

AeroEclipse[®] XL

Reusable Breath Actuated Nebulizer
Nebulizador reutilizable accionado por la respiración



Instructions for Use / Instrucciones de uso

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Rx ONLY

Quantity: 1
Part No. 69010



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ENGLISH

INDICATIONS FOR USE

The **AEROECLIPSE[®] XL R BAN** is a single patient, reusable device, intended to be used by patients who are under the care or treatment of a licensed healthcare provider or physician. The device is intended to be used by these patients to administer aerosolized medication prescribed by a physician or healthcare professional. The intended environments for use include the home, hospitals and clinics. The device may be used with a compressor capable of delivering a flow of 2.75 to 8 liters per minute (lpm) under an operating pressure of 15 to 50 pounds per square inch (psi).

IMPORTANT SAFETY INFORMATION

The following statements will be used to draw attention to potential use errors that could cause harm.

NOTE - Indicates information to which the user should pay special attention.

CAUTION - Information for preventing damage to the product or causing personal injury.

WARNING - Important safety information for hazards that could cause serious injury or death.

BEFORE YOU BEGIN

1. This package should contain one reusable **AEROECLIPSE[®] XL R BAN** with mouthpiece, one **EZ Twist** TUBING and one Instructions for Use. If any parts are missing, please contact the authorized dealer from whom you purchased this unit. To download an electronic copy of this Instructions for Use, visit www.monaghanmed.com
2. Prior to use, carefully examine the product for foreign objects, damaged or missing parts. If any parts are missing or a defect is noticed, contact the authorized dealer where you originally purchased your reusable **AEROECLIPSE[®] XL R BAN**.
3. Read your Instructions for Use to be sure you understand all instructions for use, cautions and warnings before starting a nebulizer treatment. If you have questions about the performance or usability of this product, please contact your healthcare professional prior to use.
4. The nebulizer should be replaced after 6 months of use. Be sure to follow the use and cleaning instructions as outlined in this Instructions for Use, and replace your nebulizer within the timeframe indicated to ensure it functions correctly. Failure

to follow the appropriate cleaning instructions may have an adverse effect on device performance.

5. It is recommended that you have an extra nebulizer on hand in the event your nebulizer becomes damaged, lost or otherwise unusable.

SETTING UP YOUR NEBULIZER

For nebulizer part descriptions see Figure 1.

CAUTION: The reusable **AEROECLIPSE[®] XL R BAN** can deliver aerosolized medication in either **BREATH ACTUATED** or **CONTINUOUS** Mode. In **BREATH ACTUATED** Mode, medication is delivered on inspiration only and may result in an increase of the dosage to the lungs. Clinicians should take this information into consideration when determining dosage.

1. Prior to use, inhale and exhale through the Mouthpiece to verify the movement of the **GREEN FEEDBACK BUTTON** located on the top of the device (Fig. 1). The button should move up and down freely. If not, move the **MODE SELECTOR** to the **BREATH ACTUATED** position (▲ - Fig. 2). If the **GREEN FEEDBACK BUTTON** still does not move freely contact your authorized distributor for a new unit.
2. Examine the **MOUHPIECE** to ensure the **EXHALATION VALVE** is on the bottom, facing down to ensure exhaled breath is directed away from the face.
3. For patients unable to use the **MOUHPIECE**, the reusable **AEROECLIPSE[®] XL R BAN** can be used with an optional **Mask** by removing the **MOUHPIECE** and inserting the **Mask** into the **MOUHPIECE** opening (Fig. 3). The reusable **ComfortSeal[®] Mask** (Fig. 4) has an **ELBOW ADAPTER** that can be inserted directly into the Mouthpiece opening.

NOTE: When using the reusable **AEROECLIPSE[®] XL R BAN** with a **ComfortSeal[®] Mask**, ensure a secure seal all around the edge of the Mask. Even tiny gaps may allow ambient air to enter the Mask, significantly reducing the amount of medication delivered.

4. Unscrew and remove the **NEBULIZER TOP**. Carefully place prescribed medication into **NEBULIZER CUP** (Fig. 5). The reusable **AEROECLIPSE[®] XL R BAN** has a minimum fill of 1 mL and a maximum fill of 6 mL. Reattach the **NEBULIZER TOP**, making sure to line up the **WHITE CYLINDER** with the **STEM** of the **NEBULIZER CUP** and gently hand tighten

until a stop is detected, as shown in Figure 6. Ensure nebulizer is kept in an upright position so medication does not spill, (e.g. Use your compressor's nebulizer cup holder).

5. Attach one end of the supplied **EZ Twist** TUBING to the fitting on the bottom of the nebulizer and the other end to your compressed air source. Ensure both ends are securely connected.

NEBULIZER TREATMENT

The reusable **AEROECLIPSE[®] XL R BAN** can be operated in **CONTINUOUS** MODE (constantly producing aerosol) by rotating the **MODE SELECTOR** to the **CONTINUOUS** MODE position (△ - Fig. 2). The nebulizer can be returned to **BREATH ACTUATED** Mode by rotating the **MODE SELECTOR** to the **BREATH ACTUATED** position (▲ - Fig. 2).

- Always follow your healthcare professional's treatment instructions.
- The reusable **AEROECLIPSE[®] XL R BAN** should be used with the **Ombra[®] Table Top or Portable Compressors** or an air source capable of delivering a flow of 2.75 to 8 Lpm under an operating pressure of 15 to 50 psi (1.03 to 3.45 bar).

WARNING: Close supervision is necessary when the product is used by or near infants, children or anyone requiring assistance to use the device. It contains parts that may present a choking or strangulation hazard. **DO NOT LEAVE CHILDREN UNATTENDED DURING TREATMENTS.**

BREATH ACTUATED MODE

Ensure the **MODE SELECTOR** is in **BREATH ACTUATED** position (▲ - Fig. 2).

1. While sitting in a comfortable, upright position, switch on your compressor.
2. Place the **MOUHPIECE** in your mouth, ensuring your lips are sealed around the edge. Be careful not to cover the **EXHALATION VALVE** on the bottom of the **MOUHPIECE**, as doing so will prevent the valve from functioning properly.
3. Inhale slowly and deeply. As you inhale, the **GREEN FEEDBACK BUTTON** on the top of the nebulizer (Fig. 1) will move down, indicating that the reusable **AEROECLIPSE[®] XL R BAN** is producing aerosol in response to your inhalation.
4. Exhale normally through the device. The valve on the mouthpiece only opens during exhalation to allow air to exit the device. This helps prevent re-breathing of exhaled air. During exhalation, the **GREEN FEEDBACK BUTTON** returns to the up position indicating no aerosol is being produced (Fig. 7).
5. Continue to breathe normally through the device until it begins to make a "sputter" noise or as instructed by your healthcare professional.
6. Switch off the compressor when finished with your treatment.

NOTE: If you are unable to trigger the device during inhalation (unable to get the **GREEN FEEDBACK BUTTON** to go down when you breathe in) it can be manually operated with your index finger by depressing/releasing the **GREEN FEEDBACK BUTTON** in coordination with your breathing. Alternatively, you may switch the device to **CONTINUOUS** MODE (△ - Fig. 2).

CONTINUOUS MODE

Ensure the **MODE SELECTOR** is in **CONTINUOUS** position (△ - Fig. 2).

In **CONTINUOUS** Mode, the nebulizer may be used with the reusable **ComfortSeal[®] Mask**. Refer to 'Setting Up Your Nebulizer', Step 3 on how to properly use a mask with the nebulizer.

1. While sitting in a comfortable, upright position, switch on your compressor.
2. **Mouthpiece:** Place the **MOUHPIECE** in your mouth, ensuring your lips are sealed around the edge. Be careful not to cover the **EXHALATION VALVE** on the bottom of the **MOUHPIECE**, as doing so will prevent the valve from functioning properly.
Mask: Place the mask securely over your nose and mouth, ensuring you have a good seal with the edge of the mask and face. Even tiny gaps may affect medication delivery.
3. Inhale slowly and deeply. The **GREEN FEEDBACK BUTTON** will stay down for the duration of the treatment, indicating the device is constantly producing aerosol, (Fig. 7)
4. Exhale normally through the device. The **EXHALATION VALVE** on the **MOUHPIECE** or **Mask** will open allowing air to exit the device.
5. Continue to breathe normally through the device until it begins to make a "sputter" noise or as instructed by your healthcare professional.
6. Switch off the compressor when finished with your treatment.

CLEANING YOUR NEBULIZER

Ensure you clean your nebulizer between each treatment.

- For optimum performance you should replace your nebulizer every 6 months or sooner if it shows signs of damage.

1. PREPARATION

Immediately after each treatment, all parts of the reusable **AEROECLIPSE[®] XL R BAN** (excluding tubing) must be cleaned of medication residue and contamination.

To do this, disassemble nebulizer as follows:

- 1.1 Rotate the **MODE SELECTOR** to the **BREATH ACTUATED** position before cleaning to ensure free movement of the parts.
- 1.2 Remove the **EZ Twist** TUBING from the bottom of the nebulizer.
- 1.3 Unscrew and remove the **NEBULIZER TOP** and remove **MOUHPIECE** from the **NEBULIZER CUP**.

CAUTION: Failure to follow manufacturer's cleaning or disinfection instructions may have an adverse effect on device performance. Do not disassemble the product beyond what is recommended in the cleaning instructions or damage may result.

2. AT HOME

Ensure you clean your nebulizer between each treatment.

2.1 RECOMMENDED METHOD

- Wash the three nebulizer parts (excluding tubing) in a solution of warm water and liquid dish detergent for about 5 minutes.
- Rinse in clean, warm water.
- Dry according to instructions in Section 2.3.

2.2 ALTERNATIVE METHOD

- The reusable **AEROECLIPSE[®] XL R BAN** disassembled into its three parts (excluding tubing) may be washed in a dishwasher by securing the nebulizer parts in a basket on the top rack. Wash in a normal wash cycle, being sure to remove the basket prior to the drying cycle.
- Dishwashing with overly dirty dishes is not recommended.
- Dry according to instructions in Section 2.3.

2.3 DRYING

- To dry, shake the nebulizer parts to remove any excess water.
- We recommend you briefly reconnect the **EZ Twist** TUBING to the bottom of the nebulizer cup and the compressed air supply to clear the air pathway.
- Allow parts to air dry thoroughly before reassembling.
- The nebulizer components may also be dried with a clean lint-free cloth prior to reassembly.

EZ TWIST TUBING

Occasionally you may notice condensation on the inside of your tubing. This is normal. To remove the condensation, simply connect one end of the **EZ Twist** TUBING to a pressurized air source, and allow the air to run without the nebulizer attached. This will force air through the tubing, drying the inside. To clean the exterior, wipe with a damp cloth. Ensure the tubing is dry prior to storage.

3. DISINFECTION INSTRUCTIONS

The reusable **AEROECLIPSE[®] XL R BAN** (excluding tubing) should be disinfected at least every other treatment day using any of the methods listed below.

A. BLEACH

- Prior to disinfection, follow Section 1 and 2 'Cleaning Your Nebulizer'. Do not dry or reassemble the device.
- The three nebulizer parts (excluding tubing) may be soaked in 1.50 bleach to water solution (approximately 1 tablespoon bleach in 3/4 cups water) for 3 minutes. Rinse well with clean water. You may substitute a respiratory equipment disinfectant (such as Milton[®], Doodle[®] or Control III[®]) for the bleach solution by following the manufacturer's instructions for use.
- Dry according to instructions in Section 3.1.

B. BOILING

- Prior to disinfection, follow Section 1 and 2 'Cleaning Your Nebulizer'. Do not dry or reassemble the device.
- The three nebulizer parts (excluding tubing) may be boiled in water for 15 minutes. Place the individual nebulizer parts in the water once it has reached the boiling point. Remove from water and allow to cool.



