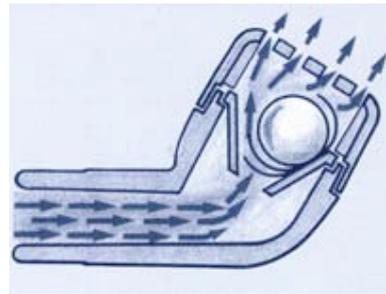


fig 1

fig 2



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. cleared).

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).



Directions for use:

The patient should be seated with back straight and head slightly tilted upward so the upper airway is wide open. 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. 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. 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.

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 over-fatigued by adding a session