Clotalyst® and GPS® III Platelet Concentration Kit with ACD-A

Launch Packet
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Why Sell Clotalyst® with GPS® III separator?

- Offers surgeon and patient completely autologous product
- Allows us to target competition
- System advantages utilizing ATM style tips and aerosol spray kit
- Produce PRP and autologous serum
Basic Sales Story

Confidential material intended solely for the Biomet Biologics sales force. Not for redistribution.

• Add $200 to GPS® III separator with ACD-A total, add no cost to case which equals added revenue.

(EXAMPLE)
• If an account is utilizing the Harvest system for $400, plus the $150 they might be spending for a coagulate agent, we can offer the Clotalyst® at $500, potentially saving the facility money, $50 per case, while gaining GPS®III business.

• Eliminates threat of competition coming in at lower price and taking business away

What associate needs to know?
• Incubation time

• Reagent explanation

• Works with GPS®III separator with ACD-A

• Works well with ATM tips and Aerosol Spray Kit (preferred)

• Works with CoAxial Spray Kit And Applicator Tips

• Variability from patient

What Doctor needs to know?
• Totally Autologous

• Produces 6ml of Clotalyst® autologous serum output and 6ml of PRP

• Works well in wet and bloody environments

• CoAxial Spray Kit And Applicator Tips for variety of applications

• Patient Variability

• Mixed with PRP for bone grafting

Complementary Products
• Bonus II® DBM and Bone Graft Convenience Kit

• Packaged with GPS®III separator with ACD-A
Basic Sales Story

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Targets Accounts
- All existing GPS®III separator with ACD-A accounts
- PRP customers
- Rotator Cuff procedures

Competition
- Bovine $ x 75–150
- Recombinant $ x 75–150
System Overview

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Clotalyst® Kit with GPS® III separator with ACD-A

The Clotalyst® kit is packaged with a GPS®III separator with ACD-A and Clotalyst® disposable. The kit provides all necessary components to process platelet rich plasma and autologous serum from a small amount of the patient’s blood.

The contents of the Clotalyst® with GPS®III separator with ACD-A kit

- Clotalyst® Disposable
- Clotalyst® Reagent
- GPS®III separator with ACD-A disposable
- Blood draw needle, ACD-A (anticoagulant), necessary syringes, etc.

Capital equipment needed includes:

- Clotalyst® Heater
- Centrifuge with appropriate buckets for GPS®III separator and Clotalyst® disposables
- Clotalyst® and GPS®III separator with ACD-A counterbalance (Unive

Clotalyst® Kit with GPS®III separator Process:

IMPORTANT: Press on button on Clotalyst® heater before preparation of GPS®III separator and Clotalyst® separator. This will preheat the heater to 25°C (takes about 10 minutes). This will ensure consistent output of the autologous serum and will save time during preparation of the GPS®III separator and Clotalyst®. If the on button is not pushed prior to the incubation cycle, the cycle timer will not start until 25°C is reached. This may give the appearance that the cycle is longer than the 25 minutes it is advertised at.

1. **Blood Draw:**

   Draw 60 ml of anticoagulated blood using the ACD-A and blood draw materials provided in the kit (5ml of ACD-A, 55ml of whole blood).

2. **Load Clotalyst® Separator:**

   1. Unscrew blue cap on Clotalyst® separator and attach reagent syringe (4 ml mixture of ethanol and calcium chloride). Hold disposable vertically and completely inject reagent. The ethanol stabilizes the serum produced in the process by binding the anti-serum. The calcium chloride, a base solution, neutralizes the acidic ACD-A in the blood. The Calcium is also critical in the clotting cascade.

   2. Attach blood-filled syringe to red capped side and introduce 12 ml of anticoagulated blood.
3. **Incubate:**
   1. Mix anticoagulated blood and reagent by inverting separator at least 12 times, until blood and reagent are mixed completely with the glass beads. This causes the blood (and especially the platelets) to come in contact with the glass beads. The glass beads have a negative charge, which causes the blood to clot.
   2. Place separator into Clotalyst® heater with glass beads distributed evenly and filter on topside of horizontal tube. Begin incubation cycle (25 minutes at 25°C is the optimal time/temperature to produce the maximum amount of serum per sample).

4. **Load GPS®III separator with ACD-A and SPIN:**
   1. Unscrew cap on center port No. 1 and discard green packaging post
   2. Slowly load blood into center point
   3. Push Open/Stop on control panel. The “unlocked” indicator will illuminate. Turn latch counterclockwise to open lid. Place lid into centrifuge.
   4. Fill GPS® III separator counterbalance with 60ml of sterile saline and place into opposite side of centrifuge
   5. Close the lid by rotating the lid latch clockwise. “Latched” indicator will illuminate. Set speed to 3200 RPM and time to 15 minutes. Press green button to start spin. Once spin is complete, press red button to illuminate the “Unlocked” indicator. Twist latch counter clockwise to open lid.

5. **Clot Disruption & Remove GPS® III separator from centrifuge:**
   1. 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
   2. Remove GPS® III disposable from centrifuge

6. **Spin Clotalyst® & GPS® III separator with ACD-A PPP/PRP Extraction:**
   1. Place Clotalyst® separator into the centrifuge with the appropriate orange Clotalyst® counterbalance on the opposite side. Close lid by rotating the lid latch clockwise. “Latched” indicator will illuminate. Set speed to 3200 RPM and time to 5 minutes. Press green button to start spin.
   2. To extract the platelet poor plasma (PPP) from GPS®III disposable with ACD-A, remove yellow cap on side port No. 2 and connect the 30ml syringe. Slowly tilt tube while withdrawing PPP. Replace yellow cap.
   3. Remove red cap on side port No.3 from GPS® III with ACD-A disposable and connect 10ml syringe. Withdraw 2 ml of PRP. With 10 ml syringe attached, suspend the platelets by shaking the tube for 30 seconds. Extract the remaining platelet rich plasma (PRP) contents into the attached 10 ml syringe
7. **Transfer of PRP and PPP to sterile field**
   1. Take 6-8 ml of PRP and transfer from syringe to red cup on sterile field. Take 25 ml of PPP and transfer from syringe to yellow cup on sterile field.

8. **Extract serum & Transfer of Clotalyst® output:**
   1. Once the Clotalyst® spin is complete, press red button to illuminate the “Unlocked” indicator. Twist latch counter clockwise to open lid. Gently remove the separator from the centrifuge without disturbing the stratified layers. Connect 12 ml syringe to center port of Clotalyst® disposable and slowly extract approximately 6ml of autologous serum while holding the separator vertically.
   
   2. Take 6ml of Clotalyst® output and transfer from syringe to clear cup on sterile field

   **Note:** 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 at 3200 rpm’s to dislodge the clot, allowing the remaining thrombin to be extracted.

   3. **Storage:** 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 1 hour. Discard output if it is not used within the provided time frames.

**Clotalyst® Advantages:**

- Autologous source, eliminating possible hypersensitivity reactions
- Clots PRP mixed with bone graft in approximately 15 seconds
- Maximizes potential of product when used with mixing tips or aerosol spray kits
- Increase price point due to lack of competition
- Biomet Biologics is the market Leader in platelet technology, allowing easy access to sell to existing accounts
- Platelet market share of approx 50%
- Loyal customer base
- PRP market momentum
- Deep product line
- Strong sales force
- Competitors do not have anything like it
- Stable up to 4 hours after preparation
System Overview

Clotalyst® Disadvantages:

- Product acceptance
- Strong bovine and synthetic acceptance in market
- Currently sold with GPS® III kit only
- Only works well when clotting with PRP
- Inconsistency when clotting with Plasmax® plasma concentration system

Opportunities:

- Platelet rich plasma market growth and momentum
- Product line depth with the addition of the Clotalyst® kit and bone graft convenience kit