ALBERTA PRECISION LABORATORIES

Leaders in Laboratory Medicine

FIBRYGA® Reconstitution Instructions

Applicability

This document applies to all APL, AHS, Covenant Health, and other health care professionals involved in the transfusion of blood components and products in Alberta.

Supplies Required

Contained in Box

- FIBRYGA® product (Vial of FIBRYGA® lyophilized powder)
- 50 mL sterile water for injection (volume of WFI to be added to vial)
- Octajet Transfer device
- Luer Lock particle filter

Separate Supplies

- Sterile plastic 50mL Luer lock syringe
- Alcohol swabs

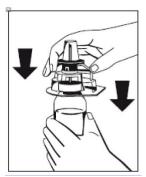


Aseptic technique must be used at all times

Instructions

*Note:

- Reconstitution video: FIBRYGA© Reconstitution Guide Canada YouTube
- If you are reconstituting multiple vials, each vial should be individually prepared according to the instructions below.
- 1. Ensure that the diluent and FIBRYGA® product vial(s) are at room temperature.
- 2. Remove the caps from the FIBRYGA® and the sterile water vials to expose the central portion of the rubber stoppers.
- 3. Clean the surface of the rubber stoppers with an antiseptic solution and allow them to dry.
- 4. Peel away the lid of the outer package of the Octajet transfer device. To maintain sterility, leave the Octajet device in the clear outer packaging.
- 5. Place the FIBRYGA®bottle on a flat, level surface.
- 6. Take the Octajet in its outer package and invert it over the FIBRYGA® bottle. Holding the Octajet package, place it onto the center of the FIBRYGA® bottle until the clips of the product spike are locked.



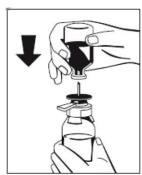
7. Carefully remove the outer package from the Octajet, being careful not to touch the water spike (navy blue). Leave the Octajet firmly attached to the bottle.

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8. With the FIBRYGA® bottle held firmly on the level surface, invert the WFI and place it at the center of the water spike. Push the blue plastic cannula of the Octajet firmly through the rubber stopper of the WFI bottle.



10. While stabilizing the WFI, remove the distance ring and press the WFI bottle down. WFI will flow into the FIBRYGA®bottle.

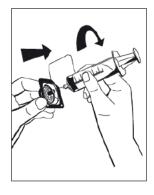


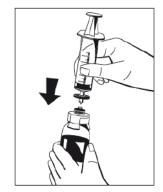


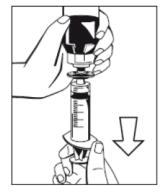
- 11. When the transfer of the WFI is complete, gently swirl the product bottle until the powder is fully dissolved. Do not shake the bottle as this causes foam formation. The powder should be dissolved completely within approximately five minutes and should take no longer than 30 minutes.
- 12. Turn the blue WFI bottle connector to bring the position markers together. Removed the WFI bottle together with the water spike.



13. While holding the provided filter in its outer package, attach sterile syringe to the filter, and then connect the filter to the Octajet Luer Lock on the reconstituted product bottle. Withdraw the solution through the filter into the syringe.







- 14. Detach the filled syringe from the filter and discard the empty bottle and used filter.
- 15. Label the syringe per AHS Transfusion of Blood Components and Products Policy and Procedure.

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16. Refer to the FIBRYGA® product monograph for administration instructions.

Troubleshooting Instructions

If the vacuum is lost or is insufficient to transfer the entire volume of diluent:

- 1. Grasp the outer rim of the Octajet component.
- 2. Carefully remove the navy blue Octajet cannula and diluent together from the product.
- 3. Place both bottles on a clean surface or countertop.
- 4. Carefully detach the navy-blue component of the Octajet from the diluent bottle and discard.
- 5. Swab the diluent bottle top with an antiseptic swab.
- 6. Using a sterile syringe with a blunt needle attached, draw a volume of air into the syringe that is equivalent to the remaining volume of diluent in the bottle.
- 7. Inject the air into diluent bottle.
- 8. Invert the bottle and draw the remaining diluent into the syringe.
- 9. Remove the needle from the syringe and attach the syringe to the Octajet Luer lock that is still attached to the product.
- 10. Carefully empty the syringe into the product bottle.
- 11. Continue with Step 13 above.

Contact Information

For questions or comments regarding this document, please contact Transfusion.SafetyTeam@albertaprecisonlabs.ca.

References

FIBRYGA® Product Monograph. Available from www.octapharma.ca.