

Dear patient,
The entire package leaflet must be read carefully because of the content of the important information of the usage of this respiratory therapy device. If further questions occur, please contact your doctor or pharmacist.

Contents:

- main part with mouthpiece
- funnel
- stainless steel ball
- vented screw-on headpiece
- instruction manual

Fields of application

resi is a device for respiratory therapy that helps to loosen sticky, viscous bronchial slime, even with constricted airways. resi is intended for use by patients with obstructive airway diseases, such as chronic bronchitis, chronic obstructive bronchitis or similar ailments.

Principle of action and scheme

The respiratory therapy device is a small, pipe-shaped product consisting of a mouthpiece, a funnel, a stainless steel ball and a perforated headpiece. At rest (without respiratory movement), the stainless steel ball closes the funnel. When the patient exhales, a positive expiratory pressure (PEP) is created in the device and the airways. The PEP prevents the airway from collapsing through resi and increases until it is large enough to move the stainless steel ball so that it rolls up the wall of the funnel (Figure 1). Exhaling through the resi creates vibrations that increase the pressure in the bronchial tubes - down to the deepest branches - and vibrate the exhaled air so that the mucus is loosened from the bronchial walls and can be better transported away toward the mouth.

This movement clears the way through the funnel and allows the pressure or air to escape. Then the stainless steel ball falls back and closes the opening in the funnel again. This causes the pressure to build up again in the unit (Figure 2). The process repeats rapidly during exhalation, causing the bronchi to vibrate with oscillating positive exhalation pressure (OPEP). Tilting up or down causes the stainless steel ball to move faster or slower.

Contraindications

The therapy device is **not** to be used if the patient suffers from a pneumothorax. (A pneumothorax is an abnormal collection of air in the space between the lung and the chest wall. This may lead to a partial or complete collapse of one of the lung lobes.)

Warnings

The material used for the construction of resi is impact-resistant but breakable under high use of force. Please be careful: dropping the device on a hard surface (e.g. tiles) can cause damage. Especially the stainless steel ball and other parts of the resi are not to be put in the mouth (Caution, choking hazard!). Do not sterilize the device with gas with ethylene oxide, hot air, hydrogen peroxide or radiation! The device will be melted or destroyed in a microwave vaporizer! If too much pressure is built up in the ball body, it blowback may cause damage to the teeth.

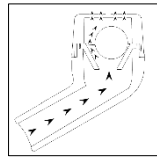


Figure 1

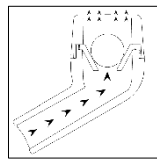


Figure 2

Side Effects

No side effects will occur by using resi as described. In case of elevated breathing speed, mild dizziness and numbness can occur around the mouth and in the hands. If these side effects occur, the use of the device must be stopped immediately. The symptoms will subside after a few minutes with normalized breathing. Dangerous overpressure in the lungs is not created during the use of resi because exhaling forcefully will lift the stainless steel ball out of the funnel, clearing the way for air and the pressure to escape. The pressure generated during slow and relaxed breathing is only slight and amounts to pressure fluctuations of about 10 – 25 cm water column. For patients with a sensitive bronchial system, this has no irritating effect on the airways.

Note

Please report all serious incidents directly to the manufacturer and to relevant national authorities.

Application instructions

To enable a successful airway therapy, please always follow the instructions. Adult supervision is recommended during usage and cleaning by children.

Before the first use

We recommend cleaning resi thoroughly and allow it to dry before using it for the first time. Recommended cleaning with hot water containing soap or dish soap and rinsing completely. Once resi is dry, it can be assembled as described in the next paragraph:

- Take the main part ① in your hand.
- Place the funnel ② in the indentation provided.
- Place the stainless steel ball ③ in the funnel.
- Screw the head part ④ to the main part. The screw connection is tight when both semicircular marks on the head and main part form a flush circle (Figure 3).

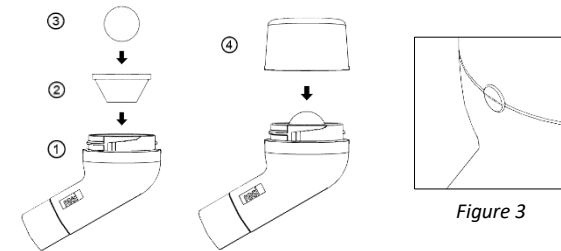
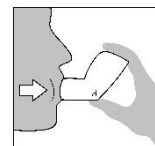


Figure 3

Using resi

1. For the best possible success we recommend sitting relaxed on a table with your elbows on the top. Please make sure not to cover the holes of resi while holding it in your hands
2. Put the mouthpiece in your mouth.
3. Inhale slowly and relaxed through the nose and hold this breath for 1 - 2 seconds.
4. Then breathe out slowly and for as long as possible via the mouthpiece. Make sure to keep your cheeks taut by tensing the muscles.
5. Keep the device in your mouth and repeat step 2 and 3, do not to strain or breathe rapidly.
6. You are using resi correctly, when you feel distinct, thumping vibrations in the chest. You may need to raise or lower the device to determine the ideal position.



7. If you should experience a coughing impulse, try to huff the mucus loosened by the application of resi up as if you were breathing on a pane of glass. With this so-called “huffing” you avoid strained coughing, which in turn would make it more difficult to remove the mucus, since the bronchi are being constricted due to the coughing.

Frequency of use

Our recommendation is to apply resi several times a day.

Cleaning of resi

For hygienic reasons, we recommend that resi is used individually.

1. Cleaning the device at home

Clean the device daily to keep it hygienically clean and avoid contamination with germs. Cleaning instructions:

- Disassemble the device.
- In case of severe dirt accumulation in the device, we recommend pre-cleaning with water and soap or dish soap
- All 4 components of resi should now be placed in boiling tap water for 3 minutes. Make sure that all components are completely submerged.
- Let resi dry under a clean cloth in a warm place (overnight recommended).
The device can also be cleaned in the dishwasher.

2. Cleaning in a clinical setting, etc.

Disinfection through immersion in a disinfectant is possible, as long as the manufacturer’s instructions are followed. Experimental testing has demonstrated effectiveness with conventional alcohol-based disinfectant (70 % ethanol content). Cleaning with a vaporizer is recommended. In addition, autoclaving up to 134°C with superheated steam is possible. resi is also suitable for cleaning in the dishwasher.

Storage instructions

The medical device should not be stored below 0°C and above 50°C (ideal: room temperature) and should be kept away from children!

Disposal instructions

Dispose resi in the household waste. Packaging and instructions in the paper waste.

Technical characteristics

The OPEP device weighs approx. 58 g. The stainless steel ball for generating the oscillation weighs approx. 28 g. The pressure generated in resi by exhalation of the user can be varied between 10 – 25 cm water columns. When using resi while it is in a horizontal position, the frequency at which the stainless steel ball oscillates during expiration is approximately 15 Hz.

Material

resi is made of POM and is dyed blue (BLUE RAL 5002).

	Anel AG Weyermannsstrasse 12 3008 Bern, Switzerland		Lot designation		Medical device
	International Associates Auditing & Certification Limited The Black Church, St Mary's Place, Dublin 7, D07 P4AX Ireland EUAR@ie.ia-net.com		“Usable until”		Protect from sunlight
	State of information: 03.02.2023		Follow the instructions for use		For reuse on a single patient
					Temperature limits