ORBCoN
Ontario Regional Blood Coordinating Network

Inspiring and facilitating best transfusion practices in Ontario.

Reconstitution of Fibrinogen Concentrate (FC) and Prothrombin Complex Concentrate (PCC) Outside of the Transfusion Medicine Laboratory (TML)

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June 1, 2025

Objectives

After completing this learning, participants will be able to:

- Define the steps to safely reconstitute FC and PCC (the brands utilized at your hospital).
- Identify the documentation requirements for reconstituting FC and PCC.
- Describe general considerations when reconstituting FC and PCC outside TML.

Consult your hospital's policies and procedures for additional details specific to your facility.

Outline (1)

Outline (2)

Rationale for this learning: Canadian Transfusion Medicine Standards

Canadian Standards Association
Blood and blood components

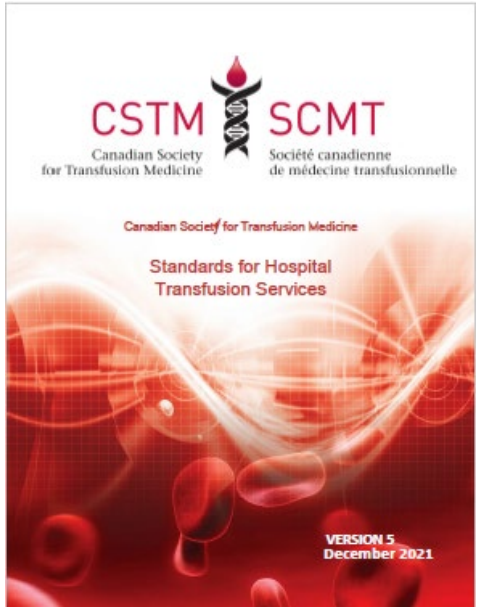
The purpose of this standard is to promote the safety, efficacy and quality of blood collection, storage, processing and transfusion. The standard is approved by the Technical Committee and stems from equivalent national and international standards as well as Canadian practice and current scientific knowledge. It must be viewed along with the Health Canada Blood Regulations.

Canadian Standards Association

- 14.4.1 *"Blood products shall be prepared in accordance with the manufacturer's instructions."*
- 14.4.2 *"All service personnel within and outside the transfusion service who prepare blood products for administration shall be trained and qualified for the functions they perform. Competency shall be assessed following training and at regular intervals thereafter, as determined by the facility."*
- 14.4.3 *"The preparation record shall include the name of the person who prepared the product for administration and the date and time of preparation."*

Rationale for this learning: Canadian Transfusion Medicine Standards

Canadian Society for Transfusion Medicine
Standards for Hospital Transfusion Services



These standards are to be used by hospitals as a tool for the development of policies, processes and procedures. Transfusion Services must also meet all national, provincial or territorial standards and/or regulations.

Canadian Society for Transfusion Medicine

- 2.14 *"The transfusion service shall ensure there is a competency program for all medical, clinical and support staff involved in any transfusion related activity, including the preparation of blood components and blood products for administration. The evaluation shall be done following training and at a frequency defined by the facility. The program shall include:*
  a) evaluation of theoretical and practical knowledge
  b) additional training when indicated"
- 5.6.9.1 *"Reconstitution of blood products shall follow manufacturer's recommendations."*
- 5.6.9.2 *"A label shall be applied to reconstituted blood products prior to issue as indicated in 5.6.2 Labelling."*

Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device

REMINDER: Only reconstitute when ready to administer.

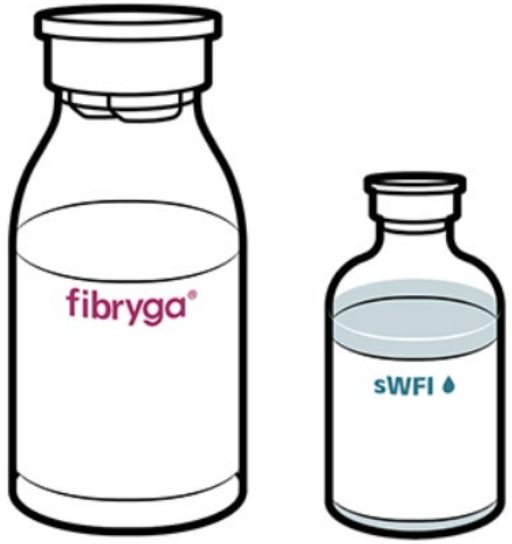
- Fibryga® is available as 1 g/bottle (vial), reconstituted with 50 mL of solvent (water for injection).
- Use appropriate aseptic technique.
- Single use only.
- TML will provide product label(s) and kit(s) containing:
  solvent bottle, Fibryga® powder bottle, Octajet® transfer device, filter.

- Also required: alcohol swabs, 50 mL syringes, needles, sterile administration bag.

Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device

Step 1
Check Expiry Date & Temperature

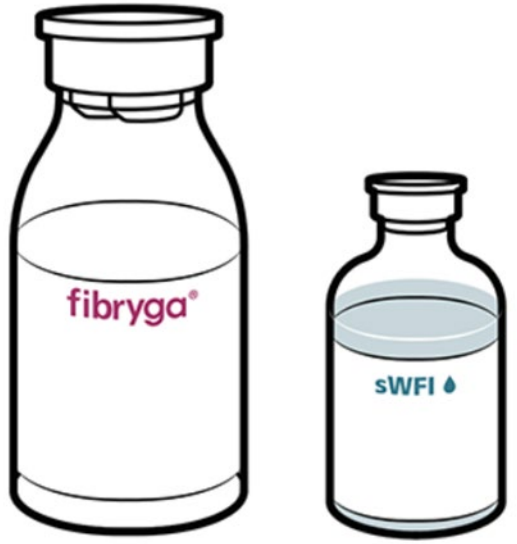
- Verify product expiry date (on the kit packaging and the bottles) is acceptable.
- Ensure the bottles of both the powder (fibryga®) and the solvent (sterile water for injection, sWFI) are at room temperature.
- During reconstitution, room temperature should be maintained.
- Room temperature augments the product powder dissolving.



Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device

Step 2
Remove Caps, Clean Rubber Stopper of Powder & Solvent Bottles

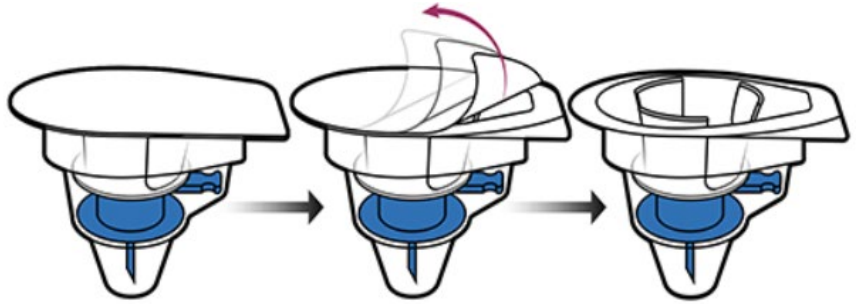
- Remove the cap from both the fibryga® powder and the solvent (sWFI) bottles.
- Using a circular motion, clean the exposed central part of the rubber stopper of both bottles with an alcohol swab.
- Allow the stoppers of the bottles to dry.



Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device

Step 3
Open Octajet® Transfer Device

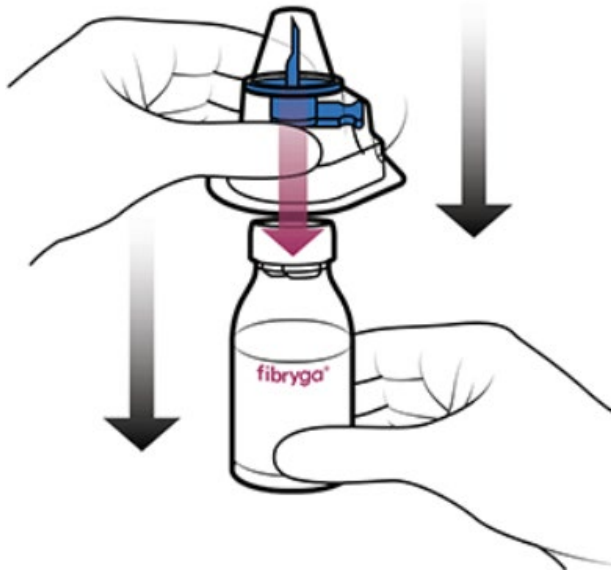
- Peel off the paper lid of the Octajet® transfer device.
- Leave the Octajet® device in the clear outer packaging to maintain sterility.



Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device

Step 4
Attach Octajet® Transfer Device to Powder Bottle

- Hold the fibryga® powder bottle on a firm flat surface.
- With the Octajet® device in its outer package, centre and invert the clear spike over the fibryga® powder bottle; spike it firmly through the centre indented area of the rubber stopper.
- Ensure the clear plastic clips of the Octajet® device are securely locked to the neck of the fibryga® powder bottle.

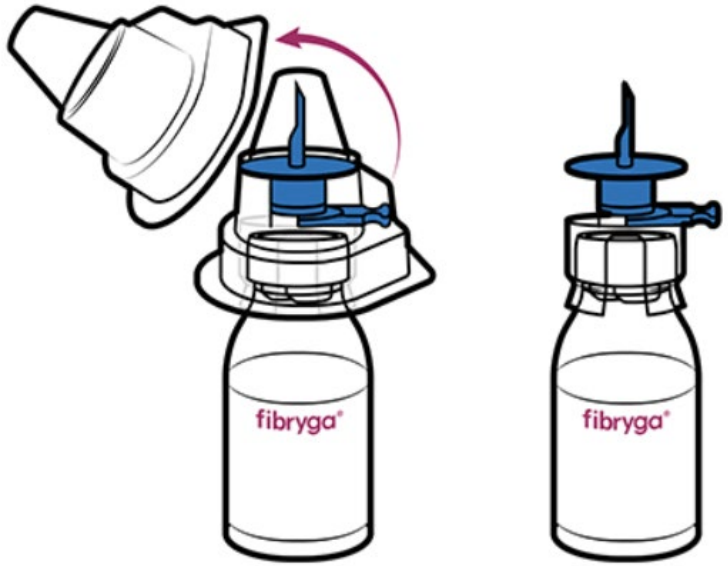


HINT: Fibryga® reconstitution is unique in that the transfer device is first spiked into the powder bottle, and secondly is the solvent bottle spiking procedure.

Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device

Step 5
Expose Blue Spike of Octajet® Transfer Device

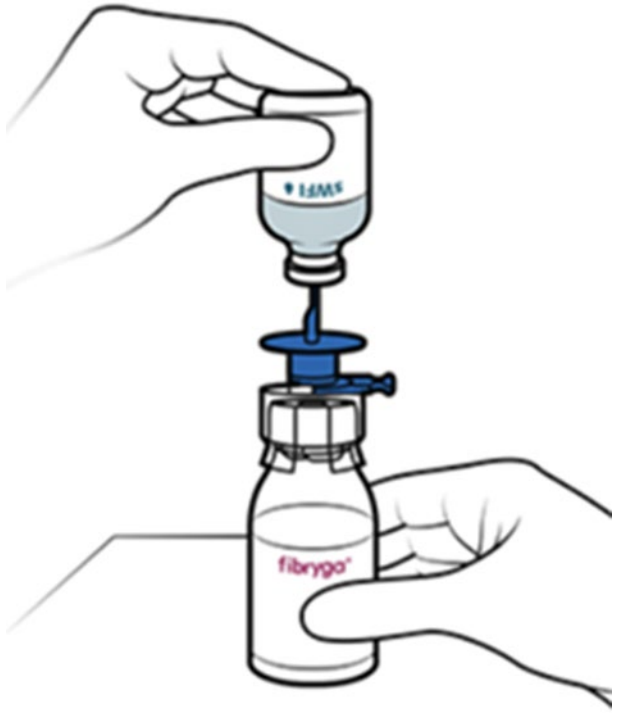
- Hold onto the fibryga® powder bottle and carefully remove the clear outer packaging of the Octajet® device to expose the blue solvent spike.
- The Octajet® device must remain firmly attached to the fibryga® powder bottle.
- Do not touch the blue solvent spike.



Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device

Step 6
Connect Solvent Bottle to Octajet® Transfer Device

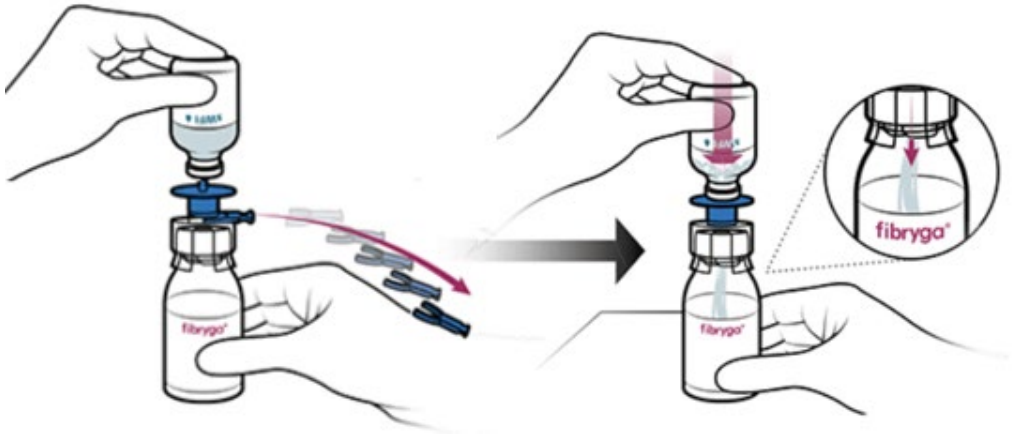
- With one hand, hold the fibryga® powder bottle on a flat surface.
- With the other hand, invert the solvent (sWFI) bottle and place it over the blue solvent spike of the Octajet® device.
- In one smooth motion, push downwards so that the blue solvent spike is just through the centre indented area of the rubber stopper of the solvent (sWFI) bottle.
- Make sure the solvent (sWFI) bottle fully covers both holes of the blue solvent spike (to prevent loss of vacuum).



Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device

Step 7
Remove Blue Spacer Ring to Mix Solvent with Powder

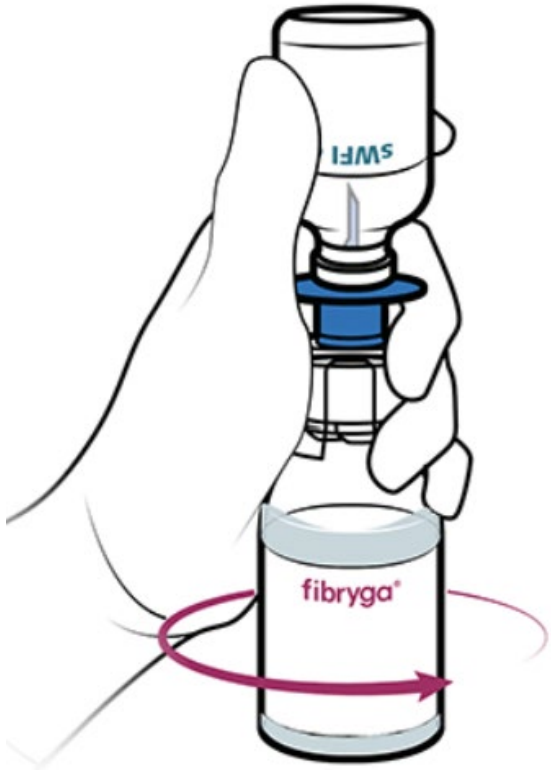
- Hold the solvent (sWFI) bottle steady and remove the blue spacer ring by pulling the blue tab (refer to red arrow on diagram).
- Press the solvent (sWFI) bottle with downward force (this starts the vacuum).
- The solvent (sWFI) will automatically flow into the fibryga® powder bottle.



Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device

Step 8
Swirl Fibryga® to Dissolve

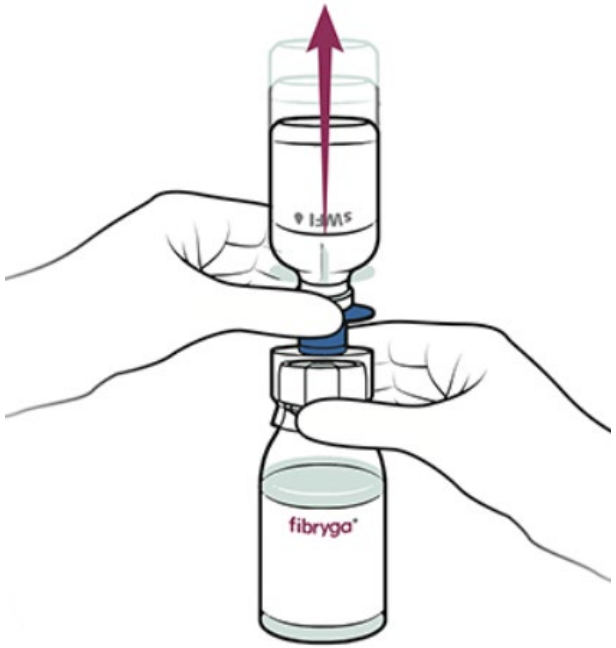
- When the solvent (sWFI) has been completely transferred, gently swirl the fibryga® powder bottle until the powder is completely dissolved.
- Do not shake the bottle as this causes foam to form (may lead to denaturation of proteins).
- The powder should be fully dissolved within about 5 minutes (should not take longer than 30 minutes).



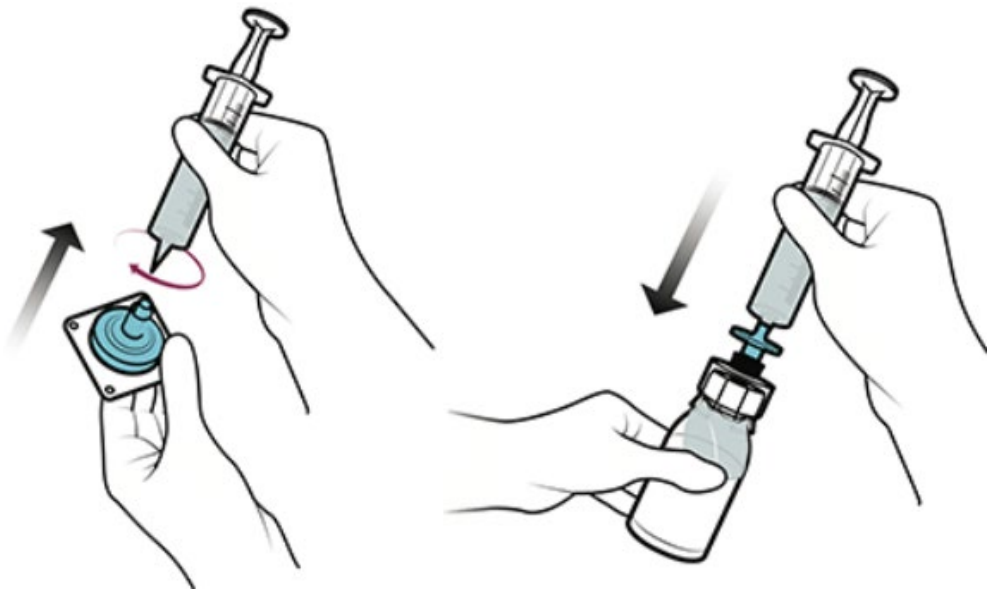
Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device

Step 9
Unlock Octajet® Transfer Device & Discard Empty Solvent Bottle

- Holding the fibryga® bottle in one hand, secure the clear part of the Octajet® device.
- In the other hand, hold the solvent (sWFI) bottle and grasp the blue disc/spike part of the Octajet® device.
- Turn this solvent connector about 45 degrees in either direction to unlock it.
- In one motion, remove the solvent (sWFI) bottle along with the blue disc/spike.
- Both the solvent (sWFI) bottle and the blue disc/spike must be removed to attach the filter (per step 10).



Step 10
Draw Air into Syringe & Attach Filter; Connect Syringe/Filter to Octajet® device/Fibryga® bottle;
Slowly Inject Air

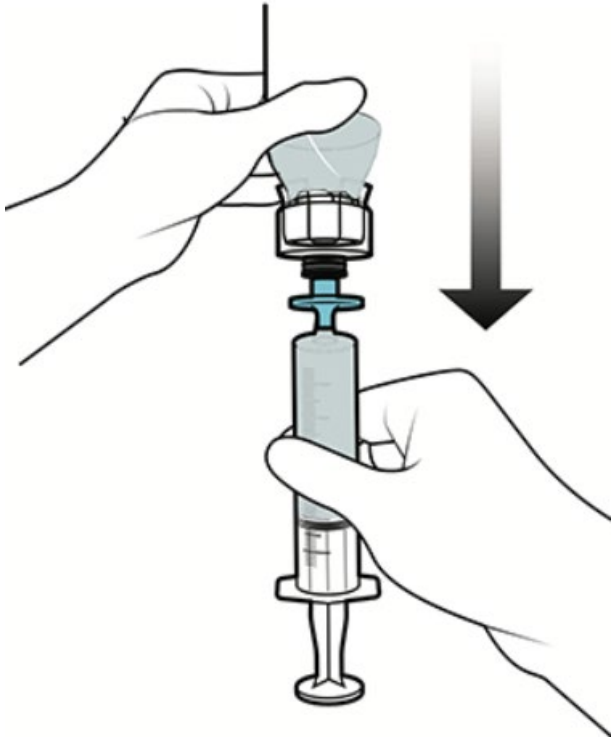


- Draw air into a sterile 50 mL syringe.
- Open the paper lid of the filter package.
- While holding the filter in its outer packaging, attach the syringe (with the air drawn up) to the filter.
- Remove the remaining outer packaging from the filter.
- Connect the filter and syringe to the luer lock of the clear Octajet® device that is on the fibryga® bottle.
- With the filter connected to the Octajet® device/fibryga® bottle, slowly inject air from the syringe into the fibryga® bottle.

Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device

Step 11
Withdraw Fibryga® & Prepare for Administration

- Invert and withdraw the fibryga® through the filter into the syringe.
- Detach the filled syringe and transfer the fibryga® to a sterile administration bag.
- Visually inspect the product; it should be colourless, not cloudy, and no deposits noted.
- Complete product label and apply to the sterile administration bag.
- Fibryga® is ready for administration.
- Discard bottle, Octajet® device, filter, syringe.



Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device Reconstitution Summary Steps 1 to 6

1. Check Expiry Date & Temperature:
Verify acceptable expiry date. Both the powder and solvent must be at room temperature.

2. Remove Caps, Clean Rubber Stopper of Powder & Solvent Bottles:
Use an alcohol swab, let dry.

3. Open Octajet® Transfer Device:
Remove the paper lid from the Octajet® device; keep it in its clear outer packaging for sterility.

4. Attach Octajet® Transfer Device to Powder Bottle:
Firmly hold the Fibryga® powder bottle on a flat surface. Invert, center, and press the clear spike of the Octajet® device into the indented area of the powder bottle's stopper to lock it in place.

5. Expose Blue Spike of Octajet® Transfer Device:
Maintain sterility and carefully remove the Octajet® outer packaging to uncover the blue spike.

6. Connect Solvent Bottle to Octajet® Transfer Device:
Invert the solvent bottle over the blue spike; push downwards so the spike is just through the indented area of the stopper. Ensure the solvent bottle fully covers both holes of the blue spike.

Product Learning Module 1: FC - FIBRYGA® Octajet® transfer device
Reconstitution Summary Steps 7 to 11

7. Remove Blue Spacer Ring to Mix Solvent with Powder:
Hold the solvent bottle steady and remove the blue spacer ring from the Octajet® device by pulling the tab. Press down on the solvent bottle, it will automatically flow into the powder bottle.

8. Swirl Fibryga® to Dissolve:
Gently swirl the Fibryga® powder bottle until fully dissolved (5-30 minutes). DO NOT SHAKE.

9. Unlock Octajet® Transfer Device & Discard Empty Solvent Bottle:
Hold the Fibryga® bottle securing the clear part of the Octajet® device. Turn the blue disc of Octajet® 45 degrees. Remove the empty solvent bottle along with the blue disc/spike.

10. Draw Air into Syringe & Attach Filter; Connect Syringe/Filter to Octajet® device/Fibryga® bottle; Slowly Inject Air:
Draw air into a 50 mL syringe. Using sterile technique, open the lid of the filter package and attach the 50 mL syringe. Connect the syringe/filter to the luer lock of the clear Octajet® device on the Fibryga® bottle. Slowly inject air from the syringe into the Fibryga® bottle.

11. Withdraw Fibryga® & Prepare for Administration:
Withdraw reconstituted Fibryga® through the filter into the syringe. Transfer to sterile administration bag, visually inspect, and label the product.

Product Learning Module 1: FC - FIBRYGA® Nextaro® transfer device

Learning for the new FIBRYGA® Nextaro® transfer device will be released soon!

If information about the FIBRYGA® Nextaro® transfer device is needed now, contact your hospital TML.

Product Learning Module 1: FC - FIBRYGA®

Administration Notes (1)

- Fibryga® is available as 1 g per bottle. Carefully review the prescriber's order. More than 1 bottle may be required to provide the dose that was ordered. As required, reconstituted Fibryga® from additional bottles may be added to the same sterile administration bag (pooled).
- Following reconstitution, Fibryga® should be used immediately. If not, storage times and conditions are the responsibility of the facility (risk of microbial contamination, manufacturer notes stability of the reconstituted solution has been confirmed for up to 24 hours at +25°C).
- Reconstituted solution is colourless. Do not administer if cloudy or deposits are observed.
- Administer at room temperature.
- Do not further dilute in any IV solutions. Do not mix with any other medicinal products.
- Fibryga® is compatible with 0.9 % sodium chloride (NaCl).

Product Learning Module 1: FC - FIBRYGA®

Administration Notes (2)

- Administer only intravenously via a separate injection/infusion line. For infusion, use a standard IV infusion set (has been filtered as part of reconstitution procedure).
- Flush the IV site with 0.9 % NaCl flush syringe prior to and following administration.
- Monitoring the patient's fibrinogen level before and during treatment is recommended.
- Indication / Rate
    - Congenital Afibrinogenemia and Hypofibrinogenemia
      Recommended maximum rate 5 mL per minute (300 mL/hour)
    - Acquired Fibrinogen Deficiency
      Recommended maximum rate 20 mL per minute (1200 mL/hour)

Product Learning Module 2: FC - RiaSTAP®

REMINDER: Only reconstitute when ready to administer.

- RiaSTAP® is available as 1 g/bottle (vial), reconstituted with 50 mL of solvent (water for injection).
- Use appropriate aseptic technique.
- Single use only.
- TML will provide product label(s) and kit(s) containing:
  Mini-Spike® dispensing pin, Pall® syringe filter, solvent bottle, RiaSTAP® powder bottle.

- Also required: alcohol swabs, 50 mL syringes, needles, sterile administration bag.

Product Learning Module 2: FC - RiaSTAP®

Step 1
Check Expiry Date & Temperature

- Verify product expiry date (on the kit packaging and the bottles) is acceptable.
- Ensure the bottles of both the solvent and the powder are at room temperature.
- RiaSTAP® is stored refrigerated between +2°C and +8°C.
- To bring the RiaSTAP® powder bottle to room temperature, gently roll the bottle in your hand (avoid shaking the bottle).
- During reconstitution, room temperature should be maintained.
- Room temperature augments the product powder dissolving.

Product Learning Module 2: FC - RiaSTAP®

Step 2
Remove Caps, Clean Rubber Stopper of Powder & Solvent Bottles

- Remove the cap from both the solvent and the powder bottles.
- Using a circular motion, clean the exposed central part of the rubber stopper of both bottles with an alcohol swab.
- Allow the stoppers of the bottles to dry.

Product Learning Module 2: FC - RiaSTAP®

Step 3
Draw up 50 mL of Solvent

- Using a 50 mL syringe and a needle, remove the 50 mL of water for injection from the solvent bottle (the diagram depicts a 10 mL syringe; in actual practice a 50 mL syringe is used).

Product Learning Module 2: FC - RiaSTAP®

Step 4
Add Solvent to RiaSTAP® Powder Bottle

- With the RiaSTAP® powder bottle on a firm flat surface, transfer the 50 mL of water for injection from the syringe into the bottle (the diagram depicts a 10 mL syringe; in actual practice a 50 mL syringe is used).
- Aim the stream of the water for injection down the side of the powder bottle (verses directly onto the powder) to minimize clumping.

Product Learning Module 2: FC - RiaSTAP®

Step 5
Swirl RiaSTAP® to Dissolve

- Gently swirl the RiaSTAP® powder bottle until the powder is completely dissolved.
- The powder should be fully dissolved within about 5 to 10 minutes.
- Do not shake the bottle as this causes the product to foam (may lead to denaturation of proteins).

Product Learning Module 2: FC - RiaSTAP®

Step 6
Insert Mini-Spike® Dispensing Pin into RiaSTAP® bottle

- Open the plastic blister package containing the Mini-Spike® dispensing pin and insert it into the stopper of the reconstituted RiaSTAP® bottle.

Step 7
Remove Blue Cap from Mini-Spike® Dispensing Pin

- Carefully remove the blue cap of the Mini-Spike® dispensing pin.
- Do not touch the white exposed dispensing pin surface.

Product Learning Module 2: FC - RiaSTAP®

Step 8
Prepare Pall® Syringe Filter

- Open the plastic blister package of the Pall® syringe filter.
- Screw a new 50 mL syringe onto the syringe filter.

Step 9
Connect the Pall® Syringe Filter & the Mini-Spike® Dispensing Pin (on the RiaSTAP® bottle)

- Screw the Pall® syringe filter with the 50 mL syringe attached onto the Mini-Spike® dispensing pin that was inserted into the reconstituted RiaSTAP® bottle.

Step 10
Withdraw RiaSTAP® & Prepare for Administration

- Invert the bottle and withdraw the RiaSTAP® through the Pall® syringe filter into the 50 mL syringe.
- Detach the filled syringe and transfer the RiaSTAP® to a sterile administration bag.
- Visually inspect the product; it should be colourless and clear to slightly opalescent, not cloudy and no deposits noted.
- Complete product label and apply to the sterile administration bag.
- RiaSTAP® is ready for administration.
- Discard bottle, dispensing pin device, filter, syringe.

Product Learning Module 2: FC - RiaSTAP® Reconstitution Summary Steps 1 to 6

1. Check Expiry Date & Temperature:
Verify acceptable expiry date. Both the powder and solvent must be at room temperature. As needed, for the RiaSTAP® powder, gently roll the bottle in your hand.

2. Remove Caps, Clean Rubber Stopper of Powder & Solvent Bottles:
Use an alcohol swab, let dry.

3. Draw up 50 mL of Solvent:
Using a needle and 50 mL syringe, draw 50 mL of water for injection from the solvent bottle.

4. Add Solvent to RiaSTAP® Powder Bottle:
With the RiaSTAP® powder bottle on a firm flat surface, transfer the 50 mL of water for injection into the powder bottle.

5. Swirl RiaSTAP® to Dissolve:
Gently swirl the RiaSTAP® powder bottle until fully dissolved (5-10 minutes). DO NOT SHAKE.

6. Insert Mini-Spike® Dispensing Pin into RiaSTAP® bottle:
Insert the Mini-Spike® dispensing pin into the stopper of the RiaSTAP® bottle.

Product Learning Module 2: FC - RiaSTAP® Reconstitution Summary Steps 7 to 10

7. Remove Blue Cap from Mini-Spike® Dispensing Pin:
Remove the dispensing pin's blue cap. Maintain sterility of the white dispensing pin.

8. Attach 50 mL Syringe to Pall® Syringe Filter:
Open the blister package of the Pall® syringe filter and screw a new 50 mL syringe onto it.

9. Connect the Pall® Syringe Filter & the Mini-Spike® Dispensing Pin (on the RiaSTAP® bottle):
Screw the Pall® syringe filter, with the syringe attached, onto the Mini-Spike® dispensing pin that was inserted into the RiaSTAP® bottle.

10. Withdraw RiaSTAP® & Prepare for Administration:
Invert and withdraw the reconstituted RiaSTAP® through the filter into the syringe. Transfer to sterile administration bag, visually inspect, and label the product.

Product Learning Module 2: FC - RiaSTAP®

Administration Notes (1)

- RiaSTAP® is available as 1 g per bottle. Carefully review the prescriber's order. More than 1 bottle may be required to provide the dose that was ordered. As required, reconstituted RiaSTAP® from additional bottles may be added to the same sterile administration bag (pooled).
- Following reconstitution, RiaSTAP® should be used immediately. RiaSTAP® is stable for 8 hours after reconstitution when stored at room temperature (+20°C to 25°C) and should be administered within this time period.
- Reconstituted solution is colourless and clear to slightly opalescent. Do not administer if cloudy or particles are observed.
- Administer at room temperature.
- Do not further dilute in any IV solutions. Do not mix with any other medicinal products.
- RiaSTAP® is compatible with 0.9 % sodium chloride (NaCl).

Product Learning Module 2: FC - RiaSTAP®

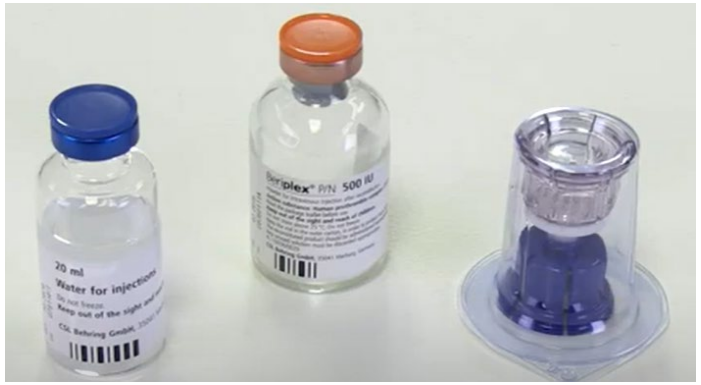
Administration Notes (2)

- Administer only intravenously via a separate injection/infusion line. For infusion, use a standard IV infusion set (has been filtered as part of reconstitution procedure).
- Flush the IV site with 0.9 % NaCl flush syringe prior to and following administration.
- Monitoring the patient's fibrinogen level before and during treatment is recommended.
- Indication / Rate
  - Congenital Afibrinogenemia and Hypofibrinogenemia
  - Recommended maximum rate 5 mL per minute (300 mL/hour)

Product Learning Module 3: PCC - Beriplex®

REMINDER: Only reconstitute when ready to administer.

- Beriplex® is available as 500 IU in 20 mL bottle/vial and 1000 IU in 40 mL bottle/vial; reconstituted with 20 mL and 40 mL, respectively, of solvent (water for injection, WFI).
- Use appropriate aseptic technique.
- Single use only.
- TML will provide product label(s) and kit(s) containing:
  solvent bottle (WFI), Beriplex® powder bottle, Mix2Vial™ transfer set.



- Also required: alcohol swabs, syringes (appropriate size, depending on dose), needles, sterile administration bag.

Product Learning Module 3: PCC - Beriplex®

Step 1
Check Date Expiry & Temperature

- Verify product expiry date (on the kit packaging and the bottles) is acceptable.
- Ensure the bottles of both the solvent (water for injection, WFI) and the powder are at room temperature.
- During reconstitution, room temperature should be maintained.
- Room temperature augments the product powder dissolving.

Product Learning Module 3: PCC - Beriplex®

Step 2
Remove Caps, Clean Rubber Stopper of Powder & Solvent Bottles

- Remove the cap from both the solvent (WFI) and the powder bottles.
- Using a circular motion, clean the exposed central part of the rubber stopper of both bottles with an alcohol swab.
- Allow the stoppers of the bottles to dry.

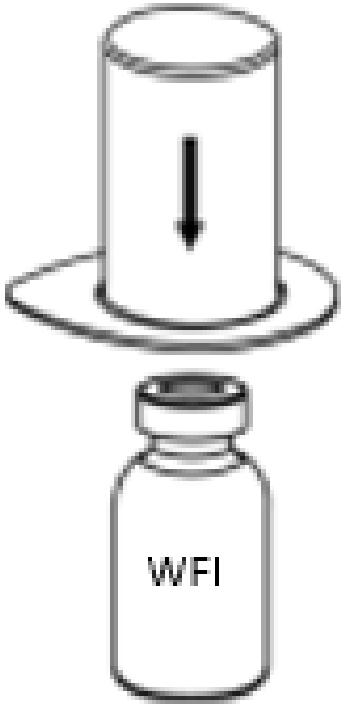
Product Learning Module 3: PCC - Beriplex®

Step 3
Peel Paper Lid off the Mix2Vial™ Transfer Set

- Peel the paper lid off the Mix2Vial™ transfer set.
- Leave the Mix2Vial™ transfer set in the clear blister package to maintain sterility.

Step 4
Connect Mix2Vial™ Transfer Set to Solvent Bottle

- Place the solvent (WFI) bottle on a flat surface and hold the bottle steady.
- Invert and centre the Mix2Vial™ transfer set in its clear blister package over the solvent (WFI) bottle.
- In one smooth motion, push the blue spike part of the Mix2Vial™ transfer set straight down through the stopper of the solvent (WFI) bottle.



HINT: blue to blue (the Mix2Vial™ transfer set blue spike part goes onto the solvent (WFI) bottle which has a blue metal rim).

Step 5
Remove Mix2Vial™ Transfer Set Clear Blister Packaging

- Securely hold the solvent (WFI) bottle and cautiously pull the clear blister package upwards to remove it from Mix2Vial™ transfer set.
- Ensure the Mix2Vial™ transfer set remains firmly attached to the solvent (WFI) bottle.

Product Learning Module 3: PCC - Beriplex®

Step 6
Add Solvent to Beriplex® Powder Bottle

- Hold the Beriplex® powder bottle steady on a firm flat surface, and invert the solvent (WFI) bottle (with the Mix2Vial™ transfer set attached).
- Firmly push the transparent spike part of the Mix2Vial™ transfer set straight down through the stopper of the Beriplex® powder bottle.
- The solvent (WFI) will automatically flow into the Beriplex® powder bottle.

Product Learning Module 3: PCC - Beriplex®

Step 7
Slowly Swirl to Dissolve

- With solvent (WFI) and Beriplex® bottles still attached, gently and slowly swirl/rotate the Beriplex® bottle until the product is fully dissolved.
- Do not shake.

Product Learning Module 3: PCC - Beriplex®

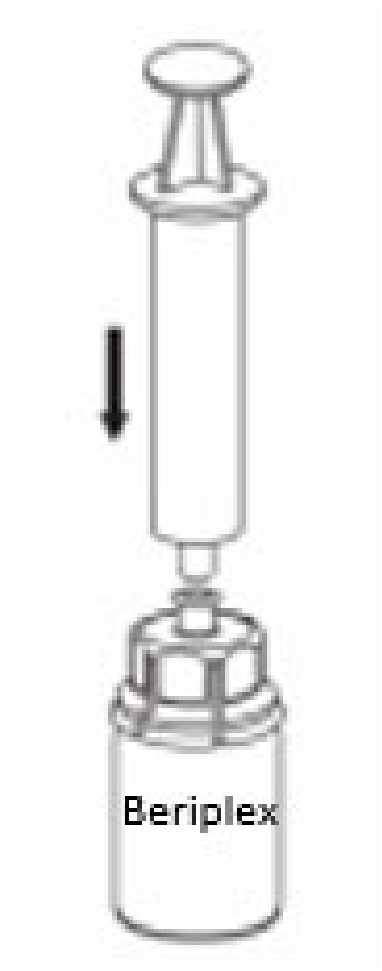
Step 8
Separate Mix2Vial™ Transfer Set; Discard the Blue part with the Empty Solvent Bottle

- With one hand, firmly hold the transparent (product side) part and with the other hand, firmly hold the blue (WFI side) part of the Mix2Vial™ transfer set.
- Unscrew (turn counterclockwise) the Mix2Vial™ transfer set into two separate pieces with the bottles still attached.
- Discard the blue part of the Mix2Vial™ transfer set and the empty solvent (WFI) bottle.
- The transparent part of the Mix2Vial™ transfer set must remain attached to the Beriplex® bottle because it includes the filter.

Product Learning Module 3: PCC - Beriplex®

Step 9
Draw Air into syringe. Connect syringe to transparent part of Mix2Vial™ set/Beriplex® bottle.
Slowly Inject Air.

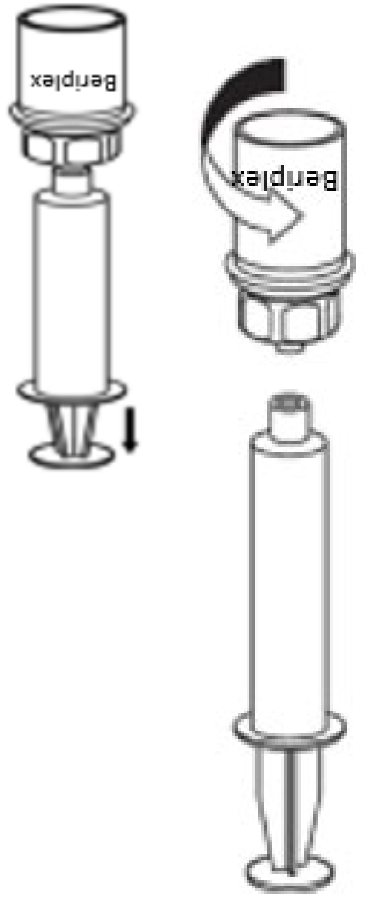
- Draw air into a sterile syringe (appropriate size, depending on the dose of Beriplex® that is being reconstituted).
- Keeping the Beriplex® bottle upright, connect (by turning clockwise) the syringe to the transparent part of the Mix2Vial™ transfer set (which is attached to the reconstituted Beriplex® bottle).
- Slowly inject air into the Beriplex® bottle.



Product Learning Module 3: PCC - Beriplex®

Step 10
Withdraw Beriplex® & Prepare for Administration

- Keep the plunger of the syringe pressed in and invert the syringe-Beriplex® bottle.
- Withdraw the Beriplex® through the filter of the transparent part of Mix2Vial™ transfer set into the syringe.
- After the Beriplex® has been transferred into the syringe, firmly hold the barrel of the syringe (keeping the plunger directed downwards) and detach (turn counterclockwise) the Mix2Vial™ transfer set and empty bottle from the syringe.
- Transfer the Beriplex® from the syringe to a sterile administration bag.
- Visually inspect the product; it should be clear to slightly opalescent, not cloudy and no deposits noted.
- Complete product label and apply to the sterile administration bag.
- Beriplex® is ready for administration.
- Discard bottle, transparent part of Mix2Vial™ transfer set, syringe.



Product Learning Module 3: PCC - Beriplex® Reconstitution Summary Steps 1 to 6

1. Check Expiry Date & Temperature:
Verify acceptable expiry date. Both the powder & solvent must be at room temperature.

2. Remove Caps, Clean Rubber Stopper of Powder & Solvent Bottles:
Use an alcohol swab, let dry.

3. Peel Paper Lid off the Mix2Vial™ Transfer Set:
Peel off the paper lid from the Mix2Vial™ transfer set; keep it in the clear blister package.

4. Connect Mix2Vial™ Transfer Set to Solvent Bottle:
Place the solvent bottle on a flat surface, hold it steady. Invert & center the Mix2Vial™ set (blue end) over the solvent (WFI) bottle, then push the blue spike down through the stopper of the bottle.

5. Remove Mix2Vial™ Transfer Set Clear Blister Packaging:
Securely hold the solvent (WFI) bottle & pull upwards to remove the clear blister package from the Mix2Vial™ set.

6. Add Solvent to Beriplex® Powder Bottle:
Hold the Beriplex® powder bottle on a flat surface. Invert the solvent (WFI) bottle & push the transparent spike of the Mix2Vial™ set straight down through the stopper of the powder bottle. The solvent (WFI) will automatically flow into the Beriplex® powder bottle.

Product Learning Module 3: PCC - Beriplex® Reconstitution Summary Steps 7 to 10

7. Slowly Swirl to Dissolve:
With the bottles connected via the Mix2Vial™ transfer set, slowly swirl/rotate the Beriplex® powder bottle until fully dissolved.

8. Separate Mix2Vial™ Transfer Set; Discard the Blue part with the Empty Solvent Bottle:
Unscrew (turn counterclockwise) the Mix2Vial™ transfer set into two separate parts (blue & transparent), carefully keeping the solvent (WFI) & powder bottles attached. Discard the Mix2Vial™ set blue part & empty solvent (WFI) bottle.

9. Draw Air into syringe. Connect syringe to transparent part of Mix2Vial™ set/Beriplex® bottle. Slowly Inject Air:
Draw air into a sterile syringe (appropriate size, depending on the Beriplex® dose). Connect the syringe to the transparent part of the Mix2Vial™ set that is attached to the upright Beriplex® bottle & slowly inject the air.

10. Withdraw Beriplex® & Prepare for Administration:
Keep the plunger of the syringe pressed in & invert the syringe-Beriplex® bottle. Withdraw reconstituted Beriplex® through the transparent part of the Mix2Vial™ set (contains the filter) into the syringe by slowly pulling the plunger back. Firmly hold the barrel of the syringe (keeping the plunger directed downwards) and detach (turn counterclockwise) the Mix2Vial™ transfer set and empty bottle from the syringe. Transfer to sterile administration bag, visually inspect, & label the product.

Product Learning Module 3: PCC - Beriplex®

Administration Notes (1)

- Beriplex® is available as 500 IU in 20 mL bottle and 1000 IU in 40 mL bottle. Carefully review the product provided from TML and the prescriber's order. More than 1 bottle may be required to provide the dose that was ordered. As required, reconstituted Beriplex® from additional bottles may be added to the same sterile administration bag (pooled).
- To ensure sterility, following reconstitution, Beriplex® should be used immediately. (contains no preservatives). Storage must not exceed 3 hours at room temperature.
- Reconstituted solution is clear or slightly opalescent. Do not administer if cloudy or deposits are observed.
- Administer at room temperature.
- Do not further dilute in any IV solutions. Do not mix with any other medicinal products.
- Beriplex® is compatible with 0.9 % sodium chloride (NaCl).
- Administer only intravenously via a separate injection/infusion line. For infusion, use a standard IV infusion set (has been filtered as part of reconstitution procedure).

Product Learning Module 3: PCC - Beriplex®

Administration Notes (2)

- Flush the IV site with 0.9 % NaCl flush syringe prior to and following administration.
- NOTE: PCC is CONTRAINDICATED in patients with heparin-induced thrombocytopenia (HIT) or with known allergies to heparin (Beriplex® contains heparin).
- Monitoring blood coagulation with appropriate coagulation assays (plasma levels of individual coagulation factors, or global tests of prothrombin complex levels [prothrombin time, INR]) before and during treatment is recommended.
- Indication / Rate
    - Treatment of bleeding and perioperative prophylaxis of bleeding in acquired deficiency of the prothrombin complex coagulation factors (factors II, VII, IX and X). For example, deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required (life threatening bleeding or emergency surgical interventions).
    - Recommended maximum infusion rate: 8 mL per minute (480 mL/hour).

Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device

REMINDER: Only reconstitute when ready to administer.

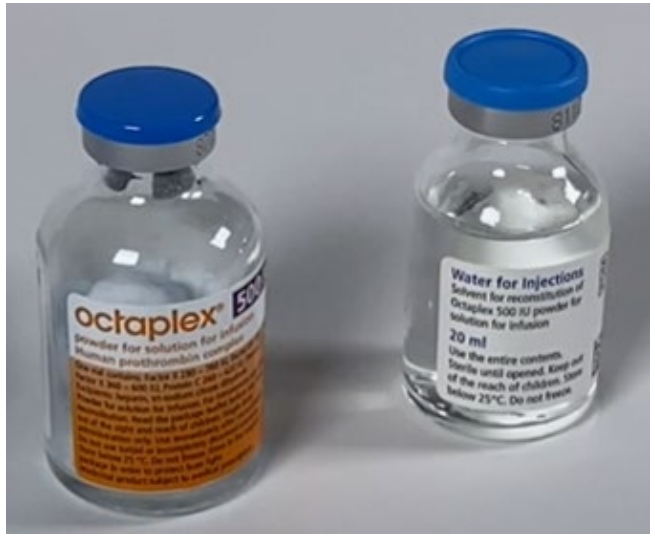
- Octaplex® is available as 500 IU in 20 mL bottle/vial and 1000 IU in 40 mL bottle/vial; reconstituted with 20 mL and 40 mL, respectively, of solvent (water for injection, WFI).
- Use appropriate aseptic technique.
- Single use only.
- TML will provide product label(s) and kit(s) containing:
  Mix2Vial™ transfer set, Octaplex® powder bottle, solvent (WFI) bottle.

- Also required: alcohol swabs, syringes (appropriate size, depending on dose), needles, sterile administration bag.

Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device

Step 1
Check Date Expiry & Temperature

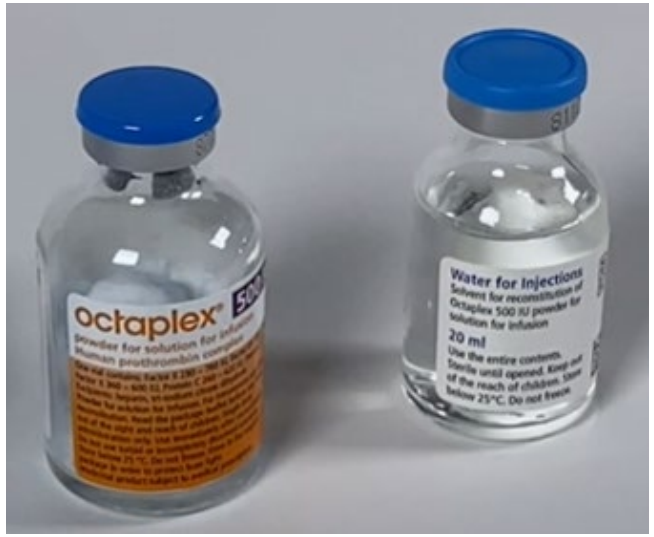
- Verify product expiry date (on the kit packaging and the bottles) is acceptable.
- Ensure the bottles of both the powder and the solvent (WFI) are at room temperature.
- During reconstitution, room temperature should be maintained.
- Room temperature augments the product powder dissolving.



Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device

Step 2
Remove Caps, Clean Rubber Stopper of Powder & Solvent Bottles

- Remove the cap from both the powder and the solvent (WFI) bottles.
- Using a circular motion, clean the exposed central part of the rubber stopper of both bottles with an alcohol swab.
- Allow the stoppers of the bottles to dry.

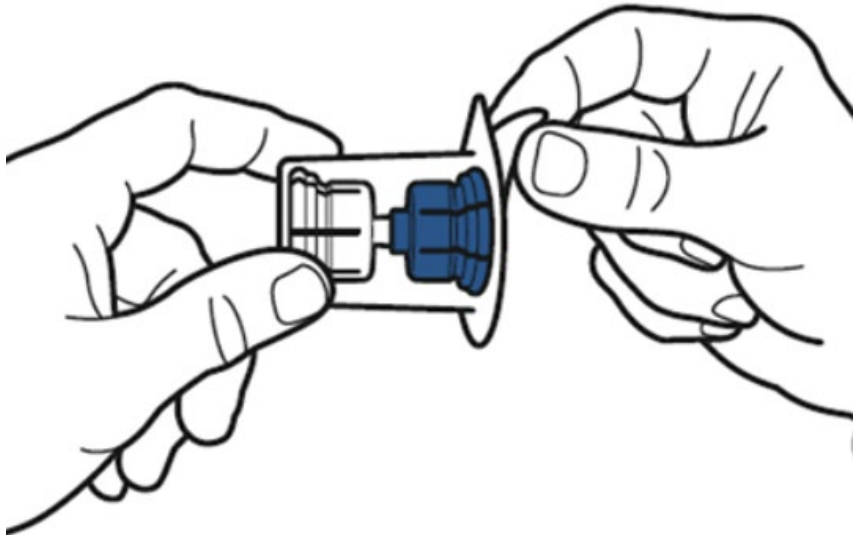


Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device

Step 3

Peel Paper Lid off the Mix2Vial™ Transfer Set

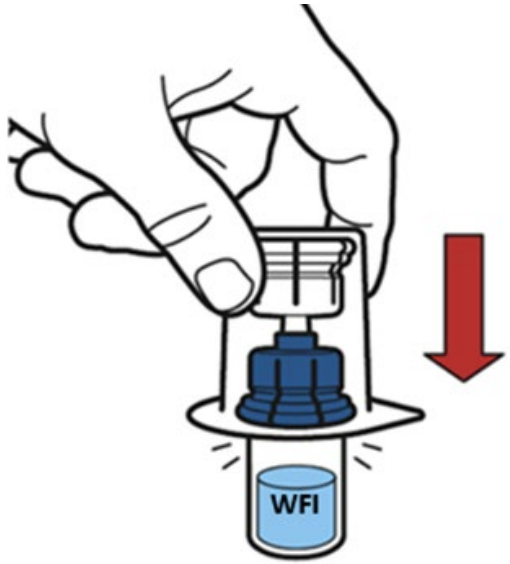
- Peel the paper lid off the Mix2Vial™ transfer set.
- Leave the Mix2Vial™ transfer set in the clear outer packaging to maintain sterility.



Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device

Step 4
Connect Mix2Vial™ Transfer Set to Solvent Bottle

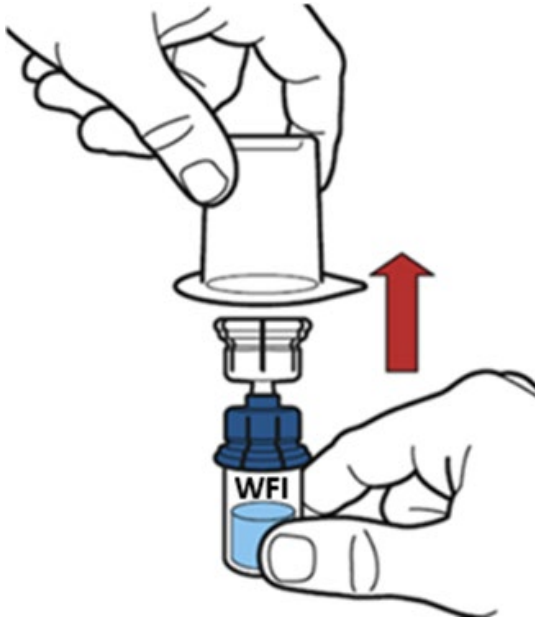
- Place the solvent (WFI) bottle on a flat surface and hold the bottle steady.
- Invert and centre the Mix2Vial™ transfer set in its clear outer packaging over the solvent (WFI) bottle.
- In one smooth motion, push the blue spike part of the Mix2Vial™ transfer set straight down through the rubber stopper of the solvent (WFI) bottle.



Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device

Step 5
Remove Mix2Vial™ Transfer Set Clear Blister Packaging

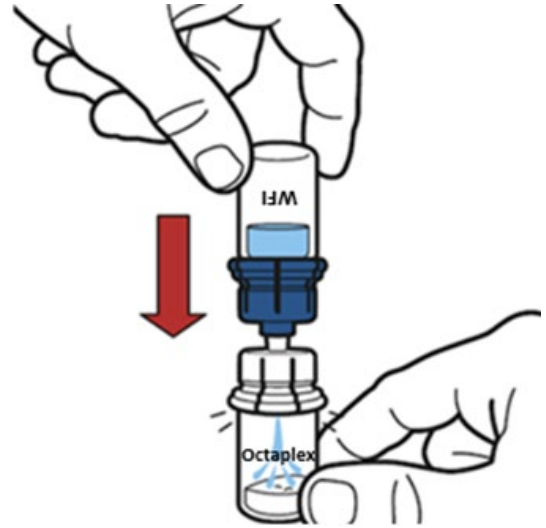
- Securely hold the solvent (WFI) bottle and cautiously remove the clear outer packaging from Mix2Vial™ transfer set.
- Ensure the Mix2Vial™ transfer set remains firmly attached to the solvent (WFI) bottle.



Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device

Step 6
Add Solvent to Octaplex® Powder Bottle

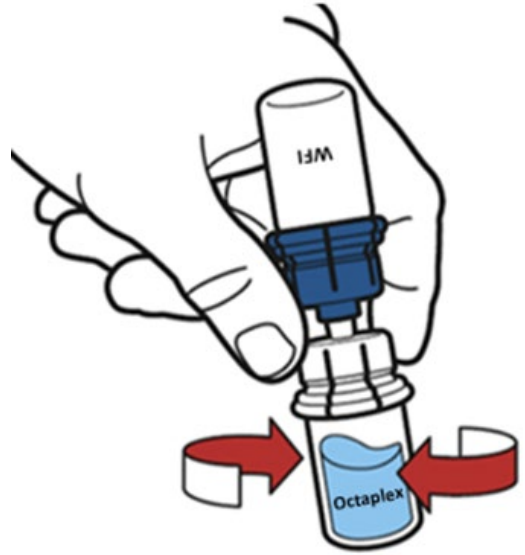
- While holding the Octaplex® powder bottle steady on a firm flat surface, invert the solvent (WFI) bottle (with the Mix2Vial™ transfer set attached) and firmly push the transparent plastic cannula end of the Mix2Vial™ transfer set through the stopper of the Octaplex® powder bottle.
- The transparent plastic cannula will snap into place.
- Maintain downward pressure as the vacuum draws the solvent (WFI) into the Octaplex® powder bottle.



Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device

Step 7
Gently Swirl to Dissolve

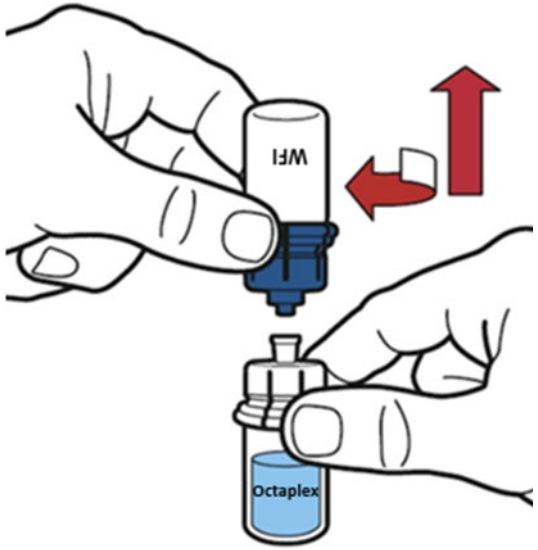
- With solvent (WFI) and Octaplex® bottles still attached, gently and slowly swirl/rotate the Octaplex® bottle until the product is fully dissolved.
- Do not shake.



Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device

Step 8
Separate Mix2Vial™ Transfer Set; Discard the Blue part with the Empty Solvent Bottle

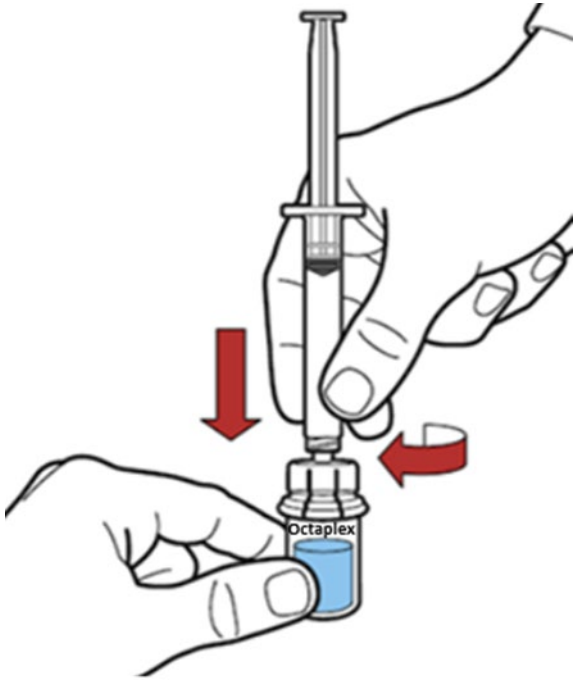
- With one hand, firmly hold the transparent (product side) part and with the other hand, firmly hold the blue (WFI side) part of the Mix2Vial™ transfer set.
- Unscrew (turn counterclockwise) the Mix2Vial™ transfer set into two separate pieces with the bottles still attached.
- Discard the blue part of the Mix2Vial™ transfer set and the empty solvent (WFI) bottle.
- The transparent part of the Mix2Vial™ transfer set must remain attached to the Octaplex® bottle because it includes the filter.



Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device

Step 9
Draw Air into syringe. Connect syringe to transparent part of Mix2Vial™ set/Octaplex® bottle.
Slowly Inject Air.

- Draw air into a sterile syringe (appropriate size, depending on the dose of Octaplex® that is being reconstituted).
- Keeping the Octaplex® bottle upright, connect (by turning clockwise) the syringe to the transparent part of the Mix2Vial™ transfer set (which is attached to the reconstituted Octaplex® bottle).
- Slowly inject air into the Octaplex® bottle.



Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device

Step 10
Withdraw Octaplex® & Prepare for Administration

- Invert the syringe-Octaplex® bottle and withdraw the Octaplex® through the filter of the transparent part of the Mix2Vial™ transfer set into the syringe.
- After the Octaplex® has been transferred into the syringe, firmly hold the barrel of the syringe (keeping the barrel directed downwards) and detach (turn counterclockwise) the Mix2Vial™ transfer set and empty bottle from the syringe.
- Transfer the Octaplex® from the syringe to a sterile administration bag.
- Visually inspect the product; it should be colourless to slightly blue, not cloudy and no deposits noted.
- Complete product label and apply to the sterile administration bag.
- Octaplex® is ready for administration.
- Discard bottle, transparent part of the Mix2Vial™ transfer set, syringe.

Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device Reconstitution Summary Steps 1 to 6

1. Check Expiry Date & Temperature:
Verify acceptable expiry date. Both the powder & solvent must be at room temperature.

2. Remove Caps, Clean Rubber Stopper of Powder & Solvent Bottles:
Use an alcohol swab, let dry.

3. Peel Paper Lid off the Mix2Vial™ Transfer Set:
Peel off the paper lid from the Mix2Vial™ transfer set; keep it in the clear blister package.

4. Connect Mix2Vial™ Transfer Set to Solvent Bottle:
Place the solvent (WFI) bottle on a flat surface, hold it steady. Invert & center the Mix2Vial™ set (blue end) over the solvent (WFI) bottle, then push the blue spike down through the stopper of the bottle.

5. Remove Mix2Vial™ Transfer Set Clear Blister Packaging:
Securely hold the solvent (WFI) bottle & pull upwards to remove the clear blister package from the Mix2Vial™ set.

6. Add Solvent to Octaplex® Powder Bottle:
Hold the Octaplex® powder bottle on a flat surface. Invert the solvent (WFI) bottle & push the transparent spike of the Mix2Vial™ set straight down through the stopper of the powder bottle. Maintain downward pressure as the vacuum draws the solvent (WFI) into the powder bottle.

Product Learning Module 4: PCC - Octaplex® Mix2Vial™ transfer set/device Reconstitution Summary Steps 7 to 10

7. Gently Swirl to Dissolve:
With the bottles connected via the Mix2Vial™ transfer set, gently, swirl/rotate the Octaplex® powder bottle until fully dissolved.

8. Separate Mix2Vial™ Transfer Set; Discard the Blue part with the Empty Solvent Bottle:
Unscrew (turn counterclockwise) the Mix2Vial™ transfer set into two separate parts (blue & transparent), carefully keeping the solvent (WFI) & powder bottles attached. Discard the Mix2Vial™ set blue part & empty solvent (WFI) bottle.

9. Draw Air into syringe. Connect syringe to transparent part of Mix2Vial™ set/Octaplex® bottle. Slowly Inject Air:
Draw air into sterile syringe (appropriate size, depending on the Octaplex® dose). Connect the syringe to the transparent part of the Mix2Vial™ set that is attached to the upright Octaplex® bottle & slowly inject the air.

10. Withdraw Octaplex® & Prepare for Administration:
Keep the plunger of the syringe pressed in & invert the syringe-Octaplex® bottle. Withdraw reconstituted Octaplex® through the transparent part of the Mix2Vial™ set (contains the filter) into the syringe by slowly pulling the plunger back. Firmly hold the barrel of the syringe (keeping the plunger directed downwards) and detach (turn counterclockwise) the Mix2Vial™ transfer set and empty bottle from the syringe. Transfer to sterile administration bag, visually inspect, & label the product.

Product Learning Module 4: PCC - Octaplex® - Nextaro® transfer device

Learning for the new Octaplex® Nextaro® transfer device will be released soon!

If information about the Octaplex® Nextaro® transfer device is needed now, contact your hospital TML.

Product Learning Module 4: PCC - Octaplex®

Administration Notes (1)

- Octaplex® is available as 500 IU in 20 mL bottle and 1000 IU in 40 mL bottle. Carefully review the product provided from TML and the prescriber's order. More than 1 bottle may be required to provide the dose that was ordered. As required, reconstituted Octaplex® from additional bottles may be added to the same sterile administration bag (pooled).
- Following reconstitution, Octaplex® should be used immediately. Octaplex® can be stored for up to 8 hours at +2°C to +25°C, provided the sterility of the stored product is maintained. If stored, Octaplex® should be protected from light.
- Reconstituted solution is colourless to slightly blue. Do not administer if cloudy or deposits are observed.
- Administer at room temperature.
- Do not further dilute in any IV solutions. Do not mix with any other medicinal products.
- Octaplex® is compatible with 0.9 % sodium chloride (NaCl) and 5 % dextrose in water.
- Administer only intravenously via a separate injection/infusion line. For infusion, use a standard IV infusion set (has been filtered as part of reconstitution procedure).

Product Learning Module 4: PCC - Octaplex®

Administration Notes (2)

- Flush the IV site with 0.9 % NaCl flush syringe prior to and following administration.
- NOTE: PCC is CONTRAINDICATED in patients with heparin-induced thrombocytopenia (HIT) or with known allergies to heparin (Octaplex® contains heparin).
- Monitor blood coagulation with appropriate coagulation assays (plasma levels of individual coagulation factors, or global tests of prothrombin complex levels [prothrombin time, INR]) before and during treatment is recommended.
- Indication / Rate
    - Treatment of bleeding and perioperative prophylaxis of bleeding in acquired deficiency of the prothrombin complex coagulation factors (factors II, VII, IX and X). For example, deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required (life threatening bleeding or emergency surgical interventions).
    - Recommended initial infusion rate 1 mL per minute (60 mL/hour) followed by 2-3 mL per minute (120-180 mL/hour), if appropriate.

Product Learning Modules
Supplementary Information - FC Indication

A. As per Product Monographs

B. Bloody Easy 5.1 handbook

- “Major or massive hemorrhage from surgery or trauma when fibrinogen <1.5 g/L.”
- “Acute phase of acute promyelocytic leukemia with fibrinogen <1.5 g/L.”
- “Hemorrhage after cardiac surgery or peripartum with fibrinogen <2.0 g/L.”
- “Intracranial hemorrhage secondary to Tissue Plasminogen Activator treatment with fibrinogen <2.0 g/L.”

  * Lab test: Clauss fibrinogen assay; Normal fibrinogen 1.5 – 4 g/L.

C. National Advisory Committee on Blood and Blood Products

- “The use … in acquired hypofibrinogenemia is supported by studies, including a high-quality randomized trial in bleeding patients undergoing cardiovascular surgery … including bleeding obstetrical patients among others.”
- “Both fibrinogen concentrates appear to have similar efficacy in improving clot firmness in a dilutional hypofibrinogenemia model in vitro.”

Product Learning Modules
Supplementary Information – PCC Indication

A. As per Product Monographs

B. Bloody Easy 5.1 handbook

- “Reversal of anti-Xa inhibitors: PCC at a dose of 2,000 IU (repeated in 1 hour if hemostasis is not achieved) is being used across Canada. Data to support its use is limited …”

C. National Advisory Committee on Blood and Blood Products

- Treatment of bleeding in patients receiving direct FXa inhibitor anticoagulants
    - “PCC should only be considered in patients with severe or life-threatening bleeding … no randomized trials published.”
    - “The optimal dosing strategy is uncertain with 2000 IU (fixed dose) or 25-50 IU/kg (to a maximum of 3000 IU) being the most common.”
- NAC also lists some unique patient scenarios (if plasma is refused) as well as some with limited evidence that are not promoted (coagulation defects/bleeding in cardiac surgery).

Product Learning Modules
Supplementary Information – Provincial Massive Hemorrhage Protocol, Statement 37
PCC & FC Indication - Hospitals unable to issue plasma for massive hemorrhage protocol

37	**At institutions lacking sufficient resources to issue plasma (e.g., no thawing device or no plasma stocked in inventory), Prothrombin Complex Concentrates (PCC) 2000 IU can be substituted for coagulation factor replacement. Fibrinogen replacement should be given concurrently with PCCs unless the fibrinogen level is known to be ≥1.5g/L.** Similar to the challenges with cryoprecipitate, some smaller organizations may have challenges in providing plasma during an MHP (no thawing device or not stocked in the laboratory due to rarity of use). In these situations, a reasonable option is to transfuse PCCs and fibrinogen concentrates. This is a common strategy employed in many European countries and outcomes appear to be similar to a plasma resuscitation strategy in trauma, usually guided by viscoelastic point-of-care testing.[85] This strategy should be seen as a bridge prior to transport to an institution capable of definitive surgical management and more complete transfusion support. For pediatric patients a dose of 25 IU/kg of PCCs (rounded to the closest 500 IU) up to a maximum of 2000 units is suggested.[86,87]

Documentation Learning Modules

This section outlines the documentation responsibilities of the health care professional (HCP) reconstituting FC or PCC outside of TML.

These requirements are guided by Canadian Transfusion Medicine standards.

The information can be recorded in various sections of the patient's health record and in paper-based and/or electronic formats.

The documentation learning modules for reconstituting FC or PCC outside of TML include:

- Module 5: Product Label
- Module 6: Transfusion Record

Documentation Learning Module 5: Product Label (1)

- TM Standards define required elements for the label affixed to blood products. TM Standards also identify requirements for the label affixed to modified (e.g., reconstituted, pooled) blood products.
- However, TM Standards do not explicitly state labelling parameters for blood products reconstituted and pooled outside of TML. Some interpretation is necessary.

ALWAYS REFER TO YOUR HOSPITAL'S SPECIFIC POLICIES.

Documentation Learning Module 5: Product Label (2)

- TML provides labelling for products reconstituted outside of the laboratory.
  This may include several labels, with one label corresponding to each product kit/powder bottle issued.
  Alternatively, one label that includes the lot number(s) of all product kits/powder bottles issued for that patient dose may be provided.
  Complete all labelling as provided by TML.

- Some TML label details may be pre-populated or manual entry (must be clear and legible) of all information may be necessary.

- The TML label must be compared to the original manufacturer's product labelling, with no discrepancy identified. Validate/enter the information ***VERY CAREFULLY*** as it will be used for the pre-transfusion checks and if a transfusion reaction occurs (vein [donor] to vein [recipient] traceability).

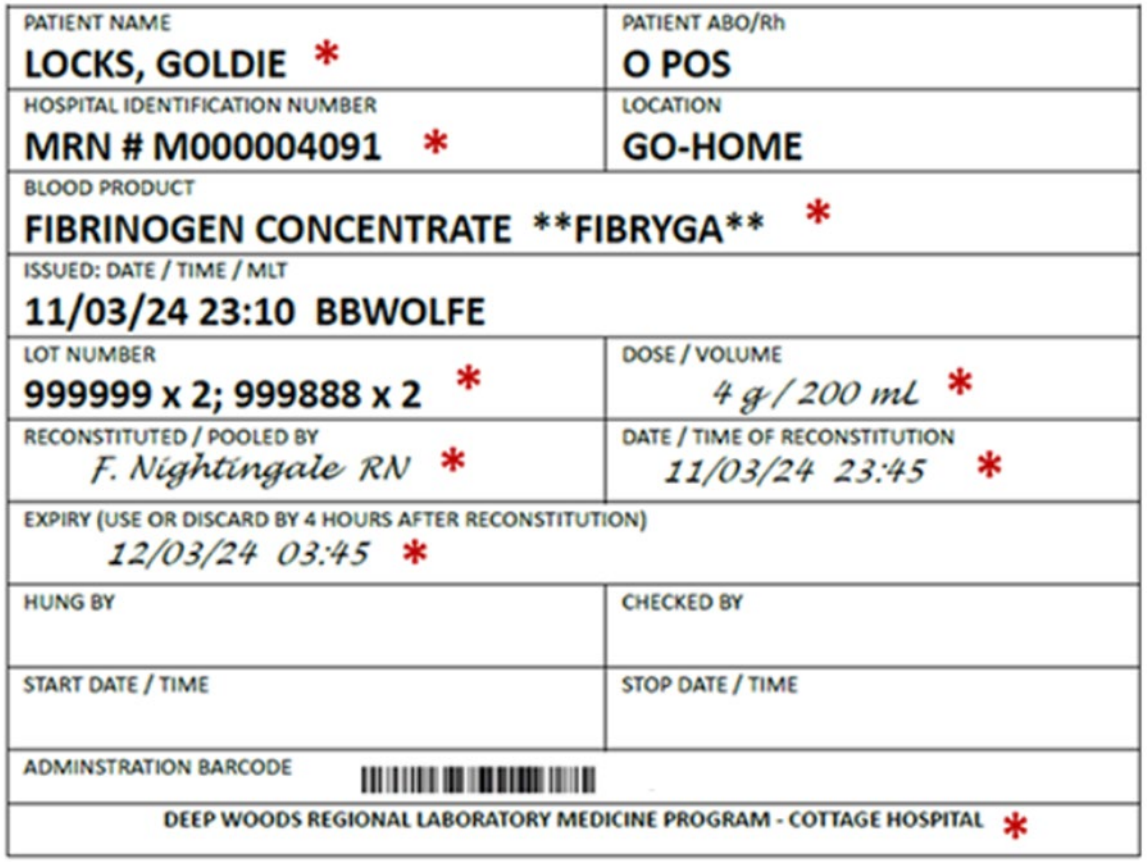
Documentation Learning Module 5: Product Label (3)
Example FC Label (i)

Each * outlines details of product label required elements.

Patient's first & last name →

Patient's unique hospital identification number →

Lot/unique blood product identification number (this number is found on the product packaging as well as the product powder bottle); for the dose ordered, products from the same manufacturer with varying lot numbers may be combined or pooled →



PATIENT NAME LOCKS, GOLDIE *	PATIENT ABO/Rh O POS
HOSPITAL IDENTIFICATION NUMBER MRN # M000004091 *	LOCATION GO-HOME
BLOOD PRODUCT FIBRINOGEN CONCENTRATE **FIBRYGA** *	
ISSUED: DATE / TIME / MLT 11/03/24 23:10 BBWOLFE	
LOT NUMBER 999999 x 2; 999888 x 2 *	DOSE / VOLUME 4 g / 200 mL *
RECONSTITUTED / POOLED BY F. Nightingale RN *	DATE / TIME OF RECONSTITUTION 11/03/24 23:45 *
EXPIRY (USE OR DISCARD BY 4 HOURS AFTER RECONSTITUTION) 12/03/24 03:45 *	
HUNG BY	CHECKED BY
START DATE / TIME	STOP DATE / TIME
ADMINSTRATION BARCODE	
DEEP WOODS REGIONAL LABORATORY MEDICINE PROGRAM - COTTAGE HOSPITAL *	

← Type of blood product (if more than one brand is available at the hospital, brand name is required for brand specific reconstitution & administration details)

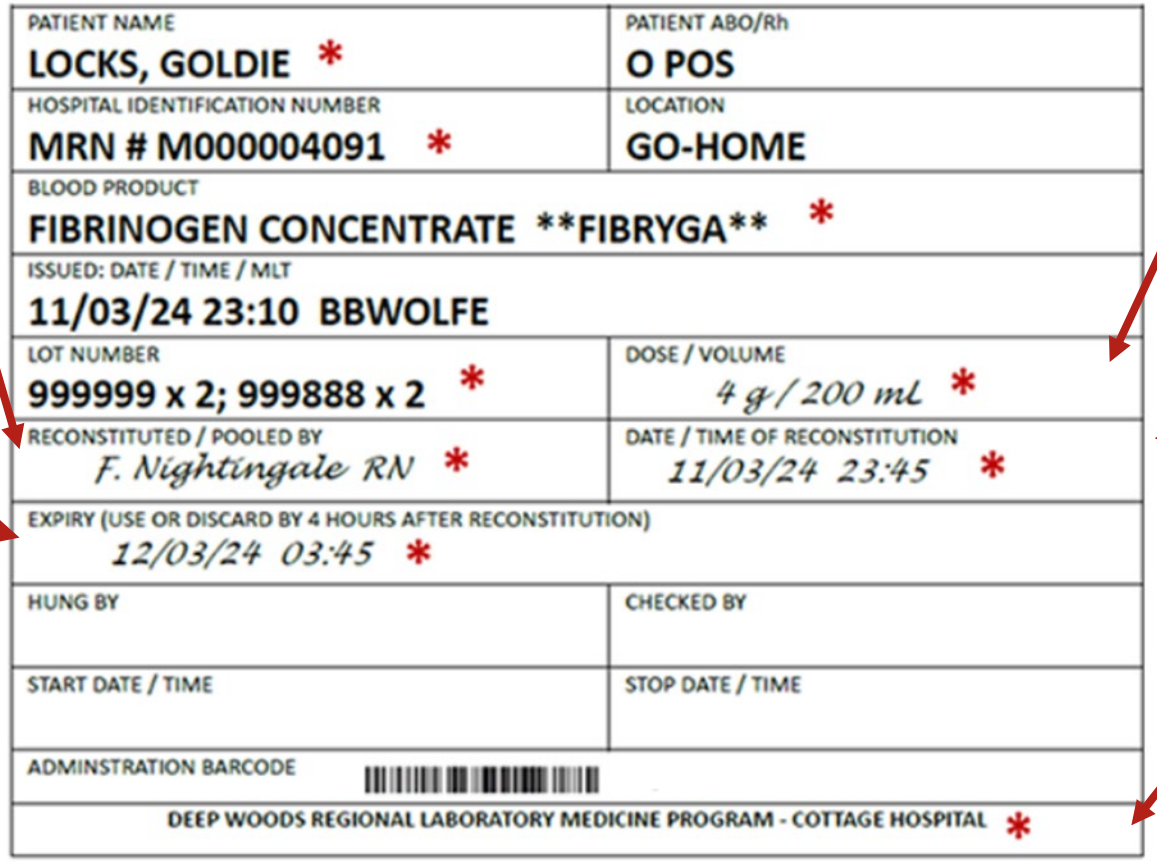
NOTE: The LOT NUMBER is fictitious for purposes of this example.
Actual LOT NUMBER configurations:
Fibryga® & Octaplex®
1 letter, 3 numbers, 1 letter, 4 numbers
RiaSTAP® & Beriplex®
letter P, 9 numbers

Documentation Learning Module 5: Product Label (4)
Example FC Label (ii)

Each * outlines details of product label required elements.

Reconstituted/pooled modifications (if reconstituted bottles of product were not combined in one sterile administration bag, cross out pooled) performed by: HCP responsible is identified (name/signature/ hospital ID number)

Expiry date & time must be stated (in this example, the hospital specific policy for expiry is 4 hours from time of reconstitution)



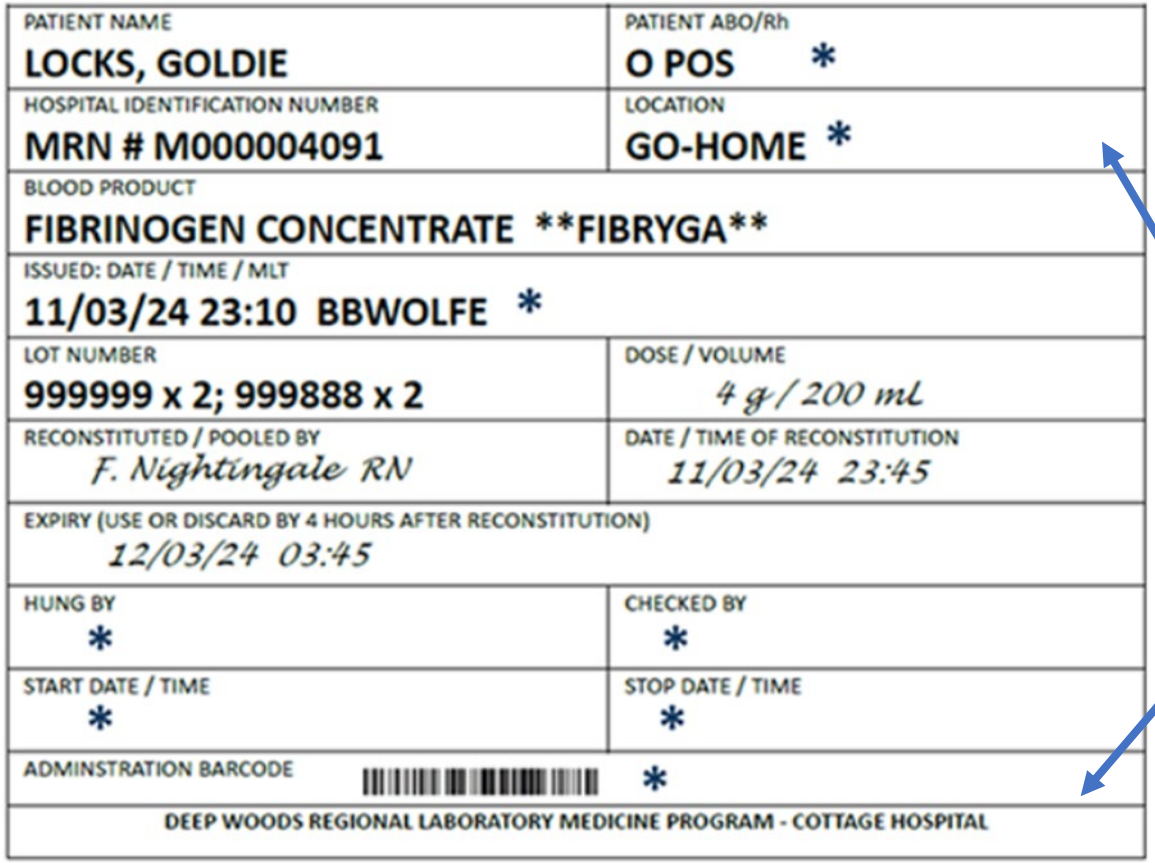
Dose/volume of the product (verify as per order & per reconstitution procedure).

Date & time of reconstitution is required to determine expiry

Name of the hospital/facility where the modification was performed.

Documentation Learning Module 5: Product Label (5)
Example FC Label (iii)

Each * outlines details of product label information that some hospitals may include (standard fields for all labels). The fields listed below are not mandatory for FC or PCC.
ALWAYS REFER TO YOUR HOSPTIAL'S SPECIFIC POLICIES.



PATIENT NAME	PATIENT ABO/Rh
LOCKS, GOLDIE	O POS *
HOSPITAL IDENTIFICATION NUMBER	LOCATION
MRN # M000004091	GO-HOME *
BLOOD PRODUCT	
FIBRINOGEN CONCENTRATE **FIBRYGA**	
ISSUED: DATE / TIME / MLT	
11/03/24 23:10 BBWOLFE *	
LOT NUMBER	DOSE / VOLUME
999999 x 2; 999888 x 2	4 g / 200 mL
RECONSTITUTED / POOLED BY	DATE / TIME OF RECONSTITUTION
F. Nightingale RN	11/03/24 23:45
EXPIRY (USE OR DISCARD BY 4 HOURS AFTER RECONSTITUTION)	
12/03/24 03:45	
HUNG BY	CHECKED BY
*	*
START DATE / TIME	STOP DATE / TIME
*	*
ADMINSTRATION BARCODE *	
DEEP WOODS REGIONAL LABORATORY MEDICINE PROGRAM - COTTAGE HOSPITAL	

The date & time of issue must be readily available to the transfusionist. Hospitals may include this information on the product label or the transfusion record or both. In this example it is on the label & the HCP responsible is identified (name/signature/hospital ID number).

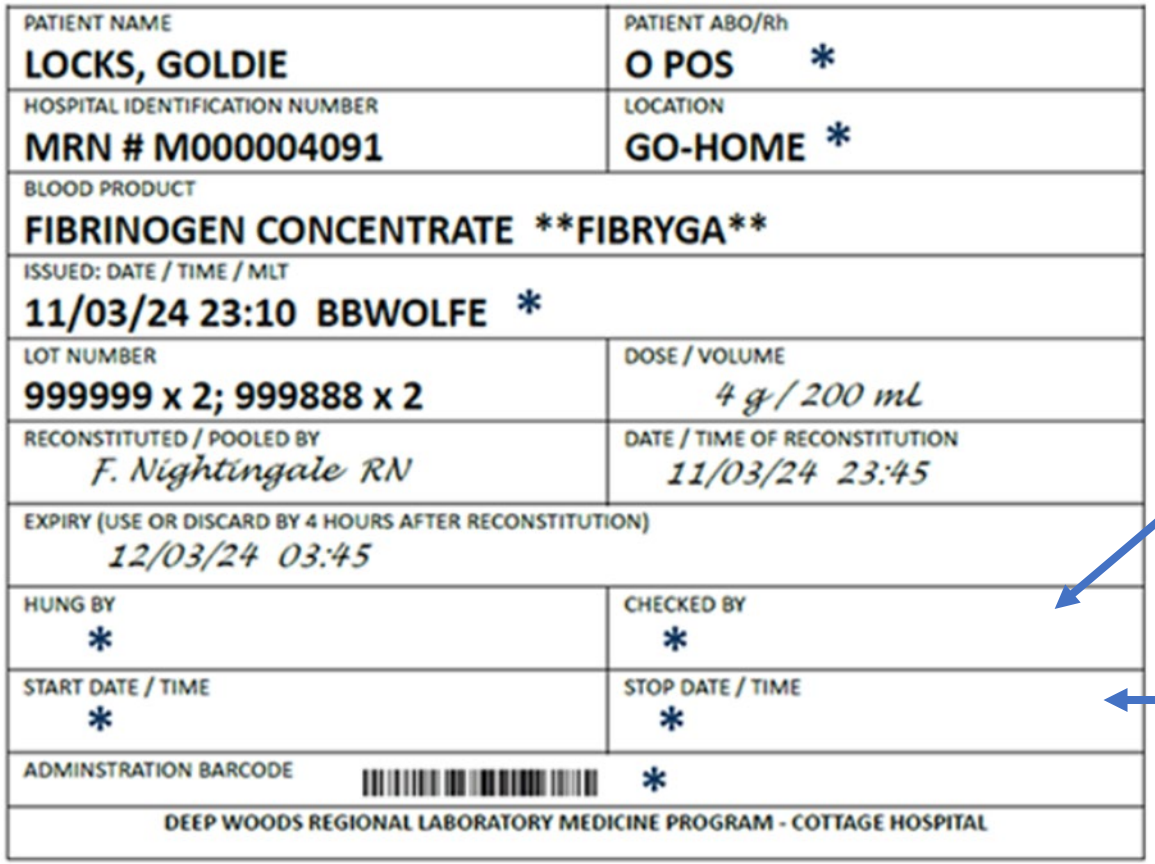
Patient ABO/Rh blood groups are not relevant for blood product transfusion. This field may be blank.

Patient location may be helpful but is not required.

Administration barcode may be included by hospitals with electronic health record documentation systems.

Documentation Learning Module 5: Product Label (6)
Example FC Label (iv)

Each * outlines details of product label information that some hospitals may include (standard fields for all labels). The fields listed below are not mandatory for FC or PCC.
ALWAYS REFER TO YOUR HOSPTIAL'S SPECIFIC POLICIES.



PATIENT NAME **LOCKS, GOLDIE**	PATIENT ABO/Rh **O POS** *
HOSPITAL IDENTIFICATION NUMBER **MRN # M000004091**	LOCATION **GO-HOME** *
BLOOD PRODUCT **FIBRINOGEN CONCENTRATE **FIBRYGA****	
ISSUED: DATE / TIME / MLT **11/03/24 23:10 BBWOLFE** *	
LOT NUMBER **999999 x 2; 999888 x 2**	DOSE / VOLUME *4 g / 200 mL*
RECONSTITUTED / POOLED BY *F. Nightingale RN*	DATE / TIME OF RECONSTITUTION *11/03/24 23:45*
EXPIRY (USE OR DISCARD BY 4 HOURS AFTER RECONSTITUTION) *12/03/24 03:45*	
HUNG BY *	CHECKED BY *
START DATE / TIME *	STOP DATE / TIME *
ADMINSTRATION BARCODE *	
DEEP WOODS REGIONAL LABORATORY MEDICINE PROGRAM - COTTAGE HOSPITAL	

Hung by is not required but may be included by some hospitals

Start date/time is not required but may be included by some hospitals

Checked by is not required but may be included by some hospitals

Stop date/time is not required but may be included by some hospitals.

Documentation Learning Module 6: Transfusion Record (1)

- TM Standards require the name of the HCP who prepared (reconstituted, pooled) the product for administration as well as the date and time of preparation are documented on the patient's health record.

- TML provides a Transfusion Record (chart label, transfusion form) for products reconstituted outside of the laboratory.
  This may include several Transfusion Records, with one record corresponding to each product kit/powder bottle issued.
  Alternatively, one Transfusion Record that includes the lot number(s) of all product kits/powder bottles issued for that patient dose may be provided.
  The Transfusion Record(s) must incorporate/document each bottle of product that was reconstituted & administered to the patient.

  Complete the Transfusion Record or Records as provided by TML.

ALWAYS REFER TO YOUR HOSPITAL'S SPECIFIC POLICIES.

Documentation Learning Module 6: Transfusion Record (2)

- The Transfusion Record(s) may be paper-based and/or electronic format.

- Some Transfusion Record details may be pre-populated or manual entry (must be clear and legible) of all information may be necessary.

- Validate/enter the information ***VERY CAREFULLY*** as it is part of the patient's health record and may be referenced if a transfusion reaction occurs or in the event of a future manufacturer product recall (vein [donor] to vein [recipient] traceability).

Documentation Learning Module 6: Transfusion Record (3)
Example paper FC Transfusion Record (i)

Each * outlines details of Transfusion Record required elements pertaining specifically to reconstitution.

Patient's first & last name

Lot number is found on the product label as well as on the original product packaging and vial (for the dose ordered, products from the same manufacturer with varying lot numbers may be combined or pooled)

NOTE: The LOT NUMBER is fictitious for purposes of this example.
Actual LOT NUMBER configurations:
Fibryga® & Octaplex®
1 letter, 3 numbers, 1 letter, 4 numbers
RiaSTAP® & Beriplex®
letter P, 9 numbers

DEEP WOODS REGIONAL LABORATORY MEDICINE PROGRAM
COTTAGE HOSPITAL
111 Under the Bridge St., Somewhere, Ontario, Canada L0L 1O1
TRANSFUSION RECORD
DATE: 11/03/24

* PATIENT: LOCKS, GOLDIE 22/F * MRN # : M000004091 ** O Pos **
TYPENEX #: SPEC #:
LOCATION : GO-HOME
* PRODUCT : FIBRINOGEN CONCENTRATE ** FIBRYGA **
* LOT # : 999999 x 2; 999888 x 2

ISSUED : 11/03/24 23:10 BBWOL PICK UP & TRANSPORT : Mama Bear
ISSUE COMMENTS :

* RECONSTITUTED / POOLED : * DOSE : 4 g. VOLUME : 200 ml
* DATE/TIME : 11/03/24 23:45
* BY : F. Nightingale RN

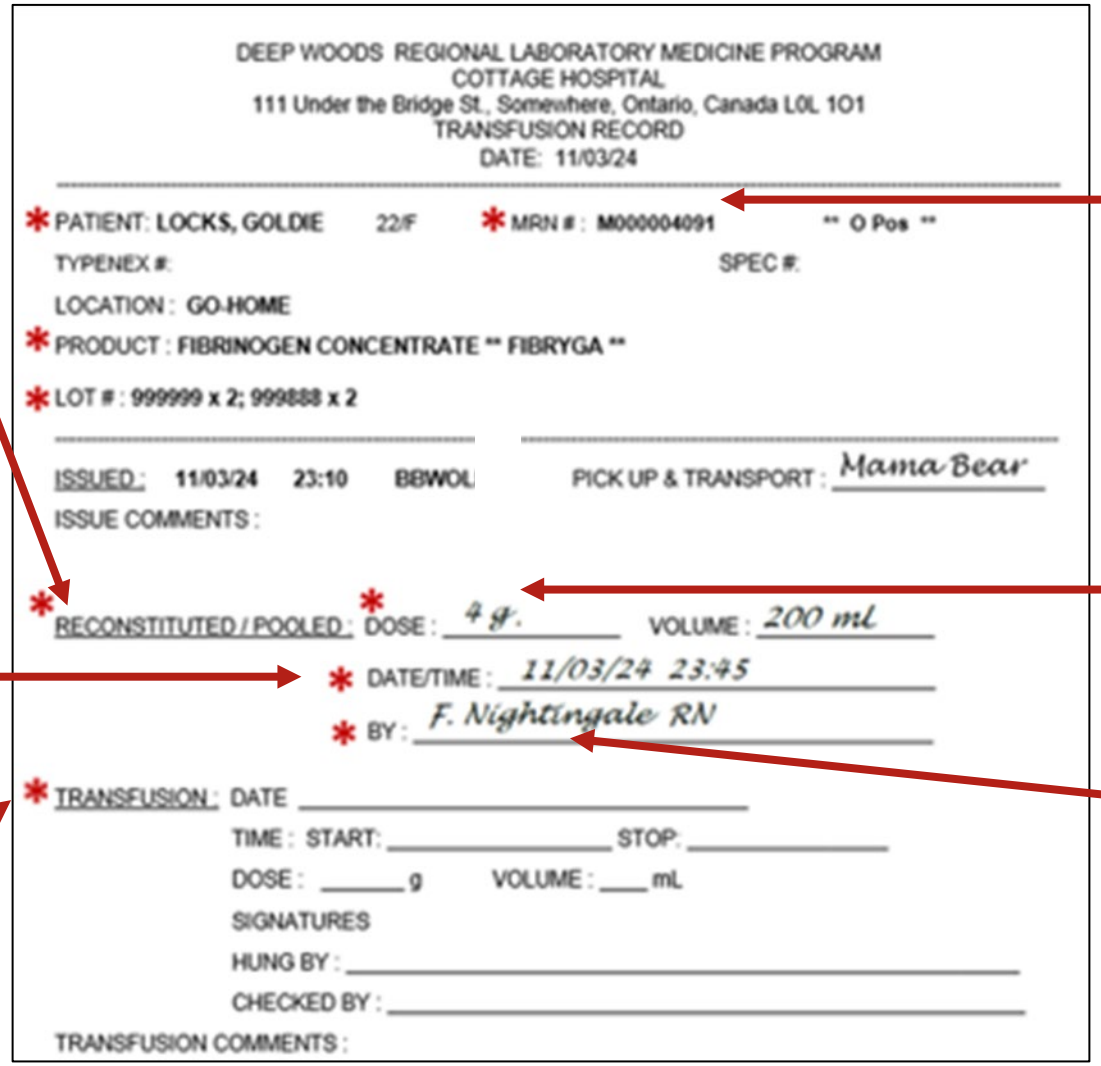
* TRANSFUSION : DATE
TIME : START: STOP:
DOSE : g VOLUME : mL
SIGNATURES
HUNG BY :
CHECKED BY :
TRANSFUSION COMMENTS :

In this example, MRN # the Patient's unique hospital identification number

Product: if more than one brand is available at the hospital, brand name is required for brand specific reconstitution & administration details.

Documentation Learning Module 6: Transfusion Record (4)
Example paper FC Transfusion Record (ii)

Each * outlines details of Transfusion Record required elements pertaining specifically to reconstitution.



DEEP WOODS REGIONAL LABORATORY MEDICINE PROGRAM
COTTAGE HOSPITAL
111 Under the Bridge St., Somewhere, Ontario, Canada L0L 1O1
TRANSFUSION RECORD
DATE: 11/03/24

* PATIENT: LOCKS, GOLDIE 22/F * MRN # : M000004091 ** O Pos **
TYPENEX #: SPEC #:
LOCATION : GO-HOME
* PRODUCT : FIBRINOGEN CONCENTRATE ** FIBRYGA **
* LOT # : 999999 x 2; 999888 x 2

ISSUED : 11/03/24 23:10 BBWOL PICK UP & TRANSPORT : Mama Bear
ISSUE COMMENTS :

* RECONSTITUTED / POOLED : * DOSE : 4 g. VOLUME : 200 ml
* DATE/TIME : 11/03/24 23:45
* BY : F. Nightingale RN

* TRANSFUSION : DATE
TIME : START: STOP:
DOSE : g VOLUME : mL
SIGNATURES
HUNG BY :
CHECKED BY :
TRANSFUSION COMMENTS :

Reconstituted/pooled: modifications performed must be documented (if reconstituted vials of product were not combined in one sterile administration bag, cross out pooled)

Date & time of reconstitution must be documented and informs product expiry

Complete mandatory transfusion documentation requirements as per hospital specific policy

Dose and volume of the product (verify as per order & per reconstitution procedure)

The name/signature/hospital ID number of the HCP who prepared (reconstituted, pooled) the product for administration must be documented.

Reconstitution of FC & PCC Outside of TML Summary (1)

- Confirm the dose per bottle (vial) and the dose the prescriber ordered. More than 1 bottle may be required to provide the dose that was ordered.
- Verify the product expiry date is acceptable (noted on product solvent and powder bottles as well as the manufacturer kit packaging).
- Use appropriate aseptic technique (sterile elements, handwashing, gloves, designated clean area specified for reconstitution of blood products).
- Product and kit are for single-use only.
- Precisely follow the details of the manufacturer's stepwise instructions.
- Use only the solvent provided in the product kit for reconstitution.
- Ensure both the powder and the solvent (water for injection) are at room temperature. During reconstitution, room temperature should be maintained. Room temperature augments the product powder dissolving.

Reconstitution of FC & PCC Outside of TML Summary (2)

- After the solvent (water for injection) has been added to the powder bottle, gently and slowly swirl or rotate the bottle to completely dissolve the product powder.
- A final step of the reconstitution procedure is to withdraw the reconstituted product from its bottle through a filter (included in the device provided by the manufacturer).
- Reconstituted product from additional bottles of the same brand may be added to the same sterile administration bag (pooled).
  Pooling of reconstituted product of the same brand with varying lot numbers is acceptable.
- Do not use reconstituted products that are cloudy or have deposits.
- Do not further dilute in any IV solutions. Do not mix with any other medicinal products.
- Administer only intravenously via a separate injection/infusion line. For infusion, use a standard IV infusion set (has been filtered as part of reconstitution procedure).
- Flush the IV site with 0.9 % sodium chloride flush syringe prior to and following administration.

Reconstitution of FC & PCC Outside of TML Summary (3)

- Complete the product label(s) (provided by TML) by validating the lot number on the powder bottle is identical to the lot number listed on the product label.
- As per your hospital policy, document the expiry time of the reconstituted product on the product label.
- Complete the transfusion record(s) (provided by TML) by validating the lot number on the powder bottle is identical to the lot number listed on the transfusion record.
  Add the name/signature/hospital ID number of the person who prepared the product and the date and time of reconstitution.
- These products contain no preservatives; ideally administer immediately once reconstitution steps are completed and product is transferred from the bottle to a sterile administration bag.

  If the product is not administered immediately, follow manufacturer's guidelines and your hospital policy for storage following reconstitution.

Resources

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A quick reference PDF of the eLearning content is available:
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Glossary & Abbreviations (1)

Blood Component: a therapeutic part of blood planned for transfusion (e.g., red blood cells, platelets, granulocytes, plasma, cryoprecipitate).

Blood Product: a therapeutic product derived from human blood plasma and produced by a manufacturing process, also referred to as plasma protein product (e.g., albumin, coagulation products, factor concentrates, immunoglobulins).

Fibrinogen Concentrate (FC): is a manufactured source of human fibrinogen (fibrinogen has a critical role in hemostasis).

Health Care Professional (HCP): a person associated with a specialty or a discipline, who is qualified and allowed by regulatory bodies to provide a healthcare service to a patient.

Issue: release of a blood component or blood product from TML (temperature-controlled environment) to the clinical area, synonymous with dispense.

Massive Hemorrhage Protocol (MHP): a protocol to guide management of a massively bleeding patient.

Modification: manipulations/procedures performed by TM to blood components or blood products required to meet patient specific transfusion needs and/or to facilitate transfusion. Includes (Health Canada regulations defines irradiating, pooling and washing as “transformations”):
a) aliquoting (splitting)
b) irradiating
c) pooling
d) removing supernatant (concentrating)
e) thawing
f) washing
g) reconstituting (blood products).

Pooled: for this learning, refers to the act of combining two or more bottles of reconstituted blood product.

Prescriber: for this learning, refers to health care professionals who are authorized to order transfusion of blood components and blood products (physicians, physician assistants, nurse practitioners, midwives, dentists).

Glossary & Abbreviations (2)

Prothrombin complex concentrate (PCC): is a coagulation factor concentrate that contains the vitamin K dependent procoagulant factors (II, VII, IX and X), Protein C and Protein S, and is manufactured with heparin added.

Standard Operating Procedure (SOP): written instructions for a series of steps or tasks, completed to produce a result or product.

Sterile Water for Injection (sWFI): sterile fluid provided in a reconstitution kit

Transfer Device or Transfer Set: equipment provided in a reconstitution kit, used to combine the solvent and powder

Transfusion Medicine (TM): hospital department that performs transfusion-related serological testing and oversees provision of blood components and/or blood products, also known as the Transfusion Service.

Transfusion Medicine Laboratory (TML): hospital laboratory for TM services; also known as the Blood Bank.

Transfusionist: Regulated health care professional who administers a blood transfusion.

Water for Injection (WFI): sterile fluid provided in a reconstitution kit

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Acknowledgements

The Ontario Regional Blood Coordinating Network (ORBCoN) gratefully acknowledges funding support provided by the Ontario Ministry of Health. The views expressed in this presentation are those of the authors and of ORBCoN and do not necessarily reflect those of the Ontario Ministry of Health or the Government of Ontario.

ORBCoN is indebted to Octapharma and CSL Behring for their collaboration and sharing of the graphics utilized in the product modules.

A special note of appreciation to the following hospitals and their staff for their expert review:

- **Guelph General Hospital, Guelph**
  - Sandra Bakker, MLT, Charge Technologist, Transfusion Medicine.
- **Health Sciences North, Sudbury**
  - Marvin Jones, MLT, BSc (MLS), Charge Technologist, Transfusion Medicine.
  - Renee Fillier, RN, MN, CNCC(C), Virtual Critical Care and CCRT Clinician, Critical Care Program.
- **Joseph Brant Hospital, Burlington**
  - Lynda Gaskin, MLT, Charge Technologist, Transfusion Medicine.
  - Melany Owens, RN, BScN, MHM, Professional Practice Educator, Emergency Department & Diagnostic Imaging; Assistant Clinical Professor, McMaster University School of Nursing.
- **Unity Health, Toronto**
  - Lisa Manswell, RN, MN, Transfusion Safety Nurse, St. Michael's Hospital.

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Reconstitution of Fibrinogen Concentrate (FC) and Prothrombin Complex Concentrate (PCC) Outside of the Transfusion Medicine Laboratory (TML)

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