

Instructions For Use

READ ME FIRST!



PARI O-PEP SYSTEM

For Single Patient Use (One Person) Only

CAUTION

U.S. Federal Law restricts this device to sale by or on the order of a physician. Read all warnings and instructions before use. Improper use can result in serious or fatal illness or injury. PARI O-PEP device is not sterile.

WARNING

1. To reduce the risk of increased bacterial growth, infection, illness or injury from contamination, thoroughly clean and dry all parts of the PARI O-PEP at the end of every treatment following the included instructions.
2. Close supervision is necessary when this product is used by or near children and physically or mentally impaired. Never use when sleeping or drowsy.
3. This product contains small parts that may present a choking hazard to small children. **ALWAYS USE CLOSE ADULT SUPERVISION WHEN ADMINISTERING A TREATMENT TO A CHILD. DO NOT LEAVE CHILD UNATTENDED DURING TREATMENT.**
4. Before use, inspect the PARI O-PEP for proper assembly as indicated in these instructions. Use of improperly assembled PARI O-PEP could diminish the effectiveness of the treatment.

INTRODUCTION

Positive Expiratory Pressure (PEP) therapy has been shown to be beneficial for opening of airways in the lungs, and can assist with secretion clearance. It may also be used as a substitute for pursed-lip-breathing in order to promote muscle strengthening and endurance. Such therapy requires a controlled breathing technique that results in an increase of air pressure in the lungs when exhaling. One effect of such an increased pressure is that air can be pushed slightly deeper into the lungs, where it may help to loosen secretions, which can then be coughed up.

O-PEP OPERATING PRINCIPLE

The PARI O-PEP (Oscillating Positive Expiratory Pressure) is a respiratory therapy device designed for temporary application to mobilize secretions or mucus in the lower respiratory tract, strengthen the respiratory tract and alleviate shortness of breath. The patient exhales repeatedly into the device against a movable ball, causing a vibration that is transmitted to the lungs. This causes the deeper respiratory tract to open. By doing this, the lungs are exercised and secretions are mobilized and able to move up the airways.

The O-PEP produces a range of oscillation frequencies between 6 and 20 Hz, which corresponds to the range of the pulmonary resonant frequencies in humans. The efficacy of the O-PEP relies on attaining oscillation frequencies in this range during treatment.

The oscillation frequency produced by the O-PEP when in the horizontal position is approximately 15 Hz. This frequency can be adjusted by changing the incline of the O-PEP slightly up to reach a higher frequency, or down to reach a lower frequency from its original horizontal position. Patients can adjust the O-PEP to the resonant frequency by selecting a tilt angle that results in the best transmission of vibrations to the airways.

INDICATIONS FOR USE

The PARI O-PEP is intended for use as a Positive Expiratory Pressure Device, and is designed to help patients improve secretion clearance. The PARI O-PEP is intended for adult and pediatric patients ages 5 and older, for use in home, hospital, and sub-acute institutions.

CONTRAINDICATIONS AND SIDE EFFECTS

O-PEP must not be used by individuals who are coughing up blood or suffering from pneumothorax, right ventricular insufficiency or tuberculosis.

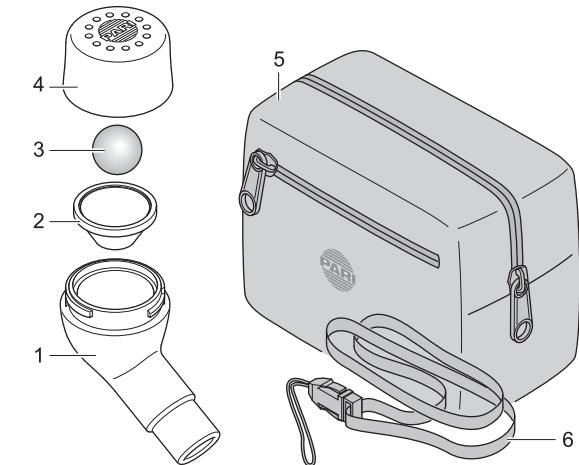
The following side effects can occur: dizziness or lung over-expansion.

If you notice any of these side effects, discontinue the treatment immediately. Contact your doctor or therapist to discuss how to proceed with treatment. Inform your doctor or therapist if you notice any side effects that are not listed in these instructions for use.

GETTING STARTED

1. Make sure that you have all of the components illustrated (See Components Section). If not, contact the dealer where you purchased your PARI O-PEP.
2. Read these Instructions for Use. Make note of all warnings and safety instructions. If you do not understand any portion of these Instructions for Use, contact PARI Patient Connection at 1.800.FAST.NEB (327.8632), then press 2.
3. Clean your PARI O-PEP System prior to first use as described on page 5.

COMPONENTS



(1) Lower part with mouthpiece

(2) Funnel

(3) Ball

(4) Upper part

(5) Carrying Case

(6) Lanyard

HOW TO USE PARI O-PEP

WARNING

To reduce risk of injury and improper treatment, you must be alert throughout the PARI O-PEP therapy in order to control your breathing technique and to dispose of any secretions that are coughed up. This device is not recommended for children under 5 years of age. The creation of a higher-than-recommended pressure in the lungs may, in some circumstances, result in injection of air into the pleural space around the lungs (pneumothorax), which could lead to lung collapse. To reduce risk of pneumothorax and lung collapse, avoid excessive "pushing" when exhaling.

Use Only According To Your Physician's Instructions

ASSEMBLING THE PARI O-PEP

1. Attach the lanyard to the lower part (FIG. A).

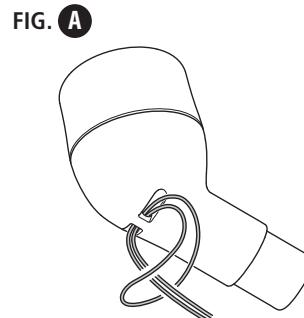
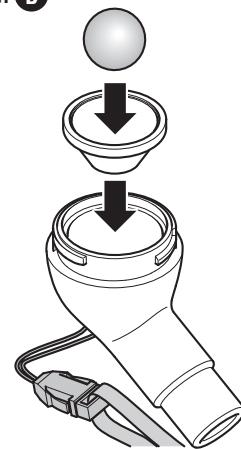


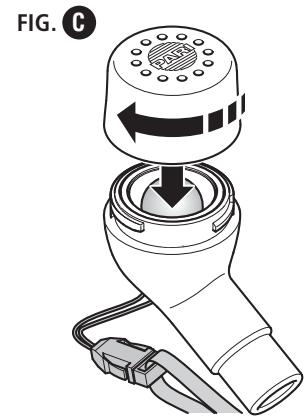
FIG. B



2. Insert the funnel in the lower part (FIG. B).

3. Place the ball in the funnel (FIG. B).

4. Screw the upper part onto the lower part (FIG. C).



You have the option of using the lanyard to prevent the PARI O-PEP from falling or being dropped during treatment. Children should always be supervised when using the O-PEP especially when used with the lanyard.

PERFORMING TREATMENT

FIG. D



1. Sit in a relaxed, upright position.
2. Support the PARI O-PEP and hold it so that the mouthpiece is horizontal to the floor.
3. Slowly inhale and then place your lips tightly, but comfortably around the mouthpiece. (FIG. D)
4. Make sure that the holes in the upper part are unobstructed and not covered by your hand.
5. Breathe out slowly and completely through your mouth and into the PARI O-PEP slowly and for as long as possible. As you do this, tense your cheek muscles and keep your cheeks taut.
6. Remove the PARI O-PEP from your mouth to inhale (do not attempt to inhale through the device).
7. Repeat the cycle of breathing in and out for 10 to 15 breaths. End the treatment session if the exertion becomes too great.
8. Treatment will not be effective if the patient breathes in too rapidly or displays excess exertion to breathe.

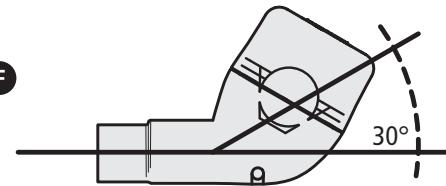
NOTE: The PARI O-PEP can be adjusted to the patient's resonant frequency by moving the O-PEP slightly up or down to achieve maximum vibrations. See Figures E and F. These vibrations in the lungs can be felt as the patient exhales. After establishing a comfortable position, the patient can begin therapy.

FIG. E



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FIG. F

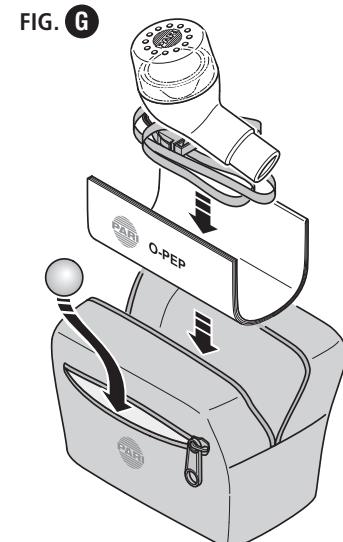


CLEANING THE PARI O-PEP SYSTEM

1. Disassemble the PARI O-PEP and rinse the parts with warm, running tap water for about 10 seconds.
2. Place the parts in a solution of warm tap water and liquid dish soap for 5 minutes.
Note: Do not use chlorine bleach or other chlorine-containing products or detergents.
3. Rinse the parts thoroughly with warm, running tap water for about 30 seconds.
4. Air dry the parts on a clean, lint-free cloth. Reassemble PARI O-PEP when dry and store.

STORING THE PARI O-PEP SYSTEM

1. After cleaning your PARI O-PEP, store it in the nylon case as shown (FIG. G).



Discard your PARI O-PEP after 6 month's use

Manufactured for:
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