

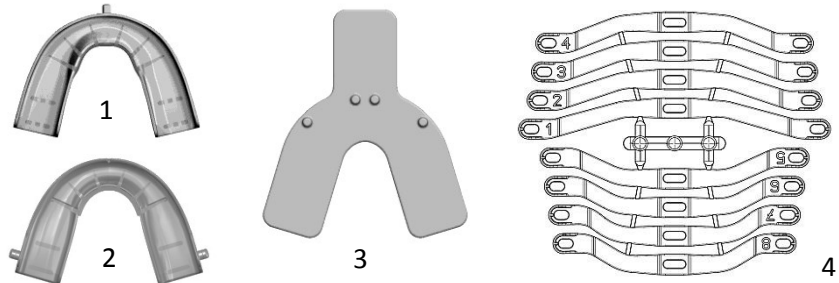
# Somnofit®-S

## Mandibular advancement device to treat snoring and sleep apnea

### Instruction for use

#### Content of the set:

- An upper moulding with 1 front hook (1)
- A lower moulding with 2 back hooks (2)
- A teethprint plate (3)
- A floating thermometer
- A ventilated storage box
- A set of 8 supple straps
- Instructions for use



#### Classification

The mandibular advancement device is a class 1 medical device in compliance with European directive 93/42 CE. The CE acronym is displayed on the device.

#### How does Somnofit work ?

Somnofit is based on the medical anti-snoring solution known as mandibular advancement. It 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 its effectiveness.

#### 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)

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.

#### 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, 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 (thermo-forming) and installation

1● Place the thermometer in a saucepan containing 7 to 8 centimetres of cold water and heat the water. Turn off the heat source when the red line reaches the blue mark on the thermometer (optimal temperature). Let the **upper moulding** sit in the hot water for 3 minutes, then proceed to point 2.

**Important remark regarding the teeth impression (points 2+3):** to obtain successful impressions, the material must be hot and the interval between removal from the saucepan and taking the impression must be limited to 10-15 seconds.

2● Sit or stand in front of a mirror. Take the upper moulding out of the hot water using a spoon, and shake it to remove any water. Place the upper moulding on upper teeth and align the central line of the moulding with the central line between the superior central incisors. Press gently upwards with your fingers in order that the moulding follows the shape of the dental arch. Move quickly to point 3.

3● Hold the moulding on the teeth with one hand and insert the toothprint plate in mouth with the other hand. Bite hard to print the shape of your teeth. Remain teeth tight and push your fingers against lips and cheeks to print perfectly the faces of your teeth. Release the pressure of teeth.

4● Keep the upper moulding in mouth but remove the toothprint plate. Follow points 1 to 3 with the **lower moulding** without using the toothprint plate. Align the central line of the lower moulding with the hook of the upper moulding. Release the pressure of teeth and wait 2 minutes so that the moulding cools down. Remove the mouldings and rinse it in cold water.

5● Remove the strap Nr 4 with a cutter. Keep the other straps. Insert the hook of the superior moulding into the central hole of the strap and turn a quarter. Place the holes of extremity of the strap on the hooks of the lower moulding and turn a quarter to lock the strap.

### Adjusting the adaptation to the teeth

How well is the moulding adaptation 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 uncomfortable part made of thermo-formable material can be trimmed off.

### 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 Nr. 4. This strap moves approximately the lower jaw for 6 mm in comparison with the usual position without SOMNOFIT.

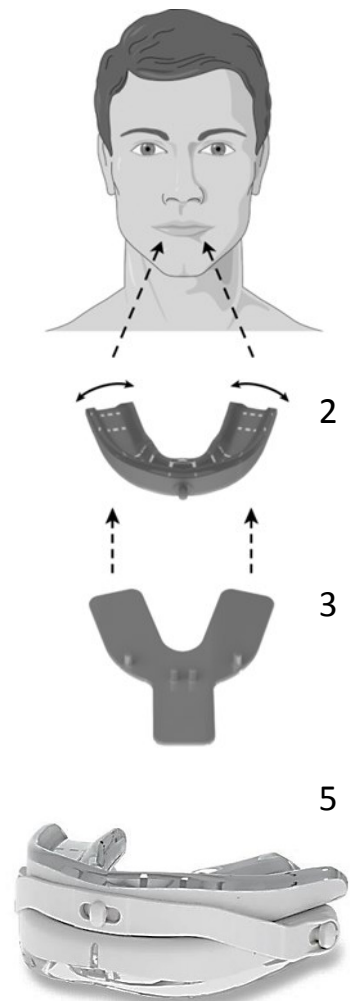
According to each dental morphology, the real value of the advancement can vary. After some nights of adaptation, adjust the lower jaw advancement according to the following principles:

- If the traction of the jaw is too strong and uncomfortable, use a strap of an inferior value.
- If snoring doesn't diminish sufficiently, use a strap of a superior value.

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

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