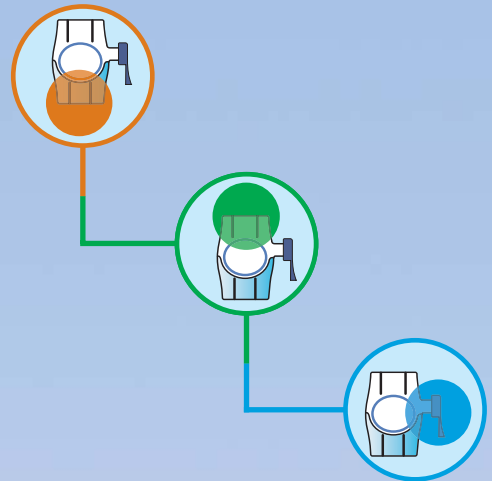


AS EASY AS 1-2-3

A detailed guide to product mixing using aseptic technique

BEFORE YOU BEGIN

Bring vials to room temperature. Wash hands and put on gloves.
Remove vial caps. Cleanse stoppers with alcohol swab and allow to dry.



BAXJECT II
Needle-less Transfer Device

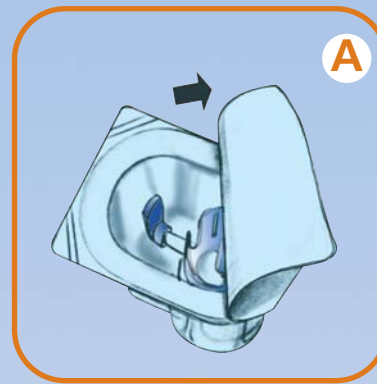
USER'S GUIDE

HOW TO MIX MORE THAN ONE VIAL WITH A LARGE SYRINGE

- Mix all product vials, using a new BAXJECT II device for each vial, as directed in Step 1 and Step 2
- Follow Step 3 to draw the product from each vial into the large syringe

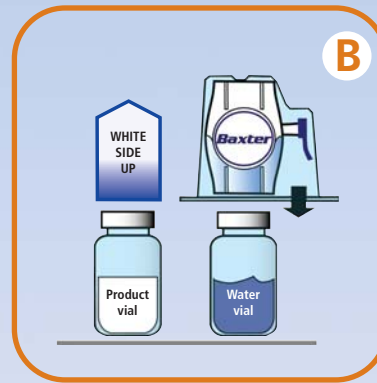
The BAXJECT II device is intended for use with a single vial of product and is for single use only. Dispose of BAXJECT II as directed by your clinician.

1 CONNECT water vial



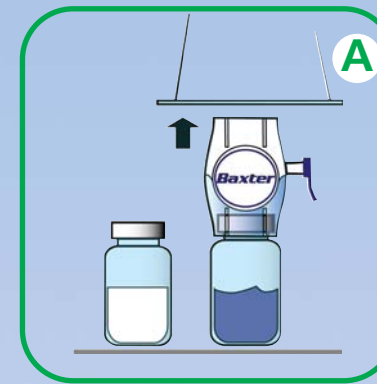
- Remove lid from package without touching the device

Do not remove device from package.



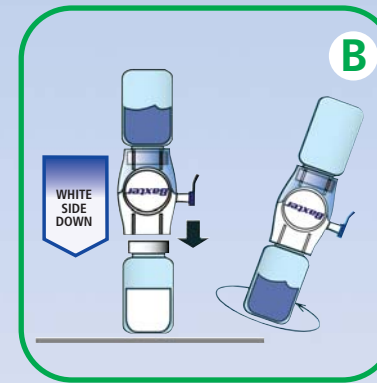
- Place vials on hard flat surface
- Invert device over water vial (WHITE SIDE UP)
- Press down until CLEAR spike pierces water vial stopper

2 CONNECT product vial



- Grip package at the edge and remove from device

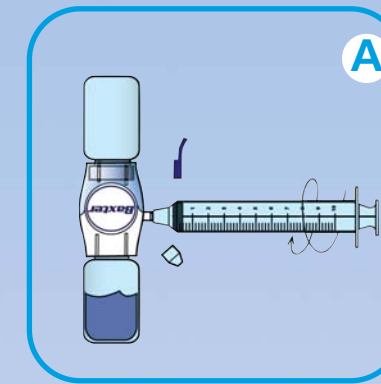
Do not remove blue cap. Do not touch white spike.



- Invert device with water vial attached (WHITE SIDE DOWN, water vial on top)
- Press down until WHITE spike pierces product vial stopper
- Wait for water to enter product vial
- Swirl gently to dissolve product

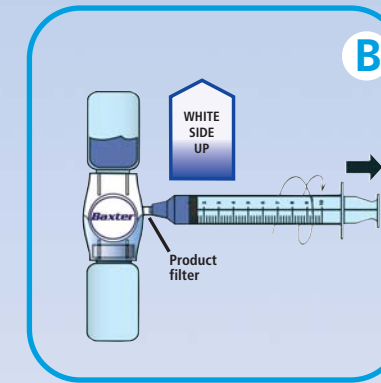
It is acceptable for a small amount of water to be left behind. If the water does not transfer successfully, please refer to Troubleshooting Information on the reverse side of this guide.

3 WITHDRAW mixed product



- Remove blue cap from device
- Remove syringe cap, if present
- Connect syringe to device

Do not inject air.



- Invert device (WHITE SIDE UP, product vial on top)
- SLOWLY pull plunger back to withdraw mixed product
- Disconnect syringe

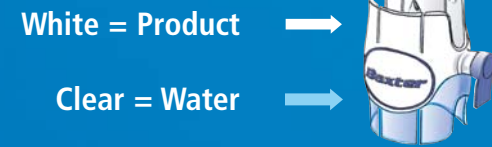
If you find it impossible to withdraw some or all of the mixed product into the syringe, there may be air in the device. Please refer to Troubleshooting Information on the reverse side of this guide.

TROUBLESHOOTING INFORMATION

If water did not successfully transfer, do the following:

1 Place the WATER vial on the bottom

2 Identify the WHITE and CLEAR portion of the Baxject II device

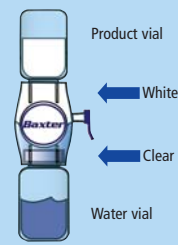


3 Determine which side of the device is connected to the WATER vial:

- If WATER vial is (correctly) connected to CLEAR side, go to SCENARIO A
- If WATER vial is (incorrectly) connected to WHITE side, go to SCENARIO B
- If you find it impossible to withdraw some or all of the mixed product into the syringe, there may be air in the device—go to SCENARIO C

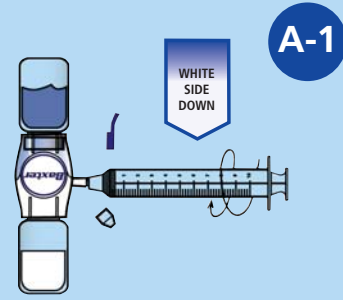
NOTE: IF THESE 3 TROUBLESHOOTING STEPS FAIL TO ADDRESS THE PROBLEMS YOU ARE HAVING, PLEASE CONTACT YOUR DOCTOR OR LOCAL HEMOPHILIA TREATMENT CENTER

BAXJECT II
Needle-less Transfer Device



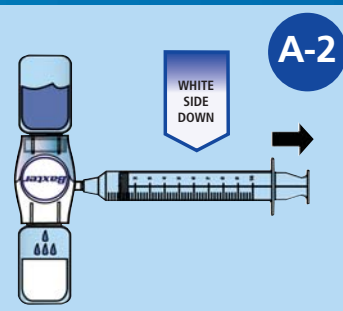
SCENARIO A

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



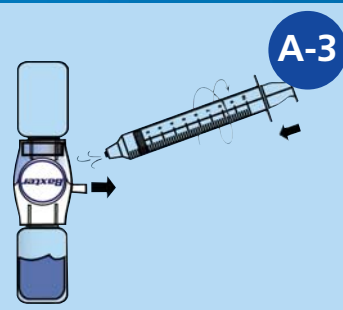
A-1

- Turn the device with vials attached so that the WATER vial is on top
- Remove the caps from the device and the syringe
- Connect the syringe to the device



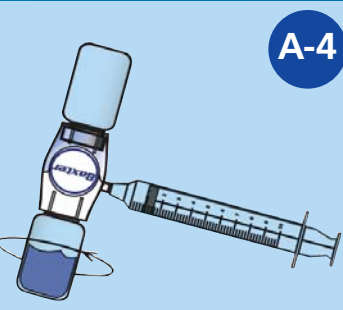
A-2

- Pull the plunger back SLOWLY to withdraw any air from the vials
- This will force water into the PRODUCT vial



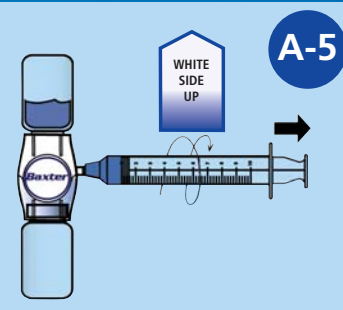
A-3

- Disconnect the syringe from the device
- Press the plunger to expel any air from the syringe
- Reconnect the syringe to the device



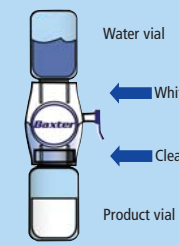
A-4

- Swirl gently until the product is completely dissolved



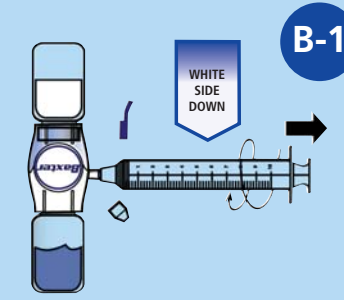
A-5

- Turn the device with vials attached over so that the PRODUCT vial is on top
- SLOWLY withdraw the prescribed amount of mixed product into the syringe
- Disconnect the syringe



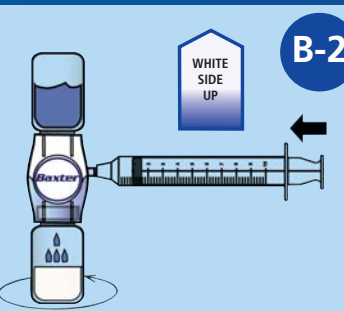
SCENARIO B

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



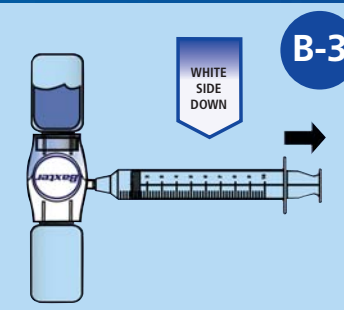
B-1

- Keep the WATER vial on the bottom
- Remove the caps from the device and the syringe
- Connect the syringe to the device
- Pull the plunger back SLOWLY to withdraw any air from the vials



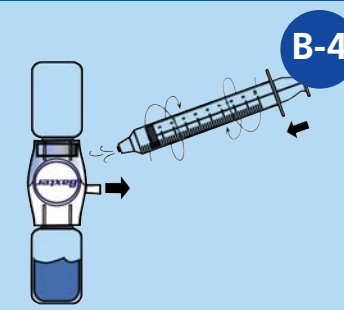
B-2

- Turn device with vials attached so WATER vial is on top
- SLOWLY press plunger to inject all air back into the vials
- This will force water into the bottom vial
- Swirl gently until powder is completely dissolved



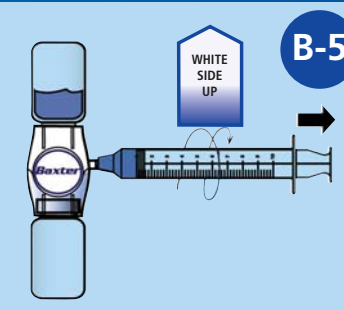
B-3

- Turn the device with vials attached over so that the PRODUCT vial is on top
- SLOWLY withdraw all air into the syringe by pulling the plunger back
- This draws mixed product into the bottom vial



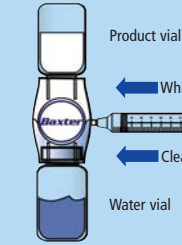
B-4

- Disconnect the syringe
- Press the plunger to expel all the air from the syringe
- Reconnect the syringe to the device



B-5

- Turn the device with vials attached over so that the vial containing mixed product is on top
- SLOWLY withdraw the prescribed amount of mixed product into the syringe
- Disconnect the syringe



SCENARIO C

IF you have injected air into the vials in error OR if you cannot withdraw the prescribed amount of mixed product and there is a significant amount left behind in the PRODUCT vial proceed as follows:

C-1

- Ensure that the PRODUCT vial is on top
- If you have withdrawn some product into the syringe, but cannot withdraw the full volume, inject all the mixed product in the syringe back into the device



- If you cannot withdraw any product into the syringe, go to Step C-2

C-2

- Turn the device with vials attached over so that the WATER vial is on top



- Now follow the instructions in Scenario A, starting with Step A-2

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