

Back 2Sleep



The surprising secret to restful
nights

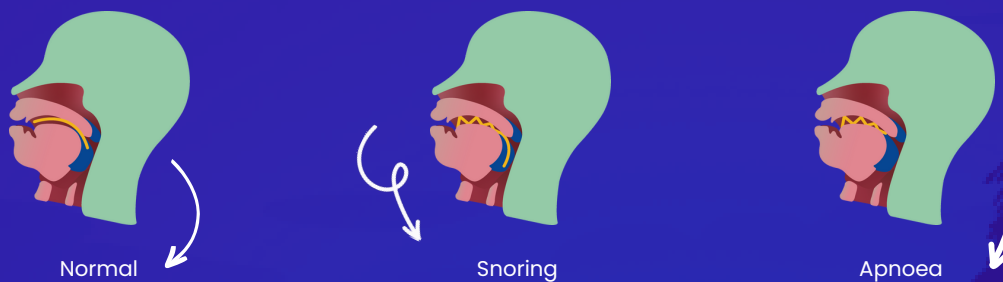


Snoring and Sleep Apnea Treatment Device

From snoring...

- A high prevalence, increasing with advancing age^{1,2,4}
 - Up to **60%** of **men** and **34%** of **women** of all ages which represent around **125 million** European people
- A risk to society and family¹
 - **Isolation** due to fear of disturbing the surroundings
 - Couple sleeping in **separate** rooms

Physiopathology of snoring and sleep apnea syndrome¹



Deformation of the upper airway muscles during **inspiration** with possible complete **obstruction**.

... to sleep apnoea

- Snoring may be just a sign of sleep apnea syndrome (SAS)^{1,3}
 - **10 to 15%** of snorers have over **5 apneas per hour**
 - Around **26 million** European people suffer from **SAS**
 - Only **15%** patients are **diagnosed** and **treated**
- SAS : a syndrome with serious consequences⁵
 - **11% to 37%** of patients with **heart failure** have **sleep apnea**
 - Risks of stroke are multiplied by **2** or **3**

1 - Chays I, Florent I. Le ronflement. Abrégés Masson 2010, 136p, p:9-21

2 - Pessey JJ, Lombard L. Ronchopathie chronique. EMC, ORL 20, 261-A10, 2001, 15p.

3 - Claire Gourier-Fréry et Claire Fuhrman, Département des maladies chroniques et traumatismes, Institut national de veille Sanitaire (2012)

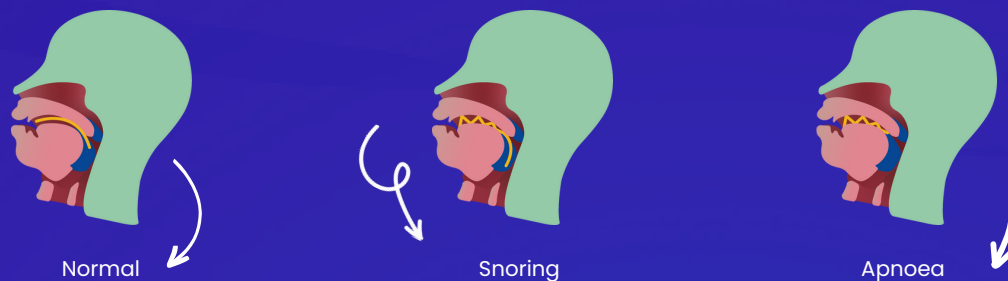
4 - Damien Bidaine, Gérard Vincent, En finir avec les ronflements, 2015, p129.

5 - Shahar et al. Sleep-disordered breathing and cardiovascular disease: cross-sectional results of the Sleep Heart Health Study. Am J Respir Crit Care Med. 2001 Jan;163(1):19-25.

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What is Back2sleep ?

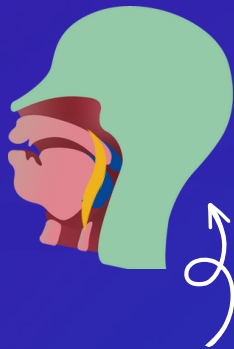
Back 2 Sleep is a **tube-shaped** medical device that is inserted from the nose. The tip of the tube reaches the soft palate (near the uvula).

Back 2 sleep aids breathing by preventing the **obstruction** of the airway which causes poor sleep, frequent awakening during sleep and snoring.

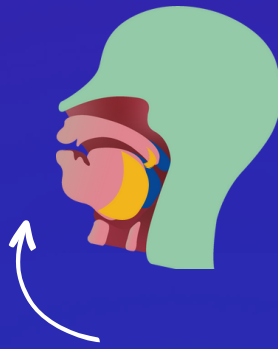
Back 2 sleep is made from extremely **soft** material and is designed to be used by many patients with **minimal discomfort**. Back 2 sleep is made of stainless steel, silicone and glycerine.

Back2sleep, how it works ?

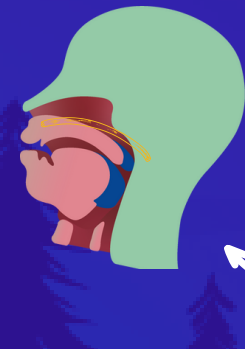
Back2sleep prevents mechanically the **obstruction** of the upper airway.



Various causes can lead to airway **obstruction**.



The shape of the face or aging can cause **obstruction** by the soft **palate** or **pharynx**.



The appropriate size of back2sleep keeps the **airway open**.



To get started with back2sleep, we designed a kit for first use

Each morphology being different, back2sleep Starter kit allows you to **determine** the most **effective** model of back2sleep to **reduce** or **eliminate snoring** and **sleep apnea**.



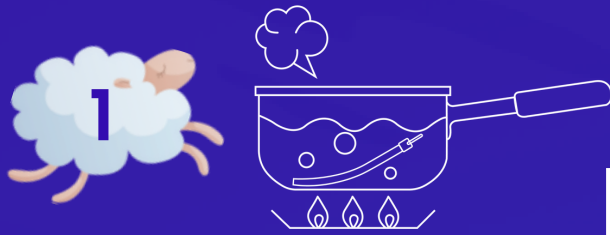
Why this kit has been designed ?

Starter kit was designed to **help** patients choose the **correct nostril** and **size** of back2sleep and gradually help them get used to using the length of back2sleep, that suits them.

The more a patient tolerate a longer back2sleep, the more effective it will be. On the contrary, if it is too short, it will not be efficient.



Instructions for use in 7 easy steps



Disinfect the tube



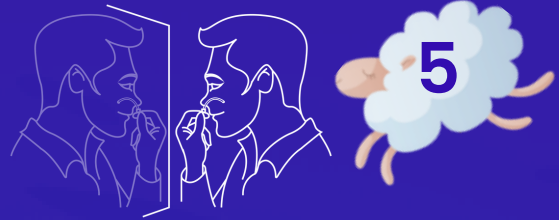
Drain tube



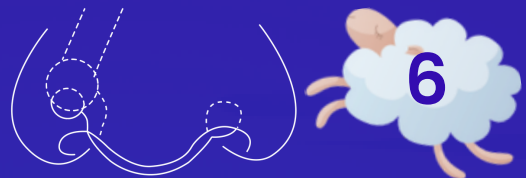
Wash your hands



Put 5cm of the lubricant outside the tube



In front of a mirror, insert the tube on the lubricated side



Make sure the final position of the back2sleep is correct



The next day, clean the mucus under lukewarm water



Back2sleep, proven effective

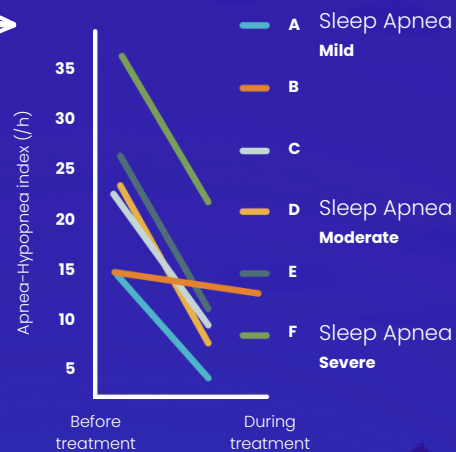
PILOT STUDY 2015⁵

• Methodology

Pilot study run over one month on **6 patients** with mild to severe cases of **Sleep Apnea Syndrome (SAS)** in order to **evaluate** the **effectiveness** and **tolerance** of back2sleep.

- **Improvement** of the Apnea-Hypopnea index confirmed by the improvement of the oxygen saturation index

- **Improvement** of snoring index in **all** patients



• Results

- Improvement of AHI (Apnea Hypopnea Index) and oxygen saturation in patients with mild to moderate cases of SAS.
- **Diminution** of snoring in all patients.
- All patients have shown a **good tolerance** to the device (no undesirable effect observed).
- Good **observance** during the treatment.

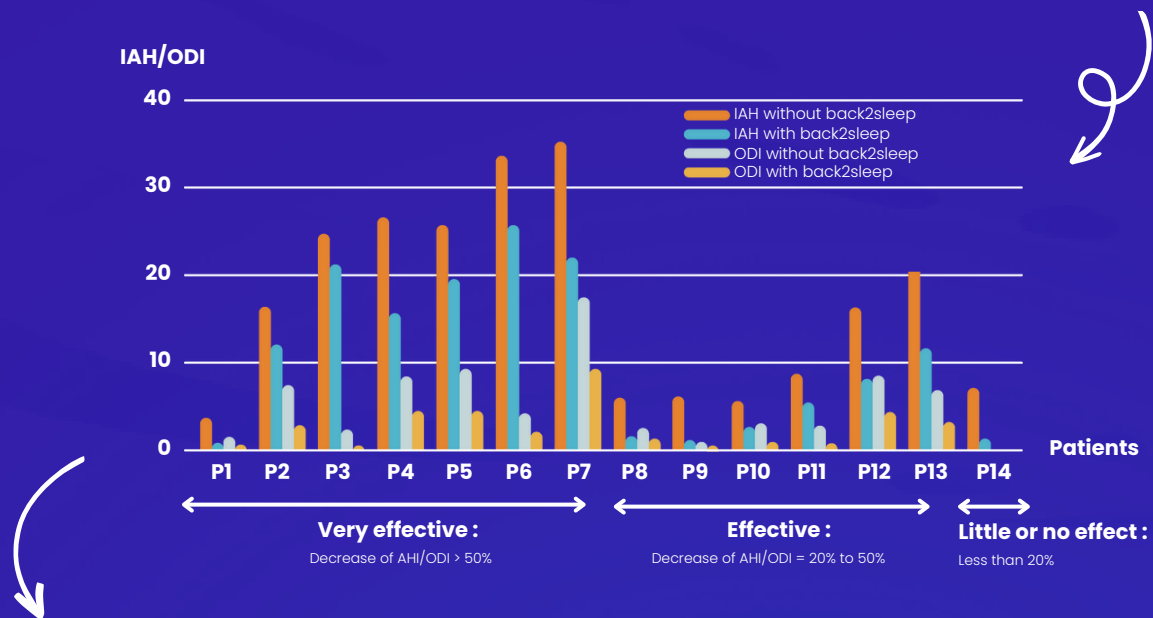
• Conclusion

Ready made medical device back2sleep offers an **alternative** treatment for patients having a **mild to moderate** case of **obstructive sleep apnea** syndrome who can not tolerate the treatment with CPAP, or for people with snoring.

CLINICAL STUDY 2016⁶

• Methodology

Home sleep testing made by **Watch PAT** (AHI, ODI, RDI, TST measurements, position, snoring, stage of sleep) on **14 patients** with mild to severe **Sleep Apnea Syndrome**.



• Results

Observed **decrease** in Oxygen Desaturation Index (ODI) and Apnea Hypopnea Index (AHI) for all the patients except for one (p14).

5 - Hirata Y, Satoh M. Pilot Study of a Nasal Airway Stent for the Treatment on Obstructive Sleep Apnea. Journal Sleep of Disorders & Therapy 2015, 4:4
6 - Study made in Tokyo by seven dreamers laboratories inc. under the supervision of Dr Satoh Makoto (University of Tsukuba, Japan)

Contraindications

- Not suitable for patients with disorders or illness of the nasopharynx airway
- Do not use on unconscious patients
- Not suitable for patients with agitated sleep or who are unable to use the device properly
- Not suitable for children
- Persons under guardianship must use the device under the supervision of a third person
- Do not use under the influence of alcohol or drugs
- Do not eat or drink anything but water while the device is inserted
- Do not reuse the device. Reusing the device creates a risk of infection for patients

What are your odds of having a sleep apnea ?

I. Snoring

1. Do you snore ?

- Yes
- No
- Don't know

If you answered 'yes' :

2. Your snoring is :

- Slightly louder than breathing
- As loud as talking
- Louder than talking

3. How often do you snore ?

- Almost every day
- 3-4 times per week
- 1-2 times per week
- 1-2 times per month
- Rarely or never

4. Has your snoring ever bothered other people?

- Yes
- No
- Don't know

5. Has anyone noticed that you stop breathing during your sleep ?

- Almost every day
- 3-4 times per week
- 1-2 times per week
- 1-2 times per month
- Rarely or never



II. Sleepiness

6. How often do you feel tired or fatigued after your sleep ?

- Almost every day
- 3-4 times per week
- 1-2 times per week
- 1-2 times per month
- Rarely or never

7. During your waking time, do you feel tired, fatigued or not up to par ?

- Almost every day
- 3-4 times per week
- 1-2 times per week
- 1-2 times per month
- Rarely or never

8. Have you ever nodded off or fallen asleep while driving a vehicle ?

- Yes
- No

9. How often does this occur ?

- Almost every day
- 3-4 times per week
- 1-2 times per week
- 1-2 times per month
- Rarely or never



III. Facteurs de risque

10. Risk factor ?

- Yes
- No
- I don't know


At least **2 positive categories** indicate a high probability of **sleep apnea**.
A consultation with an **ENT doctor** or a **pulmonologist** is recommended.


Any of the **YELLOW** answers are **POSITIVE** answers.

Back 2Sleep



CONTACT US

 www.back2sleep.eu

 +33 (0)1 40 41 00 04

 support@back2sleep.eu

Back2sleep is a class I medical device. This is a regulated healthcare product which falls under the regulation of the CE marking. Read the instructions for use inside the package carefully. If any problem occurs, immediately consult a physician.

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