



 **OPTISLEEP**

*Version 1.1*  
*Application and care information*



***Dear SICAT OPTISLEEP user,***

Congratulations on your new SICAT OPTISLEEP. We hope that you can sleep well again and have a good night's rest thanks to your SICAT OPTISLEEP! From now on, daytime sleepiness and fatigue should be a thing of the past.

Your dentist has had this SICAT OPTISLEEP therapeutic appliance produced for you individually.

SICAT OPTISLEEP reduces and alleviates snoring and/or mild to moderate obstructive sleep apnea (OSA) in adults (from the age of 18) while they sleep.

These instructions provide you with information about the treatment with SICAT OPTISLEEP, describe the applications as well as provide important information on cleaning and caring for the therapeutic appliance.

Should you have any questions in relation to the SICAT OPTISLEEP therapeutic appliance, please contact your dentist. Please also visit our website for patients [www.optisleep.com](http://www.optisleep.com).

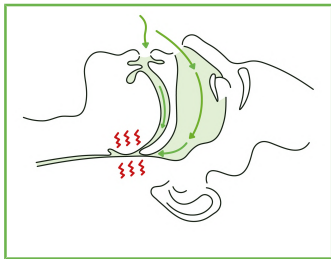
***Your SICAT OPTISLEEP team***

## THE SICAT OPTISLEEP TREATMENT

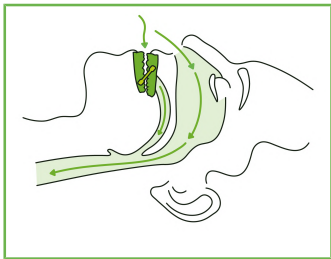
The SICAT OPTISLEEP therapeutic appliance works in accordance with the mandibular-protrusion principle:

The therapeutic appliance is worn in the mouth while sleeping and holds the lower jaw in a slightly pulled-forward treatment position.

This results in a widening of the respiratory tract and at the same time activates the muscles of the tongue and soft tissue providing additional stability to the airway. This reduces snoring noises and the respiratory tract remains open.



*blocked respiratory tract*



*free respiratory tract thanks to **OPTISLEEP***

## THE SICAT OPTISLEEP THERAPEUTIC APPLIANCE

The therapeutic appliance was individually created for you and consists of

- a splint for the upper jaw,
- a splint for the lower jaw,

which are connected by interchangeable connector pairs. These are available in different lengths so that your dentist can adjust the position of the lower jaw to the best possible position during the course of treatment.

**⚠ CAUTION!** Federal Law (USA) restricts use of this device to or on the order of a physician, dentist or licensed practitioner.



## ***USING THE SICAT OPTISLEEP THERAPEUTIC APPLIANCE***

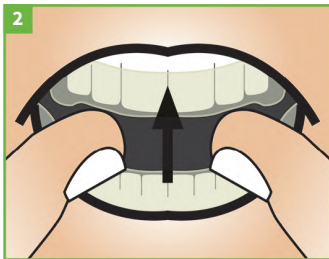
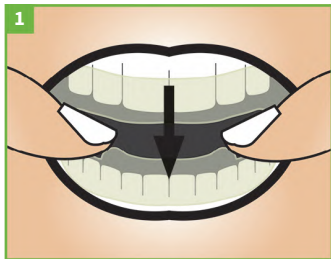
### **Fitting of the therapeutic appliance**

Perform the first fitting of the therapeutic appliance in the presence of your dentist.

### **Inserting the therapeutic appliance**

Before using the therapeutic appliance, ensure that the connectors have been correctly fitted.

Slide the therapeutic appliance completely into the mouth. First, place the lower jaw splint and then the upper jaw splint on the teeth by applying a little pressure. The splint snaps onto the teeth and should stay securely in place.



**Do not attempt to attach the appliance forcibly. If you encounter problems insert-  
ing the appliance, consult your dentist.**

### Removing the therapeutic appliance

It should be possible to remove the therapeutic appliance from your teeth by exerting a slight amount of force.

Place your thumbs on the lower splint in the area of the molars on both sides and lever these upward with equal slight pressure. Then carefully pull the upper splint from the teeth. Do not use the connector pins to lever out the appliance.



## Adjusting the treatment position

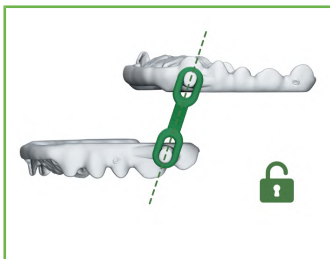
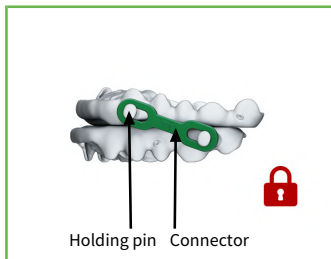
The SICAT OPTISLEEP therapeutic appliance can be set to one of a total of 10 different treatment positions using connectors of various lengths.

Your dentist has provided you with a therapeutic appliance which has already been set to the correct treatment position. Do not change the position without consulting your dentist first!

## Removing the connectors

The connector is connected with both the upper and lower jaw splint with holding pins. In order to remove the connector, it has to be **positioned perpendicular to the splint** so that the fastener for removing the connector is released. The connector can only be removed when in this position!

After you have positioned the connector perpendicularly, remove it by pulling via the holding pin. Hold the splint with your other hand to stabilize it at the height of the holding pin.

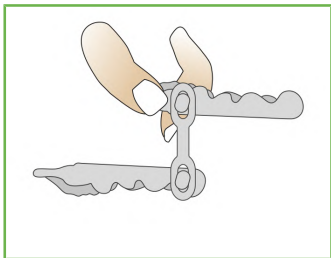
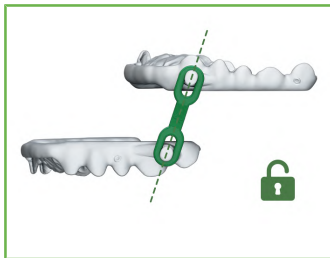




## Securing the connector

The connector is connected with the upper and lower jaw splint via holding pins.

In order to secure a connector in place, this needs to snap into the holding pin of the splint. To do this, apply slight pressure and guide the long hole of the connector perpendicularly to the splint via the holding pin. The connector then snaps into place with a click.



**When securing the connector, please make sure that you hold the splint with the other hand so that the splint is not overly strained.**

There are various versions of splints and connectors that differ only slightly from each other. Please note that they must not be combined. Please discuss with your doctor which connectors should be used when changing in order to prevent a loss of function of your splint.

**Please use the SICAT OPTISLEEP connectors V1.1 for SICAT OPTISLEEP V1.1.**



## **CLEANING AND CARING FOR YOUR SICAT OPTISLEEP THERAPEUTIC APPLIANCE**

- Always brush your teeth thoroughly prior to inserting the therapeutic appliance. Even tartar can be deposited on the splint. Have it removed regularly.
- Clean the therapeutic appliance thoroughly every morning after removing it, using a soft toothbrush under warm running water. You should use this toothbrush exclusively for cleaning your SICAT OPTISLEEP therapeutic appliance. You can clean your therapeutic appliance occasionally with a mild detergent (e.g. washing-up liquid) or a mild oxygen-free prosthesis cleaner.
- After cleaning the SICAT OPTISLEEP therapeutic appliance, always store it in the provided storage container in a cool and dry place at room temperature.
- Protect the therapeutic appliance from direct sunlight and heat.
- Keep the SICAT OPTISLEEP in a safe place that is inaccessible to pets.
- Remove the therapeutic appliance before eating or drinking in order to avoid damaging it.

### **Indications relating to care**

The use of prostheses cleaners which contain oxygen could result in the plastic in your therapeutic appliance becoming permanently damaged. The use of hot water and toothpaste could result in damage. The use of UV light might also lead to material damage. Altering the therapeutic appliance yourself could lead to damage or a risk of injury. Incorrect cleaning may lead to loss of warranty.

### Damaged therapeutic appliances

Regularly inspect your therapeutic appliance for damages. Examples of such damage include deformations, cracks, breaks, or loose parts.

A damaged or broken therapeutic appliance may no longer be used because this entails the risk of injury. Should this indeed happen, please contact your dentist immediately.

### WARRANTY

Your SICAT OPTISLEEP therapeutic appliance was produced for you individually in a fully-digitalized process using your 3D picture data.

Even though the digital planning and production of SICAT OPTISLEEP guarantees the greatest possible accuracy, it can nevertheless not be guaranteed that the therapeutic appliance will definitely stop the snoring and/or the obstructive sleep apnea (OSA). We recommend that you have your therapeutic appliance checked by your dentist at regular intervals.

The manufacturer provides you with a warranty for your SICAT OPTISLEEP therapeutic appliance covering any manufacturing faults and material defects over the entire service life of the splint, i.e. 2 years. Please do not use your therapeutic appliance after the end of its service life. Visit [www.sicat.com](http://www.sicat.com) to read the warranty conditions and discuss it with your doctor.

## ***INDICATIONS FOR USE AND CONTRAINDICATIONS***

### **Indications**

The SICAT OPTISLEEP therapeutic appliance is indicated for use in adults to

- to reduce or alleviate snoring and
- to reduce or alleviate mild to moderate obstructive sleep apnea

### **Contraindications**

The SICAT OPTISLEEP therapeutic appliance may not be used in the following cases:

- |                          |                               |
|--------------------------|-------------------------------|
| ■ Central sleep apnea    | ■ Persons under 18 years      |
| ■ Loose teeth            | ■ Toothless jaw               |
| ■ Advanced periodontitis | ■ Severe respiratory diseases |

## Clinical benefit

The SICAT OPTISLEEP device is intended to reduce or alleviate snoring or mild to moderate obstructive sleep apnea (OSA). This is achieved by placing the lower jaw in a forward position, which widens the lateral dimension of the pharynx, stabilizes hyoid bone and soft palate, stretches tongue muscles, and prevents the posterior rotation of the jaw. This, in turn, improves the patient's ability to exchange air during sleep.

Patients treated with mandibular advancement devices (MADs) achieve a general improvement of their health status. In detail several parameters are improved. The apnea-hypopnea index (AHI) is reduced, the compliance of the therapy can be increased, combination therapies allow better treatment due to higher compliance, and a decrease in comorbidities is recognized.

### Possible side effects

Wearing the therapeutic appliance can lead to increased salivation. Pain in the jaw joints and muscles, the palate, gums and the teeth, as well as headaches can also occur temporarily.

It can happen that you recognize a slight change of occlusion after taking out the SICAT OPTISLEEP in the morning. Normally, this will go away quickly. Finding your normal bite again can be accelerated by jaw exercises, chewing gum or the like or by using a special bite trainer.

If slight medical complaints persist, please contact your dentist.

Long-term effects could be, under certain circumstances, movement of the teeth or changes to the dental occlusion.

In the event of severe pain, respiratory problems, nausea, allergic reactions or unintended tooth movements, remove the splint and contact your dentist immediately.

**We recommend regular check-ups with your dentist!**



Your SICAT OPTISLEEP therapeutic appliance will be given to you by your dentist in a SICAT OPTISLEEP storage container.

Store the cleaned and dried therapeutic appliance in the SICAT OPTISLEEP storage container.

Please contact your dentist regarding the proper disposal of your SICAT OPTISLEEP.

If serious incidents (such as severe injuries) occur in connection with the product, these must be reported to the manufacturer and the competent authority.

If you have any questions or suggestions regarding your SICAT OPTISLEEP therapeutic appliance, please visit our websites:

[WWW.OPTISLEEP.COM](http://WWW.OPTISLEEP.COM)





## NOTES

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## NOTES

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## NOTES

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# OPTISLEEP

WWW.OPTISLEEP.COM

PRACTICE / INFORMATION

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**Manufacturer**

SICAT GmbH & Co. KG - Friesdorfer Str. 131-135 - 53175 Bonn, Germany

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