

A First Line Treatment for Sleep Disordered Breathing



aveoTSD[®]
anti-snoring aid

Good Health through Quality Sleep

www.aveosleep.ca

Sleep Disordered Breathing Snoring & Obstructive Sleep Apnoea

Snoring and Obstructive Sleep Apnoea (OSA) are caused by the airway narrowing or even occluding during sleep. These sleep disorders pose a serious risk to personal relationships and health. The aveoTSD is a medical device that has been clinically proven to treat problem Snoring and OSA.

What Causes Snoring ?

Snoring is caused by a narrowing of the upper airway during sleep due to any or all of the following:

- Large tonsils and uvula, a soft palate, and over-relaxed muscles and tongue falling back into the oropharynx.
- Snoring occurs because air travels faster through the narrowed airway causing the relaxed soft tissues of the throat (tonsils, soft palate, uvula or excessive flabby tissue) to vibrate. This vibration is the sound of snoring.
- In some cases, nasal congestion from allergies, nasal cavity deformities and internal obstructions, can contribute to narrowing of the airway.

Is Snoring harmful ?

Snoring may be symptomatic of Obstructive Sleep Apnoea (OSA). The word 'Apnoea' is Greek for 'without breath', where the tongue is completely sucked against the back of the throat and blocks breathing.

OSA signs & symptoms

- Snoring, gasping, irregular breathing during sleep
- Stopped breathing (apnoeic) episodes during sleep
- Morning Headaches
- Extreme daytime sleepiness
- Frequent nocturnal urination - Nocturia
- Night time Reflux / Heartburn / GERD
- Memory deficit
- Depression
- Hypertension / high blood pressure
- Diabetes

Increased risk factors for OSA

- Hereditary snoring is primary risk factor
- Male
- Large neck circumference:
Women > 40cm
Men > 43cm correlates with an increased risk of OSA
- Obesity, BMI > 30
- Diagnosis of hypertension
- Excessive use of alcohol or sedatives
- Smoking

Prevalence of Sleep Disordered Breathing


- 60% of Men and 40% of Women between 41 – 65 years old are habitual Snorers. Snoring increases greatly once people reach the age of 35 years. *Young T, Peppard PE, Gottlieb DJ. Epidemiology of obstructive sleep apnea: a population health perspective. Am J Respir Crit Care Med 2002.*
- Snoring and OSA is quite common in Children aged 2 – 7 , particularly at times of upper respiratory tract infection when the tonsils enlarge. *Ali NJ, Pitson D, Stradling JR. Natural history of snoring and related behaviour problems between the ages of 4 and 7 years. Arch Dis Child 1994.*
- Sleep Disordered Breathing is commonly experienced in Women during their later stages of pregnancy. *Santiago JR, Nolleto MS, Kinzler W, Santiago TV. Sleep and sleep disorders in pregnancy. Ann Intern Med. 2001.*

Obstructive Sleep Apnoea is directly linked to:

- Hypertension / Strokes
- Cardiovascular Disorders
- Diabetes
- Obesity
- Dementia / Memory problems
- Depression
- Reflux / Heartburn / GERD
- Nocturia
- Insomnia
- Nocturnal Asthma , COPD
- Impotence



Introducing aveoTSD®



Attaches to the end of the tongue, using gentle suction.

Available in 3 sizes, with different titration gradients available.

The aveoTSD has been approved by all food and drug, and therapeutic goods administrations in Australia, Canada, EEC, Japan, New Zealand and USA (by prescription only).

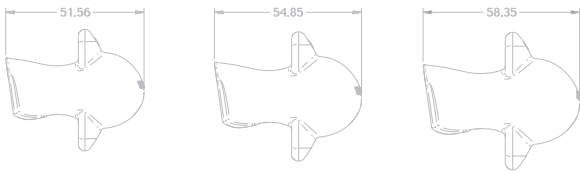
The aveoTSD is a treatment for SDB that Family Doctors, Dentists, Pharmacists and other Medical Practitioners can offer directly to their patients.

Is an intuitive fit and requires no specialist fitting. But, medical coaching advised.

aveoTSD is made from ISO 10993-1 medical grade silicone.

The aveoTSD supports a wider primary health care base and assists people who need specialist diagnosis to reach CPAP treatment.

aveoTSD® Sizes



aveoTSD is available in 3 sizes to fit a broad range of tongue sizes, the 'M' size which comes as the standard size unit, being found to fit the majority.

Less than 5% require the 'S' and 'L' sizes.

Please contact support@aveotsd.com for more information regarding sizes available

Warranty of the aveoTSD®

The aveoTSD comes with a six-month replacement warranty from the date of purchase for product defects determined to be caused by manufacture.

The life expectancy of the aveoTSD is 12 months. With proper use and care (daily rinsing etc.) this could stretch up to 24 months.

aveoTSD® Titration Accessory



aveoTSD Titration Accessory is available in 2 sizes.

The aveoTSD can be titrated by either 5mm or 9mm, increasing tongue protrusion to increase airway patency.

aveoTSD® Care & Cleaning

aveoTSD should be cleaned daily by rinsing in hot water.

Once a week the aveoTSD should be given a thorough wash, then rinse. Allow to air dry.

The aveoTSD can be sterilized by either cold sterilant or clinical procedures such as autoclave.

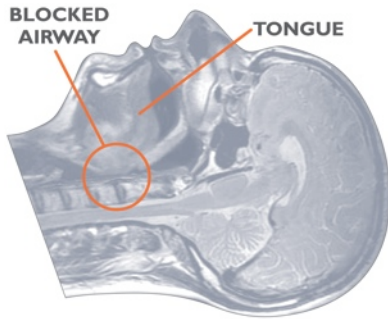
Mouth-wash to clean or store the device in, is not recommended as the liquid may contain alcohol which will damage the medical silicone used to manufacture the aveoTSD.

The aveoTSD® is a simple, inexpensive, non-invasive and clinically proven medical device to treat Sleep Disordered Breathing.

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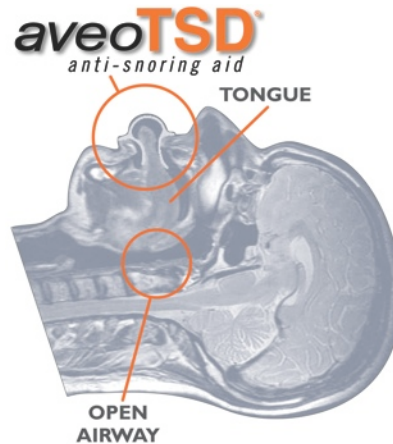
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How aveoTSD® Works



In this M.R.I.* image, the tongue falls to the back of the airway as a person lies asleep. This blocks the airway, leading to Obstructive Sleep Apnoea and /or Snoring.

*Magnetic Resonance Imaging
GE Signa Profile EXCITE 0.2T



This M.R.I. image shows the aveoTSD holding the tongue gently forward, preventing it falling back and obstructing the airway. Note how the airway is now open and clear. This stops or greatly reduces Snoring and prevents obstruction of airway, treating Obstructive Sleep Apnoea.

aveoTSD® Clinical Trials

aveoTSD has been clinically proven** to treat Mild to Moderate Obstructive Sleep Apnea.

**An independent clinical study on the aveoTSD was published in *SLEEP*:

Comparison of Mandibular Advancement Splint and Tongue Stabilizing Device in Obstructive Sleep Apnoea. A Randomised Controlled Study.

Sheryn A Deane, MDSc Ortho.; Peter A Cistulli, MD, PhD.; Andrew T Ng, MBBS.; Biao Zeng, MD, PhD.; Peter Petocz, PhD.; M Ali Darendeliler, PhD.

Department of Orthodontics, Faculty of Dentistry, University of Sydney, Sydney Dental Hospital, Sydney, Australia. Centre for Sleep Disorders and Respiratory Failure, St George Hospital, Sydney, Australia. *SLEEP*, Vol. 32, No.5, 2009.

A clinical study on the Tongue Stabilizing Device was published in *Sleep and Breathing*:

The Efficacy of a Novel Tongue Stabilizing Device on Polysomnographic Variables in Sleep Disordered Breathing: a Pilot Study.

Kingshott R., Jones D., Taylor D., Robertson C., *Sleep and Breathing*, Vol. 6, November 2002.

*Clinical study shows maximum Tongue Protrusion (aveoTSD) opens the airway by up to 140% more on a cross sectional area basis, comparatively, maximum Mandibular Protrusion (MAS / MAD's) opens the airway by up to only 40% more on a cross sectional area basis. *Effect of Mandibular and Tongue Protrusion on Upper Airway Size During Wakefulness.*

Kathleen A. Ferguson, Leslie L. Love, and C. Francis Ryan. *Am J Respir Crit Care Med* 1997.

Comparison of Polysomnographic Variables Between Baseline, MAS, and TSD. (Table from Sydney study, 2009.)

Variable	Baseline Mean ± SD	MAS Mean ± SD	p Value	TSD Mean ± SD	p Value
TST, min	400 ± 51	347 ± 77	ns	320 ± 97	ns
REM sleep, min	53 ± 22	63 ± 28	ns	53 ± 31	ns
NREM sleep, min	286 ± 41	283 ± 64	ns	269 ± 76	ns
Arousal Index/h	33 ± 16	21 ± 9	0.004	21 ± 11	0.001
Sleep efficiency %	80 ± 11	78 ± 17	ns	79 ± 11	ns
AHI/h	27 ± 17	12 ± 9	0.000	13 ± 11	0.002
MinSaO ₂ %	84 ± 7	87 ± 5	ns	88 ± 6	ns
Airway Vol., cm ³	15 ± 6	15 ± 6	ns	18 ± 6	ns

TST = total sleep time; AHI = apnea hypopnea index; MinSaO₂ = minimum oxygen saturation.

Clinically proven to open the airway more than other oral appliances on a cross-sectional area basis* through gentle tongue protrusion.

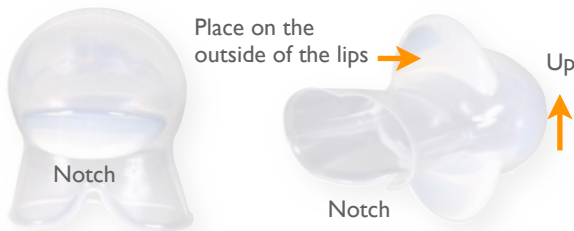
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aveoTSD® Fitting Guide

1. Preparing to fit the device

- The Regular (medium) size is recommended for most users. (More than 95% of users fit the medium size)
- Before use, rinse the aveoTSD under warm water. This helps to ease the device onto the patients' tongue.

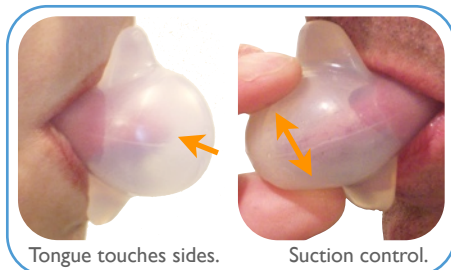


- Make sure the V-notch in the aveoTSD is facing down, to fit around the patients' lingual frenulum.
- In some extreme cases, a patient may require more room for the frenulum – the V-notch can be modified to provide this room. Please contact support@aveotSD.com .

2. Attaching the device to tongue

The device attaches through negative suction;

- Advise to push tongue gently into the aveoTSD, until the tongue just touches the sides of the device.



- Gently squeeze the upper and lower ends of the bulb with forefinger and thumb.
- By using a gentle repeated pumping action, the tongue will be drawn gently into the aveoTSD.
- Draw the tongue into the device until the device is firmly attached, not too tight and not too loose.
- This is important - too much suction will cause discomfort; not enough will cause the aveoTSD to fall off.
- Help patients practice getting used to the best fit (correct suction level) to ensure the aveoTSD stays on throughout the night.

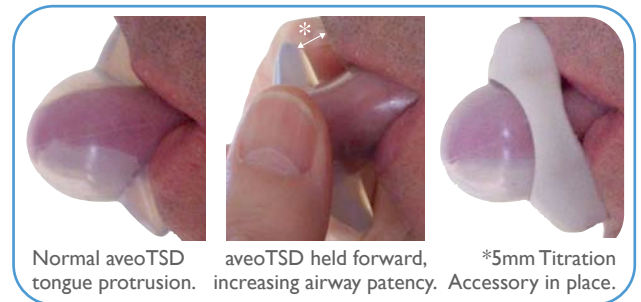
3. Recommend practice

To achieve optimum results:

- Do step 2 repeatedly to get the correct fit. This will help patients get accustomed to having the device attached to their tongue.
- Some patients adapt immediately to the aveoTSD, while others may take up to a week to adapt and achieve compliance.
- It is very important for the patient to be absolutely relaxed.

Trouble shooting

- Excessive salivation is common with some patients during the initial stages. This will subside over time. If the patient does find this a problem, recommend placing a towel over the pillow.



- If the patient continues to snore or the airway is still obstructed, there may be a need to get more of the tongue further forward to open the airway further. To achieve this, the patient may require a 'spacer' which is used to titrate or protrude the tongue further forward. Please contact support@aveoTSD.com .
- If the patient is unable to get a good fit, i.e., device keeps falling off, or device is too tight, a different size may be required.
- More than 95% of users will fall into the Medium size. If the person is obviously large or much smaller than average build, they would fall under the less than 5% of patients that require a smaller or larger version of the aveoTSD. See aveoTSD Sizes for more information.

Checking tongue-tied status:

- Ask the patient to stick out their tongue. This is to make sure their tongue is free-moving and the aveoTSD will be suitable.
- A small percentage of people cannot stick out their tongue beyond their lips. These are highly exceptional cases but very obvious. In such cases, the aveoTSD will not be suitable unless this is first resolved.

Medical Professional coaching increases compliance.

The patient should be made aware of how the aveoTSD® fundamentally works, i.e., it holds the tongue in a forward position during sleep, keeping the airway open.

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www.aveosleep.ca

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Ethics International Inc.

aveoTSD is sold worldwide:

Australia

Austria

Canada

Germany

Ireland

Japan

New Zealand

Qatar

Switzerland

Netherlands

United Kingdom

United States

More information: www.aveotsd.com



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