

**Bayer Vial Adapter Reconstitution Instructions**

**For reconstitution of JIVI® and Kovaltry®**



**\*\*IMPORTANT\*\***

Aseptic technique must be used at all times

**Applicability**

This document applies to health care professionals who reconstitute blood products using a double-ended transfer needle device.

**Supplies Required**

Use only the supplies and pre-filled syringe of diluent (contents) provided with the product for reconstituting the product. The vial adapter must be used for reconstitution to ensure the product is filtered.

**Contained in Box**

- Vial of lyophilized product
- Pre-filled diluent syringe and plunger rod for syringe
- Vial adapter
- Butterfly infusion set
- Alcohol swabs

**Separate Supplies**

- Sterile plastic Luer lock syringe, large enough to contain dose if:
  - You are combining multiple vials\*
  - The pre-filled glass syringe with diluent is not compatible with the needless connect for the patient's intravenous catheter\*\*
- IV administration pump and set (if required)

**Instructions:**

Always work on a clean, flat surface and wash your hands before performing the following procedures.

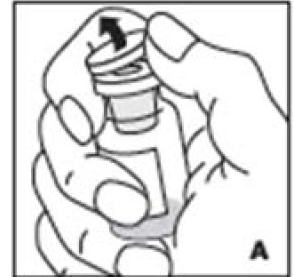
\*Note: If you are reconstituting multiple vials, each vial should be individually dissolved according to the instructions below, then use a separate larger luer lock syringe to draw back the dissolved content of each vial. Do not detach the diluent syringes or the large luer lock syringe until you are ready to attach the large luer lock syringe to the next vial adapter.

\*\*Note: The pre-filled glass syringe with diluent used to reconstitute and administer product may not be compatible with all needless connectors for intravenous catheters (e.g. ICU Medical MicroClave® Neutral Connector). You may need to withdraw reconstituted product into a sterile 10 mL plastic syringe with a standard luer-lock connector.



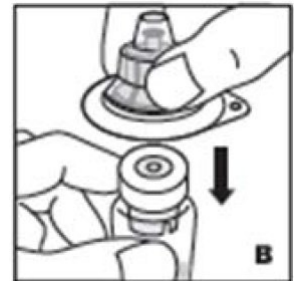
## Bayer Vial Adapter Reconstitution Instructions

1. Warm both the unopened product vial and prefilled diluent syringe in your hands to a comfortable temperature (do not exceed 37°C).
2. Remove the protective cap from the vial (A). Aseptically cleanse the rubber stopper with a sterile alcohol swab, being careful not to handle the rubber stopper.

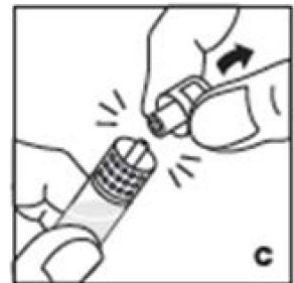


3. Place the product vial on a firm, non-skid surface. Peel off the paper cover on the vial adapter plastic housing. **Do not remove the adapter from the plastic housing.**

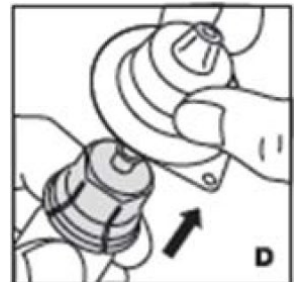
Holding the adapter housing, place over the product vial and firmly press down (B). The adapter will snap over the vial cap. **Do not remove the adapter housing at this step.**



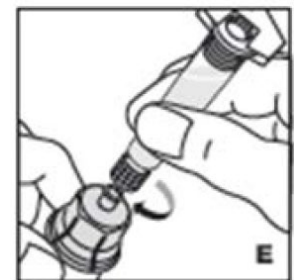
4. Holding the syringe by the barrel, snap the syringe cap off the tip (C). **Do not touch the syringe tip with your hand or any surface.** Set the syringe aside for further use.



5. Remove and discard the adapter plastic housing.



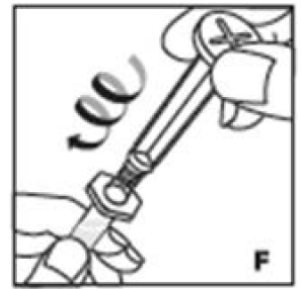
6. Attach the prefilled syringe to the threaded vial adapter by turning clockwise (E).



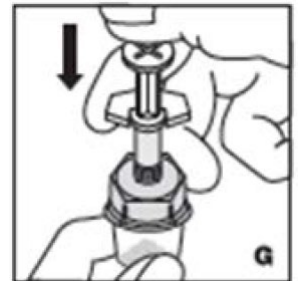


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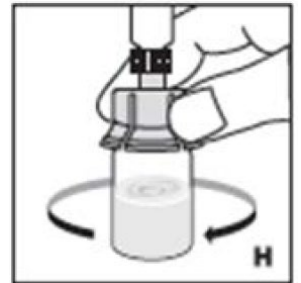
7. Remove the clear plastic plunger rod from the carton. Grasp the plunger rod by the top plate. **Avoid touching the sides and threads of the plunger rod.** Immediately attach the plunger rod by turning it firmly clockwise into the threaded syringe rubber stopper (F).



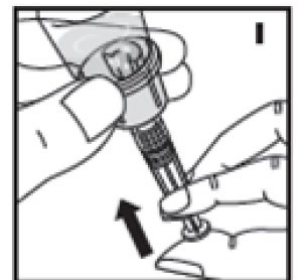
8. Inject the diluent slowly by pushing down on the plunger rod (G).



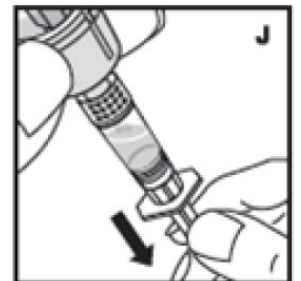
9. Swirl vial gently until all material is dissolved (H). **Do not shake vial.** Be sure that all powder is completely dissolved. **Do not use if solution contains visible particles or is cloudy.**



10. Push down on the plunger to push all the air back into the vial. Then, while holding the plunger down, turn the vial with syringe upside-down (invert) so the vial is now above the syringe (I).



11. For a single vial:  
Withdraw all the solution into the syringe by pulling the plunger rod back slowly and smoothly (J). Tilt the vial to the side and back to make sure all the solution has been drawn toward the large opening in the rubber stopper and into the syringe.



For multiple vials:

Reconstitute each vial following steps 1 – 9. **Leave the vial adapter on each vial.** Use a larger plastic syringe (not provided) to withdraw the solution from each vial after reconstituting as described above.

**Remove as much air as possible before removing the syringe from the vial by slowly and carefully pushing the air back into the vial.**

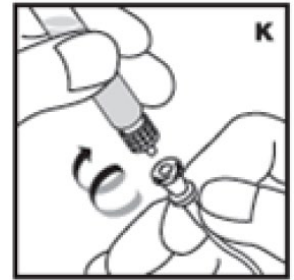


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12. Detach the syringe with plunger rod from the vial adapter by turning counter-clockwise. Attach the syringe to the administration set provided and inject intravenously (K).

Note: Follow the instructions for the infusion set provided.

Note: If the solution is not to be used immediately, the syringe cap should be carefully replaced. Do not touch the syringe tip or the inside of the cap.



13. Label the syringe with a medication label per [Transfusion of Blood Components and Blood Products policy PS-59](#) Section 9.6.
14. Detach the syringe from the vial adapter by gently pulling and turning the syringe counterclockwise. Discard the vial with the adapter attached.

### Contact Information

For questions or comments about this document, please contact [Transfusion.SafetyTeam@aplabs.ca](mailto:Transfusion.SafetyTeam@aplabs.ca)

### References

KOVALTRY® Product Monograph. Available from <https://www.bayer.com/sites/default/files/2020-11/kovaltry-pm-en.pdf>

JIVI Vial Adapter Instructions for Use. Available from [https://www.jivi-us.com/download/Jivi\\_Vial\\_Adapter\\_Tearpad.pdf](https://www.jivi-us.com/download/Jivi_Vial_Adapter_Tearpad.pdf)

[Transfusion of Blood Components and Blood Products policy PS-59](#) (Section 9.6)