

A GUIDE TO RECONSTITUTING WITH BAXJECT II

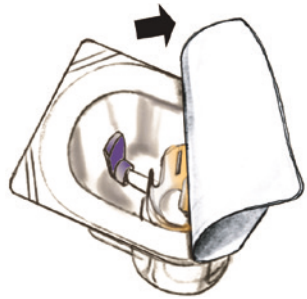
This guide is for patients who have been prescribed ADVATE or RIXUBIS

Step 1 - Connect the water vial

A.

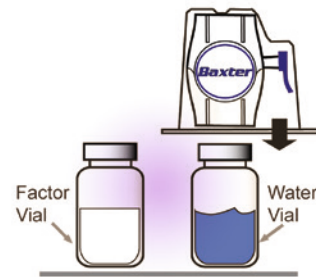
Open the BAXJECT II device by peeling away the paper lid without touching the inside.

- Do not remove the device from the package



B.

On a flat surface, turn the package over and press straight down to insert the CLEAR plastic spike fully through the stopper over the water vial.



Step 2 - Connect the factor vial

C.

Grip the package at its edge and pull it off, leaving the BAXJECT II attached to the water vial.

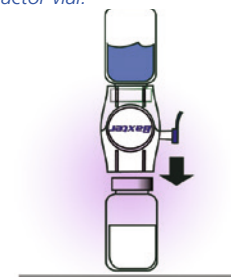
- Do not remove the blue cap
- Do not touch the exposed white spike



D.

Turn the water vial with attached BAXJECT II device upside down so that it is on top.

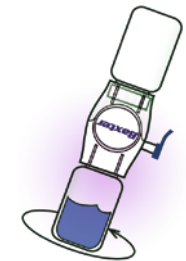
Press straight down to insert the WHITE spike fully through the factor vial stopper. A straw will extend downwards from the white spike and water will be drawn into the factor vial.



E.

Swirl gently until all the powder is dissolved.

- Do not shake



N.B. It is acceptable for a small amount of water to be left behind.

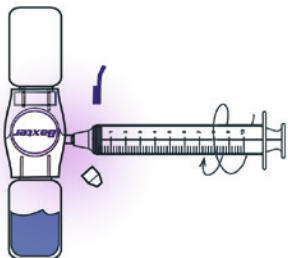
Step 3 - Withdraw the dissolved factor

F.

Make sure you use a Luer-lock syringe. Remove the blue cap from the device. Remove the syringe cap if it is present. Connect the syringe to the device.

DO NOT INJECT AIR

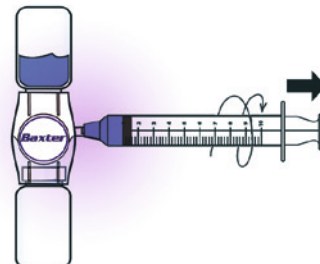
If you inject air into the device in error, go to Scenario C overleaf.



G.

Turn the device over so that the vial containing the dissolved factor is now on top. Withdraw the prescribed volume of dissolved factor into the syringe by pulling the plunger back SLOWLY. Disconnect the syringe.

If you have injected air into the device in error, a significant amount of dissolved factor can leak back into the water vial. If this happens and you cannot withdraw the full volume of dissolved factor prescribed, go to Scenario C overleaf.



The BAXJECT II device is intended for use with a single vial of factor and may be used only once. Therefore, reconstituting and withdrawing a second vial of dissolved factor into the syringe requires the use of a second BAXJECT II device. If you need to use a greater quantity of dissolved factor* in a large syringe:

- Mix all the factor vials, using a new BAXJECT II device for each vial, as directed in steps A to E
- Follow steps F and G to draw the dissolved factor from each vial into the large syringe

Dispose of BAXJECT II as directed by your doctor or nurse.

If you have any queries about reconstituting your factor using this device please contact your haemophilia centre.

* Please read the instructions for use that came with your factor.

White = Factor vial

Clear = Water vial



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TROUBLESHOOTING

Recovery instructions:

If the water did NOT transfer successfully: Follow these steps first, then the scenario below for your problem.

1. Position the device with the water vial on the bottom.

2. Identify the **WHITE** and **CLEAR** portions of the BAXJECT II device.



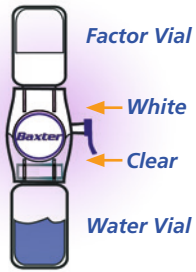
3. Determine which side of the device is connected to the water vial.

- ✓ If the **WATER vial** is **CORRECTLY** connected to the **CLEAR** side, go to **Scenario A***
- ✗ If the **WATER vial** is **INCORRECTLY** connected to the **WHITE** side, go to **Scenario B**

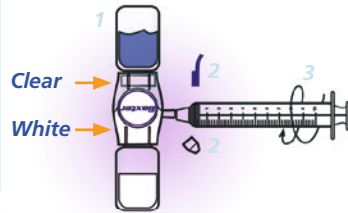
* N.B. If the water does not go through properly, it could mean that the vacuum has been broken, which may have compromised sterility. If you have any concerns, please contact your doctor or local haemophilia centre.

Scenario A

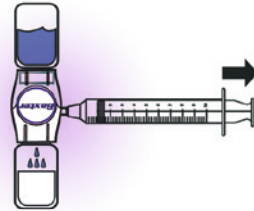
The **WATER vial** is connected to the **CLEAR** side of the BAXJECT II device **CORRECTLY**.



4.
 1. Turn the device so that the water vial is positioned on top.
 2. Make sure you use a Luer-lock syringe, remove the caps from the syringe and the device.
 3. Connect the syringe to the device.

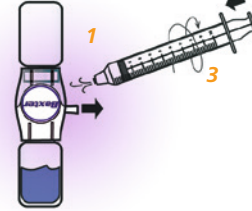


5. Pull the plunger back slowly to withdraw air from the vials. (This will force the water into the factor vial.)



6.
 1. Disconnect the syringe from the BAXJECT II device.
 2. Press the plunger to expel any air from the syringe.
 3. Reconnect the syringe to the device.

DO NOT INJECT AIR

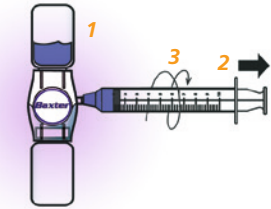


7. Swirl gently until the powder is completely dissolved.

DO NOT SHAKE

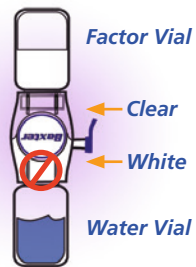


8.
 1. Turn the system over so that the factor vial is positioned on top.
 2. Withdraw the prescribed volume of dissolved factor into the syringe by pulling the plunger back **SLOWLY**.
 3. Disconnect the syringe.

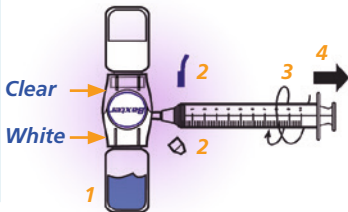


Scenario B

The **WATER vial** is connected to the **WHITE** side of the BAXJECT II device **INCORRECTLY**.

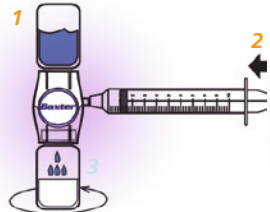


4.
 1. Keep the water vial on the bottom.
 2. Make sure you use a Luer-lock syringe, remove the caps from the device and the syringe.
 3. Connect the syringe to the device.
 4. Slowly pull back the plunger to withdraw air from the vials.

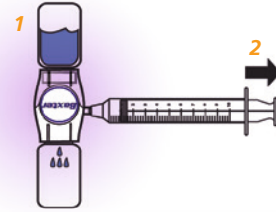


5.
 1. Turn device so water vial is on top.
 2. **SLOWLY** press plunger to inject air back into the vials. (This forces water into the bottom vial.)
 3. Swirl gently until powder is completely dissolved.

DO NOT SHAKE

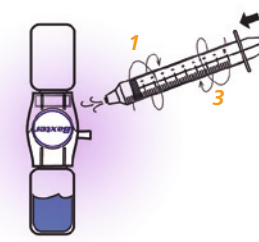


6.
 1. Turn the system over so that the factor vial is positioned on top.
 2. Withdraw air into the syringe by pulling the plunger back **SLOWLY**. (This forces the factor into the bottom vial.)

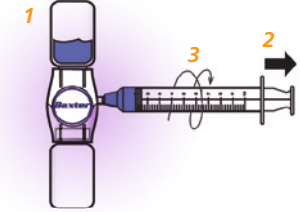


7.
 1. Disconnect the syringe.
 2. Press the plunger to **EXPEL** all the air from the syringe.
 3. Reconnect the syringe to the device.

DO NOT INJECT AIR



8.
 1. Turn the system over so that the vial containing the dissolved factor is positioned on top.
 2. Withdraw the prescribed volume of dissolved factor into the syringe by pulling the plunger back **SLOWLY**.
 3. Disconnect the syringe.



Scenario C

Recovery instructions:

If air has been injected into the system and you cannot withdraw the full volume of dissolved factor prescribed.

A significant quantity of dissolved factor has leaked back into the water vial. You have injected air into the vials in error.

1. Turn the device over so that the water vial is on top. Now follow the recovery instructions in Scenario A, starting with Step 5 and omitting Step 7.

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