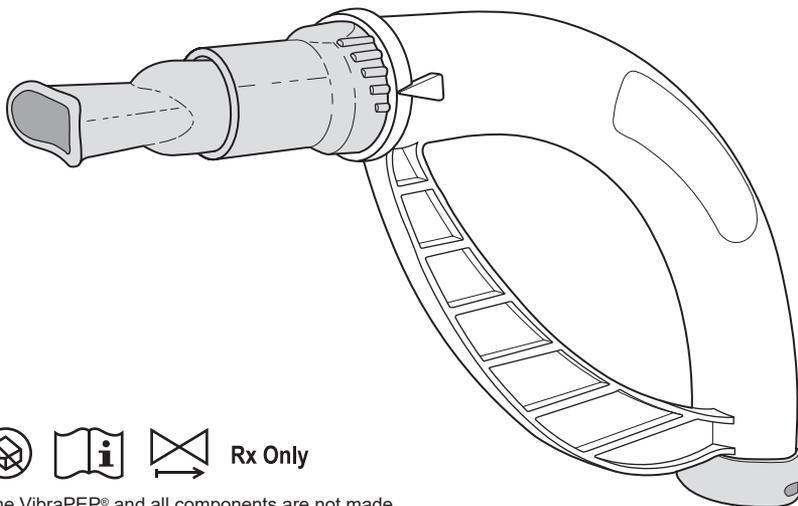


# VibraPEP®

## VibraPEP® Oscillatory PEP Therapy Device

### Instructions For Use

REF 44F50 / 44F10



Rx Only

The VibraPEP® and all components are not made with natural rubber latex.

Single Patient Use.

Patient - Children four (4) years and older to adults



Manufactured for and Distributed by:

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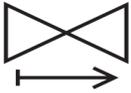
Designed in Oregon

Made in Mexico

LIT-3313 Rev. D. 2020-12-29

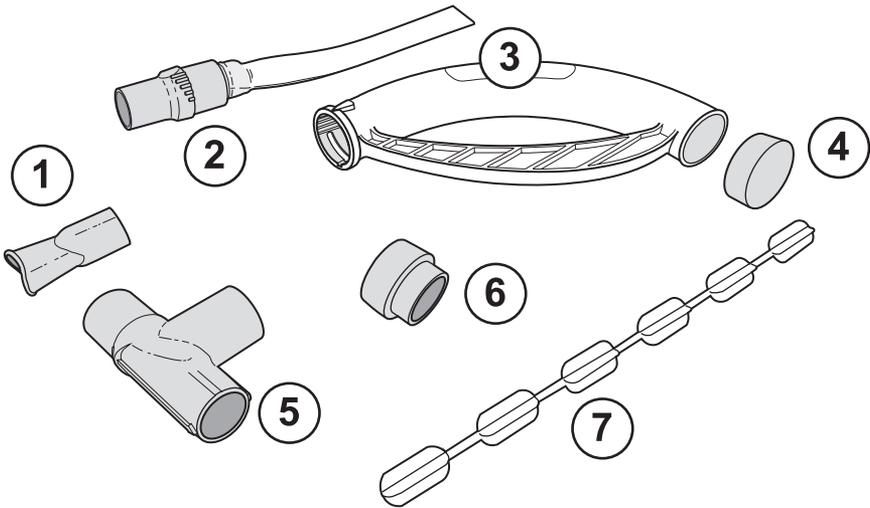
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Valved Tee Adapter contains a valve that allows air flow in only one direction.

**Rx Only** Prescription only - Device is restricted to use by or on the order of a physician



1. Mouthpiece
2. Therapy Selector & Flow Valve Assembly
3. Curved Tube with Handle
4. Cap

5. Valved Tee Adapter Accessory\*
6. 22 mm Cap Adapter
7. Drying Aid

\* Note: Accessory may or may not be included in your kit.

## VibraPEP® Oscillatory PEP Therapy Device

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### DESCRIPTION

The VibraPEP Oscillatory PEP Therapy System (OPEP) is a single patient use (one person) device that provides Positive Expiratory Pressure (PEP) Therapy for spontaneously breathing patients. For patients with lung disorders where secretion clearance may be a problem, it facilitates the detachment and removal of bronchial secretions. By delivering PEP and airflow oscillation to the lungs, the combination of pressure and flow variation causes vibrations in the thorax resulting in loosening and liquefying of the bronchial mucus, which can then be more easily expelled.

The VibraPEP consists of a flat Flow Valve inserted into a Curved Tube. As the patient exhales through the VibraPEP, the Flow Valve pressure increases and buckles at the bending of the Curved Tube. When the peak pressure is reached, the Flow Valve end opens and is catapulted against the wall, releasing its pressure. This process is repeated, providing an oscillation effect at a constant pressure and flow rate during the entire exhalation phase.

### INTENDED USE

The VibraPEP Oscillatory PEP Therapy System (OPEP) is a Positive Expiratory pressure device designed to exercise patient's lungs and to improve secretion clearance. The device may be connected via a Valved Tee Adapter for use with a jet nebulizer for aerosol drug delivery. The VibraPEP is not intended to be used while connected to a jet nebulizer to deliver nebulized steroidal drugs or antibiotics.

Patient – Children four (4) years and older to adults

Environment – Hospital, clinics, physician offices, home setting

### CONTRAINDICATIONS

Although no absolute contraindications to the use of PEP Therapy have been reported, the following should be carefully evaluated before a decision is made to initiate therapy:

- Inability to tolerate increased work of breathing
- Hemodynamic instability
- Intracranial pressure (IPC) > 20 mm Hg
- Acute sinusitis
- Recent facial, oral or skull surgery or trauma
- Epistaxis
- Esophageal surgery
- Active hemoptysis
- Untreated pneumothorax
- Nausea
- Known or suspected tympanic membrane rupture or other middle ear pathology
- Acute abdominal pathology
- Abdominal aortic aneurysm
- Hiatal hernia
- Pregnancy
- Presence of reduced coronary artery perfusion such as in acute cardiac myocardial infarction.

## SIDE EFFECTS

Some side effects may be experienced including:

- Hyperventilation
- Low grade dizziness
- Numbness of mouth and hands

## WARNINGS

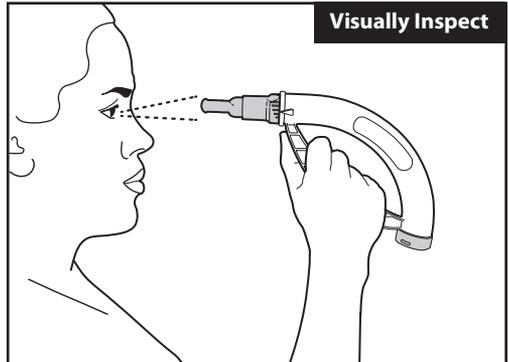
Use of this device at excessive pressures may have adverse effects. Expiratory pressures above 20 cm H<sub>2</sub>O in patients sensitive to increased transpulmonary pressure may develop one or more of the adverse side effects listed herein.

Clinical judgment should be used to guide the adjustment of the appropriate settings for each individual patient. Failure to match the appropriate resistance setting on the different marks of the Therapy Selector with the patient's expiratory flow may result in failure to achieve the therapeutic objectives of Oscillatory PEP Therapy or one or more of the following adverse side effects.

- Increased work of breathing that may lead to hyperventilation and hypercarbia
- Increased intracranial pressure
- Cardiovascular compromise
- Myocardial ischemia
- Decreased venous return
- Air swallowing, with increased likelihood of vomiting and aspiration
- Claustrophobia
- Pulmonary barotraumas

## BEFORE USE

Visually inspect the device to ensure that the unit is free of contamination and foreign objects. PEP therapies for bronchial hygiene require spontaneously breathing patients.



## INSTRUCTIONS FOR USE

The VibraPEP has five settings as indicated by the position of the Therapy Selector. The device comes preset at position 1. If this is the first use, ensure it is set to this position.

## ADJUSTING THE SETTINGS

By rotating the Therapy Selector, pressure and flow can be adjusted to achieve optimal therapy for each patient. Refer to specifications for the range of airway pressures that may be increased based upon patient efforts.

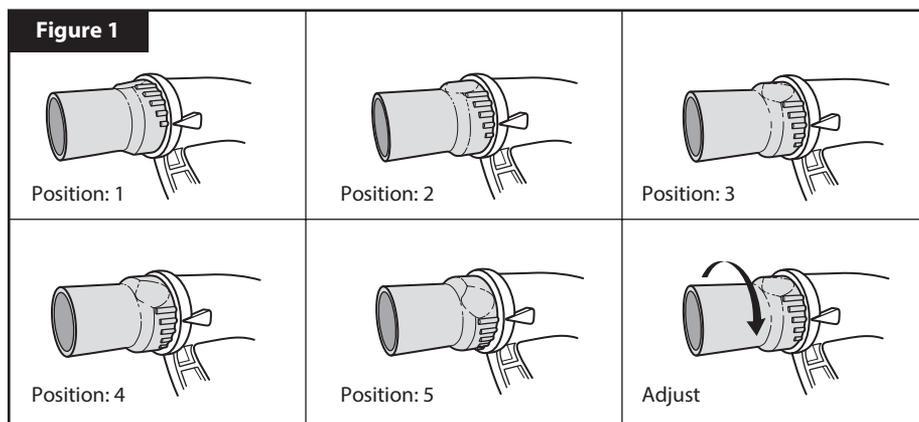
For patients requiring a permanent PEP with added pressure oscillations above baseline (CombinedPEP®), begin therapy at the initial position 1 (smallest marking) of the VibraPEP and adjust to positions 2 or 3 respectively. (see Figure 1)

For patients requiring a gradual rising pressure followed by a sudden drop in pressure (DynamicPEP®), begin therapy at positions 4 or 5. (see Figure 1)

Direct the patient to exhale through the VibraPEP to functional residual capacity (FRC). Exhalation should be active but not forced. Adjust the Therapy Selector on the VibraPEP as needed to result in an inspiratory to expiratory ratio (I:E ratio) of approximately 1:3 over a period of 3 to 4 seconds. Have the patient remove the mouthpiece from their mouth and perform several forced expiratory maneuvers (“huff coughs”) to raise secretions.

Evaluate the level of breathing effort and the amount of mucus coughed up. If results are not acceptable, adjust the Therapy Selector setting until the desired therapeutic effect is achieved. When the optimal therapeutic setting is determined, maintain this position.

Patients should be reevaluated periodically or with any change in status.



## PATIENT

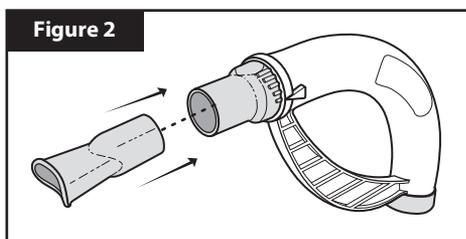
### INSTRUCTIONS FOR USE

The Therapy Selector settings should be adjusted as recommended by your health care provider.

The VibraPEP is not position dependent and can be used while in a lying, sitting or standing position.

When using this device, it is important to keep your cheeks flat and firm to maximize effectiveness. Do not expand your cheeks during exhalation. Exhalation should be natural and not forced.

1. To begin, adjust the Therapy Selector to the setting your health care provider has previously advised (Position 1-5)
2. Insert the Mouthpiece into VibraPEP device. (see Figure 2)
3. Place the mouthpiece into your mouth and form a tight seal with your lips.
4. Breathe in through your nose, then exhale naturally into the device keeping your cheeks flat.
5. For maximum benefit, try to suppress coughing until the end of your treatment.
6. Always follow your health care provider's instructions.



**CAUTION:** If during treatment you feel dizzy or lightheaded or have any other discomfort, discontinue treatment and contact your health care provider.

### VibraPEP USE WITH NEBULIZER

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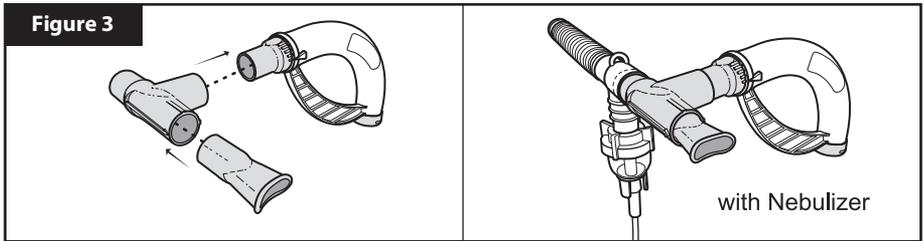
- The VibraPEP with Valved Tee Adapter is only compatible with a jet nebulizer that has a 22 mm fitting.
- Your health care provider will advise which medication to use for combined treatments.
- Medications which open your airways or help to thin mucus are good choices to use with the VibraPEP. These medications would help remove or thin the mucus in your lungs.
- The VibraPEP Mucus Clearing Device is not intended to be used while connected to a jet nebulizer to deliver nebulized steroidal drugs or antibiotics.

**CAUTION:** Viscous medication may potentially alter the Flow Valve performance.

## INSTRUCTIONS FOR USE, VibraPEP WITH NEBULIZER

(see Figure 3 for proper placement)

1. Assemble the jet nebulizer as described in the nebulizer supplied Instructions for Use.
2. Remove the Mouthpiece from the Therapy Selector and place the Valved Tee Adapter over the Therapy Selector opening as indicated in Figure 3.
3. Connect the nebulizer to the Valved Tee Adapter and insert the mouthpiece into the opposite end. (See Figure 3 for proper placement) Note: Valved Tee Adapter can only connect one way.
4. Turn on the air source or compressor to power the nebulizer.
5. Sit in a relaxed, upright position.
6. Place the mouthpiece into your mouth and form a tight seal with your lips.
7. Inhale the aerosol completely then exhale through the VibraPEP at a slow constant rate keeping your cheeks flat.
8. Repeat breathing phases until medication is gone.
9. For maximum benefit, try to suppress coughing until the end of your treatment.
10. Always follow your health care provider's instructions.

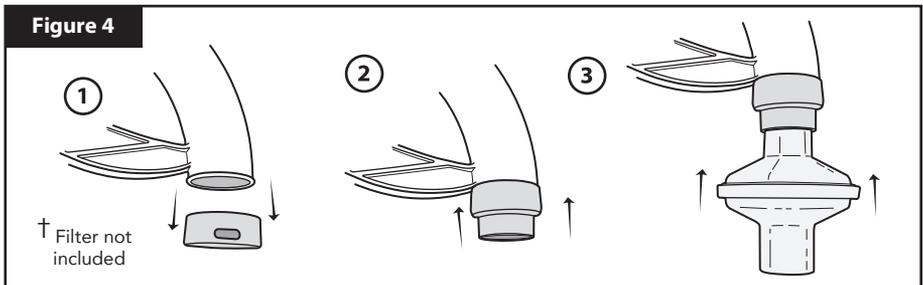


## INSTRUCTIONS FOR USE, VibraPEP WITH 22 mm CAP ADAPTER

The VibraPEP 22 mm Cap Adapter may replace the standard Cap that comes attached to the VibraPEP.

To attach a filter to the distal end of the VibraPEP, follow the steps below. (See Figure 4)

1. Remove existing Cap from the VibraPEP.
2. Attach the 22 mm Cap Adapter to the distal end of the VibraPEP.
3. Attach Filter†
  - The 22mm Cap Adapter will accept fittings with a 22 mm outer diameter.
  - Ensure a secure fit of all connections.
  - Follow the filter's supplied Instructions for Use for replacement guidance.



## CARE AND CLEANING INSTRUCTIONS

### WARNING

- The VibraPEP is for single patient use (one person) only.
- Do NOT share your VibraPEP with other patients.
- Product should be replaced after 6 months of use or immediately if damaged.
- Failure to follow the cleaning instructions may have an adverse effect on device performance.

### Note to Clinician:

Use your clinical assessment of the patient's disease state to determine the method and frequency in which the device should be cleaned or disinfected.

If used in combination with a nebulizer, the device should be rinsed after use to remove any residue that may have deposited on exhalation.

## DISASSEMBLE

- Remove the Mouthpiece (Figure 5), from the Therapy Selector.
- Remove the Therapy Selector from the Curved Tube by rotating the Therapy Selector counterclockwise past position 1. (see Figure 6 and Figure 7)
- Do not detach the Flow Valve from the Therapy Selector.
- Remove Cap from bottom of Curved Tube. (see Figure 8)

Figure 5

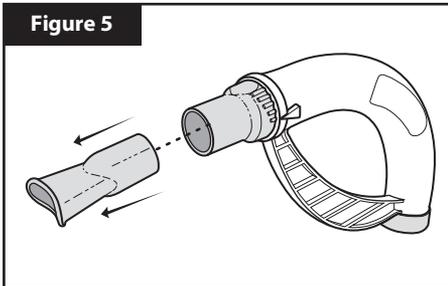


Figure 6

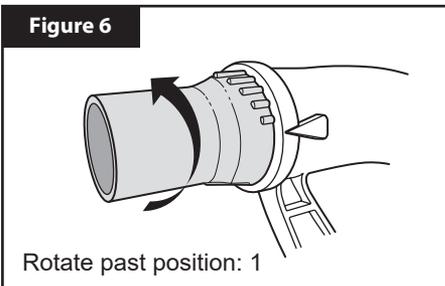


Figure 7

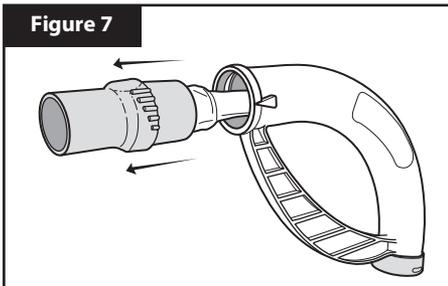
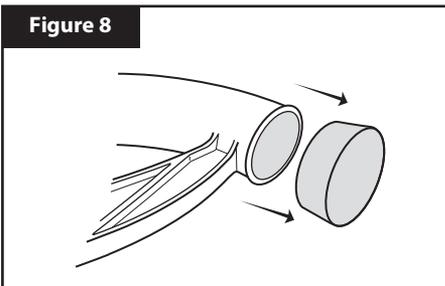


Figure 8



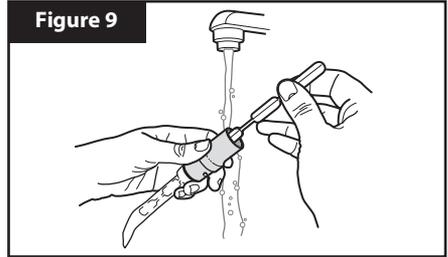
### Note:

It is not necessary to remove the Flow Valve from the Therapy Selector

## CLEANING

### Insert the Drying Aid

- To facilitate cleaning, run water through the Therapy Selector + Flow Valve Assembly while inserting the Drying Aid, allowing cleaning and rinsing solutions to flow freely. (see Figure 9)
- The Drying Aid should be inserted into the Flow Valve during all cleaning procedures.



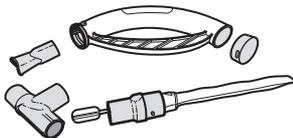
### CLEANING METHODS

**Rinse:** Run water through the Therapy Selector and Flow Valve to clear any particulate. Shake out excess water from components, and air dry.

**Hand Wash:** Gently wash all parts in warm soapy water, using common dishwashing liquid. To remove visible contaminants, you may soak all VibraPEP components in warm, soapy water as required. Thoroughly rinse all components in water. Allow parts to air dry completely before reassembling.

**Boiling:** The VibraPEP may be disinfected by boiling all parts in water. Place a heat resistant rack on the bottom of a pan to prevent plastic parts from coming in contact with the hot bottom. Bring water to a boil (212° F/100° C). Place all components into the boiling water for 10 minutes. Remove from water and allow parts to cool and air dry thoroughly before reassembling.

**Dishwasher:** The VibraPEP may be cleaned using a dishwasher. NOTE: Place small parts in a dishwasher basket on the top shelf. Ensure parts are thoroughly cool and dry before reassembling.

CLEANING INSTRUCTIONS	 SOAP & WATER	 BOILING WATER	 DISHWASHER	 AIR DRY
		  10 min.	 Top Shelf	 Overnight

## Inspect the VibraPEP

- Visually inspect the parts to ensure that they are clean, if not then repeat the cleaning cycle.
- Visually inspect all parts for damage. If damaged, discontinue use and consult your health care provider.

## REASSEMBLE

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- Insert the Therapy Selector with attached Flow Valve into the Curved Tube. (See Figure 10)
- Make sure that the notch on the Therapy Selector aligns with the opening on the Curved Tube. (see Figure 11)
- Adjust the Therapy Selector to the setting your health care provider has previously advised. (Position 1-5) (see Figure 12)

