

aveoTSD[®]

anti-snoring aid

User Manual



Stop snoring. Sleep better. Get aveoTSD[®].

*aveo*TSD® User Manual Contents

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Introducing the *aveo*TSD[®]

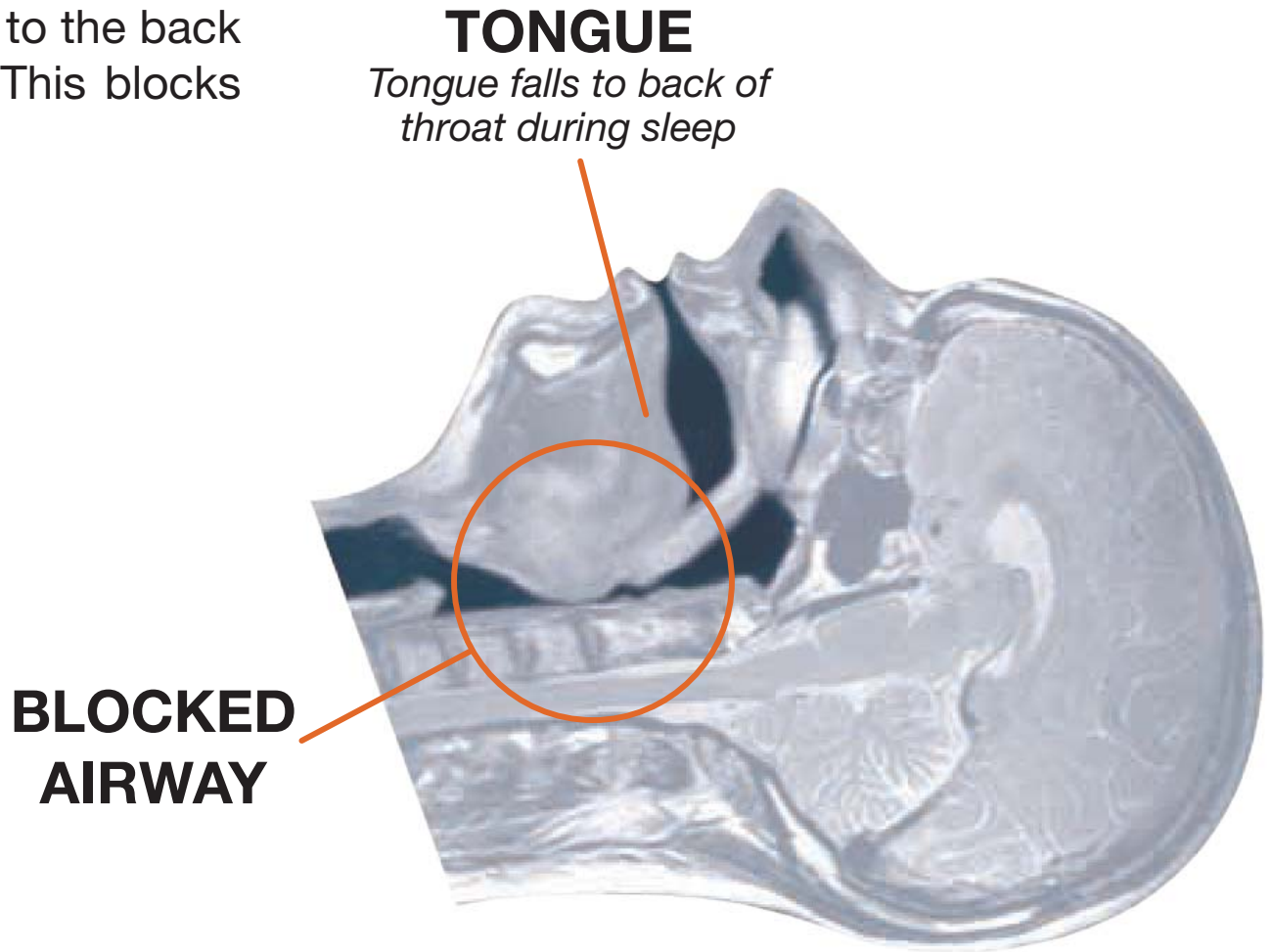
Tongue Stabilizing Device

The aveoTSD[®] anti-snoring device was developed after several years of clinical research on the treatment of problem snoring. Unlike traditional mandibular advancement devices, the aveoTSD does not attach to the teeth and does not require fitting by a dental sleep specialist.

The aveoTSD is cost-effective and easy to use. For many patients, it will eliminate or greatly reduce problem snoring, making it an effective anti-snoring treatment.

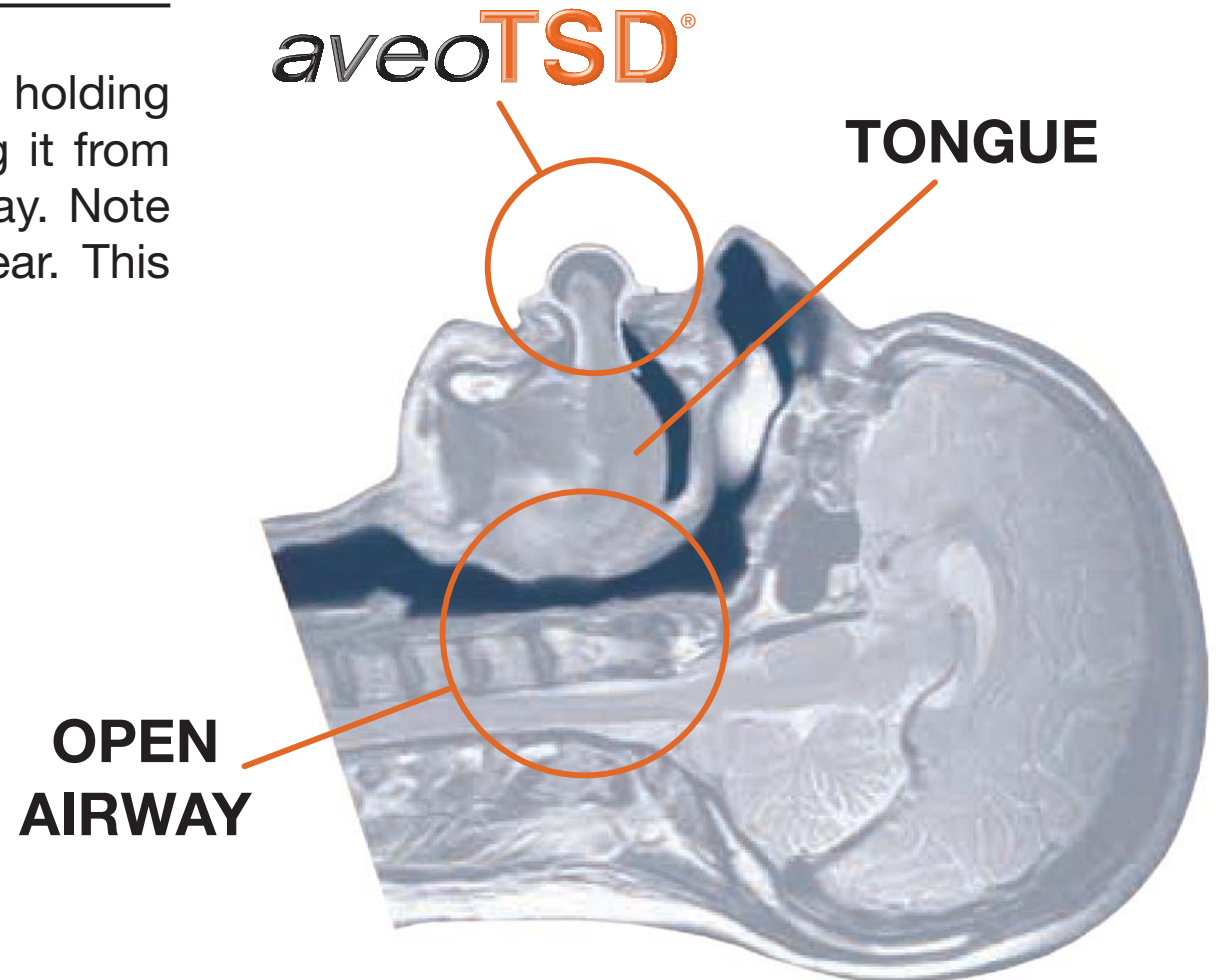
Without *aveoTSD*[®]

In this MRI image, the tongue falls to the back of the throat as a person sleeps. This blocks the airway, leading to snoring.



With *aveoTSD*[®]

This MRI image shows the *aveoTSD* holding the tongue gently forward, preventing it from falling back and obstructing the airway. Note how the airway is now open and clear. This stops or greatly reduces snoring.



aveoTSD[®] User Instructions

The aveoTSD[®] is a medical device used to treat problem snoring. It requires correct fitting so it can be used in the most comfortable manner. Carefully read the following instructions to ensure the best possible results from the aveoTSD anti-snoring device.



The V-notch fits around the lingual frenulum, which holds the tongue to the floor of the mouth.

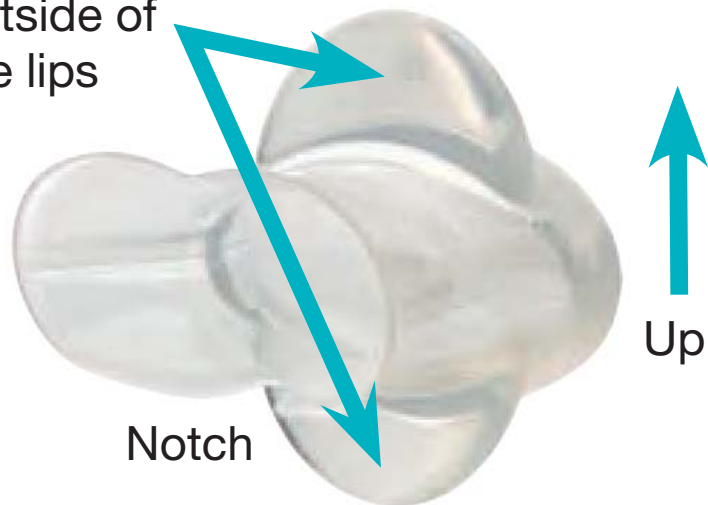
The tongue is free-moving and can easily change size, shape and position. It is unlikely you will damage your tongue with the aveoTSD device.

The aveoTSD is available in the U.S. by prescription from a dental or medical physician.

aveoTSD[®] User Instructions

1. Rinse the aveoTSD under hot water. This helps to ease the device onto the patient's tongue. Make sure the V-notch is facing down, as shown in the illustration below.

Place on the
outside of
the lips



2. Push tongue gently into the aveoTSD, until it touches the sides of the device.
3. Gently squeeze the upper and lower ends of the bulb between the forefinger and thumb.

aveoTSD[®] User Instructions

Note the changes in suction created. This is important: too much suction will cause discomfort; not enough suction will cause the aveoTSD to fall off during the night. Practice until the device is held firmly and comfortably.

By using a gentle repeated pumping action, the tongue will be drawn gently into the device. Make sure the device is not too tight or too loose.

4. Initially, keep the aveoTSD on your tongue for about 10 minutes at a time, adjusting it by increasing or reducing suction to find the most comfortable fit. This will ensure you are not pushing on the lingual frenulum,



which holds the tongue to the floor of the mouth.

5. Use of the aveoTSD may initially cause discomfort; however, this will subside. Experiment with the device to find the position and

aveoTSD[®] User Instructions

suction pressure most comfortable for you.

6. Suction the aveoTSD to the tongue in an agreeable position before going to sleep. Initially, it is easier to fit while sitting or standing.
7. To remove the device, press in on the sides to break suction. If you prefer, squeeze the bulb with your thumb on the bottom and forefinger on top.
8. After use, thoroughly clean and rinse the aveoTSD with hot water. Store in the container provided. Do not rinse or store the device in mouthwash or any other chemical



product that contains alcohol, as this may damage the medical silicone.

Extra support in using the *aveoTSD*[®]

Some people will be able to use the aveoTSD[®] comfortably within a couple of days. However, for most patients, it takes one to two weeks for discomfort to disappear. Perseverance with the aveoTSD will be rewarded!

As you achieve compliance, it is likely there will be a reduction in sudden awakenings or gasping for air during sleep. This will mean a good night's rest, giving you more energy through the day and a feeling of improved well being.

The aveoTSD will also provide less disturbance for your partner. However, it is possible because of anatomical features and/or other health-related problems that some people may

have difficulty using this device. If you are unable to use the aveoTSD, or symptoms persist, please contact your primary health care provider or dentist for further consultation.

For some people, perseverance and patience is needed, particularly for suction control. This skill will be learned over time.

My aveoTSD falls off – Adjust the aveoTSD onto the tongue until the device stays on and you get a good night's sleep.

Salivating – While awake, we swallow frequently. Asleep, we swallow much less. When something is placed between the jaws, saliva-

Extra support in using the *aveoTSD*[®]

tion is a normal response. Some people may salivate excessively with initial usage of the aveoTSD, but this side effect will reduce within a week or so of continued use.

My tongue has strong sensations – Adjust the aveoTSD by either withdrawing the tongue slightly or reducing the suction a little (see user instructions). Tilt or twist the device while it has suction OR move the aveoTSD slightly forward on the tongue. Tongue-tied users should consult their doctors to check whether minor procedure could free the tongue. This condition is very rare.

I have difficulty swallowing and a gagging sensation (along with salivating) – You may have your tongue extended too far. Move the unit back off the tongue slightly, to give the tongue a little more flexibility. Always discuss any problems with your primary health care provider or dentist.

aveoTSD® Issues, Solutions and Support Chart

A. Can use, but aveoTSD comes off during night

Too little suction. Move tongue farther into device to create more suction. Continued usage will reduce “falling off” within a few weeks.



Continue using the device, practice will improve skill.

Experienced by less than 20% of users

B. Can use, but aveoTSD creates sensation on tongue

Too much suction. Reduce suction and move tongue slightly out. Sensation will diminish or disappear as tongue becomes accustomed to the device.



Continue using the device, practice will improve skill.

Experienced by less than 15% of users

C. Have problems fitting aveTSD under tongue

Check on lingual frenulum and tongue-tied status with your doctor. A simple procedure can correct this issue.



Do not use the device for three days. Then try again, making sure the device is not irritating the lingual frenulum under the tongue, and that it feels comfortable. If there are also “B” symptoms, stop using device for three days, then try again.

Experienced by less than 15% of users

Tongue-tied less than 0.06% of users

aveoTSD® Issues, Solutions and Support Chart

D. Increased salivation

Most users will experience this initially, as salivating is automatic. After a week or so, the brain recognizes the device is not food and stops salivating.

> Persevere. Some people create more saliva than others.

Experienced by 80-95% of users

E. Cannot swallow with device in place and saliva builds up

Swallowing during sleep happens far less often than when we are awake. With the device in the mouth, saliva builds up. If the tongue is too stretched it is less flexible, so swallowing will be more difficult.

> Ease aveoTSD® off tongue slightly so that some flexibility returns to the tongue. When salivation reduces, so will the gagging feeling.

Experienced by less than 5% of users

F. Physical changes to aveoTSD

If the device smells, it may not be properly cleaned, or a dental check may be needed. If device looks different, ensure you are not using mouth-wash or alcohol-based cleaning agent, which can damage the device.

> Refer to care and cleaning (p.14).

Experienced by less than 0.01% of users

G. Tongue has changed color

This is linked to “B” on previous page. Reduce suction pressure on tongue by gently squeezing the aveoTSD and moving tongue slightly out of the device.

> Others have also experienced this. It is important to realize that in most cases, these symptoms are caused by the use of medication for treatment of high blood pressure or cholesterol.

Experienced by less than 0.01% of users

*aveo*TSD[®] Side Effects

No moderate or serious side effects have been reported. Reported side effects are temporary and occur only during initial practice and use. Refer to Issues, solutions and support chart if you have difficulty with initial usage.

During initial usage, should discomfort or other perceived side effects occur, stop using the aveoTSD until the cause is established.

Seek medical attention or review practice steps to correctly fit the device.

Anecdotal Observations

Disclaimer: The aveoTSD® cannot and does not make treatment claims on the medical conditions below, all of which have been published as health consequences of snoring. If you experience any of the medical conditions below, or are currently being treated for any of those conditions, please consult your doctor if usage of the aveoTSD reduces any symptoms.

Snoring reduced or stopped: Reduced tiredness and daytime sleepiness is one of the most reported benefits.

Nocturnal bathroom visits reduced/stopped: This also is a major benefit as quality sleep is obtained. Recent medical research finding substantiate this.

Blood pressure reduction: Improvement in blood pressure has been noted by doctors for many aveoTSD users. It is a published medical fact that snoring treatment can reduce blood pressure.

Problem snoring and GERD (heartburn and reflux) are known as partnership diseases. Use of the aveoTSD has helped reduce heartburn and reflux.

Depression: Some aveoTSD users and their doctors have found use of the aveoTSD improved their symptoms of depression, allowing reduced pharmaceutical treatment, which benefits the patient. Some aveoTSD users with Night Asthma and COPD have reported improvement from those problems when snoring is treated. A number of aveoTSD users with nasal blockage have reported clearance of the nasal passage with use of the device.

Many aveoTSD users have reported increased good health, allowing them to exercise and better control their diet. (Obesity is currently becoming a general sleep research topic along with diabetes linked to habitual snoring.)

Keep your primary health care provider or dentist informed of aveoTSD usage if you are being treated for any of the above health conditions.

aveoTSD[®] Care and Cleaning

Keep the aveoTSD[®] clean by rinsing it daily in hot water. Do not use mouthwash to clean or store the device, as alcohol will damage the medical silicone used to manufacture the aveoTSD.

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

Once a week, give your aveoTSD a thorough wash, then rinse. Use denture cleaning solution to give it a weekly or monthly wash for long-term use.

To release seal of container:



Squeeze sides



Ease apart



Remove device

Warranty

Innovative Health Technologies (New Zealand) Ltd. will provide a six-month replacement warranty from the date of purchase for product defects determined to be caused by the manufacturer.

The aveoTSD is a medical device used to treat problem snoring. (See Frequently Asked Questions on p.17 for more information.)

The device is clinically proven and has regulatory approvals to be marketed as a Class 1 medical device in Australia, Canada EEC, Hong Kong, Japan, New Zealand, USA and other countries. Patents have been granted in those countries.

The aveoTSD can be prescribed to patients via a dentist or medical physician, who can also advise on problem snoring and its potentially serious health consequences. This advice may also include a visual anatomical check to ensure the device fits properly.

Users of the aveoTSD need one to three days, occasionally more than two weeks, to achieve compliance.

Warranty

Practice and perseverance is needed for all medical devices. Some people are able to adapt to their use quickly; others require more practice and sometimes professional or medical assistance.

Innovative Health Technologies (New Zealand) Ltd. cannot therefore warranty compliance usage issues. Usage is a personal matter in ensuring the device works properly.

Innovative Health Technologies (New Zealand) Ltd. has an ongoing post-development support program to improve the product. The program also aims to improve correct usage

(compliance) through instructions to health professionals and users. Further user support will be obtained from professional and user feedback as product usage widens.

The aveoTSD product life has not yet been established, but 12 months use should be a minimum, provided proper care is given to the device.

Users should follow instructions in this booklet and are advised to seek early advice and/or treatment if problems arise.

Frequently Asked Questions

What causes snoring?

Snoring is caused by a narrowed airway during sleep. This can be due to large tonsils or a long soft palate or uvula. Overweight people who have excessive flabby tissue in the throat also experience snoring. All of these areas relax during sleep.

As well, nasal congestion from allergies or deformities of the cartilage between the two sides of the nose, or other internal nasal obstructions, can contribute to narrowing the airway.

However, the most common cause of a narrowed airway is a tongue muscle that becomes too relaxed during sleep, and gets sucked back into the throat with each breath (refer to MRI images). Snoring occurs because air travels faster through a narrow tube than through a broad one. This rapidly moving air causes the relaxed soft tissues of the throat (tonsils, soft palate, uvula or excessive flabby tissue) to vibrate. It is this vibration that is the sound of snoring. By keeping the airway open, air travels more slowly, reducing throat vibrations, and thus reducing or stopping snoring. One of the most effective ways of keeping the airway open during sleep is by holding the tongue forward.

Is snoring harmful?

New research suggests that problem snoring can cause hypertension and, as a result, increased blood pressure during sleep.

This airway obstruction causes the heart rate to fall below normal, with decreases in blood-oxygen levels. The obstruction will not clear until the brain oxygen level falls low enough to partly wake the sleeper with a release of adrenaline. This is an automatic body reaction, and is intended to prevent suffocation.

The airway obstruction is usually broken with one or several often loud gasps to take in fresh air. Due to the adrenaline release, the heart rate is increased above normal.

This event may happen hundreds of times a night for someone suffering from problem snoring, which means the sleeper does not get a deep, restorative sleep.

Most common causes of snoring

- A tongue that becomes too relaxed during sleep
- Large tonsils, long soft palate or uvula
- Being overweight: A recent study showed that a 10 percent weight gain may lead to a six-fold increase in the likelihood of developing habitual problem snoring
- Nasal congestion from colds, allergies or deformities of cartilage in the nose
- Smoking, alcohol or medication (which causes drowsiness)
- Hypothyroidism: Due to a lack of thyroid hormones, sufferers tend to have a large tongue as well as increased fat deposits in the tissue of the upper airway
- Menopause: Post-menopausal women were shown to have more than twice the risk of problem snoring

Snoring has been linked to an increased risk of:

- High blood pressure
- Cardiovascular disorders
- Depression
- Impotence
- Reflux and heartburn
- Obesity
- Diabetes
- Strokes
- Memory problems

How many people suffer from problem snoring?

More than 60 percent of the adult population has some form of problem snoring, particularly among those age 50 and older. As people age, the tissue in the upper airway loses its elasticity and tends to vibrate more during breathing, increasing the sound of snoring. It also reduces the airway size, and during sleep the tongue is more easily sucked into the back of the throat, obstructing the airway.

At least 60 percent of men and 40 percent of women over the age of 40 snore. Snoring is also quite common in children between the age of 2 and 7, particularly if they have a chest infection or enlarged tonsils.

Snoring is also commonly experienced by women during the latter stages of pregnancy. Snoring can also lead to a condition known as Obstructive Sleep Apnea.

aveoTSD[®] development/history

We spend one-third of our lives asleep, and the quality of that sleep has a real impact on our quality of life.

Problem snoring can be treated, but until now, a treatment that is simple to use, noninvasive and cost-effective was not available.

The aveoTSD[®] was developed over several years, with the last few years being spent developing the current model designed by Dr. Chris Robertson of New Zealand. Dr. Robertson is an internationally recognized researcher in Sleep Medicine. “Aveo” is Latin for “be well.”

Quality of sleep and sleep medicine are relatively new areas within health care, with a growing awareness of the serious health consequences of problem snoring.

It is now recognized that snoring is a health warning, and the ability to diagnose and treat sleep-related problems associated with snoring means many people now have a greatly enhanced quality of life.

Australia
www.aveotsd.com.au

Austria
www.aveosleep.eu

Canada
www.aveosleep.ca

Germany
www.aveosleep.eu

Ireland
www.tlcperformance.org

Japan
www.aveotsd.com

New Zealand
www.aveotsd.co.nz

Qatar
www.lnnomed-intl.com

Switzerland
www.aveosleep.eu

The Netherlands
www.stoppenmetsnurken.nl

United Kingdom
www.aveosleep.co.uk

United States
www.getaveo.com

aveoTSD[®]

anti-snoring aid

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Australian Patent No. AU776822

Canadian Patent No. CA2432023

European Patent No. EPI349521

Japanese Patent No. JP544615/2001

Hong Kong Patent No. HK1060041

New Zealand Patent No. NZ526404

United States of America Patent No. US7073506

International Patents (Pending)

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