

oxyhero
CPAP pro



Instruction manual

Delivery includes



1 oral shield device; 1 storage box; 2 thermometer strips; 1 instruction manual.

Fitting



Instruction manual

1. What is the oxyhero CPAP pro shield and what is it used for?

The oxyhero CPAP pro is a combination of an oral shield- and an anti-snoring mouth guard made of thermoplastic material. It is inserted into the mouth to prevent air leaking out of the mouth („mouth leaks“) during CPAP therapy.

2. Intended use and scope of application

Intended use

The oral shield device is used to prevent mouth leakage. Mouth leakage occurs when the air introduced into the upper airway via a CPAP (Continuous Positive Airway Pressure) escapes through the mouth.

Mouth leakage can occur when a patient suffering from obstructive sleep apnoea is receiving therapy using CPAP and their upper airway is connected to the ventilation system via a CPAP nasal mask or nasal pillow mask.

Area of application

The oral shield device is used for mouth leaks that occur during therapy for obstructive sleep apnea (OSA) when using CPAP. It can be used with all types of CPAP masks, the most common application is together with CPAP nasal masks and CPAP nasal pillow masks. The oral shield device can be used with CPAP devices, but also with APAP (autoCPAP), BIPAP or VPAP devices.

The use of the oral shield device is not recommended in the following instances.

- If the oral shield device cannot be attached to the upper jaw with sufficient stability e.g. if a removable full or partial denture is worn; or if less than 4 of the 6 anterior teeth (incisors and canines) are firmly in place.
- If braces must be worn at night in the front part of the mouth.
- During severely and permanently impaired nasal breathing, or when CPAP ventilation through the nose is not possible.
- During acute inflammations or injuries to the mouth or dental area (in this case, however, the usage must be temporarily suspended only, i.e. until you have recovered from these impairments).

3. What is the target group for therapy with the oxyhero CPAP pro?

Therapy with the oxyhero oral shield device is intended for patients with obstructive sleep apnoea who are being treated with a CPAP device and who experience air leakage through the mouth (so-called mouth leaks). As a result, their CPAP therapy is either not effective because the required therapeutic pressure cannot be built up or the therapy only works with a very high ventilation pressure, which is difficult for the patient to tolerate and there is a risk that they

will discontinue the therapy or at least not comply with the instructions for use.

4. Performance characteristics of the product and expected clinical benefit of the therapy

Performance characteristics

The oxyhero oral shield device mechanically prevents air from escaping through the mouth. Breathing air or ventilated air, which is introduced into the body via the nasal airways as part of CPAP therapy, cannot escape through the mouth. Air enters and leaves the body exclusively via the nasal opening and thus via the CPAP ventilation system connected at that point.

Expected clinical benefit of the therapy

A reduction or complete elimination of mouth leaks in CPAP therapy. This provides more efficient respiratory support for the patient.

5. Risks and undesirable effects

- Spitting out: If the ventilatory pressure in the upper airway is too high, the patient may unconsciously spit at the oxyhero shield. As a consequence mouth leaks may reoccur, until the shield is replaced.
- Slight burns in the event of improper fitting: If the detailed instructions for fitting the shield are not followed, slight burns may occur under certain circumstances. Fitting requires working with hot

water at 65° Celsius.

- Ingestion: Accidental swallowing of the shield is not possible. The dimensions of the shield are too large for it to be easily swallowed. In addition, the increased air pressure in the upper airways due to ventilation means that the shield is always under pressure to be pushed out of the mouth and never inwards towards the throat.



If the adverse side effects persist, discontinue use of the mouthguard and seek medical advice.

6. Preparatory Measures - Fitting

Before the first use, the oxyhero shield must be customized to fit the patient's bite.

General Information

The water bath for fitting the oxyhero oral shield device must have a temperature of 65° Celsius. If the water temperature is too low, the material of the shield will not be softened sufficiently in the water bath and cannot be customized correctly. If the water temperature is too high, the material of the shield becomes too soft very rapidly once it has been immersed and loses its structural stability. It can then easily clump together and becomes unusable.

Fitting

1. First clear your nasal passages, using a nasal

douche if necessary.

2. Perform the fitting in front of a mirror.

3. Practice inserting the oxyhero oral shield device into your mouth and gently bite down on the bite plate of the shield. When doing so, make sure that the two air holes are facing down. Don't worry if the unmoulded shield feels large and bulky - the fitting process will make it much smaller.

4. **a** Please prepare the following: a medium-sized, heat-resistant bowl, about 1.5 l of boiling water and half a glass of tap water (cold to lukewarm; about 150 ml), a fork / spoon and a timer (smartphone clock / stopwatch).

5. First, pour the glass of tap water into the bowl. Now stir the water in the bowl with the enclosed temperature measuring strip and slowly add the hot water and continue to steadily stir it with the temperature measuring strip **b**. It is important to add the hot water slowly because there is a 15 second delay before the temperature indicator on the gauge changes colour. Rapid pouring can result in the display still showing 65° C, for example, but the actual water temperature may already be significantly higher.

Please continue pouring and stirring until the white temperature field on the measuring strip with the designations „65 °C“ turns black **c**.

6. As soon as the field marked „65 °C“ has turned black, please stop the supply of hot water

immediately. Remove the temperature measuring strip from the water. Now immerse the shield in the hot water for 60 seconds. After approx. 40 seconds, the shield will start to become waxy soft and after the 60 seconds have elapsed, the unmoulded shield can easily be shaped (note: the unmoulded shield must not change its shape as a result of the heating, in particular it must not start to shrink dramatically - this would be a sign that the water is too hot or that the unmoulded shield has been heated for too long). When the time is up, carefully lift the shield out of the water from underneath with a fork or spoon **d**.

NOTE: Ensure all hot water is completely removed from the oral shield device. Otherwise there is a risk of burning.

CAUTION: Before inserting, always perform a check (e.g. by holding it briefly against the wrist)

to ensure the oral shield device will not cause burns to the mouth.

IMPORTANT: Please note that the shield must not remain in the hot water for too long. Otherwise, the material would soften too much and there would be a risk that the unmoulded shield would become severely misshapen. This can cause problems when inserting it into the mouth or, in the worst case, make the unmoulded shield completely unusable.

7. Now take the shield in your hand at one of the two tapered ends **e**. Please make sure that the different parts of the shield do not touch each other (for

example, the ends) **f**. The points of contact would immediately stick together and make the shield unusable. So please do not press the shield together!

8. IMMEDIATELY insert the shield onto your upper teeth, with the holes facing downward. Gently bite down on the bite plate and close your lips around the shield.

9. Suck your lips and cheeks in POWERFULLY against the shield and at the same time press the plate on the inside upwards against the palate with your tongue. Hold this position for about 60 seconds. If necessary, also press the shield upward against the outside and inside of the front teeth of the upper jaw with the thumb and index finger of both hands. The shield should fit snugly against the outside of your upper row of teeth and the inside of the palate and be fairly tight **g**.

10. Rinse the shield under cold water and then reinsert it to check the fit. You should be able to close your lips comfortably with only a discreet sensation of pressure.

11. If necessary, repeat steps 5-10 until the oxyhero oral shield device fits comfortably. Please use a new temperature measuring strip for the new fitting, as each strip can only be used once.

Note: You can mould the oxyhero oral shield device with a commercially available floating thermometer (instead of the enclosed temperature measuring strips). The target temperature for moulding the

shield is 65° Celsius.

7. How do I use the oxyhero oral shield device correctly?

The oxyhero oral shield device is worn together with a CPAP nasal mask or CPAP nasal pillow mask.

Before inserting the shield into your mouth, i.e. before going to bed, clear the nasal passages, e.g. with a nasal douche. Rinse the clean shield briefly with cold water and insert it in the front of the mouth (please bear in mind that at first, it may take a few nights until you have become fully accustomed to the shield and no longer feel as though you have a foreign body in your mouth). Then put on the CPAP mask and start ventilation.

The shield should be rinsed with cold water after each removal from the mouth. Please follow the cleaning instructions.

8. How do I determine whether the oxyhero oral shield device is effective or being used correctly?

The easiest way to find out is to ask your sleeping partner whether air continues to escape through your mouth during sleep. The shield does not hermetically seal the mouth, but allows minimal pressure equalization via the two small air holes. They prevent excessive pressure from building up in the mouth and prevent the shield from being forced out of the mouth too easily. This protection against excess pressure

does not affect the effectiveness of the shield. It is normal for small amounts of air to escape through the mouth via the air holes. If you are sleeping alone, resort to the following methods.

The CPAP device continuously records data on ventilation pressure. From this data, it is also possible to determine (if necessary with the support of the treating sleep laboratory / sleep physician) whether there are any air leaks.

Finally, a dry mouth in the morning indicates that there was a continuous flow of air through the oral cavity during sleep. i.e. that air has escaped through the mouth.

9. How do I deal with the functional challenges of using the oxyhero oral shield device?

Spitting out at night

If the oxyhero oral shield device has not been inserted correctly, i.e. does not adhere tightly to the upper teeth, it may be spat out during use. Mouth leaks may occur as a result. In this case, clean the shield and insert it again. If it still does not fit tightly, the fitting process must be repeated.

In a few cases, the shield is spat out during sleep despite a tight fit. This usually occurs at the beginning of therapy, when the body has not yet become accustomed to the change in breathing. In this case, the user should allow a few weeks for the body to

become accustomed to the shield.

Pressure points due to the shield on the soft tissue that connects the upper lip to the gum

After successful fitting, the oxyhero oral shield device may feel too large and/or cause pressure on the gums and the soft tissue that connects the upper lip to the gum (labial frenulum). This reduces the patient's propensity to wear the shield. Check the fit of the shield. If it is too large for your mouth, carefully trim the edges with a sharp knife or sharp scissors at the pressure points. Finally, check that it fits correctly.

Distortion due to heat

If the oxyhero oral shield device is exposed to excessive heat over a long period of time or is stored in an environment that is too hot (especially with direct sunlight), it may deform. It then becomes unusable and must be replaced.

10. In what situations should I seek medical advice?

We recommend consulting your doctor before using the oxyhero oral shield device if you suffer from one of the following conditions or find yourself in one of these following situations.

- Nasal breathing is permanently, severely impaired (► ENT physician / sleep laboratory).
- Patient uses a removable partial denture / full

denture or night braces in the mouth or jaw area (► Dentist).

- Acute inflammation or injury in the mouth or dental area (► dentist)
- Technical problems with the fitting of the oxyhero oral shield device (► here we recommend asking your dentist or ENT specialist to take over or assist with the fitting - they may charge you for this service).

11. Proper cleaning, care and storage

Cleaning and care

For daily use, rinse the oxyhero oral shield device exclusively with cold water and store it in a cool, dry place in the plastic box provided. At regular intervals, but at least once a week, the shield should be cleaned with an antibacterial mouthwash.

To do this, dilute the mouthwash with lukewarm water and clean the shield with a soft toothbrush. Then rinse the shield carefully with cold water.

Please do not soak or immerse the shield in the mouthwash for a longer period of time. The surface of the shield is sensitive and may be damaged by the mouthwash.

For cleaning, please do not use off-the-shelf commercial cleaning tablets designed for dental or maxillary prostheses or cleaners for braces. These are too aggressive for the soft surface of the shield

and will corrode or damage it.

Storage

Please store the oxyhero shield in a cool and dry place in the storage box supplied, out of the reach of children and pets. The lifespan of the shield is usually 18-24 months. Special stress (severe bruxism (teeth grinding), high oral acidity...) can significantly shorten the lifespan.

12. How do I determine whether the oxyhero oral shield device is still fit for use?

If the surface of the shield is cracked, broken or otherwise damaged, it must be replaced. Please use your household waste to dispose of shields that are damaged or need to be replaced.

Should a serious incident occur in connection with the fitting or use of the oxyhero oral shield device, please report it to the competent authority in the EU country you reside in and to the manufacturer.