

Sterile Water for Inhalation, USP

Prefilled Bubble Humidifiers • with Adaptor

These instructions contain important information for safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient and/or clinician.

NOTE: DISTRIBUTE THIS INSERT SHEET TO ALL PRODUCT LOCATIONS.

1. **DESCRIPTION:** Disposable, single patient use Respiratory therapy bottle with humidifier adapter. The disposable humidifier adapter is provided non-sterile. The internal contents of the bottle are sterile unless opened or damaged.
2. **INDICATIONS FOR USE:** The product is intended to humidify a patient's oxygen flow during oxygen administration and is intended for single patient use in Respiratory Therapy.
3. **CONTRAINDICATIONS:** None known.
4. **WARNINGS:**
 - 4.1 These products are intended for inhalation only, not for parenteral use or for injections or in preparations to be used for injection. Incorrect use can result in patient injury.
 - 4.2 This product is intended for single patient use. Discard unused water. Failure to do so may result in patient injury.
 - 4.3 Ensure all connections are secure. Failure to do so may result in inadequate oxygen flow to the patient
5. **CAUTIONS:**
 - 5.1 Federal (USA) Law restricts this product to sale by or on the order of a physician.
 - 5.2 Do not use if the product or container is opened or damaged.
 - 5.3 Avoid excessive heat or freezing as this may damage the bottle and result in leaking.
 - 5.4 Follow standard infection control procedures as specified by the Centers for Disease Control and Prevention (USA) or local equivalent.
 - 5.5 Do Not Reuse: products require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the product for subsequent re-use may adversely affect the integrity of the product or lead to deterioration in performance.
6. **SET-UP AND USE:**
 - 6.1 Snap off the outlet port trigger from the bottle and discard (do not twist off).
 - 6.2 Attach the adapter to the inlet of the bottle. Check for secure fit before attaching the oxygen nut to flow meter.
 - 6.3 Attach to flow meter. Set flow rate to 4 lpm and verify airflow through outlet port of the bottle.
 - 6.4 Confirm the alarm function prior to use. Leaving the flow rate at 4 lpm, occlude the outlet port of the bottle and listen for an audible alarm to sound.
 - 6.5 Attach oxygen tubing to small bore outlet port on bottle.
 - 6.6 Adjust flow rate as directed by physician.
 - 6.7 Discard unused portions upon completion of therapy.
7. **STORAGE AND HANDLING:**
 - 7.1 Dispose of this product in a safe manner according to local guidelines for disposal of contaminated waste.
 - 7.2 Store at room temperature. Avoid freezing or excessive heat.



Sterilized using aseptic processing techniques



CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Do Not Reuse



Do not use if package is damaged



Do not resterilize



Not made with natural rubber latex



Instructions for use



Warnings



Lot number



Non-pyrogenic



Manufactured date



Expiration date



Keep dry



Keep away from sunlight