

The Happy Sleep device:

The Happy Sleep device is a patent protected oral mandibular advancement device for treating snoring and regaining a peaceful night's sleep.

Designed by world-renowned sleep medicine expert, A/Prof. Dr Jack Gerschman, the Happy Sleep device has proven to be effective in managing snoring in clinical studies, and is compliant with TGA regulations for a Class I Medical Device. The Happy Sleep device comprises two parts: an inner mouthpiece and an outer piece, both made of soft, high-quality material designed for the medical industry.

The inner mouthpiece is designed with multiple mechanisms of action, including gently advancing the lower jaw, restoring tension in the upper airway and preventing soft tissues from collapsing and obstructing the upper airway, preventing snoring and improving breathing throughout the night.

The outer piece attaches to the inner mouthpiece and snaps back over the mouth and cheeks to help hold the inner mouthpiece in place.

Effective, comfortable and convenient.

HAPPY Sleep

FOR A HAPPIER WORLD

www.happysleep.au

HAPPY Sleep

FOR A HAPPIER WORLD

ANTI-SNORING MOUTHPIECE

INSTRUCTIONS FOR USE

This is an oral mandibular advancement device designed to treat snoring by keeping your airways open during use.

Suitability:

The Happy Sleep device is suitable for adults suffering from snoring.

What to expect:

It can take a few days to weeks to become comfortable wearing the device. Patients may experience increased salivation or discomfort in the teeth during the initial period, as with any denture or orthodontic appliance.

If you experience excessive or prolonged discomfort, bleeding, loose or moving teeth, excess jaw pain, limited jaw movement, bite changes, obstruction of breathing or other symptoms that may be associated with wearing the Happy Sleep device, stop using the device immediately and contact a licensed medical or dental practitioner for advice.

We recommend advising your Dentist during your periodic visits that you are using the Happy Sleep device.

Contraindications:

Do not use the Happy Sleep device without consulting a licensed medical or dental practitioner if you:

- Suffer from mild-moderate obstructive sleep apnea
- Suffer from central sleep apnea
- Have a history of Temporomandibular Joint Disorder (TMD)
- Have mobile teeth or crowns
- Have received dental implants in the last year
- Have dentures fitted to teeth without consulting a dentist to fit the device
- Have periodontitis or abscesses
- Are under the age of 18
- Have a history of chronic asthma, emphysema or any respiratory disorder
- Suffer material allergies
- Have pre-existing gum disease
- Suffer from physical or psychological difficulties except under the supervision of a caretaker.

Please read these instructions carefully before use:



1. Clean your teeth prior to use.



2. Remove the device from the container, ensuring that all contents listed on the box are present.



3. Inspect the device for signs of tears, cracks, damage, colour changes, peeling or obstructions in the hollow airway tube at the end of the inner mouthpiece. Please contact the manufacturer if any of these are present.



4. Place the device in its storage container, fill with clean cold water and insert a denture cleansing tablet like Steradent™ for a maximum of 3 minutes to clean the device prior to use.



5. Thoroughly rinse the device and the inside of the storage container under clean cold water.



6. If the device is not already assembled, attach the outer piece to the inner piece and then flip the outer piece away from your mouth and place the inner mouthpiece in your mouth with the V-shaped indent facing upwards.



7. Ensure the inner mouthpiece sits snugly against your teeth and gums without significant room for movement, that it is not causing pain or discomfort and that your teeth are resting on the device. Allow the outer piece to 'snap' back so it covers your mouth and cheeks.

General Use Information

- Brush your teeth thoroughly before using the device.
- Do not share your Happy Sleep device with anyone else including children.
- The Happy Sleep device works best when sleeping on your side.
- If the Happy Sleep device is uncomfortable or causes soreness, contact a dental practitioner.

Care & Handling

- The Happy Sleep device must be **cleaned before each use** by placing it inside the storage container **with clean, cold water and denture cleansing tablets such as Steradent™ for a maximum of 3 minutes** to avoid damaging the material.
- After cleaning the Happy Sleep device with denture cleansing tablets, thoroughly rinse the device and inside of the storage container in clean cold water.
- Do not use alcohol based denture cleansing tablets.
- Do not brush the Happy Sleep device with a toothbrush or use toothpaste to clean the device.

- Do not use hot or boiling water, harsh chemicals or household cleaning products such as bleach or ammonia.
- Dry the Happy Sleep device with a clean towel after cleaning.
- Store the Happy Sleep device in a cool dry place, preferably inside the container provided.
- Keep the Happy Sleep device out of reach of children and/or pets.
- Attach the outer piece to the internal mouthpiece whenever the device is being used.
- Inspect the Happy Sleep device for signs of tears, cracks, damage, colour changes, peeling, debonding of material or obstructions in the hollow airway tube

- at the end of the inner mouthpiece. Please contact the manufacturer if any of these are present.
- Keep the Happy Sleep device out of direct sunlight.
- The Happy Sleep device should be used for up to 12 months of use.
- If the Happy Sleep device is damaged, worn out, expired or otherwise no longer required, please return to the manufacturer.
- Test the Happy Sleep device in your mouth before using during sleep.

EFFECTIVE
COMFORTABLE
CONVENIENT

FOR
REDUCED
SNORING

CONVENIENT
TRAVEL
COMPANION

Snoring and other conditions

The Happy Sleep Device is indicated for snoring. Snoring may be a sign of sleep apnea, which is a medical condition associated with cardiovascular risks, neurovascular risk, risk of work and motor vehicle accidents and mortality.







We recommend that you speak with a licensed medical or dental professional about your snoring and whether you may have sleep apnea. Only use the Happy Sleep in the situations listed under "Suitability".

Australian Sponsor and Manufacturer

Sleep Sound Pty Ltd
Suite 2, 71 Kooyong Road, Caulfield North,
Victoria, Australia, 3161.
Phone: 1300 770 013

Returns/Questions

Phone: 1300 770 013
Email: info@happysleep.au
Money Back Guarantee Terms & Conditions:
happysleep.au

NAME	DESCRIPTION	PICTURE
Manufacturer	The medical device manufacturer.	
Sponsor	The sponsor is responsible for supply of this device	
Manufacture date	YYYY-MM-DD The date the medical device was manufactured.	
LOT	The manufacturer's batch code so that the batch or lot can be identified.	
REF	The manufacturer's catalogue number so the medical device can be identified.	
Keep away from light	The device needs protection from light sources.	
Caution	The user must consult instructions for use for important cautionary information such as warnings and precautions not presented on the device itself.	
Blue man with book	The instruction manual/booklet must be read.	