

Xyntha® Solofuse™ Reconstitution

*** IMPORTANT ***

Aseptic techniques must be used at all times.

Supplies Required:

- Use only the materials and pre-filled syringe of diluent (0.9% sodium chloride) provided in the Xyntha kit for reconstituting the product.
- Luer Lock syringe (large enough to contain dose) if:
 - You are combining multiple syringes*
 - The pre-filled glass syringe with diluent is not compatible with the needless connector for the patient's intravenous catheter (e.g. ICU Medical MicroClave® Neutral Connector)
- Luer-to-luer connector (not included in kit) if you are combining multiple syringes

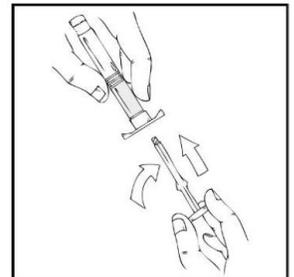
Instructions:

*Note: If you are reconstituting multiple Solofuse syringes of Xyntha, each Solofuse syringe should be individually dissolved according to the instructions below. Step 9 provides instructions for using a separate larger luer lock syringe to draw back the dissolved content of each syringe.

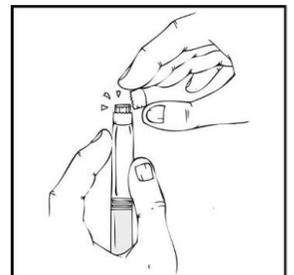
**Note: The pre-filled glass syringe with diluent used to reconstitute and administer product may not be compatible with all needless connectors for intravenous catheters (e.g. ICU Medical MicroClave® Neutral Connector). You may need to withdraw reconstituted product into a sterile 10 mL plastic syringe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

1. Allow the pre-filled dual-chamber syringe of freeze-dried Xyntha to reach room temperature.
2. Remove the contents of the Xyntha Solofuse Kit and place on a clean surface, making sure you have all the supplies you will need.
3. Grasp the plunger rod as shown in the diagram. Avoid contact with the shaft of the plunger rod. Screw the plunger rod firmly into the opening in the finger rest of the Xyntha Solofuse by pushing and turning firmly until resistance is felt (approximately 2 turns)

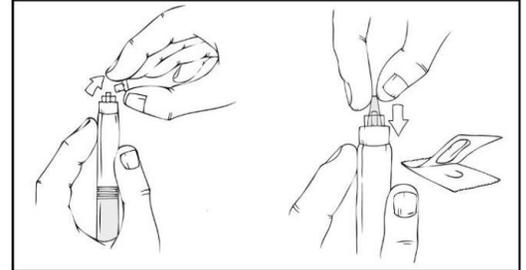
Note: Once the white tamper-evident seal is removed, keep the Xyntha Solofuse in the upright position throughout the reconstitution process to prevent possible leakage.



4. Holding the Xyntha Solofuse upright, remove the white tamper-evident seal by bending the seal right to left (or a gentle rocking motion) to break the perforation of the cap and expose the grey rubber tip cap of the Xyntha Solofuse

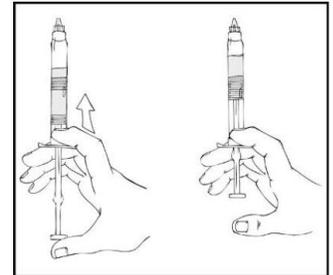


5. Remove the protective blue vented sterile cap from its package. While holding the Xyntha Solufuse upright, remove the grey rubber tip cap and replaced it with the protective blue vented cap (prevents pressure build-up). Avoid touching the open end of both the syringe and the protective blue vented cap



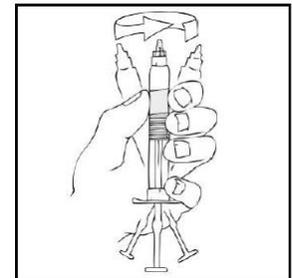
6. Gently and slowly advance the plunger rod by pushing until the two stoppers inside the Xyntha Solufuse meet, and all the diluent is transferred to the chamber containing the Xyntha powder

Note: To prevent the escape of fluid from the tip of the syringe, the plunger rod should not be pushed with excessive force.

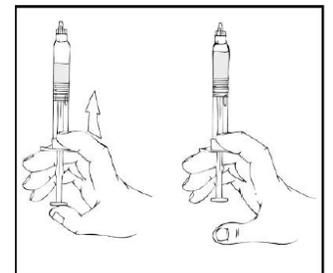


7. With the Xyntha Solufuse remaining upright, swirl gently several times until the powder is dissolved.

Note: The final solution should be inspected visually for particulate matter before administration. The solution should be clear to slightly pearly and colourless. If it is not, the solution should be discarded and a new kit should be used.

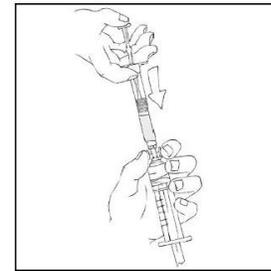
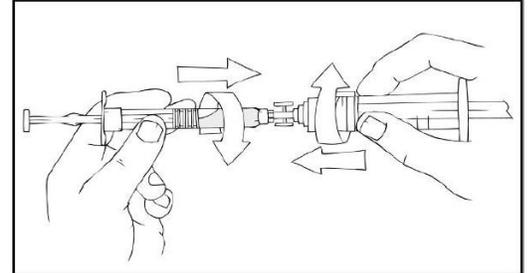


8. Again, holding the Xyntha Solufuse in an upright position, slowly advance the plunger rod until most, but not all, of the air is removed from the product chamber



9. To combine Solufuse syringes:

- Remove the luer-to-luer syringe connector from its package.
- Remove the protective blue vented cap, connect a sterile 10 cc or larger luer lock syringe to one opening (port) in the syringe connector and the Xyntha Solufuse to the remaining open port on the opposite end.
- With the Xyntha Solufuse on top, slowly depress the plunger rod until the contents empty into the 10 cc or larger luer lock syringe
- Remove the empty Xyntha Solufuse and repeat for any additional reconstituted syringes
- Remove the luer-to-luer syringe connector from the 10 cc or larger luer lock syringe and attach the infusion set.



Note: If the solution is not used immediately, the syringe should be stored upright and the protective blue vent cap should remain on the Xyntha Solufuse until ready to infuse. The reconstituted solution may be stored at room temperature prior to administration, but should be administered within 3 hours after reconstitution or removal of the grey rubber tip cap.

COMMENTS:

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References: Xyntha® (moroctocog alfa) Product Monograph www.pfizer.ca*For questions or comments about this document, please contact Transfusion.SafetyTeam@ahs*