OPTISLEEP

SICAT OPTISLEEP Version 1.1
Instructions for use for the treating dentist
English

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1 THE OPTISLEEP THERAPEUTIC APPLIANCE

The SICAT OPTISLEEP is a patient-specific bimaxillar therapeutic appliance for symptomatic treatment of snoring and sleep apnea. A mandibular protrusion is achieved by flexible connectors fastened on both sides. They are connected to custom-fit maxilla and mandible splint parts. Protrusion may result in a widening of the respiratory tract and at the same time activates the muscles of the tongue and soft tissue.

Intended purpose and target group

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.

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.

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

Planning and manufacturing

SICAT OPTISLEEP therapeutic appliances are custom-made for each patient. The appliance is prescribed and ordered individually for each patient by a dentist with the necessary expertise. SICAT designs the therapeutic appliance based on this order. SICAT or a partner laboratory then produces it.

1.1 INDICATIONS FOR USE

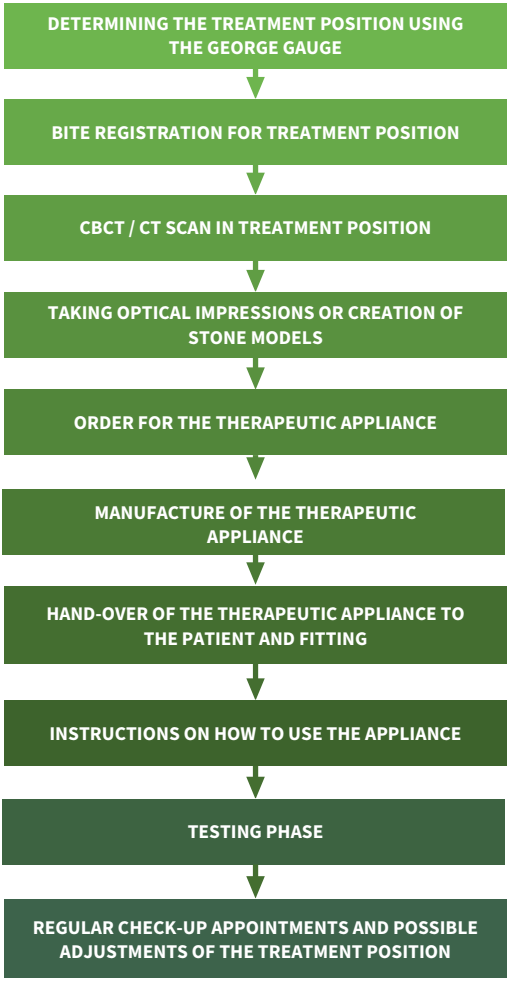
SICAT OPTISLEEP is indicated for use in adults to

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

1.2 CONTRAINDICATIONS

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

2 SICAT OPTISLEEP WORKFLOW



3 DETERMINING THE TREATMENT POSITION USING THE GEORGE GAUGE

You can use the George Gauge to measure the maximum protrusion of the mandible and determine a treatment position based on this.

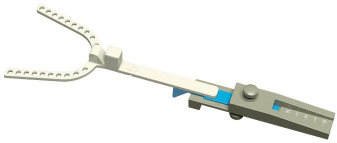


Figure 1: Bite fork in George Gauge

Ensuring sufficient vertical clearance

As SICAT OPTISLEEP has a flat occlusal surface, a minimum distance of 2.5 mm between the upper and lower jaw over the entire maxillary/mandibular arch is required.

To ensure that sufficient clearance is provided, you can proceed as follows:

1. Place a rigid plate with a thickness of 2.5 mm between the patient's teeth which covers the back teeth (see figure).

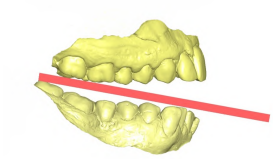


Figure 2: Ensuring sufficient vertical clearance

2. Measure the vertical opening between the front teeth.

3. If you use a rigid plate, replace the plate between the patient's teeth with a bite fork.

4. Transfer the measured vertical opening to the bite fork by applying a sufficient amount of composite to the incisal bite surface of the bite fork or using bite tabs before the final bite registration.

Inserting the George Gauge into the patient's mouth

1. Loosen the lower screws of the George Gauge.

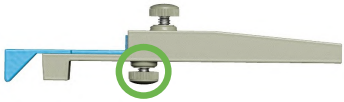


Image 1: Lower screw of the George Gauge

2. Move the lower jaw incisor brace so that the patient's lower font teeth fit into the groove between the lower jaw incisor braces.

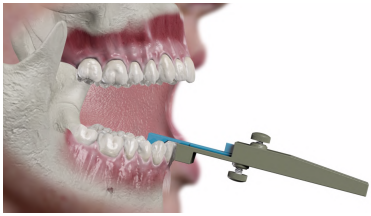


Figure relating to 2: George Gauge on lower front teeth

3. Center the center line display above the middle lower incisors.

4. Fix the lower screws of the George Gauge.

5. Remove the George Gauge from the patient's mouth.

6. Loosen the upper screws of the George Gauge.

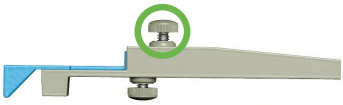


Figure relating to 6: Upper screw of the George Gauge

7. Slide the bite fork with the upper jaw incisor nut upward into the housing of the George Gauge.

8. Have the patient bite with his or her lower or upper incisors into the lower or upper groove.

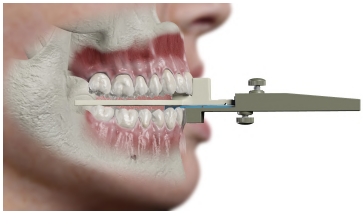


Figure relating to 8: Using the George Gauge

9. **In the case of a pronounced Curve of Spee or open bite, you may fill the upper groove with plastic composite in order to ensure sufficient clearance.**

Measuring the maximum protrusion

1. Have the patient move their lower jaw forward several times as exercise. You should measure the maximum protrusion around three times in succession to ensure that the measured values are correct.

2. Have the patient move his or her lower jaw into the centric position (terminal occlusion).

3. Note the position on the mm scale of the George Gauge.

4. Have the patient move his or her lower jaw as far as possible in the direction of protrusion.

5. Note the position on the mm scale of the George Gauge.

Adjusting the treatment position

1. Remove the George Gauge from the patient's mouth.

2. Calculate the value of the desired protrusion.

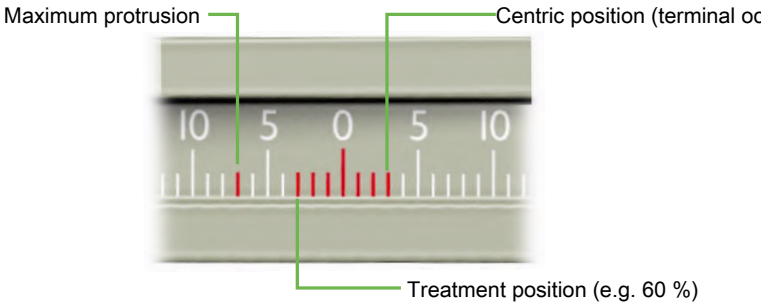


Figure relating to 2: Calculation of treatment position (example)

3. Insert the bite fork into the George Gauge until the end of the bite fork lies at the position calculated on the mm scale.

4. Fix the upper screw.

Bite registration in treatment position

The bite registration in the treatment position determines the position of the lower jaw in the therapeutic appliance. Proceed as follows:

1. Place registration material on the bite fork on the side for the mandible and on the side for the maxilla. Leave out the area of the upper jaw incisor groove and the lower jaw incisor groove.

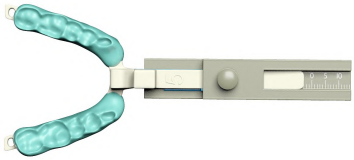


Figure relating to 1: Registration material on the George Gauge bite fork

2. **When performing the bite registration, ensure that there is enough registering material to get sufficient impressions even with the required clearance. When performing the bite registration for patients with a pronounced Spee's curve, ensure that the bite fork does not become deformed.**

3. Place the George Gauge with the lower jaw incisor groove on the patient's lower front teeth and have the patient bite down in the upper jaw incisor groove. **Always ensure that there is no movement of the center line apart from the natural movement of the patient.**

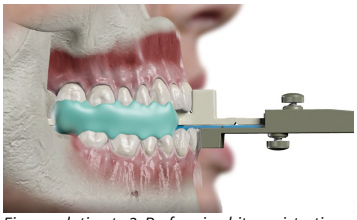


Figure relating to 3: Performing bite registration

4. Allow the registration material to cure.
5. Remove the George Gauge from the patient's mouth.
6. Loosen the upper screws of the George Gauge.
7. Remove the bite fork from the George Gauge.

You can test the treatment position by asking the patient to place the George Gauge on the teeth in his or her upper and lower jaw and hold the intended treatment position for 2 to 3 minutes. The patient can then be asked about his or her well-being.

4 3D X-RAY SCAN

- Ensure that the patient's lower jaw is in the treatment position when taking the scan, ideally by inserting the George Gauge bite fork with registration material.
- Ensure that the patient loosely rests his or her tongue against the palate, does not swallow and breathes calmly when the scan is taken in order to capture the upper breathing zone without interferences.
- Ensure that all the necessary image information is contained in the CBCT scan (see figure 1). The patient's upper and lower jaw must be captured in full in the X-ray. Otherwise, it is not possible to register the optical impressions.
- Ensure that the gap-free bite registration material covers the teeth securely (for example the George Gauge bite fork).
- Ensure that the patient does not move during the scan in order to avoid movement artifacts (see figure 2).
- Ensure that at least four teeth per quadrant on the 3D X-ray scan do not have any metal artifacts (see figure 3).

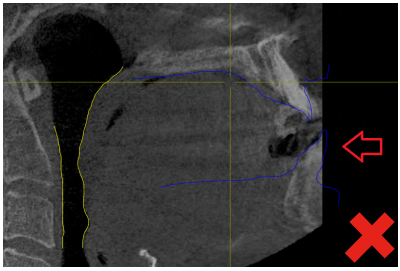


Figure 1: Missing areas in the CBCT data

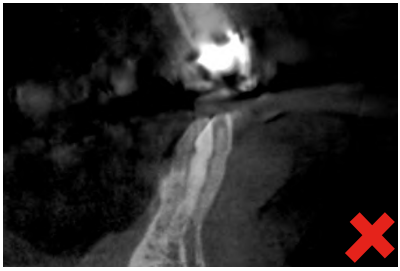


Figure 2: Patient movement

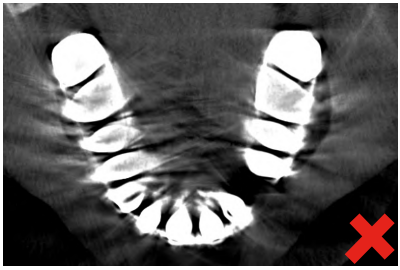


Figure 3: Metal artifacts

5 OPTICAL IMPRESSIONS

- When taking exposures of the optical impressions, ensure that the rows of teeth of the patient's upper and lower jaw are captured in full. Otherwise, it is not possible to manufacture a therapeutic appliance.
- Please note that the optical impressions must not be older than 3 months.
- When taking the optical impressions, make sure that the camera accurately captures the transition between teeth and mucous membrane. The transition contains important retention areas that are necessary to ensure a good fit of the therapeutic appliance.
- When registering the optical impressions, ensure that they were taken at roughly the same time as the 3D X-ray scan since, otherwise, the jaw situation will not correspond to the situation captured (see figure 4). A guiding value here is a maximum of 90 days in between the time when the scan was taken and the optical impression.
- Ensure that the optical impressions do not contain any errors and that they are suitable for planning. Potential errors are:
  - Holes (please see figure 5)
  - Distortions (please see figure 6)
  - Misalignment (please see figure 7)
  - Artifacts (please see figure 8)
  - Noise (please see figure 9)
  - Tartar and plaque

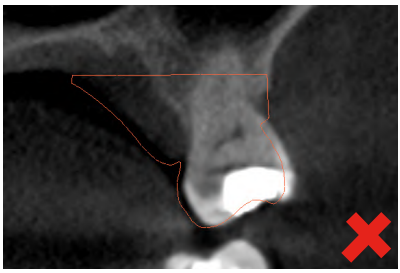


Figure 4: Optical surface data does not match the jaw situation

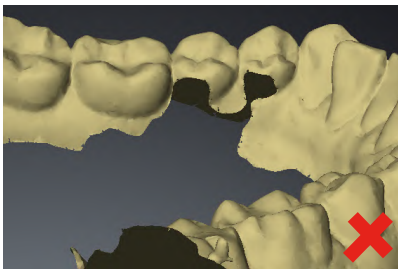


Figure 5: Holes in the surface data

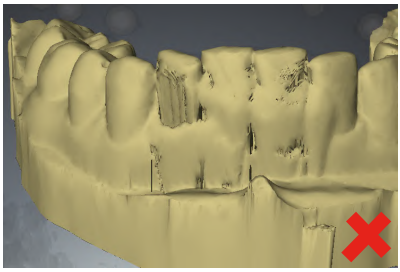


Figure 6: Distortions in the surface data

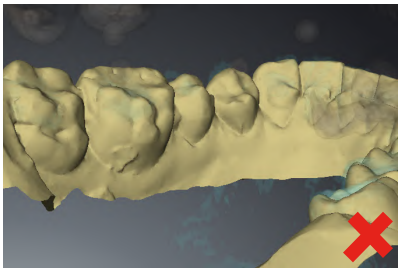


Figure 7: Misalignment in the surface data

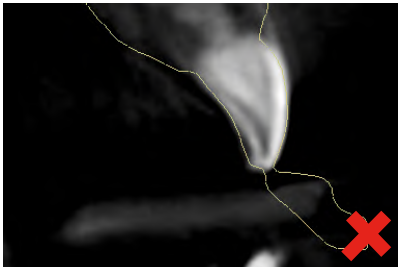


Figure 8: Artifacts

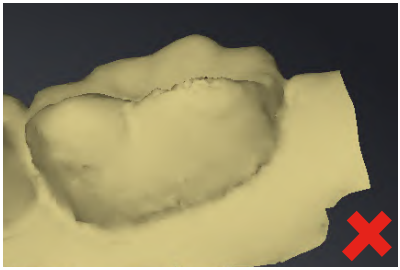


Figure 9: Noise

Please make sure that the optical impressions are of good quality when taking them. Faulty optical impressions cannot be used to manufacture a therapeutic appliance, meaning that the impression has to be re-taken.

6 INDICATIONS OF TEETH STATUS

- Ensure that the upper jaw and lower jaw do not contain any elongated teeth. If elongated teeth are contained, these must be taken into consideration through additional clearances at the time of the interocclusal recording with the bite fork.
- Ensure that the upper jaw and lower jaw do not contain any removable partial or full dentures.
- Ensure that there are at least 3 teeth in each quadrant in the premolar and molar area. Otherwise, it cannot be guaranteed that the therapeutic appliance can be fixed in position securely.
- Ensure that no changes are planned with regard to the dental status, such as hollowing of areas for future crowns or fillings. The therapeutic appliance cannot be prepared for future changes in dental status.
- Ensure that there are no temporary prostheses in the mouth. A change of the tooth surface means that the therapeutic appliance will no longer be correct and the patient can no longer use it.
- Ensure that there are no gaps in these areas, if possible: Tooth areas 13-15, 23-25, 36-38, 46-48, or in the American tooth scheme 4-6, 11-13, 17-19, 30-32.
- Ensure that there are no loose teeth in the mouth.
- Ensure that there is no advanced periodontitis.
- Ensure that the second premolar in the lower jaw is not the end tooth.
- Ensure that there are enough usable undercuts and retention areas. Crown margins, pronounced crests, poor buccal fillings or the like cannot be used.

7 UNPACKING THE SICAT OPTISLEEP THERAPEUTIC APPLIANCE

SICAT provides SICAT OPTISLEEP with the following components:

- Therapeutic appliance consisting of a splint for the upper jaw, a splint for the lower jaw and attached connectors
- Connector set with connectors in different lengths for setting the treatment position.
- Storage container
- Gift bag to be handed over to the patient
- Care information for the patient
- Instructions for use for the treating dentist

The connectors attached guarantee that the treatment position you plan will be achieved. Please check that connectors of the correct length are connected to the splint.

Clean the therapeutic appliance before you first insert it into the patient's mouth. Make sure that no impurities get onto the therapeutic appliance when handling. You will find information on the cleaning agents to be used at *Cleaning and storing the SICAT Optisleep therapeutic appliance [▶ Page 27]*.

8 ADJUSTING THE TREATMENT POSITION

10 pairs of connectors with different lengths are available to adjust the degree of protrusion of SICAT OPTISLEEP. The difference in length is 1 mm resulting in an overall variability of 10 mm.

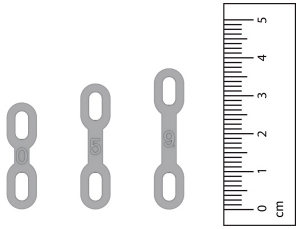


Figure 1: Connector lengths (example)

A short connector (Fig. 2) results in a reinforcement of the protrusion, while a long connector (Fig. 3) results in a reduction of the protrusion.

Figure 2: Maximum protrusion with connector 0

Figure 3: Minimum protrusion with connector 9

By default, SICAT plans the longest connector for the design that fits the treatment position defined by you. Therefore, as many short connector pairs as possible are available for further protrusion.

During the break-in period, we recommend beginning the treatment with a longer connector than originally planned in order to prevent muscular tensions.

There are various versions of splints and connectors that differ only slightly from each other. Please note that they must not be combined.

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

Fastening and loosening the connector

The fastening holes in the connectors and connector pins on the pins are oval. This means that the connectors can only be superimposed on the respective splint by pressing on them lightly at right angles. This position cannot be assumed when the splint is being worn (Fig. 4), thereby preventing it from slipping accidentally during treatment. You can fix the connectors by aligning them vertically to the upper jaw splint or lower jaw splint (Fig. 5) and pressing on the pins of the respective splint. You will hear a click when the connector locks in correctly.

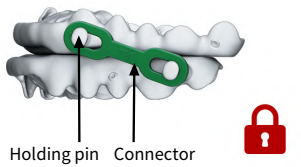


Figure 4: Connector cannot be loosened

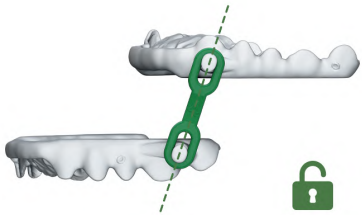


Figure 5: Connector can be loosened

When securing the connector, please make sure that you hold the splint with the other hand (Fig. 6) so that the splint is not overly strained.

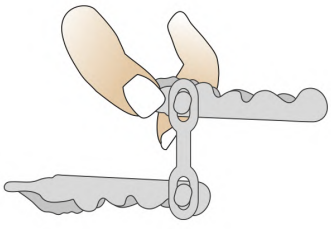


Figure 6: Holding the therapeutic appliance

The connectors must be changed when a change of protrusion for optimization of treatment is required if the length of the connectors, especially in the center part, has changed or if other deformations are visible.

9 INSERTING THE SICAT OPTISLEEP THERAPEUTIC APPLIANCE

In order to optimally insert the SICAT OPTISLEEP into the patient's mouth, please proceed as follows:

1. Ensure that the upper jaw and lower jaw are correctly aligned. The attachment point for the connector is on the upper jaw at the front and at back in the case of the lower jaw.

2. Slide the therapeutic appliance completely into the mouth.

3. First place the lower jaw splint and then the upper jaw splint on the teeth by applying a little pressure.

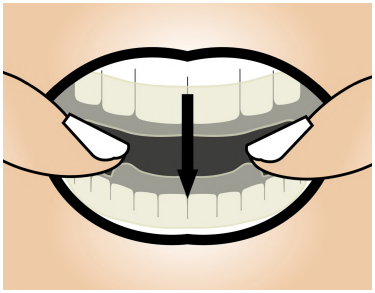


Figure 1: Inserting lower jaw splint

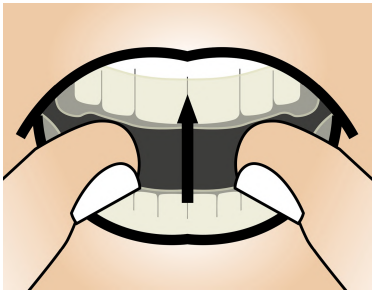


Figure 2: Inserting upper jaw splint

4. The appliance snaps onto the teeth and should stay securely in place. Please also refer to the chapter *Fitting* *[▶ Page 23]*.

10 REMOVING THE SICAT OPTISLEEP THERAPEUTIC APPLIANCE

To remove the therapeutic appliance from the patient’s mouth, proceed as follows:

1. Ensure that it is possible to remove the splint from the patient's teeth by exerting only little force. Please also refer to the chapter *Fitting* *[▶ Page 23]*.

2. Place your thumbs on both sides of the lower jaw splint in the area of the molars and lever the splint upward with equal, slight pressure to remove the appliance. Do not use the connector pins to remove the appliance.

3. Repeat the procedure for the upper jaw splint.

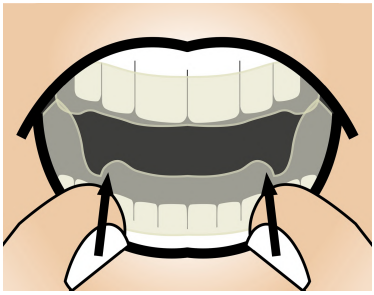


Figure 1: Removing lower jaw splint

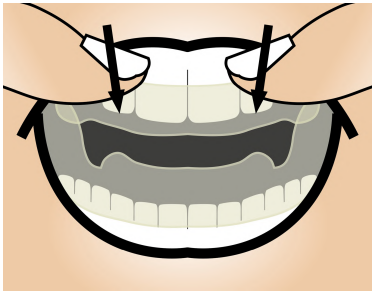


Figure 2: Removing upper jaw splint

11 FITTING

A first fitting and a testing phase will take place.

During the first fitting, please pay attention to the following:

- Before handing over the SICAT OPTISLEEP to the patient, check that the therapeutic appliance fits exactly in the patient's mouth. The splint should engage well and sit firmly on the teeth so that the splint does not come loose when the mouth is opened. In addition, the patient should be able to remove the therapeutic appliance with relative ease.
- When choosing a shorter or longer connector, bear in mind that the forces acting on the splint will change. If you plan to use different connector lengths at the beginning of treatment, please check the fit of the therapeutic appliance with each of these connector lengths.

The testing phase extends over the period between the first fitting of the SICAT OPTISLEEP to the patient and the first check-up appointment in order to reliably assess the fitting of the appliance for long-term and effective treatment. SICAT recommends that the first check-up be carried out no later than 8 weeks after the first fitting.

11 FITTING

During the testing phase, please pay attention to the following:

- During this time, the patient must wear the splint daily.
- If the following known side effects occur during the testing phase, you must decide whether SICAT OPTISLEEP is still indicated for the patient. This includes:
  - Pain in the temporomandibular joints
  - Breathing difficulties
  - Allergic reactions
  - Inflammations
  - Loosening of the teeth
  - Permanent excessive salivation
  - Unintentional tooth movements due to a change in occlusion
- Contact SICAT if you notice an inadequate fit of the therapeutic appliance. Never alter the splint yourself as this will void the warranty and the safe use of the therapeutic appliance can no longer be ensured.
- If the patient has the feeling that the bite is incorrect in the morning, he/she can remedy this through jaw exercises, by chewing or by using an occlusion trainer.

12 INSTRUCTING THE PATIENT

Please pay attention to the following:

- Instruct the patient on how to use and handle the therapeutic appliance prior to first use.
- Practice inserting and removing the therapeutic appliance together with the patient. For further information about this see *Inserting the SICAT OPTISLEEP therapeutic appliance [▶ Page 21]* and *Removing the SICAT OPTISLEEP therapeutic appliance [▶ Page 22]*.
- Inform the patient about possible risks associated with using the therapeutic appliance. For further information about this see *Safety instructions [▶ Page 30]* and the Application and care information for the patient.
- Inform the patient that treatment with the therapeutic appliance should begin immediately after delivery. Otherwise, the splint may no longer fit accurately as a result of natural tooth movements.
- Inform the patient that the therapeutic appliance must be worn every night while sleeping.
- Inform the patients that the therapeutic appliance only works as long as it is worn.
- Inform the patient that the therapeutic appliance will cease to fit properly after only a few days if it is worn irregularly. This is a result of natural tooth movements.
  It can happen that the patient recognizes a slight change of occlusion after taking out the SICAT OPTISLEEP in the morning. Normally, this will go away quickly. Finding the normal bite again can be accelerated by jaw exercises, chewing gum or the like or by using a special bite trainer.
- Inform the patient that the formation of tartar may lead to bad fit of the splint as well as to regular removal of tartar.
- Ask the patient to keep a sleep diary in order to be able to better judge the treatment position and recognize possible side-effects, if any, early on.
- Give the patient the contact details for your medical practice for possible follow-up questions.

13 REGULAR CHECK-UPS

Make regular checkup appointments with your patients. Check the course of treatment at regular intervals and adjust the treatment position if necessary. Information on this can be found in the section *Adjusting the treatment position [▶ Page 19]*.

14 CLEANING AND STORING THE SICAT OPTISLEEP THERAPEUTIC APPLIANCE

Please note the following before using and handling the therapeutic appliance:

- Clean the therapeutic appliance before you first insert it into the patient's mouth.
- Make sure that no impurities get onto the therapeutic appliance during handling.

Inform the patient that the following instructions for correct, careful cleaning and care must be observed:

- The therapeutic appliance must be removed before eating and drinking.
- Before inserting the therapeutic appliance, the patient must always thoroughly brush his or her teeth. Tartar should be removed regularly for better preservation of the splint.
- The therapeutic appliance must be cleaned after each use with a soft toothbrush and lukewarm water.
- Before putting the therapeutic appliance in the provided storage box, it must be dried to prevent possible germ growth.
- The therapeutic appliance must occasionally be cleaned with a mild detergent (e.g. washing-up liquid) or a mild oxygen-free prosthesis cleaner.
- The therapeutic appliance should be protected from direct sunlight and heat and be kept in a safe place that is inaccessible to pets.

15 DAMAGES AND REPAIRS

Improper cleaning and use may lead to damage.

The use of UV light for cleaning may also lead to material damage and should therefore be avoided.

What to do in case of damage

The patient should not use the therapeutic appliance and connectors if they are broken or otherwise damaged due to the risk of swallowing or inhaling small parts. Instruct your patients that a therapeutic appliance must not be worn in this case.

Repair after damage

You may not repair therapeutic appliances and connectors after damage.

16 DISPOSAL

Please dispose of the appliance in accordance with the regulations for disposing of infectious materials applicable in your country.

17 REPORTING

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

18 SICAT OPTISLEEP WARRANTY

Warranty

SICAT provides a two-year warranty for material defects and manufacturing faults of the SICAT OPTISLEEP therapeutic appliance. For warranty conditions, visit www.sicat.com.

Service life

The service life of SICAT OPTISLEEP is 2 years. We recommend that you check the therapeutic appliance regularly during its service life. Use of the therapeutic appliance must not be continued after the end of its service life. Timely replacement with a new therapeutic appliance is recommended.

19 SAFETY INSTRUCTIONS

Order

⚠**CAUTION!** An incorrect treatment plan may pose a health hazard to the patient or lead to a wrong treatment. Make sure that your order has been created for the correct treatment plan.

⚠**CAUTION!** Wrong state of tooth status in the plaster model and in the optical model could pose health hazard to the patient or lead to the wrong treatment. Make sure that the plaster model and the optical model reflect the correct tooth status and are up to date when ordering.

⚠**CAUTION!** Missing and incorrect components in the order package may lead to a faulty therapeutic appliance. Make sure that the necessary and correct components are included in your order package.

⚠**CAUTION!** Insufficient packaging of plaster models could cause damage to the plaster models. Use a robust and well padded packaging if sending plaster models.

⚠**CAUTION!** Missing label of the plaster model could result in an incorrect assignment of the patient and the plaster model. Label the plaster model with the patient information.

Instructing the patient

⚠**WARNING!** Missing to inform the patient regarding removing the therapeutic appliance and contacting you in case of breathing problems or obstruction of oral breathing could pose a health hazard to the patient. Inform the patient that he or she must remove the therapeutic appliance from the mouth immediately and contact you in case of breathing problems or obstruction of oral breathing.

⚠**WARNING!** Missing to inform the patient by qualified personnel regarding the correct handling of the therapeutic appliance and the usage of the therapeutic appliance could pose a health hazard or wrong treatment. Ensure that qualified personnel inform the patient about the correct handling of the therapeutic appliance and the usage of the therapeutic appliance.

⚠**WARNING!** Missing to inform the patient regarding contacting you in case of side effects could pose a health hazard to the patient. Instruct the patient that he or she must immediately contact you in case of pain, nausea, itching, difficulty in breathing, rashes, or any allergic reaction.

⚠**WARNING!** Failure to inform the patient that the therapeutic appliance must be removed before eating could cause damage to the therapeutic appliance. Inform the patient that he or she must remove the therapeutic appliance before eating and drinking, with the exception of drinking water.

⚠**WARNING!** The first application of the therapeutic appliance without the supervision of qualified personnel could pose a health hazard to the patient or lead to the wrong treatment. The first insertion of the therapeutic appliance must be supervised by qualified personnel.

⚠**CAUTION!** Missing to inform the patient regarding contacting you in case of undesired teeth movement or undesired changes of the dental occlusion could pose a health hazard to the patient. Inform the patient that he or she must contact you in case of undesired teeth movement or undesired changes of the dental occlusion.

⚠**CAUTION!** Missing to inform the patient regarding contacting you in case of pain or problems in the TMJ could pose a health hazard to the patient. Inform the patient that he or she must contact you in case of pain or problems in the TMJ.

⚠**CAUTION!** Missing to inform the patient regarding contacting you in case of loose teeth could pose a health hazard to the patient. Inform the patient that he or she must contact you in case of loose teeth.

⚠**CAUTION!** Failure to inform the patient of accumulating tartar could cause damage to the therapeutic appliance. Inform the patient that tartar must be removed regularly.

Usage

⚠**WARNING!** Failure to check the severity of the obstructive sleep apnea (OSA) could lead to health implications or incorrect treatment. Before using the therapeutic appliance, have the severity of the obstructive sleep apnea checked to enable selection of the best possible treatment position.

⚠**WARNING!** Using the therapeutic appliance could cause breathing problems or obstruction of oral breathing. Remove the therapeutic appliance if breathing problems occur.

⚠**CAUTION!** Wearing the therapeutic appliance could cause excessive salivation. If problems due to excessive salivation persist, remove the therapeutic appliance.

Changes to the therapeutic appliance

⚠**WARNING!** Changes to the therapeutic appliance may pose a health hazard or lead to the wrong treatment. Do not make any changes to the therapeutic appliance.

⚠**WARNING!** Combining various splint and connector versions may lead to a loss of function of the splint or to damage to health. When changing the connectors, always ensure that you use the correct version.

Treatment

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

⚠**WARNING!** The use of the therapeutic appliance is not a guarantee of successful treatment in any case. Do not act on the assumption that the use of the therapeutic appliance will reduce snoring and effectively treat obstructive sleep apnea in every case.

⚠**WARNING!** Not checking the adjustment and the position of the therapeutic appliance in the mouth of the patient could pose a health hazard to the patient or a wrong treatment. Ensure that only qualified personnel checks the adjustment and positioning of the therapeutic appliance on the jaw of the patient.

⚠**WARNING!** Lack of regular checks of the therapeutic appliance and its function by qualified personnel during treatment could pose a health hazard to the patient or lead to the wrong treatment. Ensure that qualified personnel check the therapeutic appliance and its function in the patient regularly.

⚠**WARNING!** Missing to take into account the medical history of the patient could pose a health hazard to the patient. Prior to treatment, consider the medical history of the patient and transfer the patient to the appropriate specialist, if necessary. Examples of pre-existing conditions are allergies, asthma, respiratory diseases and diseases of the respiratory tract or other relevant health problems. During treatment, regularly monitor the patient for changes in medical condition and allergic reactions.

⚠**WARNING!** Missing to monitor the patient regarding breathing problems or obstruction of oral breathing could pose a health hazard to the patient. Observe the patient regarding breathing problems or obstruction of oral breathing.

⚠**CAUTION!** Missing to monitor the patient regarding undesired tooth movement or undesired changes of the dental occlusion could pose a health hazard to the patient. Monitor the patient during treatment regarding undesired tooth movement or undesired changes of the dental occlusion.

⚠**CAUTION!** Missing to monitor the patient regarding pain in the palate, gingiva, or teeth could pose a health hazard to the patient. Observe the patient regarding pain in the palate, gingiva, or teeth.

⚠**CAUTION!** Missing to monitor the patient regarding Temporomandibular Disorder could pose a health hazard to the patient. Perform regular treatment monitoring regarding Temporomandibular Disorder.

⚠**CAUTION!** Missing to monitor the patient regarding loose teeth could pose a health hazard to the patient. Observe the patient regarding loose teeth.

⚠**CAUTION!** Wearing the therapeutic appliance could cause pain in the temporomandibular joint in some cases. Remove the therapeutic appliance if pain in the temporomandibular joint occurs.

⚠**CAUTION!** Using the therapeutic appliance could cause pain in the palate, gingiva, or teeth. Remove the therapeutic appliance if pain in the palate, gingiva, or teeth occurs.

⚠**CAUTION!** Using the therapeutic appliance could cause loose teeth. Remove the therapeutic appliance if loose teeth occur.

⚠**CAUTION!** Using the therapeutic appliance could cause tooth movements or changes in dental occlusion. Remove the therapeutic appliance if tooth movements or changes in dental occlusion occur.

Cleaning and storage

⚠**WARNING!** Using inappropriate disinfectants and the application of an incorrect disinfection process for the therapeutic appliance could cause damage to the therapeutic appliance. Only use disinfection processes and/or disinfectants suitable for PMMA (Polymethyl Methacrylate) materials.

⚠**WARNING!** Missing cleaning or disinfection of the therapeutic appliance before first use could pose a health hazard to the patient. Clean and disinfect the therapeutic appliance before first use.

⚠**WARNING!** Using hot or boiling water for cleaning the therapeutic appliance could cause damage to the therapeutic appliance. Never clean the therapeutic appliance with hot or boiling water.

⚠**WARNING!** Using denture cleaner containing oxygen for cleaning the therapeutic appliance could cause damage to the therapeutic appliance. Never clean the therapeutic appliance with a denture cleaner containing oxygen.

⚠**CAUTION!** Exposing the therapeutic appliance to direct sunlight or UV light or heat or storing it in a place that is accessible to pets may lead to damage. Inform the patient that the therapeutic appliance must be stored in a dry, suitable storage container inaccessible to pets and protected from heat.

Damage

⚠**WARNING!** A damaged therapeutic appliance could pose a health hazard. Never put a damaged therapeutic appliance into the mouth. Examples for damages are deformations, cracks, fractures, gaps, and loose parts.

Service life

⚠**WARNING!** Usage after exceeding the life time of the therapeutic appliance may pose a health hazard. Make sure that the patient does not use the therapeutic appliance after the expiry of its service life.

20 EXPLANATIONS OF LABELING

 Caution! Observe the accompanying documents.

 Order number

 Case number

 Observe the instructions for use.

 Manufacturer

 Date of manufacture

 Lot number

 Medical device

 Prescription use only (USA specific symbol)

 Keep away from sunlight

 Non-safety related tip

21 MANUFACTURER AND SUPPORT

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REVISION: 2022-03-28

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