



 **OPTISLEEP**

Application and care information



Dear SICAT OPTISLEEP users,

You know that feeling, tiredness and exhaustion dictate your daily routine. The doctor's diagnosis is that you suffer from snoring or even obstructive sleep apnea.

Your dentist had an SICAT OPTISLEEP therapeutic appliance ordered for you individually. This means that you are already holding the solution in your hands.

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

These instructions provide you with information about the treatment with SICAT OPTISLEEP, describes the use of the appliance as well as provides important tips on cleaning and caring for your new therapeutic appliance.

Should you have any questions in relation to your SICAT OPTISLEEP therapeutic appliance, please contact your dentist.

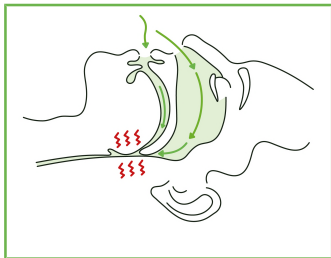
Your SICAT OPTISLEEP team

THE SICAT OPTISLEEP TREATMENT

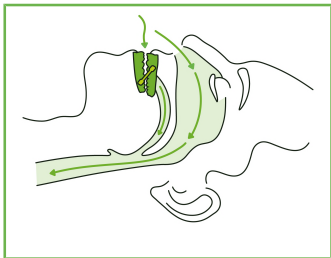
The SICAT OPTISLEEP therapeutic appliance works in accordance with the mandibular-protrusion principle:

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

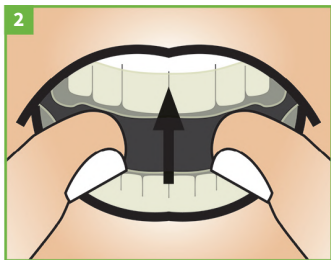
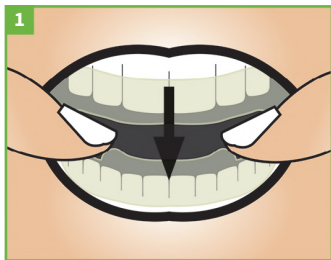
Fitting of the therapeutic appliance

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 into the mouth completely. 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 inserting 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.



Adjusting the treatment position

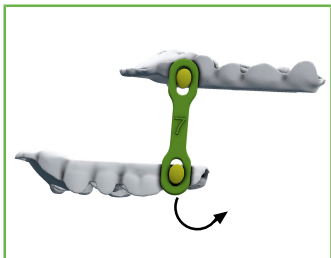
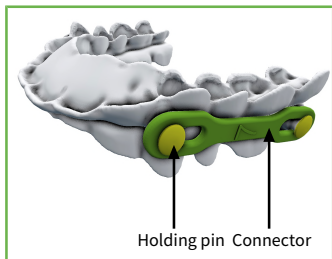
The SICAT OPTISLEEP therapeutic appliance can be set to one of a total of 10 different treatment positions using connectors of various lengths.

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!

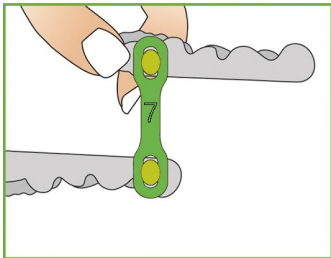
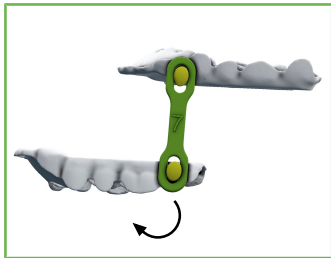
After you have positioned the connector perpendicularly, remove it by pulling via the holding pin. Hold the splint with your other hand to stabilize it at the height of the holding pin.



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 below the holding pin with the other hand in order to prevent the splint from being overly strained.



CLEAN AND CARING FOR YOUR SICAT OPTISLEEP THERAPEUTIC APPLIANCE

- Always brush your teeth thoroughly prior to inserting the therapeutic appliance.
- Clean the therapeutic appliance thoroughly every morning after removing it, using a soft toothbrush under lukewarm flowing 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. dishwashing liquid) or a mild oxygen-free denture 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.
- Remove the therapeutic appliance before eating or drinking in order to avoid damaging it.

Warnings relating to care

The use of denture 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. 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 due to 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 reduce 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 life span of the therapeutic appliance of 2 years. Please do not use your therapeutic appliance after the end of its life span.



INDICATIONS FOR USE AND CONTRAINDICATIONS

Indications for use

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
- Loose teeth
- Advanced periodontitis
- Persons under 18 years
- Toothless jaw
- Severe respiratory diseases

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.

If mild physical discomfort persists, please contact your dentist.

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

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

We recommend regular checkups with your dentist!



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

Always store the therapeutic appliance in the SICAT OPTISLEEP storage container cleaned and dried following each use.

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 should have any questions or suggestions with respect to your SICAT OPTISLEEP therapeutic appliance, please visit our website:

WWW.OPTISLEEP.COM



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WWW.OPTISLEEP.COM

PRACTICE / INFORMATION

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



Manufacturer

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

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