

# A GUIDE TO RECONSTITUTING WITH THE BAXJECT II HI-FLOW DEVICE

For patients who have been prescribed ADYNOVATE

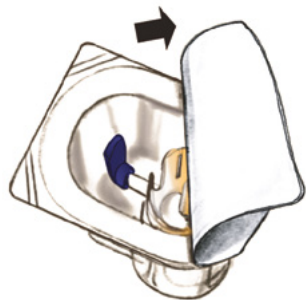
## Preparation:

- Bring the vials to room temperature (not to exceed 30°C)
- Wash your hands thoroughly with soap and warm water
- Remove the caps from the vials
- Clean the stoppers of the vials with alcohol swabs and allow them to dry

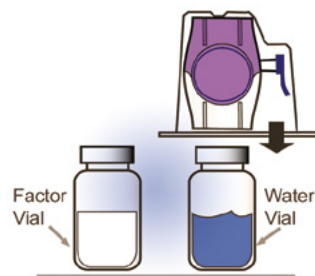
## Step 1 – Connect the water vial

**A.** Open the BAXJECT II Hi-Flow 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.



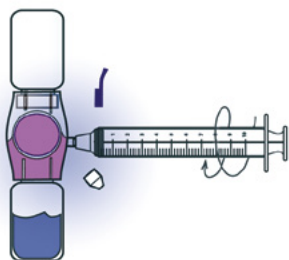
N.B. It is acceptable for a small amount of water to be left behind.

## 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.

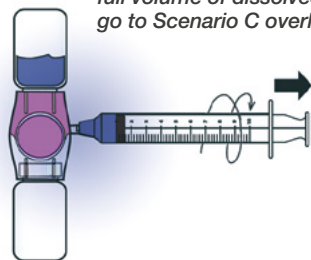
### DO NOT INJECT AIR

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.

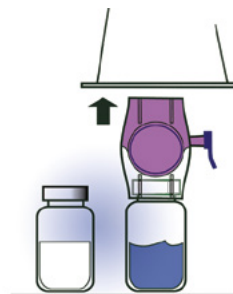
*If you have injected air into the device in error, a significant amount of dissolved factor can leak back into the water vial. If this happens and you cannot withdraw the full volume of dissolved factor prescribed, go to Scenario C overleaf.*



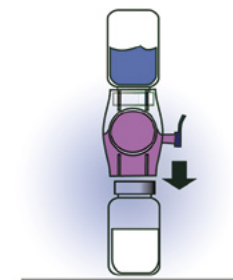
## Step 2 – Connect the factor vial

**C.** Grip the package at its edge and pull it off, leaving the BAXJECT II Hi-Flow device attached to the water vial.

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

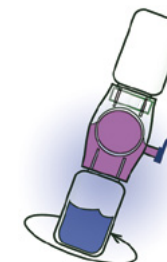


**D.** Turn the water vial with attached BAXJECT II Hi-Flow device upside down so that it is on top. Press straight down to insert the PURPLE spike fully through the factor vial stopper. A vacuum will draw water into the factor vial.



**E.** Swirl gently until all the powder is dissolved.

- Do not shake



BAXJECT II Hi-Flow is a single-use only device that is intended for use with a single factor vial. Therefore, reconstituting and withdrawing a second vial of dissolved factor into the syringe requires the use of a second 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 Hi-Flow 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

The information provided is not a substitute for professional and/or medical advice. Please consult a healthcare professional for further advice or refer to the Consumer Medicine Information (CMI) available at <http://www.medicines.org.au/files/zicadyno.pdf>

Dispose of the BAXJECT II Hi-Flow device as directed by your doctor or nurse.

Purple = Factor vial

Clear = Water vial



## 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 **PURPLE** and **CLEAR** portions of the BAXJECT II Hi-Flow device.



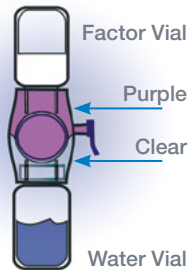
3. Determine which side of the device is connected to the water vial.

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

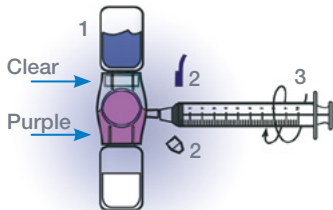
\*N.B. If the water does not go through properly, it could mean that the vacuum has been broken, which may have compromised sterility. If you have any concerns, please contact your doctor or local haemophilia centre.

### Scenario A

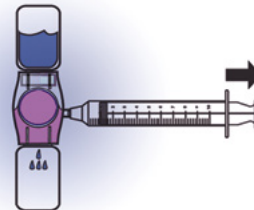
The **WATER** vial is connected to the **CLEAR** side of the device **CORRECTLY**.



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.

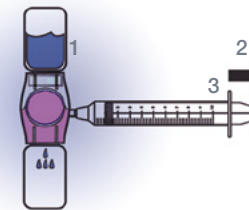


5. Pull the plunger back slowly to withdraw air from the vials. (This will force the water into the factor vial.)



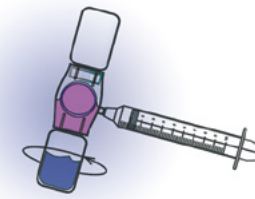
6. 1. Disconnect the syringe from the device.  
2. Press the plunger to expel any air from the syringe.  
3. Reconnect the syringe to the device.

DO NOT INJECT AIR

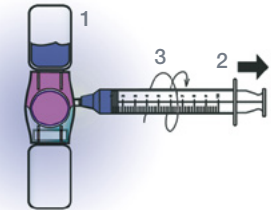


7. Swirl gently until the powder is completely dissolved.

DO NOT SHAKE

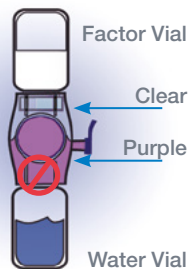


8. 1. Turn the system over so that the factor vial is positioned on top.  
2. Withdraw the prescribed volume of dissolved factor into the syringe by pulling the plunger back SLOWLY.  
3. Disconnect the syringe.

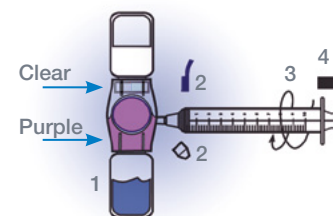


### Scenario B

The **WATER** vial is connected to the **PURPLE** side of the device **INCORRECTLY**.

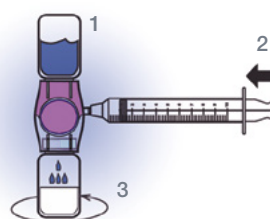


4. 1. Keep the water vial on the bottom.  
2. Make sure you use a Luer-lock syringe; remove the caps from the device and the syringe.  
3. Connect the syringe to the device.  
4. Slowly pull back the plunger to withdraw air from the vials.

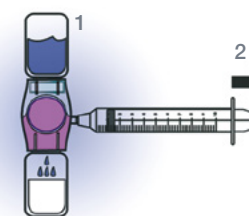


5. 1. Turn device so water vial is on top.  
2. SLOWLY press plunger to inject air back into the vials. (This forces water into the bottom vial.)  
3. Swirl gently until powder is completely dissolved.

DO NOT SHAKE

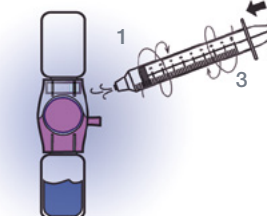


6. 1. Turn the system over so that the factor vial is positioned on top.  
2. Withdraw air into the syringe by pulling the plunger back SLOWLY. (This forces the factor into the bottom vial.)

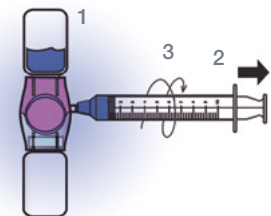


7. 1. Disconnect the syringe.  
2. Press the plunger to EXPEL all the air from the syringe.  
3. Reconnect the syringe to the device.

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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