



Instruction manual

Delivery includes



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

Fitting



Instruction manual

1. What is the somnipax shield mouthguard and what is it used for?

somnipax shield is a mouthpiece/guard combination made from thermoplastic material. It is worn in the front of the mouth to prevent breathing through an open mouth while sleeping.

The mouthguard prevents simple velar snoring (primary snoring).

somnipax shield is a class 1 medical device, Regulation (EU) 2017/745.

2. Intended use and scope of application

Intended use

The mouthguard is used to prevent simple 'velar' snoring. Velar snoring occurs when the air flowing through an open mouth causes the slackened tissue at the soft palate to vibrate. These vibrations are the sound we recognise as snoring.

Scope of application

The mouthguard is used for simple velar snoring. It is used to prevent breathing through the mouth during sleep and to switch the body over to natural nasal breathing. As the flow of air is prevented from passing through the open mouth, slackened tissue at the soft palate is no longer caused to vibrate. Snoring does not occur. somnipax shield may only be used for these purposes.

The mouthguard should not be used if any of the following apply:

- If the mouthguard cannot be firmly positioned against

the upper and lower jaw in a way that is sufficiently stable. E.g. if a full or partial removable denture is worn; or if fewer than 4 of the 6 front teeth (incisors and canines) are firmly in place.

- If braces must be worn on the front teeth at night.
- If nasal breathing is significantly and permanently impaired.
- If there is any acute inflammation or there are wounds/injuries present in the mouth or dental area (although if that is the case, the patient only needs to suspend use temporarily, i.e. while the impairment is active).

3. Who is mouthguard treatment for?

Treatment with a mouthguard is aimed at patients who suffer from simple 'velar' snoring. They experience snoring because inhaling and exhaling through an open mouth causes slackened tissue at the soft palate to vibrate. These vibrations are what we recognise as snoring noises.

Simple snoring does not cause interruptions in breathing during sleep. This means there is not a pathological sleep-related breathing disorder, but rather an impact on wellbeing. This is caused by the noise of snoring.

That being said, simple snoring can be a precursor to unhealthy forms of snoring (particularly obstructive sleep apnoea). Therefore, it is advisable to treat simple snoring yourself and to have it checked by a medical professional on a regular basis.

4. Product features and expected benefits of use

Product features

The mouthguard is a mechanical means to prevent

breathing through the mouth. The flow of air is redirected to natural nasal breathing. With no air flowing through the oral cavity, slackened tissues cannot be caused to vibrate and produce a snoring sound.

Expected benefits of use

A reduction or complete elimination of snoring caused by vibrations of the soft palate. As a result, the snorer and their sleeping companion are able to sleep undisturbed.

5. Risks and unwanted effects

- Spitting out: If, while exhaling, air pressure is too high in the upper airways, the patient may spit out the mouthguard without meaning to. As a consequence, the snoring may start up again until the mouthguard is reinserted.
- Minor burns to the skin, gums or tissue of the mouth if the mouthguard is not fitted correctly: If the detailed instructions for fitting the mouthguard are not followed, minor burns to the skin, gums or tissue of the mouth can potentially occur. Fitting requires using hot water at a temperature of approx. 65° C.
- Swallowing: It is not possible to accidentally swallow the mouthguard. The mouthguard is so large that it cannot easily be swallowed.

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

6. Preliminary steps – fitting

Before the first use, the mouthguard needs to be fitted to the patient's teeth.

General information

The water used to fit the mouthguard must be at a temperature of 65° C. If the temperature of the water is too low, the mouthguard material will not soften enough in the water and will not be easily moulded. If the temperature of the water is too high, the mouthguard material will very quickly become too soft and it will lose its shape and structure. It can then readily form into clumps and become unusable.

Fitting

1. First clean your nasal passages, using a neti pot if necessary.
2. Position yourself in front of a mirror.
3. Practise inserting the mouthguard into your mouth and bite down lightly on the plate on the inner side with your teeth. When doing this, make sure that the two air holes are facing downwards. Don't worry if the blank mouthguard feels large and bulky – it will be much smaller after the fitting.
4. Please prepare the following: a medium-sized, heat-resistant bowl, approx. 1.5 l boiling water and half a glass of tap water (cold to lukewarm; approx. 150 ml), a fork/spoon and a timing instrument (smartphone stopwatch / clock) **a**.
5. First pour the glass of tap water into the bowl. Now stir the water in the bowl using the thermometer strip enclosed and slowly add the hot water. Keep stirring continuously with the thermometer strip **b**.

It is important to add the hot water slowly because the temperature indicator on the thermometer strip changes colour with a time delay of about 15 seconds. Pouring water in quickly can mean that although the display is still showing 65° C, for instance, the actual temperature of the water is already much higher. Please continue pouring and stirring until the white temperature field on the thermometer strip labelled „65 °C“ turns black **c**.

6. As soon as the field labelled „65 °C“ has turned black, please stop pouring in hot water immediately. Remove the thermometer strip from the water. Now immerse the mouthguard in the hot water for 60 seconds. After approx. 40 seconds, the mouthguard starts to become soft and once the 60 seconds have elapsed, the blank mouthguard can easily be shaped (note: its shape must not change as a result of heating, in particular it must not start to shrink significantly – this would be a sign that the water is too hot or the mouthguard has been heated for too long). When the time is up, carefully lift the mouthguard out of the water from underneath, using a fork or spoon **d**.

NOTE: Ensure all hot water is completely removed from the mouthguard. 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 mouthguard will not cause burns to the mouth.

IMPORTANT: Please note that the mouthguard must not remain in hot water for too long. Otherwise the material will become too soft and there is a risk the mouthguard will become significantly deformed. This can cause issues

when inserting it in the mouth, or at worst make the blank mouthguard completely unusable.

7. Now take the mouthguard in your hand at just one of the two tapered ends **e**. Please be careful to ensure that no parts of the mouthguard touch one another (for example the ends) **f**. The points making contact would immediately stick together and make the mouthguard permanently unusable. So please do not press any parts of the mouthguard together.

8. Insert the mouthguard onto your upper jaw IMMEDIATELY with the holes facing downwards. Gently bite down on the plate on the inner side and close your lips around the mouthguard **g**.

9. Suck your lips and cheeks HARD into the mouthguard and at the same time press the plate on the inner side upwards against the roof of your mouth with your tongue. Hold this position for about 60 seconds. If needed, also press the mouthguard upwards against the front and back of your front teeth on the top jaw using the thumb and index finger of both hands. The mouthguard should sit closely against the front of your top row of teeth and the roof of your mouth and form quite a tight fit .

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

11. If necessary, repeat steps 5–10 until the mouthguard fits comfortably. Please use a new thermometer strip for each new fitting, as each strip can only be used once.

NOTE: You can also carry out the fitting using a standard floating thermometer (instead of the enclosed thermometer strips). The target temperature for fitting the mouthguard is 65° Celsius.

7. How do I use the mouthguard correctly?

The mouthguard is worn at the front of the mouth. To improve nasal breathing, the mouthguard can be used together with a nasal dilator or nasal strip, for instance.

Before inserting the mouthguard, i.e. before going to bed, clean your nasal passages, e.g. with a neti pot. Rinse the clean mouthguard briefly with cold water and insert it in the oral vestibule (the area between the teeth, lips and cheeks). (Please bear in mind for the first few applications that it may take a few nights until you are fully used to the mouthguard and no longer experience the sensation of a foreign object when wearing it).

The mouthguard should be rinsed with cold water each time you take it out of your mouth. Please follow the cleaning instructions.

8. How do I determine if the mouthguard is effective and/or being used correctly?

The easiest way is to ask your sleeping companion whether snoring noises continued to occur while you were asleep. The mouthguard does not seal the mouth hermetically, but allows minimal balance of pressure via the two small air holes. These prevent too much pressure from building up in the oral cavity and the mouthguard from being pushed out of the front of the mouth too easily.

This protection against excess pressure has no effect on the effectiveness of the mouthguard. It is normal for small amounts of air to escape through the mouth via the air holes. This might be perceptible as light breathing noises. If you sleep by yourself, you can use a smartphone app to record your snoring. This can help you check whether the therapy is working effectively. A dry mouth in the morning is also an indication – albeit a less decisive one – that breathing was taking place through an open mouth and snoring probably continued.

9. How do I deal with impaired functioning of the mouth-guard?

Spitting out during the night

If the mouthguard has not been inserted properly, i.e. does not adhere firmly enough to the top jaw, it may be spat out during use. Consequently, the body can revert back to mouth breathing, which causes snoring. Should this happen, clean the mouthguard and reinsert it. If it still does not form a tight fit, the fitting process must be repeated.

In rare cases, the mouthguard is spat out during sleep despite forming a tight fit. This usually occurs early on in use, 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 adapt to the mouthguard.

Pressure points at the front of the mouth (at the frenulum) due to the guard

It may be that following a successful fitting the mouthguard feels too large or presses onto the gums

within the oral vestibule and onto the frenulum. You consequently feel less willing to wear the mouthguard. Check the fit of the mouthguard. If it is too big for your mouth, carefully trim the edges at the pressure points with a sharp knife or scissors. Check that it fits correctly.

Deformation due to heat

If the mouthguard is exposed to excessive heat over a long period of time or is stored in too hot an environment (especially in direct sunlight), it can become deformed. It then becomes unusable and must be replaced.

10. When should I seek medical advice?

If any of the following apply, we recommend consulting your doctor before using the mouthguard.

- Nasal breathing is significantly and permanently impaired (► ENT doctor)
- Patient uses a full or partial removable denture or night-time braces in the mouth or jaw area (► dentist)
- Acute inflammation or wounds/injuries in the area of the mouth or teeth (► dentist)
- Technical issues with fitting the mouthguard (► here we recommend asking your dentist or ENT doctor to take over or assist with the fitting)

11. Correct cleaning, care and storage **Cleaning and care**

For everyday use, rinse your mouthguard with cold water only and store it in a cool, dry place in the plastic box provided. At regular intervals, and at least once a week,

the mouthguard should be cleaned with an antibacterial rinse. To do this, dilute the rinse with lukewarm water as specified by the manufacturer and clean the mouthguard briskly with a soft toothbrush. Then rinse the mouthguard thoroughly with cold water.

Please do not soak the mouthguard in the rinse for an extended period of time. The surface of the mouthguard is delicate and could otherwise be damaged by the rinse.

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 mouthguard and will corrode or damage it.

Storage

Please store the mouthguard in a cool, dry place in the storage box provided, out of reach of children and pets. The lifetime of the mouthguard is usually 18–24 months. Extra stress (severe bruxism, high oral acidity...) can significantly shorten its lifetime.

12. How can I determine if the mouthguard is still ok to use?

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