



INSTRUCTIONS FOR USE

InspiraChamber® Anti-Static Valved Holding Chamber is intended to be used by patients who are under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers (pMDIs). The intended environments are the home, hospitals and clinics.

INSTRUCTIONS FOR USE

THIS DEVICE CAN BE USED DIRECTLY FROM THE PACKAGE. BE SURE THESE INSTRUCTIONS AND THE INSTRUCTIONS SUPPLIED WITH THE PRESSURIZED METERED DOSE INHALER (pMDI) HAVE BEEN READ BEFORE USE.

1 Carefully inspect the device for missing parts, debris, or other damage. Remove any foreign objects prior to use. Replace the device IMMEDIATELY if damaged or missing parts are observed.

2 Remove cap(s) from pMDI and chamber (if applicable).

3 Shake the pMDI before each use as per the instructions supplied with the pMDI.

4 Insert the pMDI into the chamber's flexible back piece.

4A If SootherMask™ is needed, (i) insert your child's pacifier into the slot on the SootherMask™, and (ii) allow your child to take the pacifier into the mouth and begin sucking to allow the mask to provide an effective seal around the face. Then gently connect the chamber to the mask. If InspiraMask™ is needed, (iii) gently connect the chamber to the mask and apply the mask to your child's face with an effective seal. Note that InspiraMask™ does not have a pacifier slot.

5 (i) Put the mouthpiece into mouth and close lips to provide an effective seal, (ii) Exhale completely and then depress the pMDI. Inhale as slowly as possible. Hold breath for 10 seconds prior to resuming normal breathing for 2-3 breaths*. Slow breathing rate if the InspirAlert™ whistle sounds**. **Administer one (1) puff at a time.**

5A The SealVision™ visual indicator on the mask will move when there is a good seal. The SealVision™ is closed during inhalation and opens during exhalation. Watch the SealVision™ and wait for your child to exhale before depressing the pMDI. Continue slow breathing for 2-3 breaths after the pMDI is depressed. Slow breathing rate if the InspirAlert™ whistle sounds**. **Administer one (1) puff at a time.**

6 Follow instructions as prescribed on the pMDI for time before repeating steps 3 – 5A.

CLEANING INSTRUCTIONS

THIS DEVICE CAN BE USED DIRECTLY FROM THE PACKAGE AND SHOULD BE CLEANED WEEKLY THEREAFTER.

1 Remove the chamber's back piece and cap. Do not disassemble the device to avoid damage. Remove mask if applicable.

2 Soak the device and all its parts in warm water with liquid detergent for 15 minutes. Rinse all of the device components in clean water.

OR

3 Clean the device and all its parts face up as pictured on the top rack of the dishwasher. Wash using a commercial dishwasher detergent. **Do NOT use heavy cycles or Dry Heat settings.**

4 Shake the device to remove excess water. Dry in a vertical position. **Do NOT reassemble the device until it is completely dry.**

5 Align the back piece with the chamber to reassemble. Press firmly against a hard surface to obtain a snug fit.

Notes:

- Storage and operating range: 5°C-40°C (41°F-104°F) at 15-95% relative humidity.
- Inspect the device for cracks, debris, or damage that will prevent proper function after each cleaning. REPLACE IMMEDIATELY if any damages are observed. Environmental conditions, improper storage or cleaning can affect device life span.
- This medical device is for single-patient use and should be replaced after 12 months.
- The intended patient population for InspiraChamber® with Mouthpiece is for anyone who has been prescribed pMDI medications.
- The size of the SootherMask™ or InspiraMask™ should be determined by the size of the patient's face.
- If medication build-up is observed in your chamber, wash the inside of the chamber with a soft cloth.
- Non-BPA (BPA contents less than 0.1 mg/mL)

Cautions:

- This device should be cleaned according to these instructions to ensure proper performance.
- Do not leave InspiraChamber®, SootherMask™ or InspiraMask™ unattended with children.
- This device may be damaged if it is boiled, sterilized or cleaned at hot temperatures.

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