

CLINICAL EFFICIENCY

The **AlaxoStent** has been multiply examined for its medical efficacy. The first clinical study in the sleep laboratory of the ENT University Hospital of Erlangen, Germany (by Dr. Michael Hartl, MD) confirmed its therapeutic efficiency and acceptance by patients.

The **AlaxoStent** reduced the number of obstructive apneas as efficiently as CPAP therapy. Hypopneas were significantly or completely reduced, too.

	without therapy	with AlaxoStent	with CPAP
AHI	31/h	19/h	8.2/h
obstructive apneas	43.0	2.2	2.5
minimal oxygen saturation	79%	84%	89%

Numerous propofol sleep video endoscopies (PSE) – which allow precise localization of the airway collapses in the throat and at the tongue base in an artificial sleep – also have visualized the high effectivity of the **AlaxoStent**.

The published PSE study by Dr. János Juhász (Hospital Mainburg, Germany) demonstrates a very strong and elongated concentric collapse (left image). The soft palate and the complete throat musculature fully collapse during sleep. The **AlaxoStent** effects a continuous air passage (right image) which enables unobstructed breathing and thereby abolishes the sleep apnea.



The AHI of this patient was reduced from 74/h to 5/h.

INDICATIONS

The **AlaxoStent** is a clinically tested and CE marked prescription medical device for treatment of obstructive sleep apnea.

The attending doctor has to examine if the **AlaxoStent** is a suitable therapy for the patient. First self-application of the **AlaxoStent** by the patient shall be carried out in the presence of the physician.

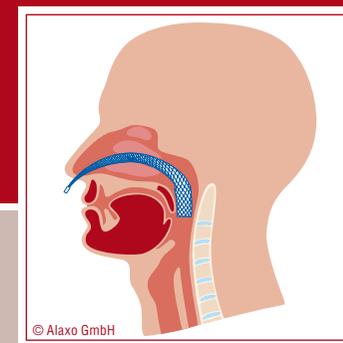
HOW DO I GET THE ALAXOSTENT?

The **AlaxoStent** can be purchased by residents in the territory of the CE mark. It is especially not yet available in the U.S. Residents of other countries may inquire at Alaxo as we are continuously expanding the network of sales partners in various regions of the world.

The attending physician shall perform testing of the **AlaxoStent** therapy with each patient. In case the patient and the physician are satisfied with the results the physician will prescribe the **AlaxoStent**.

Please contact us in advance before sending any prescription in order to buy the respective **AlaxoStent** Set. We first need to ensure that we are allowed to deliver to your country. The CE mark allows sales in all countries of the European Union but not automatically in other countries. We can deliver only to self-pay patients.

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Therapy of sleep apnea and snoring with the **AlaxoStent**

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THERAPY OF OBSTRUCTIVE SLEEP APNEA

The nCPAP therapy (nasal Continuous Positive Airway Pressure) so far is the gold standard in treatment of obstructive sleep apnea (OSA). CPAP has been successfully applied for more than two decades. The patient is ventilated during sleep by a pump and a face mask with pressurized air.

Acceptance of CPAP therapy by patients is too low so that many patients remain untreated and in a high risk of complications (e.g. diabetes, high blood pressure, heart attack, stroke). Use of the CPAP mask constitutes a significant discomfort for many patients and their partners.

Further, adaptation of the mask is labourious, and partly a full face mask is required. To avoid drying out of the mucosal tissue frequently a humidification unit is necessary in addition. Cleaning is quite time-consuming. Should the mask not tightly fit then therapeutic efficiency is affected.

DURING TRAVEL THE CPAP SYSTEM IS UNFAVOURABLE:

- » requires considerable space and contributes significant weight to baggage
- » always needs a power socket
- » is in need of explanation at airport security control.

Besides CPAP therapy especially ENT surgical procedures and oral appliances have found broader application. Yet, these are only applicable for mild to medium OSA.

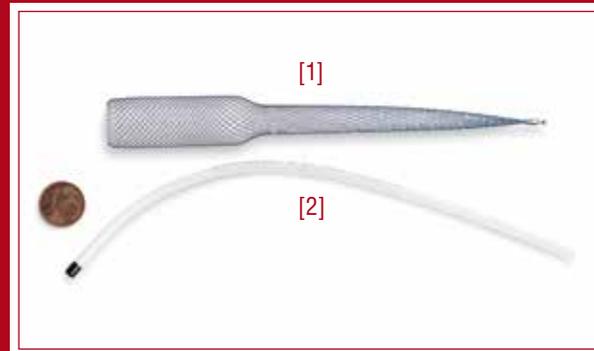
Oral appliances can treat only a tongue base collapse but not the very frequent velopharyngeal collapse.

Surgical treatments frequently provide a limited period of efficacy only. Therefore, such surgical procedures should be used only with special care. Generally, in view of the new non-surgical treatment options those should be preferred.

THE AlaxoStent

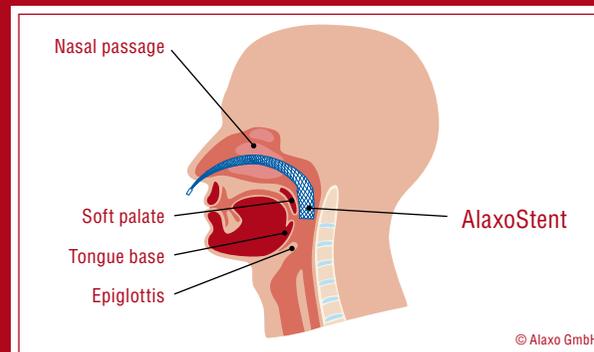
The AlaxoStent is a medical device for treatment of obstructive sleep apnea (OSA) and snoring that the patient himself inserts at night and removes in the morning. It provides numerous advantages in handling and convenience to the patients.

The stent is a smooth tubular braid [1] made from a so-called shape memory metal (nitinol). This nitinol braid is compressed in a thin tube [2] before introduction into one nostril. This tube is slowly introduced through one nasal passage to the throat.



(For comparison a 1 Cent coin is shown)

When released from this tube, the nitinol braid self-expands and attaches to the wall of the throat. Thereby, the stent prevents collapse of the airway.



THE APPLICATION

The product has been developed upon the initiative of a German OSA patient. Therefore, it notably complies with the needs and desires of the users.

The patient can move freely with the stent applied. It is visually inconspicuous. Further, the patient and his partner are not incomedodated by the noise of the CPAP pump during the night.

Last but not least the patient maintains to breathe naturally and not artificially as with CPAP therapy which is a substantial advantage. Sleeping with an open mouth does not impose a problem.

Snoring usually is completely abolished.

DURING TRAVEL THE ALAXOSTENT IS ESPECIALLY ADVANTAGEOUS:

- » small volume
- » no electric power required
- » as experienced no problems at airport security control.

The AlaxoStent must be prescribed by a physician with sufficient knowledge in treatment of OSA. The doctor instructs the patient in the correct use of the AlaxoStent and tests success of the therapy.

The emotional hurdle of introducing the stent through a nasal passage into the throat is comparable with application of a contact lens to the eye. After education by the doctor and a short training period the patient according to experience can self-apply the stent safely and quickly.

In case of strong gag reflex sensitivity the AlaxoStent may not be the appropriate therapy.