

Clinical study

The AlaxoStent has been examined for therapeutic efficacy and patient acceptance by Dr. Michael Hartl, MD, head of the sleep laboratory at the University Hospital of Erlangen, Germany.

All participants were diagnosed OSAS patients who were already successfully treated for a longer time without problems by CPAP therapy (AHI index min. 20/h; BMI \approx 30).

The results of the clinical study have been published at the 79. and 80. Annual Meetings of the German Society of Oto-Rhino-Laryngology, Head and Neck Surgery.

	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%

The AlaxoStent reduces the number of obstructive apneas as efficiently as CPAP therapy. Hypopneas are significantly reduced, too.

Due to a low number of cases with AHI>40/h in the study CE certification has been limited to an AHI up to 40/h.

All patients who have tested the AlaxoStent in the clinical study in the sleep lab reported day sleepiness to be as low as with CPAP. Use of the AlaxoStent was described to be uncomplicated and subjectively comfortable.

Indications

The AlaxoStent is a clinically tested and CE marked prescription medical device for treatment of obstructive sleep apnea for patients of age 18 and higher with an AHI up to 40/h.

The attending doctor has to be sufficiently qualified in treatment of sleep apnea and has to examine if the AlaxoStent is a suitable therapy for the patient. First application of the AlaxoStent by the patient shall be carried out in the presence of the physician.

How do I get the AlaxoStent?

You may use the AlaxoStent if you reside in the territory of the CE mark, currently in German speaking countries. Alaxo is in the process of expanding its sales activities to countries with other languages.

Ask your attending physician for testing of the AlaxoStent therapy. The physician should contact us for further details. In Germany we already have a network of physicians to which we can refer you. Also in Austria and Switzerland we can refer to some physicians. Your physician will prescribe the AlaxoStent if the results of the test will be positive.

Please contact us in advance before sending the prescription in order to buy the respective AlaxoStent Set (Start Set for 3 months or Annual Set for 12 months). We deliver to self-pay patients.

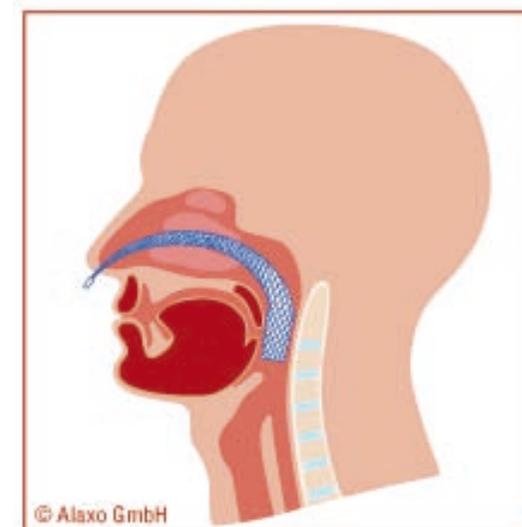
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Therapy of sleep apnea and snoring with the

AlaxoStent



Current therapy of obstructive sleep apnea

The nCPAP therapy (nasal Continuous Positive Airway Pressure) is today's gold standard in treatment of obstructive sleep apnea (OSAS). CPAP is successfully applied for more than two decades. By variation of the air pressure it is broadly applicable and individually adaptable.

Acceptance of CPAP therapy by patients in opposite is comparably low. The therapy is often terminated or even not commenced at all. Use of the CPAP mask constitutes a significant discomfort for patients and their partners.

Further, adaptation of the mask is laborious 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. For a walk to the bathroom during the night the mask has to be removed and subsequently to be correctly and tightly reapplied.

During travel the CPAP system requires considerable space and contributes significant weight to baggage. Also it always needs a power socket. At airport security control it is in need of explanation.

If the patient does not use CPAP therapy he or she remains in a high risk of complications (e.g. diabetes, high blood pressure, heart attack, stroke, etc.) due to lack of treatment.

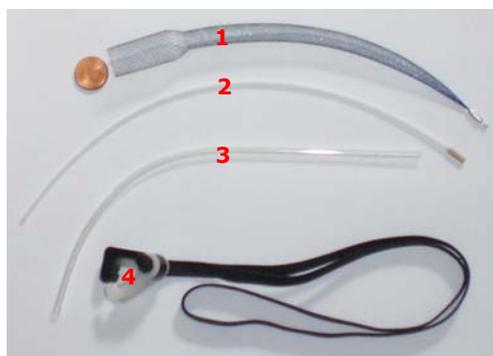
Besides CPAP therapy especially ENT surgical procedures have found broader application. Yet, these are only applicable for weak OSAS and provide a limited period of efficacy only. Some of the surgical procedures can lead to impaired or impossible applicability of CPAP therapy afterwards. Concluding, 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 maintains natural breathing. The airway is mechanically splinted so that the air can regularly flow into the lung. Thereby, the moisture content of the mucosa is not altered and drying out is avoided.

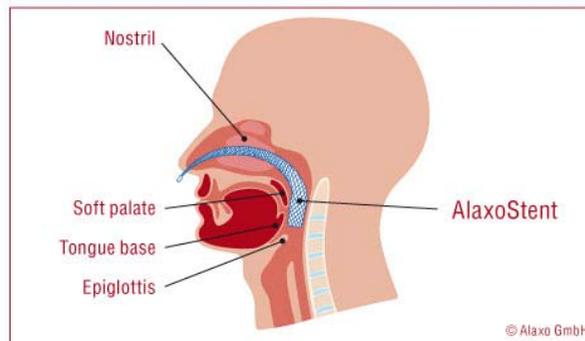
The major components of the AlaxoStent are:

- Nitinol braid (stent) [1]
- Introduction tube [2]
- Pusher [3]
- Clamp fastening [4]



(For comparison a 1 Cent coin is shown)

The AlaxoStent is a CE certified medical device. It has been developed and clinically tested for self-application by the patient. It may not be used outside of the territory of the CE mark.



Initiated by an apnea patient the AlaxoStent is comfortable, simple to use, noiseless and reliable in application.

The nitinol braid (compressed in a thin introduction tube) is self-introduced by the patient through one nostril to the throat and positioned at the upper tongue base above the epiglottis. Then the introduction tube is retracted from the nitinol braid. As a result the stent self-expands and splints the airway. Thereby it prevents obstructive apneas and snoring which result from relaxing tongue, soft palate and throat muscles.

With the stent applied one can move freely, walk to the bathroom without any problems, and the AlaxoStent is visually inconspicuous. 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, and as experienced no problems at airport security control.

Application of the stent is explained and trained by the attending physician. After a short training period the patient according to experience can self-apply the stent safely and quickly. In individual cases of strong gag reflex sensitivity the AlaxoStent may not be the right therapy.

Already in the 1980ies in the U.S. nasopharyngeal tubes have been successfully used for congenic mechanical splinting of the airway. Yet, long-term use of the polymer tubes lead to mucosal irritation. The AlaxoStent combines the advantages of the CPAP therapy with the advantages of the tube therapy. Only the smooth AlaxoStent braid made from thin metal wires transforms mechanical splinting instead of pneumatic splinting with CPAP into a successful and patient-friendly therapy.