

C € 0197



Spacer for Inhaler

Instruction for Use

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1. Important Information

1.1 General

Please read these instructions for use carefully and completely. Do not discard, so you can consult them at a later date. If you fail to comply with the instructions for use, injury or damage to the device cannot be ruled out.

If symptoms persist or if your condition worsens, discontinue the application and contact your doctor immediately.

1.2 Structure of Safety Instructions

Safety-critical warnings are categorised according to hazard levels in these instructions for use:

- The signal word **WARNING** is used to indicate hazards which, without precautionary measures, can result in serious injury or even death.
- The signal word **CAUTION** is used to indicate hazards which, without precautionary measures, can result in minor to moderate injury or impair treatment.
- The signal word **NOTICE** is used to indicate general precautionary measures which are to be observed to avoid damaging the product during use.

1.3 Treatment of Anyone who Requires Assistance

Anyone who requires assistance must be supervised constantly by an adult during inhalation therapy. This is the only way to ensure safe and effective treatment. Individuals in this group often underestimate the hazards involved, thus resulting in a risk of injury.

The product contains small parts. Small parts can block the airways and lead to a choking hazard. Therefore, make sure that you always keep all components of the product out of the reach of babies and infants. This product is only designed for patients who are able to breathe by themselves and are conscious. This is the only way to ensure effective treatment and avoid a choking hazard.

1.4 Hygiene

Only use spacers and accessories that have been thoroughly cleaned, disinfected, and dried as described in Chapter 4. Contamination or residual moisture can promote bacterial growth, increasing the risk of infection. To ensure safe use, follow these instructions:

- Each spacer is for single-patient use at home only.
- Clean and dry the device before its first use.
- Always use fresh drinking-quality tap water for cleaning and disinfection.
- Thoroughly dry all components after cleaning or disinfecting.
- Do not store the spacer or accessories in a damp environment or with wet objects.

2. Product Description

2.1 Components

Before use, make sure all components are included in your package. If any parts are missing, contact your supplier immediately. The following items are included:

- 1 x Large (Adult) Mask
- 1 x Small (Child) Mask
- 1 x Dust Cap
- 1 x Mouthpiece
- 1 x Storage Body
- 1 x Back Piece
- 1 x Valve
- 1 x Whistle

2.2 Intended Purpose

The LifeSense Breathe Spacer is a holding chamber, and is used in conjunction with medication sprays or metered dose inhalers (MIDs) in the treatment of diseases of the airways.

2.3 Intended Use

The LifeSense Breathe Spacer for Inhaler is intended for use by treating chronic obstructive pulmonary disease and asthma with medicine-assisted inhalation device.

The Spacer is a holding chamber, and is used in conjunction with medication sprays or "metered dose inhalers" in the treatment of diseases of the airways.

2.4 Combination of Medical Devices

The Spacer for Inhaler should be used in conjunction with metered dose inhalers (MIDs) in the treatment of diseases of the airways.

The metered dose inhalers is rectangular and approximately 23(\pm 2mm) long \times 16.5(\pm 2mm) wide.

2.5 Contraindications

There are no contraindications known.

2.6 Description of Function

The Spacer helps to: minimise coordination mistakes when using metered dose inhalers, avoid deposition of large quantities of medication in the oropharyngeal area, and the undesirable side effects associated therewith. With a flexible connecting adaptor, it can be used with all conventional metered dose inhalers.

2.7 Material Information

PETG/PP/ABS: Inhalation chamber, Mouthpiece

Silicone: Valve in the chamber, mask

Thermoplastic: Back piece, dust cap

Rubber: Back piece, dust cap

All materials are latex-free.

2.8 Shelf Life

The shelf life of the Spacer is 3 years. However, it is recommended to replace the product after 12 months of use or after 1,460 uses, whichever comes first.

3. Inhalation

3.1 Function Check

Clear Pathway

- When you receive the Spacer, check that the valve pathway in the mouthpiece is not blocked.
- Do not use the Spacer if the valve is obstructed.

Correct valve position

- Before each use, make sure the valve is in the correct position inside the mouthpiece (as shown in the instructions).
- If the valve is out of place, use a gentle stream of water to reposition it.
- Always dry the Spacer completely before using it again.

3.2 Preparation for Inhalation

WARNING

Because the Spacer's inhalation chamber is not fully sealed, small particles may enter and could be inhaled during use (choking hazard). Always check that the Spacer is free of foreign objects before each use.

CAUTION

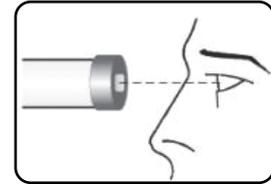
Check all product components and the accessories before each use. Replace any broken, misshapen or seriously discoloured parts. Please also follow the instructions for assembly given below. Damaged components and an incorrectly assembled holding chamber may impair the function of the holding chamber and thus the treatment as well.

CAUTION

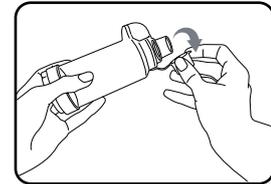
If the a mask is being used, make sure that the expiratory valve shim is pressed out. If the valve shim is deflected inward, the dosage delivered may be insufficient when inhaling.

3.3 Performing the Inhalation

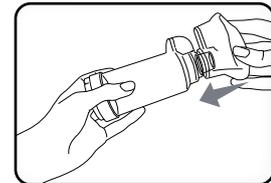
1. Carefully examine the product for damage, missing parts or foreign objects. Remove any foreign objects prior to use.



2. Hold the base of the spacer and remove the cap from the top of the chamber.

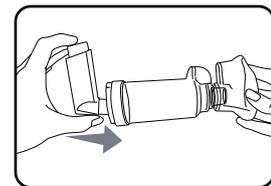


3. Place the, suitably sized, mask over the chamber mouthpiece until it fits securely.

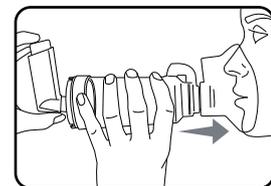


 CAUTION Before inhalation, make sure all parts are securely connected. Loose connections may result in an insufficient dose being delivered.

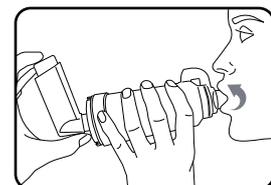
4. Remove cap from the metered dose inhaler (MDI), shake before use and insert device into the backpiece of the chamber.



5. Hold mask against the face, press MDI and inhale slowly. Keep mask in place and breath in and out through the chamber for 5-6 breaths.



6. If not using the mask, place lips around the mouthpiece, press MDI and inhale slowly*. Hold breath for 5-10 seconds.



**Slow down inhalation if you hear a tone from the device*

CAUTION

When using the mask, ensure it completely covers both the nose and the corners of the mouth. If not fitted correctly, aerosol may escape, leading to reduced effectiveness of the treatment and possible underdosage.

For potential side effects caused by escaping aerosol, please refer to the medication's instructions for use.

- Children under 18 months: Inhale 4–6 times.
- Children over 18 months: Take 2–4 deep breaths.
- Adults: One deep breath is sufficient to inhale the medication from the spacer.

If your doctor has prescribed more than one spray, wait one minute before repeating steps 3 to 5.

4. Cleaning

Regularly clean all product components and the accessories used, if they are visibly dirty immediately after use.

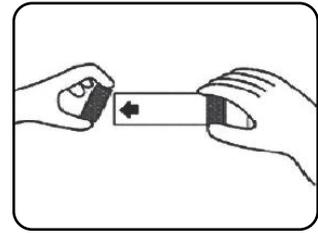
The chamber is usually cleaned once a week.

4.1 Preparation

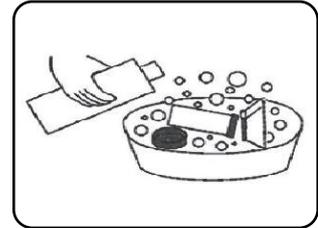
- Take the metered dose inhaler out of the connecting ring on the inhalation chamber and close it with the protective cap provided for this purpose.
- If applicable, detach the mask from the mouthpiece.
- Disconnect the mouthpiece from the inhalation chamber.

4.2 Cleaning

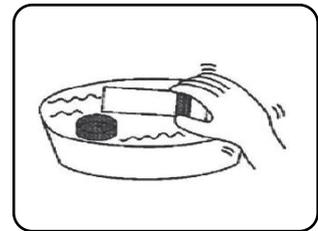
1. Remove the back piece and disassemble the other parts of the spacer.



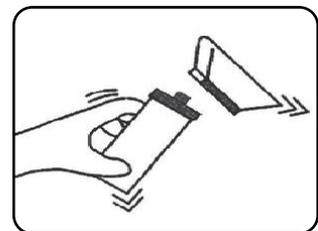
2. Soak both parts for 15 minutes in lukewarm water with liquid detergent. Agitate gently.



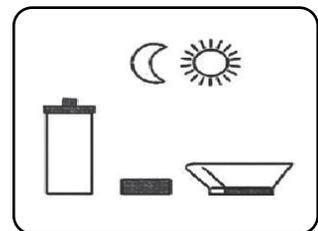
3. Rinse in clean water.



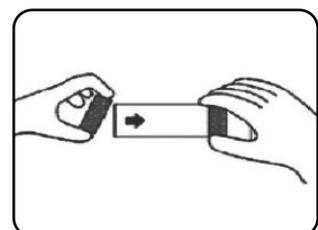
4. Shake out excess water.
Do not rub dry.



5. Let air dry in vertical position.



6. Replace back piece when unit is completely dry and ready for use.



4.3 Visual inspection

Inspect all product components after each cleaning and disinfection. Replace any broken, misshapen or seriously discoloured parts.

4.4 Drying and storage

- Dry all individual parts completely. Because of the antistatic properties of the inhalation chamber, you can dry them with a clean tea towel.
- Place the protective cap over the mouthpiece (if applicable).
Info: The protective cap protects the mouthpiece from damage during transport and storage.
- Attach the mouthpiece to the inhalation chamber (if applicable).
- Store the SPACER and its accessories in a dry, dust-free place (safely out of continuous direct sunlight).

5. Miscellaneous

5.1 Disposal

All product components can be disposed of with domestic waste unless this is prohibited by the disposal regulations prevailing in the respective member countries.

5.2 Explanation of Symbols

The following symbols are displayed on the packaging of your LifeSense Breathe product:

	Manufacturer
	Consult the Instructions for Use
	CE Symbol & Notify Body Number
	Authorised representative in the European Community/European Union
	LOT Number
	Medical Device
	Caution
	Use-By Date
	Date of Manufacture
	Single patient multiple use
	Latex Free
	Importer
	Distributor

5.3 Contact

For all product information and in the event of defects or questions about usage, please contact our Service Department:

Phone (ROI): 1800 307 777

Phone (UK): 0800 640 6253



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