

## INSTRUCTIONS FOR USE

### Solution Storage

- VYALEV Solution can be stored at room temperature up to 30 °C for up to 28 days. It is good practice to keep just one (1) carton of VYALEV Solution at room temperature at a time.
- Store the additional cartons in the refrigerator at 2 °C to 8 °C, until needed.
- **Do NOT** freeze VYALEV Solution.
- Always withdraw the entire contents of the VYALEV Solution into the Syringe. **Do NOT** save VYALEV Solution in Solution Vial for later use.
- Discard VYALEV Solution if it has been stored at room temperature (up to 30 °C) for longer than 28 days.

### Important Information

#### Solution

- **The VYALEV Solution colour may vary and has no impact on product quality.** It may be colourless, or may vary in colour anywhere between light yellow and brown, possibly with purple or red tint. It may become darker while in the Syringe.
- If refrigerated prior to use, remove the Solution Vial from refrigerated storage and allow to sit at room temperature out of direct sunlight for 30 minutes.
- Do **NOT** dilute the VYALEV Solution or fill the Syringe with any substance other than that which is prescribed to you by your Healthcare Professional.
- Administer VYALEV only with the Vyafuser Pump. Follow the steps as indicated in your Patient Instructions for Use of Vyafuser Pump.

### Disposable Components (Vial Adapter and Syringe)

- Your Vial Adapter may look different from the one illustrated in these instructions.
- A new Vial Adapter must be used with each new VYALEV Solution.
- **Do NOT** use the VYALEV Solution if it has been in the Syringe for more than 24 hours.

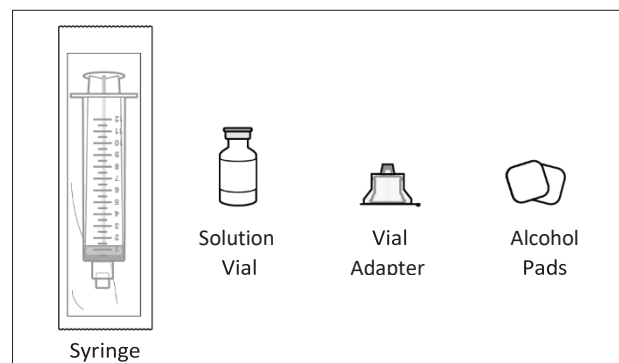
### A. Transfer Solution from Solution Vial to Syringe

- a. **Make sure your work space is clean.**

*Note:* This will help to avoid contamination.

#### 2. Gather supplies, including (see *Figure A*):

- Syringe
- Solution Vial
- Vial Adapter
- Alcohol Pads



*Figure A*

#### 3. Inspect components for expiration and for any packaging damage. This should include:

- Solution Vial (see *Figure B*)
- Vial Adapter
- Syringe

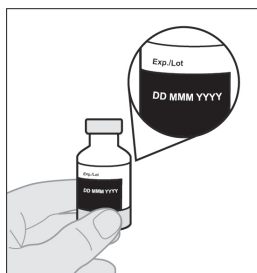


Figure B

- Verify the solution is the VYALEV Solution prescribed by your Healthcare Professional.
- **Do NOT** use any components if their sterile packaging has been damaged prior to use.
- **Do NOT** use the VYALEV Solution, Vial Adapter or Syringe if it is expired.

*Note:* The product packaging for the Infusion Set, Vial Adapter and Syringe indicate that they are sterile and how they were sterilised.

**4. Inspect the contents of the Solution Vial (see Figure C). Verify the following:**

- No cloudiness of the liquid.
- No particles observed in liquid.

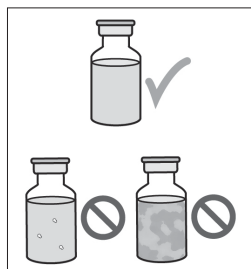


Figure C

- **Do NOT** use if the VYALEV Solution is cloudy or contains flakes or particles.

*Note:* If refrigerated prior to use, remove the Solution Vial from refrigerated storage and allow to sit at room temperature, out of direct sunlight, for 30 minutes.

- If refrigerated, **do NOT** warm the VYALEV Solution (in Solution Vial or Syringe) in any way other than letting it warm at room

temperature. For example, **do NOT** warm in a microwave or in hot water.

**5. Wash your hands with soap and water and dry them (see Figure D).**



Figure D

**6. Prepare Solution Vial.**

- a. Remove the Solution Vial Cap (see Figure E).



Figure E

- b. Wipe the top of the Solution Vial with an Alcohol Pad and allow to dry (see Figure F).

*Note:* This will help to avoid contamination.



Figure F

## 7. Prepare the Syringe.

- To minimise the risk of infections, **do NOT** let the tip of any disposable component come into contact with any unclean surfaces. If the tip of the Vial Adapter or Syringe comes into contact with an unclean surface, discard it and get a new one.

- a. Obtain a new Syringe and remove it from its packaging.
- b. Depress the rubber plunger to fully expel all air (see *Figure G*).

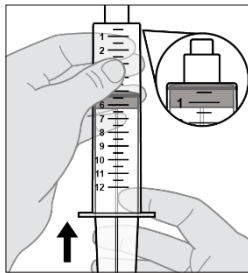


Figure G

## 8. Attach the Vial Adapter to the Solution Vial.

Please refer to your **Vial Adapter Instructions For Use** for detailed steps.

9. While holding the Vial Adapter firmly, attach the Syringe to the Vial Adapter by pushing and then screwing it into place (see *Figure H*).

- **Do NOT** overtighten.

*Note:* Your Vial Adapter may look different than in *Figure H*.

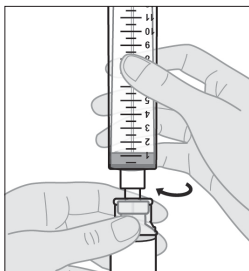


Figure H

10. Hold the Syringe vertically with the Solution Vial above the Syringe (see *Figure I*).

*Note:* Your Vial Adapter may look different than in *Figure I*.

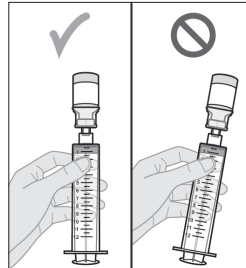


Figure I

11. Withdraw full contents of the Vial into the Syringe.

- a. While holding the Syringe firmly in one hand, pull down the Plunger Rod with the other hand to withdraw the full contents of the Solution Vial into the Syringe to around the 12 mL mark, or until you see air at the tip of the Syringe (see *Figure J*).

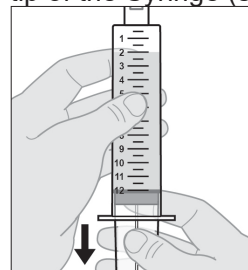


Figure J

*Note:* It is important to hold the Syringe pointing straight up.

*Note:* Always withdraw the entire contents of the Solution Vial into the Syringe.

*Note:* You will see air (head space) at the tip of the Syringe.

12. Inspect for air bubbles.

- If there are large air bubbles, they must be removed. Presence of air may affect dose delivery accuracy.

- As seen in *Figure K*, small bubbles are acceptable and the air at the tip of the Syringe (the head space) is expected.
- As seen in *Figure L*, larger air bubbles are not acceptable. While the air at the top of the Syringe (the head space) is expected, the larger bubbles are not.

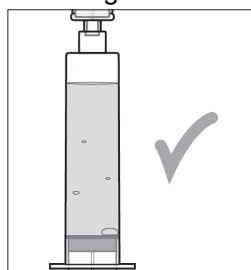


Figure K

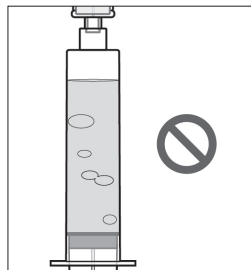


Figure L

- IF YOU SEE LARGE AIR BUBBLES, continue with **Section B: Manually Remove Air Bubbles**.
- IF YOU SEE SMALL AIR BUBBLES or DO NOT SEE ANY AIR BUBBLES, skip the next section and proceed to **Section C: Purge Air from Syringe**.

## B. Manually Remove Air Bubbles

### 13. Gather the bubbles into a single air bubble

- Slowly and gently rotate the Syringe and tilt it back and forth (see *Figure M*).
- Do NOT** shake or tap the Syringe to remove the air bubbles.

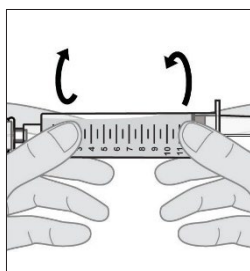


Figure M

*Note:* If there are still air bubbles, gather the bubbles by gently rotating the Syringe end over end (see *Figure N*).

- When the large bubbles are removed, continue with the next step.

*Note:* Your Vial Adapter may look different than in *Figure N*.

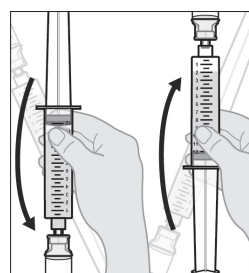


Figure N

## C. Purge Air from Syringe

### 14. Push air out of the Syringe.

- With the Solution Vial still attached, point the syringe upward.
- Slowly push the air out of the Syringe and into the Vial (see *Figure O*).

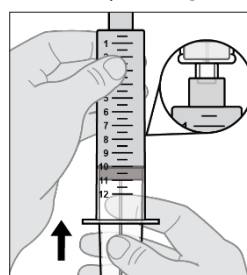


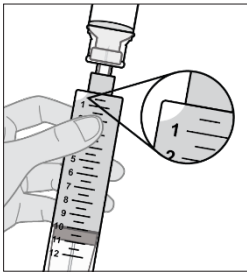
Figure O

- Continue pushing until all of the air is pushed out the Syringe and into the Solution Vial and there is Solution visible in the Syringe tip.

*Note:* Some resistance will be felt as the air is pushed back into the Solution Vial.

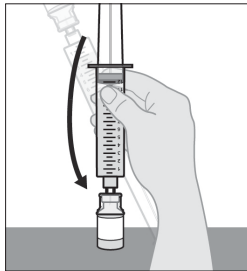
*Note:* If you are tilting the Syringe, you may see a small air bubble in the corner (see *Figure P*). This is acceptable.

*Note:* Your Vial Adapter may look different than in *Figure P*.



*Figure P*

15. Invert syringe and Solution Vial so that the Solution Vial is upright on the table (see *Figure Q*).

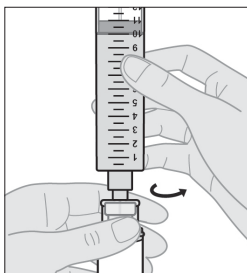


*Figure Q*

16. Disconnect the Syringe from the Vial Adapter.

- Hold the Vial Adapter firmly with one hand and the barrel of the Syringe with the other.
- Unscrew the Syringe from the Vial Adapter (see *Figure R*).

*Note:* When disconnecting the Syringe from the Vial, **do NOT** push the plunger or else the Solution will leak.



*Figure R*

- Place the Syringe on a clean surface, making sure the Syringe tip does not contact an unclean surface.

- To minimise the risk of infections, **do NOT** let the tip of any disposable component come into contact with any unclean surfaces. If the tip of the Vial Adapter or Syringe comes into contact with an unclean surface, discard it and get a new one.

17. Your Syringe is now ready for use. Follow the next step as indicated in your Patient Instructions for Use of Vyafuser Pump.

## D. Disposal

18. Used Solution Vials with the Vial Adapters still attached should be disposed of in accordance with local regulations by taking to your local pharmacy.