



AER BEATHA LTD

INNOVATIVE ASTHMA TREATMENT



Aer8®

The Aer8 spacer, CE mark, is licensed for use with most metered dose inhalers (MDIs). It is a class 1 medical device and conforms with Medical Device Regulation (EU) 2017/745. It is made in Sweden using high quality cardboard from a sustainable resource, Swedish wood pulp. It is large volume (500mL) but is easily portable as it can be popped down to collapse between uses. It is non-static, biodegradable, and environmentally friendly as it has no plastic parts. It lasts for 30 days and does not have to be washed.

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ASTHMA SUMMARY

Asthma is very common. Almost 10% of people living in the European Union have a diagnosis of asthma. Among children, asthma is the most common chronic medical condition.

ASTHMA TREATMENT

Inhaler devices are used to treat and to prevent asthma. They deliver reliever and preventer drugs directly to the lungs. There are many types of inhaler and they can be used by even the very young. They include (pressurised) metered-dose inhalers (MDIs) and dry powder inhalers (DPIs).

PROBLEMS WITH TREATMENT

Inhalers must be used properly in order to be effective.

- For MDIs, this requires co-ordination of two actions, pressing down on the device with the fingers (actuation) while its open end is held between the lips in order to release a dose of drug followed at the right instant by a normal inhalation to deliver the dose into the lungs. If the actuation and inhalation are not co-ordinated, the drug ends up in the mouth and back of the throat not in the lungs.
- For DPIs, a powerful, fast inspiration of breath is needed in order to deliver the dose of drug into the lungs. Many patients do not have a powerful enough inspiration especially when they are short of breath during an exacerbation of asthma.

No matter which device is chosen, it is essential that the patient can use it effectively. Ineffective use of inhalers is a major cause of asthma treatment failure. This is not limited to children. It is a primary cause of poorly controlled asthma in all patient age groups. Even in those patients able to use MDIs and DPIs effectively, much of the drug dose becomes stuck at the back of the throat (oropharyngeal deposition) instead of travelling down to the lungs to have its effect. Oropharyngeal deposition is especially important to avoid with preventer drugs (inhaled corticosteroids) because the steroids have many side effects (loss of voice, oral candidiasis, cataracts, risk of adrenal suppression).

IMPROVING TREATMENT: USING SPACERS WITH MDIS

Spacers (holding chambers) help to reduce the problems with MDIs because they remove the need to co-ordinate inhaler actuation with drug inhalation. The MDI is attached to the spacer and the open end of the spacer is placed between the lips. The MDI is then actuated into the spacer and the patient inhales the drug from the spacer. The spacer allows the high-speed spray of drug coming from the inhaler to slow down so there is much less oropharyngeal deposition but there is still enough time to inhale the drug effectively into the lungs. The spacers available currently cannot be used with DPIs.

PROBLEMS WITH SPACERS

Spacers, including small volume spacers, are bulky (volume range 300mL to about 700mL), not very portable and need to be cleaned so patients tend not to use them. Most are made from hard plastics, are not collapsible or recyclable and have to be incinerated for disposal.

THE AER8 SPACER

The Aer8 spacer is for use with MDIs. It is made in Sweden using high quality cardboard from a sustainable resource, Swedish wood pulp. It is large volume (500mL) but is easily portable as it can be popped down to collapse between uses. It is non-static, biodegradable, and environmentally friendly as it has no plastic parts. It lasts for 30 days and does not have to be washed. It is easy to carry.

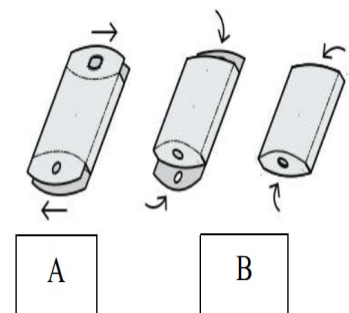
How to use Aer8 spacer



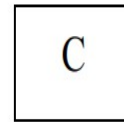
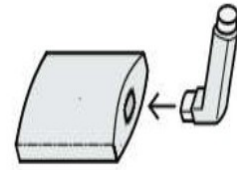
1. Remove cap from the MDI mouthpiece and shake the MDI well.



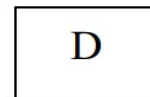
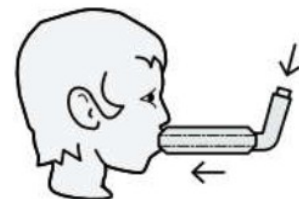
2. Pop-up the Aer8 spacer (A), close end flaps to seal the Aer8 spacer (B).



3 .Insert the upright MDI mouthpiece into the oval opening of the Aer8 spacer (C).



4. Hold the Aer8 spacer by the MDI, close your lips around the round opening on the opposite end of the Aer8 spacer(D).



5. Exhale normally into the Aer8 spacer, press down on metal canister (MDI) to release one puff of medication, wait 3 seconds.

6. Inhale slowly through the Aer8 spacer mouthpiece to take a full breath and hold for 10 seconds. Remove Aer8 spacer from your mouth, exhale into the air.

7. If your doctor has directed you to take more than one puff, repeat as required.

8. After use, remove MDI, replace mouthpiece cap.



9. Pop down the Aer8 spacer between uses and store in a clean dry place until it is next to be used.



Effect of a Swedish-made user-friendly cardboard spacer on salbutamol MDI performance

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Figure

Background

Spacers were developed to address problems of coordination and extrapulmonary drug deposition for patients using metered dose inhalers (MDIs). Respiratory experts recommend that every patient needing an MDI should regularly use a spacer, and know how to use it effectively, both for routine therapy and in an emergency (1).

Current plastic spacers are bulky, not very portable and need to be cleaned. Patients tend not to use them. The Aer8 spacer (Figure) addresses these shortcomings. Made in Sweden to Good Manufacturing Practice standards, it can be popped-up to erect and collapsed between uses. It is easily portable, large volume (500mL), non-static, compostable and much more environmentally friendly than plastic spacers.

Methods

Particle size distributions from six salbutamol (Ventolin®) MDIs were measured using a Next Generation Cascade Impactor® (NGI) set to an inlet flow rate of 30L/min and analyzed using high-performance liquid chromatography.

Based on the average mass of drug deposited in the actuator, spacer, mouth & throat and eight NGI stages, the Mass Median Aerodynamic Distribution (MMAD), Geometric Standard Deviation (GSD) and Fine Particle Dose (FPD, Respirable Dose) of the drug particles were calculated along with the Relative Standard Distribution percentage (%RSD).

Objective

•To compare drug particle size distribution and mouth and throat deposition from a salbutamol MDI with and without use of an Aer8 spacer.

Table of Results

Drug deposition area	Ventolin MDI alone (n=6)		Ventolin MDI + Aer8 Spacer (n=6)	
	Mean drug deposition (µg)	Mean %RSD	Mean drug deposition (µg)	Mean %RSD
Actuator	16	10	15	8
Spacer	Not Applicable		10	32
Mouth & Throat	48	22	2	30
NGI Stage 1	1	24	0	17
NGI Stage 2	1	25	1	13
NGI Stage 3	2	19	3	13
NGI Stage 4	12	20	17	12
NGI Stage 5	14	9	17	15
NGI Stage 6	4	8	4	12
NGI Stage 7	1	28	1	10
NGI Stage 8	1	26	0	5
Total deposition	100	5	69	11
MMAD µm	2	4	2	3
GSD	2	1	2	2
FPD µg (≤5.0µm)	32	13	40	11

Mean drug deposition (µg), MMAD (µm) GSD (µm) and FPD (µg) from salbutamol (Ventolin) MDIs alone and using an Aer8 spacer.

Interpretation of Results

- Compared with the salbutamol MDI used alone, use with an Aer8 spacer reduced mouth & throat (oropharyngeal) impaction, (mean deposition 48 µg v 2 µg), (Table).
- Total drug per actuation was reduced by the Aer8 Spacer, 69µg v 100µg with the MDI alone owing to the 2-second delay in sampling and aerosol depletion occurring with spacers (2).
- The MMAD, GSD and salbutamol respirable dose (FPD, mean 32µg v 40µg) were stable.

Conclusions

- Use of the Aer8 spacer with a salbutamol MDI reduced oropharyngeal particle impaction, with respirable dose delivery equivalent to the MDI alone.
- The Aer8 spacer respirable fine particle dose is similar to other spacers used to deliver salbutamol (3).
- With its user-friendly, environmentally-sustainable features, the Aer8 may be a viable alternative to existing plastic spacers and a useful tool for teaching patients how to use MDI devices effectively.