# SomnoCushion<sup>®</sup> Standard

Medical device for the treatment of habitual snoring in the supine position and and position-dependent mild moderate obstructive sleep apnea.

## Instructions

#### (Read carefully before use)



Description: The SomnoCushion® backpack is worn during sleep. It encourages you to sleep on your side and prevents you from turning onto your back during the night. In contrast to sleeping on your side, sleeping on your back can promote snoring and nightly breathing interruptions. The backpack cover contains a mouthinflatable air cushion for positioning. Individual adjustment options for the air cushion pressure and strap tension in the stomach and shoulder area ensure a high level of comfort. First insert the deflated cushion into the backpack cover either from above or below. Then inflate the air cushion with your mouth so that the backpack cover is completely filled. Press the valve into the air cushion. Adjust the straps so that SomnoCushion<sup>®</sup> is centered on your back as tightly as possible and without any slack.

## Indications:

- Habitual, position-dependent snoring
- Position-dependent mild and moderate obstructive sleep apnea (after medical consultation)

## Contraindications:

- (Severe) spinal complaints
- Convalescence period after back or intervertebral disc surgery
- Positional vertigo
- Position-independent sleep apnea
- Age under 18 years

## Warnings:

- Snoring can be a symptom of breathing arrest. The cause should therefore be clarified by a doctor before starting treatment.
- Particularly in patients with nocturnal breathing arrests due to obstructive sleep apnea, the therapeutic effect of the positioning therapy should be checked by appropriate diagnostic measures quite soon after the beginning of treatment.
- In the case of obstructive sleep apnea, existing heart disease, significant overweight or back problems, SomnoCushion<sup>®</sup> should only be used under medical supervision.
- SomnoCushion<sup>®</sup> should not get in contact with injured skin.

Care instructions: Wash the fabric cover at 60°C and at a low speed frequency, do not spin-dry, only air-dry. The air cushion must be removed before washing the backpack cover.

Material: Backpack cover 65 % polyester and 35 % cotton; Straps 100 % cotton; Adjuster 100 % nylon; Air cushion 100 % PVC

LOT 300.1124.0E	MD Medical device
<b>REF</b> Art. No.: 05017343	Warnings
Follow instructions for	or use
UDI (01) 426	60383460235 <del>8.1121.8E</del> -
97 A 🖓 🛶 🤆	Manufacturer:
	Tomed GmbH • Medical Products
Date of information: 04.11.2024 Doc. No.: UI.SCS.1124.GE.01	Im Rapsfeld 57 • 50933 Köln (Cologne) • Germany
	Tel.: +49 221 17067206 • Fax: +49 221 17067207
	Email: info@tomed.com • www.tomed.com

Doc. No : ULSCS 1124 GE 01

The product meets all the provisions of the CE Medical Device Regulation 2017/745 which apply to it.