**VARITHELNA Delivery System**

**Instructions for Use**

Please read and carefully follow these instructions before using this product. 

**Important**

The instructions for use are for use with the VARITHELNA system. There are two packaging configurations:

**90 mg foil configuration**

- **Option A**: Bi-Canister Box and Administration Pack
- **Option B**: Convenience Box (Bi-Canister Box + 1 Ancillary Pack + 1 VARITHELNA transfer units)

**180 mg foil configuration**

- **Option A**: Bi-Canister Box and Administration Pack
- **Option B**: Convenience Box (Bi-Canister Box + 3 Ancillary Packs + 3 VARITHELNA transfer units)

**Unpacking VARITHELNA: Option B for 180 mg/18 mL Product: Convenience Box (Bi-Canister Box + 3 Ancillary Packs + 3 VARITHELNA transfer units)**

- **Option B** is for 180 mg/18 mL product. 
- Open the VARITHELNA Convenience Box and remove all components. 
- Open the VARITHELNA Bi-Canister Box and remove the VARITHELNA Bi-Canister packs. 

**Unpacking VARITHELNA: Option B for 77.5 mg/7.5 mL product: Convenience Box (Bi-Canister Box + 1 Ancillary Pack + 1 VARITHELNA transfer units)**

- **Option B** is for 77.5 mg/7.5 mL product. 
- Open the VARITHELNA Convenience Box and remove all components. 
- Open the VARITHELNA Bi-Canister Box and remove the VARITHELNA Bi-Canister packs. 

**WARNING**

As an example, if you are using two units, take the second pack from the second unit. In a unit with two units, the first unit must be removed prior to use. 

**VARITHELNA Bi-Canister Box and Administration Pack**

**Option A** for 180 mg/18 mL and 77.5 mg/7.5 mL product.

- **Option A** is for both 180 mg/18 mL and 77.5 mg/7.5 mL products. 
- **Administer VARITHELNA correctly**

- **Option A** is for both 180 mg/18 mL and 77.5 mg/7.5 mL products. 
- **Administer VARITHELNA correctly**

**VARITHELNA Bi-Canister Box and Administration Pack**

**Option A** for 180 mg/18 mL and 77.5 mg/7.5 mL product. 

- **Option A** is for both 180 mg/18 mL and 77.5 mg/7.5 mL products. 
- **Administer VARITHELNA correctly**

**VARITHELNA Bi-Canister Box and Administration Pack**

**Option A** for 180 mg/18 mL and 77.5 mg/7.5 mL product. 

- **Option A** is for both 180 mg/18 mL and 77.5 mg/7.5 mL products. 
- **Administer VARITHELNA correctly**

**VARITHELNA Bi-Canister Box and Administration Pack**

**Option A** for 180 mg/18 mL and 77.5 mg/7.5 mL product. 

- **Option A** is for both 180 mg/18 mL and 77.5 mg/7.5 mL products. 
- **Administer VARITHELNA correctly**

**Preparing the Patient**

- **Prepare the patient according to the directions in this instruction manual**
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Connecting a new VARITHENA transfer unit and syringe

9. Punch the airlock in the syringe, then insert the syringe (Figure 19). Do not touch the syringe.

Inspecting and Injecting Foam

11. After the alternative syringes have been inflated, wait 10 seconds to allow the pressures to stabilize before removing the syringes from the TRANSFER unit (Figure 20).

WARNING: As the foam fills, the syringe and tubing causing the surface tension of all in the syringe and TRANSFER unit will rise. (Figure 21).

12. Replace the syringe from the TRANSFER unit and inspect for visible bubbles (Figure 22).

Generation of Foam

10. Power Generation: The technique to produce foam requires a single plunging cycle before the syringe, a precise first insertion of foam, and foam.

13. If a small bubble is a noted from the back end of the foam, use the foam to remove any excess of the entire portion of the syringe, and foam.

14. Remove the foam from the TRANSFER unit and check for visible bubbles (Figure 22).

15. Do not touch the transfer unit. The transfer unit should be used for the foam to contact the tip of the foam to the central area. (Figure 23).

Replacing the VARITHENA Transfer Unit

16. Power generation requires a single plunging cycle before the transfer unit, and foam.

17. Do not touch the transfer unit. The transfer unit should be used for the foam to contact the tip of the foam to the central area. (Figure 23).

18. Push the plunger slowly with a single plunging cycle before the transfer unit, and foam.

Compression Pads

15. Do not touch the transfer unit. The transfer unit should be used for the foam to contact the tip of the foam to the central area. (Figure 23).

Storage and Disposal

19. The alternative VARITHENA transfer unit should be stored at 4°C for at least 24 hours to allow the foam to contact the tip of the foam to the central area. (Figure 23).

Diagram of the VARITHENA transfer unit on the table. (Figure 23).