

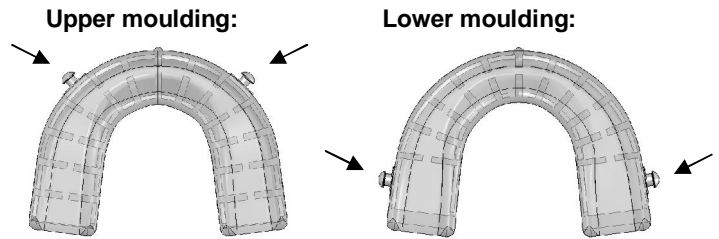
Mandibular advancement device for anti-social snoring

INSTRUCTIONS FOR USE

The Somnofit set

The Somnofit (ref. S-02) is made up of:

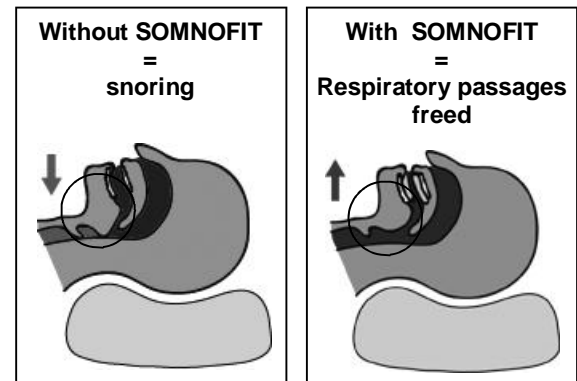
- An upper moulding with 2 front hooks
- A lower moulding with 2 back hooks
- A floating thermometer
- A ventilated storage box
- A set of 6 supple straps
- Instructions



How does Somnofit work ?

Somnofit is based on the medical anti-snoring solution known as mandibular advancement. The principle of the Somnofit advancement device consists of pulling the lower jaw forward a few millimeters in order to free the air intake passage and release the back of the tongue.

Many clinical studies show the effectiveness of a mandibular devices such as the Somnofit, which may suppress, or considerably reduce snoring and when prescribed mild to moderate obstructive



Indications and contra-indications for use

Somnofit is recommended in the following cases:

- Snoring
- Mild to moderate obstructive sleep apnoea (medical supervision required)
- Obstructive sleep apnoea at certain times: travel, camping, on a boat, holidays (medical supervision required)
- Bruxism (grinding teeth), migraines due to mandibular tensions

Somnofit is contra-indicated for patients who :

- wear a removable or partial dental prosthesis
- have mandibular joint pain
- have loose teeth or advanced periodontal disease
- upper or lower jaw with less than 10 teeth
- are under 18 years old

Precautions:

For any other problems or concerns regarding the safe and effective use of Somnofit consult your Dentist or Doctor regularly.

If you have doubt on your dental health, consult your Dentist. If you have diurnal tiredness, you may suffer from sleep apnoea. Consult your Doctor for a complete check-up.

Once the mouldings have been formed to the dentition, they cannot be readapted to another person.

Warnings, use of the Somnofit device may cause :

- dental sensitiveness after putting of the device on waking (It disappears after clenching 3 or 4 times your teeth)
- pain forward the ear, vanishing usually after some days of regular use, or becoming worse (in this last case, use a weaker forwarding strip, for instance 4,5 instead of 6,0 or consult a Doctor.
- excessive salivation initially but this generally stops when you get more used to the device
- tooth movement or change in dental occlusion (position of each jaw in a closed mouth). If the lower jaw doesn't come back in its original position after taking off Somnofit, stop wearing it.

If any unpleasant side effect persists, stop wearing the appliance and consult your Dentist or Doctor

Maintenance, life, warranty

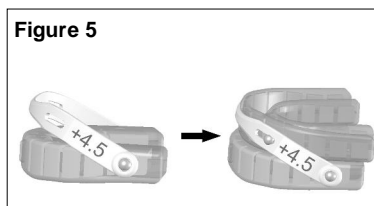
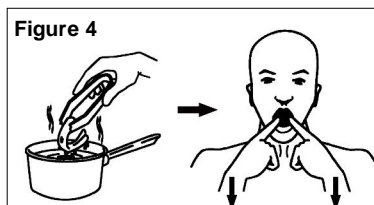
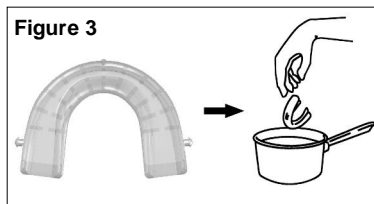
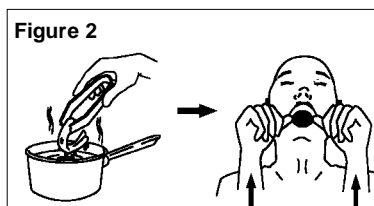
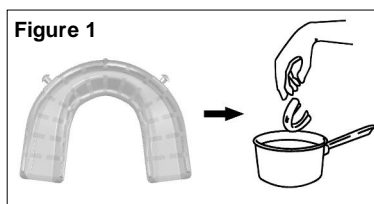
Every morning, remove your Somnofit device and brush it, rinse it and place it in a container filled with lukewarm water into which you have put a tablet of anti-bacterial scale remover. Leave it the entire day. Just before settling in mouth your Somnofit for the night, throw out the liquid and rinse it well with fresh water.

Check the general condition of the appliance regularly.

Generally speaking it has a life of from 8 to 15 months but this depends on factors such as maintenance, nocturnal clenching of the teeth (bruxism) and acidity in the mouth. So it cannot be guaranteed for a fixed period of time. It will only be covered by warranty in the event of any manufacturing faults. The results regarding the reduction of snoring or apnea cannot be guaranteed either, because they depend upon the user's anatomy. The appliance must be changed if cracks or breaks appear or if the material deteriorates.

Adaptation to the teeth (thermoforming) and installation

- 1● Place the upper part (with 2 front hooks) and the thermometer into a saucepan filled with 7 to 8 centimeters of cold water and increase the temperature of the water (figure 1). Remove the heat source once the red tube reaches the blue marker on the thermometer (optimum temperature). Leave the part in hot water during 2 minutes.
- 2● Remove the upper part from the hot water using a spoon and then shake it to get rid of the water. Stand in front of a mirror and place **simultaneously** the part onto the upper maxillary arch by aligning the vertical blue line between the two central incisors. Press firmly upwards with both thumbs placed on either side of the upper jaw respectively, clench your teeth and press the material firmly against the side of the teeth with your fingers. Maintain the pressure for at least 60 seconds. Keep the device in your mouth and rinse with cold water to fix the prints into place. (figure 2).
- 3● Repeat the same operation described in 1 for the lower part (with 2 back hooks, figure 3). Before removing it from the hot water, put the upper part back into your mouth. Remove the lower part from the hot water and then shake it to get rid of the water. Place the lower part in your mouth centering it in relation to the upper part (the two vertical ridges should be aligned with one another). Press firmly downwards with both index fingers and then gradually clench the two parts firmly with the jaw (figure 4) .
- 4● Keep the jaw clenched for at least 1 minute .
- 5● Remove both parts and place the lower part into cold water for 2 to 3 minutes to fix the prints.
- 6● Detach the marked 4,5 strap with a cutter or a pair of scissors. Keep the other straps.
- 7● Fix the supple strap on the hooks of the lower part. The marks must be seen outside. Fix the strap on the hooks of the upper part (figure 5).
- 8● Place the Somnofit into your mouth before going to sleep .



Adjusting the adaptation to the teeth

How well the moulding adapts depends on the shape of the teeth, the number of teeth and the quality of the impression taken.

If a moulding does not adapt properly to the teeth, check that the shape of your teeth is properly printed onto the moulding and, if it is not, repeat the adaptation using the right temperature and enough force to shape the appliance. Any contingent uncomfortable parts made of thermoformable material can be trimmed off using a pair of scissors or a cutter.

Adjusting the lower jaw advancement with supple straps

During a couple of nights, the user must get accustomed to wear the device and we advise him to use the strap marked +4,5. This figure represents the advancement in millimeters of the lower jaw in comparison with the usual position without SOMNOFIT. According to each dental morphology, the real value of the advancement can vary. After some nights of adaptation, adjust the lower jaw advancement according to the following principles:

-If the traction of the jaw is too strong and uncomfortable, use a strap of an inferior value (for instance +3,0 instead of +4,5).

-If snoring doesn't diminish sufficiently, use a strap of a superior value (for instance +6.0 instead of +4,5)

An advancement of +4,5 to +7,5 is usually enough. In case of sleep apnoea, the verification of the effectiveness and of the mandibular advancement must be realised preferably with a specialized Doctor.

Informations :

If you require any further information, please contact your distributor :

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