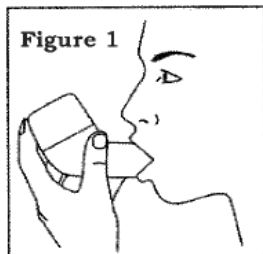


FLUTTER[®] Mucus Clearance Device

Instructions for Use



PRODUCT DESCRIPTION

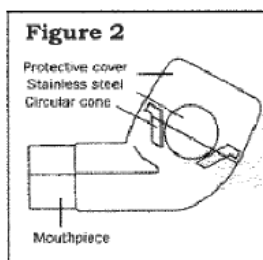
The FLUTTER[®] mucus clearance device is shaped like a pipe with a hardened plastic mouthpiece at one end, a plastic protective, perforated cover at the other end, and a high-density stainless steel ball resting in a plastic circular cone on the inside (Figures 1 and 2).

INDICATIONS

The FLUTTER[®] provides positive expiratory pressure (PEP) therapy for patients with mucus-producing respiratory conditions, including: Atelectasis, Bronchitis, Bronchiectasis, Cystic Fibrosis, Chronic Obstructive Pulmonary Disease (COPD), Asthma or other conditions producing retained secretions.

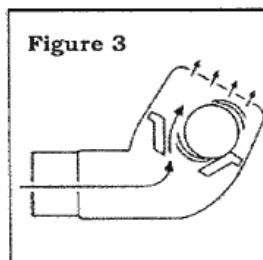
CONTRAINDICATIONS

The FLUTTER[®] is contraindicated for patients known to have pneumothorax or overt right-sided heart failure.

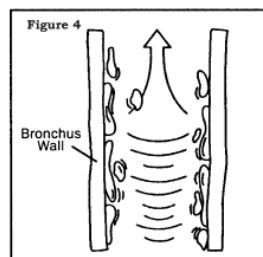


PRINCIPLES OF OPERATION

The principle of the FLUTTER[®] as a mucus clearance device is based on its ability to: (1) vibrate the airways (which loosens mucus from the airway walls); (2) intermittently increase endobronchial pressure (which helps maintain the patency of the airways during exhalation so that mucus does not become trapped as it moves up the airways); and (3) accelerate expiratory airflow (which facilitates the upward movement of mucus through the airways so that it can be more easily cleared).



The FLUTTER[®] effect occurs during the expiratory phase of respiration. Before exhalation, the steel ball blocks the conical canal of the FLUTTER[®]. During exhalation, the actual position of the steel ball is the result of an equilibrium between the pressure of the exhaled air, the force of gravity on the ball, and the angle of the cone where the contact with the ball occurs. As the steel ball rolls and bounces up and down, it creates an opening and closing cycle which repeats itself many times throughout each exhalation (Figure 3). The net result is that oscillations in expiratory pressure and airflow are produced. When the oscillation frequency approximates the resonance frequency of the pulmonary system, endobronchial pressure oscillations are amplified and result in vibrations of the airways. The vibrations produced by these oscillations cause the "fluttering" sensation from which the FLUTTER[®] derived its name. These vibrations loosen mucus from the airway walls. The intermittent increases in endobronchial pressure decrease the collapsibility of the airways during exhalation, increasing the likelihood of clearing mucus from the tracheobronchial tract. The airflow accelerations increase the velocity of the air being exhaled, facilitating the movement of mucus up the airways (Figure 4).



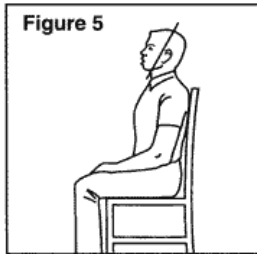
The FLUTTER[®] produces a range of oscillation frequencies between 6 and 20 Hz, which corresponds to the range of the pulmonary resonance frequencies in humans. Attaining oscillation frequencies in this range is fundamental to the efficacy of the FLUTTER[®]. The individual pulmonary resonance frequency of each patient is dependent on many factors, including lung volume, lung elasticity, and degree of airway obstruction. The frequency of oscillation that produces the best transmission of vibrations in a given patient corresponds to the pulmonary resonance frequency for that patient. When the resonance frequency of the pulmonary system is achieved, the pressure variations are amplified, maximizing the vibrations of the airway wall. These vibrations, coupled with increases in expiratory pressure and airflow, facilitate the clearance of mucus.

The oscillation frequency produced by the FLUTTER[®] when its stem is in the horizontal position is approximately 15 Hz. This frequency can be modulated by changing the inclination of the FLUTTER[®] slightly up (higher frequency) or down (lower frequency) from its original horizontal position. Adjusting the FLUTTER[®] to the resonance frequency is easily accomplished by the patient who selects the angle tilt that results in the best transmission of vibrations to his/her airways.

CLINICAL STUDY RESULTS

Cystic Fibrosis, Bronchitis and Bronchiectasis are characterized by abnormally thick mucus. Inhaled bacteria can become imbedded in these secretions, resulting in inflammation which leads to destructive disease of the lungs.

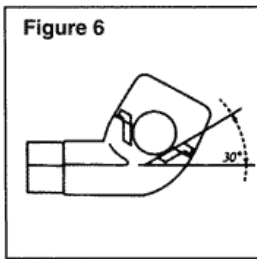
The efficacy of the FLUTTER[®] in facilitating mucus clearance in Cystic Fibrosis has been reported. The average amount of sputum expectorated with the FLUTTER[®] was over four times the amount expectorated after conventional postural drainage with percussion and vibration. Every patient expectorated more mucus with the FLUTTER[®] than with conventional postural drainage.¹



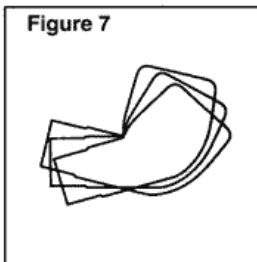
DIRECTIONS FOR USE

The patient should be seated with back straight and head slightly tilted upward so the upper airway is wide open (Figure 5). This will allow exhaled air to flow smoothly from the lungs and out through the FLUTTER[®]. As an alternative, the patient may be seated with elbows resting on a table at a comfortable level and head position as described above.

The angle at which the patient holds the FLUTTER[®] is critical (Figure 6). Initially, the FLUTTER[®] should be held so that the stem is horizontal to the floor, which places the cone at a slight tilt. The tilt insures that the ball not only bounces but also rolls during exhalation. This combined rolling and bouncing of the steel ball produces the vibrations that dislodge mucus from the airways. The FLUTTER[®] then needs to be adjusted to the patient's pulmonary resonance frequency, which is done by moving the FLUTTER[®] slightly up or down to achieve the maximum "fluttering" effect (Figure 7). This resonance is evidenced by the vibrations within the chest that can be felt by the patients. The healthcare professional can help determine if the patient has achieved the "fluttering" effect by placing one hand on the patient's back and the other hand on the patient's chest. The vibrations in the lungs can be felt as the patient exhales. After the patient has established a comfortable position and selected the proper tilt to maximize "fluttering," therapy may begin.



Beginning with Stage 1 - Mucus Loosening and Mucus Mobilization. Instruct the patient to slowly inhale to approximately 3/4 of a full breath. Place the FLUTTER[®] in the mouth with lips closed firmly around the stem. Position the FLUTTER[®] at the proper angle and perform a 2 to 3 second breath-hold. This allows the inhaled air to be evenly distributed throughout the lungs. Now the patient should exhale through the FLUTTER[®] at a reasonably fast but not too forceful speed. During the exhalation, keep the cheeks stiff, so the vibrations produced by the FLUTTER[®] are not wasted in the cheeks. Have the patient concentrate on feeling the airways vibrate and continue to exhale through the FLUTTER[®] to a level slightly further than one would exhale during normal breathing without the FLUTTER[®]. At this point the urge to cough should be suppressed. Have the patient repeat this breathing technique for another 5 to 10 breaths to loosen and mobilize as much mucus as possible. The mucus moves farther up the airways with each FLUTTER[®] exhalation. *Emphasize to the patient the importance of inhaling slowly, holding the breath 2 to 3 seconds, and suppressing the urge to cough.*



Now the patient is ready to begin Stage 2 - Mucus Elimination. Have the patient perform 1 or 2 additional breaths through the FLUTTER[®]. This time, breathe in slowly and as fully as comfortably possible. Really fill the lungs with air. Again perform a 2 to 3 second breath-hold. Now, have the patient exhale forcefully through the FLUTTER[®] as completely and as comfortably as possible. This forceful exhalation moves mucus up to a level in the lungs that triggers a cough. However, if the mucus is not easily coughed out following 1 or 2 elimination breaths, the patient should attempt a "huff" maneuver (like trying to "huff" a bread crumb out of the throat).

The standard series of 5 to 10 mucus-loosening breaths with cough suppression followed by 1 or 2 mucus elimination breaths with cough should result in successful airway clearance. If your patient is new to FLUTTER[®] therapy or has particularly thick mucus, it may take multiple repetitions of Stage 1, Mucus Loosening and Mucus Mobilization, before performing Stage 2, Mucus Elimination. Several trials may be necessary to determine the appropriate number of breaths needed in each stage for individual patients.

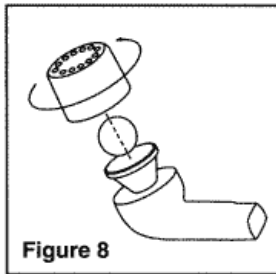
FREQUENCY AND DURATION OF USE

FLUTTER[®] therapy is complete when no further mucus can be expectorated following several diligent sequences. Frequency of use and duration of each session should be determined by the healthcare professional. FLUTTER[®] therapy is a more "goal-based" than "time-based" therapy, and experience has shown that successful clearing of the airways for most patients will occur in approximately 5 to 15 minutes. Generally, morning and late afternoon or evening sessions are recommended. Patients can avoid becoming overly tired by adding a session instead of extending any one session to a point of discomfort.

Remember, the goal of airway clearance therapy is to comfortably and efficiently remove as much mucus as possible. The FLUTTER[®] will assist your patients in achieving this goal.

CLEANING THE FLUTTER[®]

The FLUTTER[®] is recommended for single patient use only. Instruct patients to clean the FLUTTER[®] after each session to remove moisture and/or mucus (Figure 8). Disassemble and rinse all components with tap water; wipe with a clean towel, reassemble, and store in a clean, dry location. Every two days, patients should disassemble and clean their FLUTTER[®] in a solution of mild soap or detergent. Chlorine bleach or other chlorine-containing products (e.g., dishwashing detergent) should not be used. Rinse, dry, reassemble, and store.



NOTE TO PHYSICIANS AND HEALTHCARE PROFESSIONALS

The FLUTTER[®] provides positive expiratory pressure (PEP) therapy for patients who have Chronic Obstructive Pulmonary Disease (COPD) such as Asthma, Bronchitis, Cystic Fibrosis, Atelectasis, or other conditions producing retained secretions. PEP therapy, combined with forced expiratory technique (FET), or "huff" coughing, may be used for airway clearance, bronchial hygiene, or as an alternative to conventional chest physiotherapy (CPT) and pursed lip breathing. PEP therapy will help prevent accumulation of secretions; improve mobilization of secretions; promote effective breathing patterns and improve gas exchange and distribution of ventilation; improve central and peripheral airway function; prevent or reverse Atelectasis; and improve bronchodilation when used in combination with respiratory drug delivery via nebulizer or MDI spacer devices.

PRECAUTIONS

Federal law restricts this device to sale by or on the order of a physician. The patient should be instructed in FLUTTER[®] use by a licensed practitioner. The steel ball within the FLUTTER[®], if separated from the FLUTTER[®], could pose a choking hazard. The FLUTTER[®] must be handled carefully; it may break if dropped on a hard surface.

Reference:

1. Konstan MW, Stern RC, Doershuk CF. Efficacy of the FLUTTER[®] device for airway mucus clearance in patients with cystic fibrosis. J Pediatrics May 1994; 124:689-693.

Manufactured for:
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Printed in USA
U.S. Patent No. 5'018'517
FL004-0802