Calgary Zone Administration Instructions for Prothrombin Complex Concentrates (PCC):

octaplex® and Beriplex® P/N
Prothrombin Complex Concentrates are blood products, and do require informed consent. They are indicated for patients with major life threatening bleeding OR requiring urgent surgery (less than 6 hrs) AND who are on oral anticoagulant therapy.

PCCs are blood products that contain human source proteins and require informed consent to be obtained by the Most Responsible Health Practitioner.

DO dosing (Adults)

**First dose**: PCC dose ordered and Vitamin K 10 mg IV. 
Note: Vitamin K is provided in the first PCC kit and can be given IV immediately before or after PCC.

**Second dose (if needed)**: TM Physician consult is required if post infusion target INR is not achieved. A second dose of a maximum of 1000 International Units (units) may be issued.

**GENERAL ADMINISTRATION INFORMATION:**
- Prior to giving PCC: Draw CBC, PTT, INR, fibrinogen; initial INR should be greater than 1.6.
- Give Vitamin K 10 mg IV immediately prior to or following the first dose of PCC.
  - Vitamin K Administration: *IV Direct*: Dilute with 10mL of NS. Max rate: 1 mg/min. *IVPB*: Dilute in 25-100mL D5W, LR or NS; infuse over 20-60 minutes.
- Signed consent form.
- Type & Screen not required.
- Product must be filtered via Mix2 Vial™ transfer set. Filtered administration set is not required.
- PCCs can be ordered through SCM.

**RECONSTITUTION**
1. Reconstitute both vials using Mix2Vial™ transfer set provided. 1 vial of 500 unit PCC produces 20mL of reconstituted product. 1 vial of 1000 unit PCC produces 40 mL of reconstituted product. See attachment for step by step instructions.  
   Note: octaplex® may be slightly blue after mixing, this is normal. Beriplex® should be clear or slightly opalescent.
2. If vacuum fails on transfer set: Leave the transparent end of the Mix2Vial™ device attached to the PCC vial. Using a plastic syringe and needle, draw up any remaining diluent in the vial. Discard the needle. Transfer the diluent in the syringe into the PCC vial by Luer-locking the syringe onto the transparent end of the Mix2Vial™ device. Inject the diluent into vial to complete the reconstitution. (Note: the transparent portion contains the necessary filter).

**INFUSION** (must be administered within 30-60 minutes of reconstitution)

<table>
<thead>
<tr>
<th>Priming</th>
<th>First 5 minutes</th>
<th>Remainder of infusion</th>
<th>Flush</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minibag/IV pump</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Remove all saline from an appropriate size of bag of 0.9% saline.</td>
<td>Rate: 1mL/min</td>
<td>Rate: 3mL/min</td>
<td>FLUSH line with 0.9% saline following infusion to ensure all of the PCC is infused in patient.</td>
</tr>
<tr>
<td>- Replace contents with PCC</td>
<td>Pump rate: 60mL/hr Volume TBI: 5mL</td>
<td>Pump rate: 180mL/hr Volume TBI: Total volume of reconstituted product minus 5mL</td>
<td></td>
</tr>
<tr>
<td>- Using a regular administration set, prime line with PCC.</td>
<td><em>Observe for signs of anaphylaxis.</em></td>
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<tr>
<td>- Attach to IV port closest to the patient.</td>
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<tr>
<td>- Can give via CVC, PICC or peripheral IV.</td>
<td>Rate: 1mL/min</td>
<td>Rate: 3mLs/min</td>
<td>Minibag: Use 0.9% saline from mainline or a second minibag (~20 cc)</td>
</tr>
<tr>
<td>- Depending on dose ordered, 2 syringes may be required.</td>
<td>On pump- Go to <em>volume over time</em> and enter: Volume = 5mL Time to be infused over = 5 min</td>
<td>On pump – Go to <em>volume over time</em> and enter: Volume = Total volume of reconstituted product minus 5mL Time to be infused over = Calculate time to ensure remaining volume infused at rate 3mL/min</td>
<td>Syringe pump: Flush syringe tubing with appropriate volume of 0.9% saline</td>
</tr>
</tbody>
</table>

*DO NOT exceed rate of 3mL/min— may be associated with increased risk of thromboembolic complications.  
Note: MDs or NPs only- may infuse via slow IV push, not to exceed rates above.

**POST-INFUSION MONITORING & REPEAT DOSES**:
10-15 minutes following Prothrombin Complex Concentrate infusion:

- Redraw PT/INR, PTT & fibrinogen.
- If bleeding remains unabated: further dosing may be indicated. Requires correlation with PT/INR results greater than1.6 and consultation with Transfusion Medicine (TM) physician on-call (via your hospital TM department).
- The recommended maximum dose is 2500 Units reconstituted to a volume of 100 mL.

Please refer to the Calgary Zone Guidelines for Use of Prothrombin Complex Concentrates for a complete summary of product information (including indications and contraindications); available from your hospital Transfusion Medicine department.

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Instructions for Reconstitution of Octaplex®

Instructions for reconstitution:

1. Warm the octaplex® powder and water for injection (WFI) in the closed vials up to room temperature (maximum 37°C). This temperature should be maintained during reconstitution.

2. Remove the flip caps from the octaplex® vial and the WFI vial and clean the rubber stoppers with an alcohol swab.

3. Peel away the lid of the outer package of the Mix2Vial™ transfer set. Place the WFI vial on an even surface and hold the vial firmly. Take the Mix2Vial™ together with its outer package and invert it. Push the blue plastic cannula of the Mix2Vial™ firmly through the rubber stopper of the WFI vial (Fig. 1). While holding onto the WFI vial, carefully remove the outer package from the Mix2Vial™, being careful to leave the Mix2Vial™ attached firmly to the WFI vial (Fig. 2).

4. With the octaplex® vial held firmly on an even surface, quickly invert the WFI vial (with the Mix2Vial™ attached) and push the transparent plastic cannula end of the Mix2Vial™ firmly through the stopper of the octaplex® vial (Fig. 3). The WFI will be drawn into the octaplex® vial by vacuum.

5. With both vials still attached, slowly rotate the octaplex® vial to ensure the product is fully dissolved to a clear or slightly opalescent solution. Once the contents of the octaplex® vial are dissolved, firmly hold both the transparent and blue parts of the Mix2Vial™. Unscrew the Mix2Vial™ into two separate pieces with the vials still attached (Fig. 4) and discard the empty WFI vial and the blue part of the Mix2Vial™.

6. Attach a plastic sterile disposable 20 mL syringe to the transparent part of Mix2Vial™. Invert the system and draw the reconstituted octaplex® into the syringe.

7. Once the octaplex® solution has been transferred into the syringe, firmly hold the barrel of the syringe (keeping it facing down) and detach the Mix2Vial™ from the syringe. Discard the Mix2Vial™ (transparent plastic part) and the empty octaplex® vial.
Calgary Zone Administration Instructions for Prothrombin Complex Concentrates (PCC):

Hospital: 

INSTRUCTIONS FOR USE

1 Preparation
- Ensure product and water vials are at room temperature.
- Remove caps from vials and wipe stoppers with alcohol swab. Remove Mix2Vial™ package lid.

2 Connect water vial
- Place water vial on a flat clean surface and hold firmly.
- Pierce the vial with the blue tip of the transfer device. Use a quick firm motion.

3 Remove packaging
- Pull off the remaining package and discard.

4 Connect product vial
- Place PRODUCT vial on a flat surface and hold firmly.
- Turn the WATER vial along with the device upside down.
- Pierce the product vial with the clear tip of the device. Use a quick firm motion. The water flows automatically into the PRODUCT vial.
- Swirl gently, do not shake.

5 Unscrew water vial
- When water vial is empty, remove it by grasping the blue portion of the device and turning it counterclockwise.

6 Withdraw mixed solution
- Draw air into empty syringe.
- Screw syringe clockwise into the white portion of the device.
- Push air into vial.
- Turn the system upside down.
- Draw the solution into syringe.

*Mix2Vial is a trademark of West or one of its Subsidiaries.

For information on Beriplex® P/N, please refer to the product information at www.cslbehring.ca.

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