

Instruction Manual

Positional therapy shirt for prevention of snoring and sleep apnoea

1. Was ist das somnipax shirt und wofür wird es angewendet. What is the somnipax shirt and what is it used for?

The somnipax shirt is a positional therapy device used to relieve simple snoring caused by back-sleeping (also known as tongue snoring) as well as mild to moderate position-dependent sleep apnoea.

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

2. Intended use and scope of application

Intended use

The positional therapy shirt is used to prevent position-dependent snoring and interruptions in breathing during the night. Snoring occurs when the tissue in the upper airways slackens and narrows the airway. The air flows faster at the points of constriction and causes the surrounding tissue to vibrate. This is the sound we recognise as snoring.

In the case of interruptions in breathing during the night, the slackened tissue does not just narrow the airway but at times actually fully or partly obstructs it. Breathing stops for a short

time.

Scope of application

The somnipax shirt is used to prevent snoring caused by sleeping on the back and mild to moderate position-dependent sleep apnoea.

It should not be used:

- during recovery from intervertebral disc surgery
- by users with severe spinal issues
- positional vertigo
- position-independent central sleep apnoea
- by persons under 18 years of age

If you have any doubts or concerns (e.g. due to possible interactions between a medication and the positional therapy), please talk to your doctor.

3. Who is therapy with the somnipax shirt intended for?

The positional therapy shirt is aimed at two patient groups. Firstly, patients with mild to moderate, position-dependent obstructive sleep apnoea. In these people, sleeping on their back causes the tongue muscle to fall backwards into the throat, obstructing the airway. This leads to interruptions in breathing.

Secondly, the therapy is aimed at patients with simple, position-dependent snoring (so-called primary snoring). With this

type of snoring, also known as tongue snoring, the tongue slackens when the patient is in a back-sleeping position, falls backwards into the throat, and narrows the upper airways. Air turbulence at the points of constriction causes the tissue of the throat to vibrate, resulting in snoring.

4. Product features and expected clinical benefits of therapy

Product features

The somnipax shirt keeps the patient lying on their side during sleep with the help of the positioning wedge. The slackened tongue base muscle can no longer close off or significantly narrow the throat.

Expected clinical benefits of the therapy

Snoring and/or pauses in breathing triggered by sleeping position are reduced or completely eliminated – meaning undisturbed breathing while you sleep.

5. Risks and undesirable effects

It takes approx. 1-2 weeks to acclimatise to the somnipax shirt. If discomfort of the spine or other supporting structures (especially in the shoulder, neck, or throat area) should occur during use, talk to your doctor before continuing with the therapy.

6. Preparatory measures

Before use, it must be ensured the shirt is a close fit against the body. Hence, it should not be ordered too large and, if in doubt, a smaller size should be selected.

Before use, insert the positioning wedge into the wedge pocket on the back of the T-shirt.

Ensure the wedge has been completely inserted and the zip is closed.

7. How do I correctly use the somnipax shirt?

The somnipax shirt is worn directly against the body. The fit of your somnipax anti-snoring T-shirt should be comfortably snug. Therefore, there should be no loose clothing (such as pyjama tops) worn underneath. This ensures the positioning wedge sits centrally in the back area, and for this reason the somnipax shirt should not be ordered too large.

Before use, always insert the positioning wedge (hard foam roll or air cushion) into the pocket on the back of the positional therapy shirt.

The somnipax shirt should be cleaned regularly. Please follow the care instructions (see item 11.).

8. How do I know if the somnipax shirt is effective and/or is being used correctly?

Habitual snoring

The easiest way to do this is to ask your sleeping partner whether you are now sleeping on your side or stomach and whether you are continuing to snore while you sleep (please note that even with effective anti-snoring therapy, a certain residual noise level can persist due to natural breathing noises).

If you sleep alone, smartphone apps can be used to record snoring. These can help you check whether the therapy is working effectively. A dry mouth in the morning is also an indicator – albeit a weaker one – that breathing took place through an open mouth and snoring probably continued.

Obstructive sleep apnoea

Here too, your sleeping partner can be asked whether you are now sleeping on your side or on your stomach and whether interruptions in breathing are still occurring. Since treatment for obstructive sleep apnoea is always under the supervision of a doctor, however, this assessment will not be enough. Your doctor will also need to determine whether the therapy is effective (sleep endoscopy examination / polygraphy).

9. What do I do if the positional therapy shirt doesn't function correctly?

The positional therapy shirt slides around

If the positional therapy shirt is not a snug fit against the body,

there is a risk that the positioning wedge will not rest centrally on the back. In this case the wearer might still manage to sleep on their back – meaning the therapy would be ineffective.

In such cases, the positional therapy shirt is usually too large. A smaller size should be selected.

The positional therapy shirt does not keep you on your side

If the positional therapy shirt does not keep you on your side, please check that the shirt is a snug fit and that the positioning wedge has been fully inserted.

The positional therapy shirt is damaged or the positioning wedge is defective

If the positional therapy shirt is torn or the positioning wedge is defective, please stop using the shirt immediately and replace the defective part. Slight defects on the positional therapy shirt (e.g. loose threads on hem or elsewhere) do not usually affect the function of the shirt.

10. In which situations should I seek medical advice?

If any of the following apply, we recommend talking to your doctor before using the somnipax shirt:

- Severe obstructive sleep apnoea (► ENT doctor / treating sleep laboratory)
- Spinal discomfort (► orthopaedic specialist)
- When it is unclear whether the obstructive sleep apnoea

or tongue snoring is position-dependent (► ENT doctor / treating sleep laboratory)

11. Correct cleaning, care, and storage

Cleaning and care

Remove positioning wedge (air cushion or hard foam roll) from the rear insert pocket and wash the positional therapy shirt on a machine wash at 60°C. Put on a low spin and hang up to dry.

Storage

Please store your positional therapy shirt in a dry place away from direct sunlight.

12. How do I know whether the positional therapy shirt can still be used?

If the positional therapy shirt is torn or otherwise damaged, it must be replaced. The same applies if the back padding (air cushion or hard foam roll) is damaged or defective. Shirts and/or back padding that are damaged or need to be replaced should be disposed of within your household waste.

13. Manufacturer information

Manufacturer

AescuBrands UG (limited liability)
Im Gewerbegebiet 5

91093 Heßdorf, Germany
www.aescubrands.com
info@aescubrands.com

Should any serious incident occur in connection with your use of the somnipax shirt, please report it to the appropriate authorities in your country of residence as well as to the manufacturer.

14. Scope of delivery and revision status of the instructions for use

Delivery includes

- 1 somnipax shirt
- 1 positioning wedge (air cushion or hard foam roller), not included with replacement T-shirts
- 1 package information leaflet

Revision status of the package information leaflet

This package information leaflet was last revised: 03 / 2022