsaw, Indiana 46581 USA

Clotalyst™ Autologous Thrombin Collection System

ATTENTION OPERATING SURGEON
FOR INTERNATIONAL USE ONLY

DESCRIPTION
The Clotalyst™ Autologous Thrombin Collection System aids separation of the patient's own blood components through glass bead activation of platelets, and by density through the use of a Biomet Biologics centrifuge. For optimal performance, the Clotalyst™ Heater should also be used to maintain optimum temperature of components during operation.

The Clotalyst™ Autologous Thrombin Collection System permits thrombin to be rapidly prepared from a small volume of the patient's blood that is drawn at the time of treatment. The Clotalyst™ Autologous Thrombin Collection System is designed to be used in conjunction with the GPS® II, GPS® Mini and/or Plasmach™ systems. The Clotalyst™ Autologous Thrombin Collection System is designed to be used with Thermogenesis Corp. TPD™ reagent (reference Biomet part number TPDRS100T), not included in this kit.

MATERIALS
The materials used for syringes, needles, and thrombin separators consist of medical grade polymers, elastomers, glass and stain-resistant steels suitable for use in medical devices. Blood draw kit components, when supplied by Biomet, when used with a Clotalyst™ Thrombin Collection Kits, are packaged, labeled and sterilized as indicated by their individual labeling. Clotalyst™ Autologous Thrombin Collection System and blood draw kit components do not contain latex.

INDICATIONS FOR USE
Clotalyst™ Autologous Thrombin Collection System is designed to be used for the safe and rapid preparation of autologous thrombin from a small sample of anticoagulated blood at the patient's point of care. The thrombin output can be used to activate Platelet Rich Plasma (PRP), Platelet Poor Plasma (PPP), or Plasma Concentrate. This kit is not cleared or approved for marketing in the United States.

INTENDED USE
Blood is drawn from the patient, and mixed with ACD-A (an anticoagulant provided with either the GPS® II, GPS® Mini, or Plasmach™ system). The TPD™ Reagent and anticoagulated blood are then mixed in the thrombin separator (hereafter referred to as separator), and heated during the incubation step in the Clotalyst™ Heater (800-0755). After incubation, the separator is then spun in a Biomet Biologics centrifuge in accordance with centrifuge operating directions. The thrombin is then collected with a syringe.

WARNINGS AND PRECAUTIONS
1. Use proper safety precautions to guard against needle sticks.
2. Follow manufacturer instructions when using centrifuge. Use only a Biomet Biologics centrifuge (GPS®-EC centrifuge or The Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
3. Blood containing 8 to 12% ACD-A is acceptable for use with this system. For further information regarding ACD-A, please contact the supplier, Citra Anticoagulants, Inc., of Braintree, MA, at 1-800-299-3411.
4. Do not use sterile components of this kit if package is opened or damaged.
5. Single use device. Do not reuse.
6. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
7. The patient is to be made aware of general risks associated with treatment and the possible adverse effects.
8. After preparation, store thrombin at 2–6°C for up to 4 hours. For immediate use after preparation, store at 18–26°C for up to one hour. If output is stored at 18–26°C and is not used within one hour after preparation, discard output.
9. For optimal performance, all components (reagent, blood and separator) should be housed inside the Clotalyst™ Heater to allow the fluid temperature to equilibrate to 25 +/- 2°C.

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
Clotalyst™ Autologous Thrombin Collection System Kit separator is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. All other Clotalyst™ Autologous Thrombin Collection System Kit components are sterilized by the respective suppliers using irradiation or ethylene oxide gas. Do not re-sterilize. Do not use after expiration date.

INSTRUCTIONS FOR USE
NOTE: Use standard aseptic technique throughout the following procedures.

1. DRAW: 1ml of ACD-A into 12ml syringe. Draw 11ml of blood from patient. Gently, but thoroughly, mix the whole blood and ACD-A upon collection. All other Clotalyst™ Autologous Thrombin Collection System Kit components are sterilized by the respective suppliers using irradiation or ethylene oxide gas. Do not re-sterilize. Do not use after expiration date.

2. LOAD: Unscrew the cap from separator #2 of separator and attach reagent syringe. Holding separator vertically, completely inject reagent. Remove reagent syringe from the separator, unscrew clear protective inner piece from white cap, tethered to port #2, and screw white cap onto reagent injection port #2. Unscrew red cap on port #3 and attach blood-filled syringe (1ml of ACD-A and 11ml of whole blood). Holding separator vertically, slowly inject blood. Unscrew clear, protective inner piece from white cap tethered to port #3 and screw white cap onto injection port #3. Note: Dislodging black duckbill shipping protectors during the loading process is not detrimental to normal operation.

3. INCUBATE: Mix by inverting separator at least 12 times (gently without producing foam). Place separator into Clotalyst™ Heater, with glass beads distributed evenly, and begin incubation cycle (25 minutes).

4. CLOT DISRUPTION: At the end of the 25-minute incubation period, shake the separator vigorously enough to dislodge and break up any coagulum that may be present in the separator and place in a Biomet Biologics centrifuge. Place the Clotalyst™ orange counterbalance tube (800-0760) in centrifuge, directly across from separator.

5. SPIN: Close centrifuge lid. Set speed for 3.2 x 1,000 and set the time to 5 minutes. Press the start button. ENSURE BLOOD FROM ONLY ONE PATIENT IS PROCESSED PER SPIN. Once cycle is complete, open centrifuge.

6. EXTRACT THROMBIN: At the end of centrifugation, gently remove separator from the centrifuge without disturbing the stratified layers. Maximize harvest volume, the separator may be tilted towards port #3 as thrombin is extracted. If the filter becomes plugged prior to achieving 5 to 6ml of thrombin, the unit can be placed back in the centrifuge for one minute to dislodge the clot, allowing the remaining thrombin to be extracted.

7. DISCARD: Place the supplied storage tip onto syringe. For immediate use after preparation, store output at 18-26°C for up to one hour. Store between 2-6°C for up to 4 hours if output is not to be used within one hour. Discard output if it is not used within the provided time frames.

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

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

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estates
Bridgend, South Wales
CF31 3XA, UK

EC 0086

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