



Instructions for use for the medical professional
English

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1 THE OPTISLEEP THERAPEUTIC APPLIANCE

1 THE OPTISLEEP THERAPEUTIC APPLIANCE

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



⚠ CAUTION! According to US Federal Law, this product may be used only by or by instruction of physicians, dentists, or licensed practitioners.

Design and production

OPTISLEEP therapeutic appliances are customized for each respective patient. SICAT designs and develops the therapeutic appliance individually for each patient based on your order. OPTISLEEP is then produced by SICAT or a partner laboratory.

1 THE OPTISLEEP THERAPEUTIC APPLIANCE

1.1 INDICATIONS FOR USE

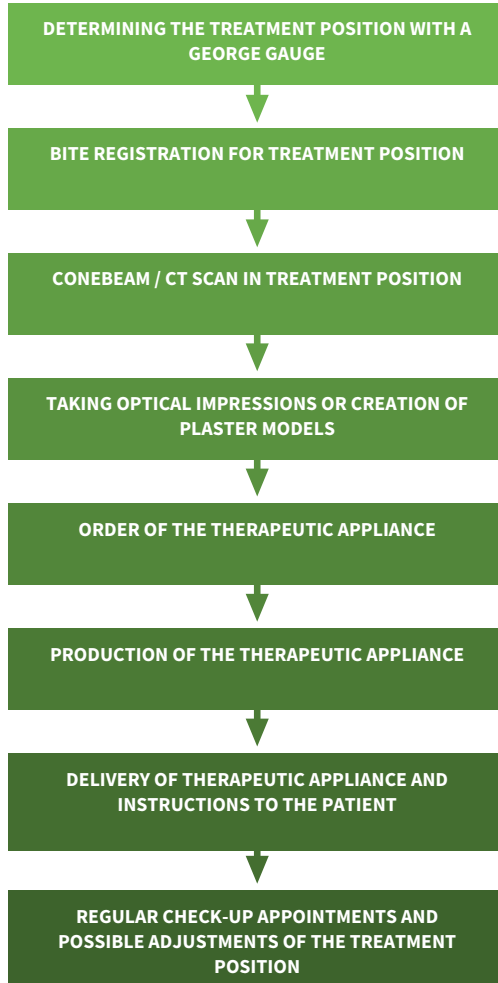
In adult population

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

1.2 CONTRAINDICATIONS

- Central sleep apnea
- Severe respiratory disorders
- Loose teeth
- Advanced periodontal disease
- Under 18 years of age
- Edentulous jaw

2 OPTISLEEP WORKFLOW

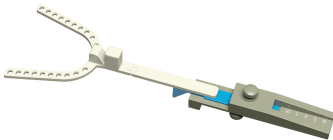


3 DETERMINING THE TREATMENT POSITION USING THE GEORGE GAUGE

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

The George Gauge is usually delivered with two different versions of the bite fork. Please **exclusively** use the white bite fork with 5 mm clearance.

Select the treatment position such that the vertical opening between the upper and lower jaw is at least 6 mm.



5 mm bite fork in George Gauge

Inserting the George Gauge into the patient's mouth

1. Loosen the lower screw of the George Gauge.

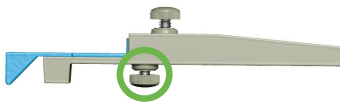


Image 1: Lower screw of the George Gauge

2. Move the lower jaw incisor clamp so that the patient's lower anterior teeth fit into the notch between the lower jaw incisor clamps. Note that the center line display is above the middle lower incisors.
3. Fix the lower screw of the George Gauge.
4. Remove the George Gauge from the patient's mouth.

3 DETERMINING THE TREATMENT POSITION USING THE GEORGE GAUGE

5. Loosen the upper screw of the George Gauge.

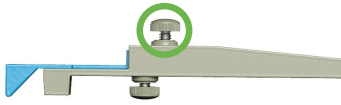


Image 5: Upper screw of the George Gauge

6. Slide the bite fork with the upper jaw incisor notch upward into the housing of the George Gauge.
7. Have the patient bite into the upper and lower notches with his upper and lower incisors.

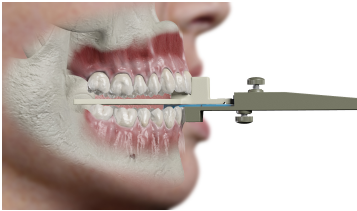


Image 7: Lower and upper jaw teeth

8. **In the case of a severe overbite, a pronounced sagittal curve of occlusion, or open bite, you may fill the upper notch with plastic composite in order to ensure sufficient vertical opening.**

Measuring the maximum protrusion

1. Have the patient move his or her lower jaw forward several times as exercise. You should measure the maximum protrusion 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.
3. Note the position on the mm scale of the George Gauge.
4. Have the patient protrude his or her lower jaw as far as possible.
5. **You may ask the patient to hold the possible treatment position for 2 to 3 minutes to see how he or she feels.**

3 DETERMINING THE TREATMENT POSITION USING THE GEORGE GAUGE

6. 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.
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. Add registration material to the bite fork on the side for the upper jaw. Leave the area around the upper jaw incisor notch free.
2. **When performing the bite registration, ensure that there is enough registration material to get sufficient impressions even with the required vertical opening. When performing the bite registration for patients with a pronounced Spee's curve, ensure that the bite fork does not deform.**
3. Insert the George Gauge into the patient's mouth.
4. Perform the bite registration for the upper jaw.
5. Remove the George Gauge from the patient's mouth.
6. Add registration material to the bite fork on the side for the lower jaw. Leave the area around the lower jaw incisor notch free.
7. Position the bite fork on the teeth of the upper jaw such that the upper teeth rest on the upper jaw incisor notch.
8. Have the patient move his or her lower jaw forwards until the lower teeth rest in the lower jaw incisor notch.

3 DETERMINING THE TREATMENT POSITION USING THE GEORGE GAUGE

9. Perform the bite registration for the lower jaw.
10. Remove the George Gauge from the patient's mouth.
11. Remove the bite fork from the George Gauge.

4 NOTES ON SCANS

3D X-ray scan

- Ensure that the patient's lower jaw is in treatment position when taking the scan (ideally by inserting the George Gauge bite fork with registration material).
- Ensure that all the necessary image information is contained in the conebeam scan (please see image 1). The patient's upper and lower jaw must be captured in full in the X-ray scan. Otherwise, it is not possible to register the optical impressions.
- Ensure that the bite registration seats gap-free on the patient's teeth (for example by using the George Gauge bite fork).
- Ensure that the patient does not move during the scan in order to avoid movement artifacts (please see figure 2).
- Ensure that at least four teeth per quadrant do not have any metal artifacts (please see figure 3).

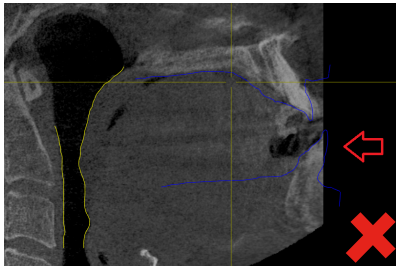


Figure 1: Missing areas in the DVT data

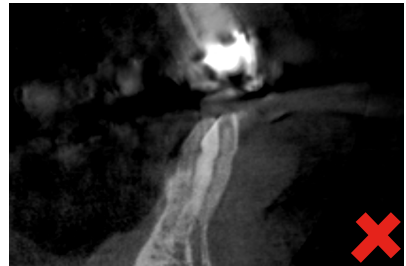


Figure 2: Patient movement

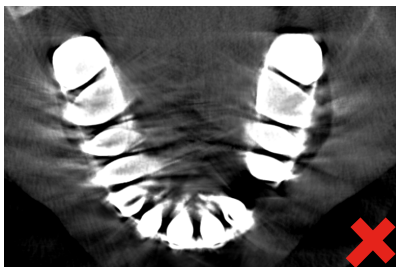


Figure 3: Metal artifacts

4 NOTES ON SCANS

Optical impressions

- When taking 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.
- Figure 1: Ensure that the optical impressions match the 3D X-ray image in terms of the time they were taken. As a guidance, there should not be more than 90 days between the times of taking the images.
- Make sure that the optical impressions do not contain any errors. Examples of errors are:
 - Holes (please see figure 2)
 - Distortions (please see figure 3)
 - Misalignment (please see figure 4)
 - Artifacts (please see figure 5)
 - Noise (please see figure 6)

4 NOTES ON SCANS



Figure 1: Optical surface data does not match the jaw situation

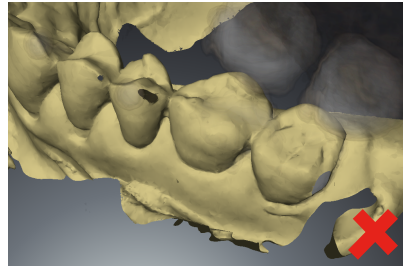


Figure 2: Holes in the surface data

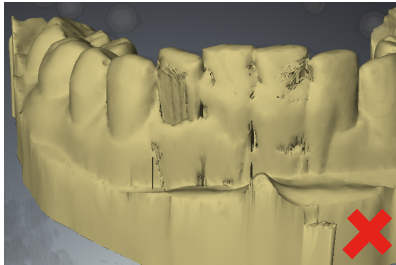


Figure 3: Distortions in the surface data

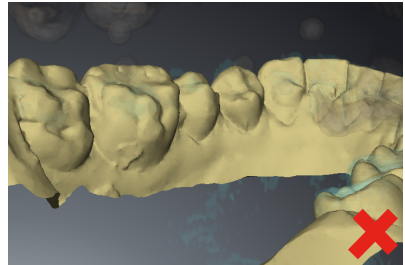


Figure 4: Misalignment in the surface data

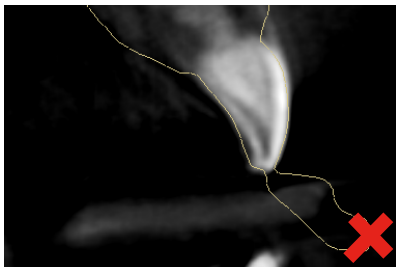


Figure 5: Artifacts

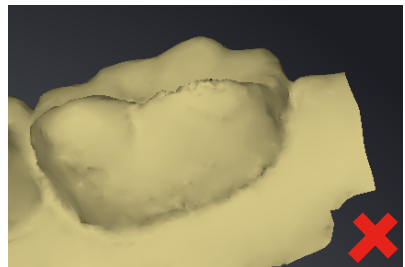


Figure 6: Noise

5 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 by 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 there are no gaps larger than 1.6 mm between two teeth. Otherwise the stability of the therapeutic appliance cannot be guaranteed.
- 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.

6 UNPACKING THE OPTISLEEP THERAPEUTIC APPLIANCE

SICAT provides the OPTISLEEP with the following components:

- OPTISLEEP, a two-piece therapeutic appliance consisting of a part for the upper jaw and a part for the lower jaw with attached connectors
- Connector set with connectors in different lengths for setting the treatment position
- Storage container
- Gift bag to give to the patients
- Patient care information
- Instructions for use for the medical professional

The connectors attached guarantee that the treatment position you plan will be achieved. Please check and ensure that you have connected the correct connectors to the 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 when handling. You will find information on the cleaning agents to be used at *Cleaning the OPTISLEEP therapeutic appliance* [▶ Page 22].

7 INSTRUCTING THE PATIENT

Please pay attention to the following:

- Instruct the patient on how to use and handle the therapeutic appliance prior to the first time of using.
- Practice inserting and removing the therapeutic appliance together with the patient. You will find information on this at *Inserting the OPTISLEEP therapeutic appliance* [▶ Page 20] and *Removing the OPTISLEEP therapeutic appliance* [▶ Page 21].
- Inform the patient about possible risks associated with using the therapeutic appliance.
- Give the patient the contact details for your practice for possible follow-up questions.

8 ADJUSTING THE TREATMENT POSITION

You may adjust the treatment position by switching between the 10 different positions using the connector pairs of different lengths. The size 4 connector corresponds with the position determined during the 3D X-ray scan (standard position). The OPTISLEEP is delivered in this position.

The distance between the individual positions is 1 mm. The following table shows the connector numbers and the respective lengths:

SIZE OF THE CONNECTOR	LENGTH OF THE CONNECTOR
0	20 mm
1	21 mm
2	22 mm
3	23 mm
4	24 mm (standard position)
5	25 mm
6	26 mm
7	27 mm
8	28 mm
9	29 mm

8 ADJUSTING THE TREATMENT POSITION

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 put on the respective appliance by pressing on them lightly at right angles. This position cannot be assumed when the appliance is being worn, thereby preventing them from slipping accidentally during treatment. You can attach the connectors by aligning them vertically to the upper jaw appliance or lower jaw appliance and pressing on the pins of the respective appliance. You will hear a click when the connector locks in correctly.



Figure 1: Connector in fixed position



Figure 2: Connector in removable position

Please pay attention when securing the connector that you hold the appliance below the holding pin with the other hand in order to prevent the appliance from being overly stressed.

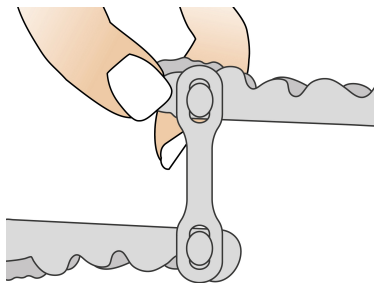


Figure 3: Holding the therapeutic appliance

9 TREATMENT

9.1 PRIOR TO TREATMENT

Please pay attention to the following prior to starting treatment:

- Check if the correct connector is mounted on the therapeutic appliance in order to ensure the correct treatment position.
- Inform the patients that the therapeutic appliance needs to be worn every night during sleep.
- Inform the patients that the therapeutic appliance only works as long as it is being worn.
- Please ask the patients to keep a sleep diary in order to be able to better judge the treatment position and recognize any possible side-effects if any early on.

9.2 DURING THE TREATMENT

Make regular check-up appointments with your patients. Control the course of treatment at regular intervals and adjust the treatment position if necessary. You will find information on this at *Adjusting the treatment position* [▶ Page 17].

10 INSERTING THE OPTISLEEP THERAPEUTIC APPLIANCE

10 INSERTING THE OPTISLEEP THERAPEUTIC APPLIANCE

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

1. Slide the therapeutic appliance into the mouth completely.
2. 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 on the lower jaw at the back.
3. First place the lower jaw appliance and then the upper jaw appliance on the teeth by applying a little pressure.

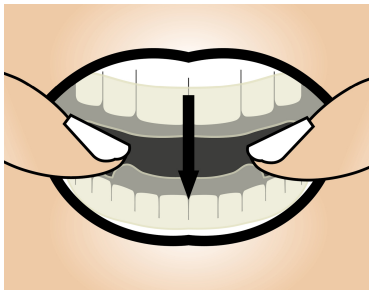


Figure 1: Lower jaw appliance

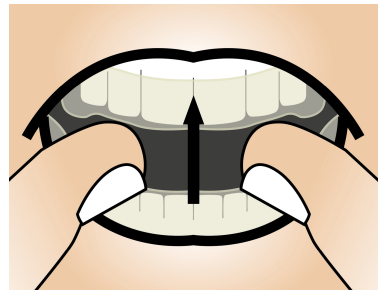


Figure 2: Upper jaw appliance

4. The appliance snaps onto the teeth and should stay securely in place.

11 REMOVING THE OPTISLEEP THERAPEUTIC APPLIANCE

11 REMOVING THE 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 appliance from the patient's teeth by exerting little force.
2. Place your thumbs on the lower appliance in the area of the molars on both sides and lever these upward with equal slight pressure. Carefully pull the upper appliance from the teeth.

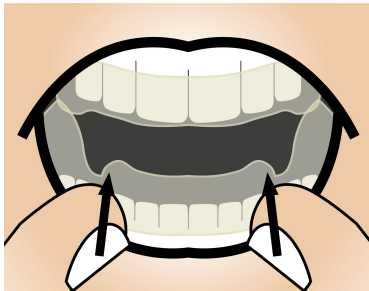


Figure 1: Lower jaw appliance

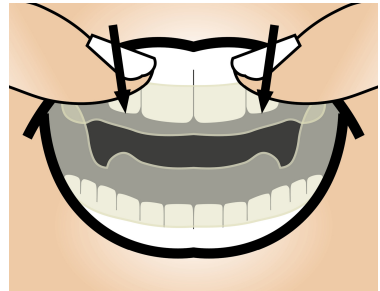


Figure 2: Upper jaw appliance

12 CLEANING THE OPTISLEEP THERAPEUTIC APPLIANCE

In order to ensure the correct and careful cleaning and care of the therapeutic appliance, please pay attention to the following:

- Inform the patient that the therapeutic appliance must be cleaned with a soft toothbrush under lukewarm running water.
- Inform the patient that the therapeutic appliance needs to be cleaned and dried before being stored in the storage container in order to prevent the potential forming of germs.
- Inform the patient that the therapeutic appliance needs to be occasionally cleaned with a mild cleaning agent or a prostheses cleaner which does not contain oxygen.

13 DAMAGES AND REPAIRS

Stress cracks

The formation of small stress cracks on the surface of the therapeutic appliance does not result in any impairment to the functionality of the therapeutic appliance.

What to do in case of damage

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

Repair after damage

You may not repair the therapeutic appliances and connectors after breakage.

14 OPTISLEEP WARRANTY

SICAT provides a two-year warranty for material and production errors of the OPTISLEEP therapeutic appliance. The life span corresponds at least to the warranty period. We recommend that you check the therapeutic appliance after a duration of use of two years at the latest. The effectiveness of the therapeutic appliance in terms of treating snoring and obstructive sleep apnea is explicitly not part of the warranty.

15 SAFETY INSTRUCTIONS

Order

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

⚠ **CAUTION!** Incorrect state of tooth status in the plaster model or in the optical model could pose health hazard to the patient or lead to an incorrect treatment. Make sure that the plaster model or 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 adequately padded packaging, if plaster models are being shipped.

⚠ **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!** Failure to inform the patient about consulting you regarding the usage of the therapeutic appliance and consulting you in the case of respiratory problems and blockages of the respiratory path may pose a health hazard to the patient. Instruct the patient that he or she must immediately remove the therapeutic appliance from his or her mouth and contact you if he or she notices respiratory problems and blockages of the respiratory path.

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

15 SAFETY INSTRUCTIONS

⚠ **WARNING!** Lack of instruction to the patient about consulting you for any side effects may pose a health hazard to the patient. Instruct the patient that he or she must immediately contact you in case of infections, pain, nausea, itching, difficulty in breathing, rashes, or any allergic reaction.

⚠ **WARNING!** Failure to inform the patient about removing the therapeutic appliance before eating or drinking may result in damage to the therapeutic appliance. Instruct the patient that he or she must remove the therapeutic appliance before eating or drinking, except when 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 an incorrect treatment. The first insertion of the therapeutic appliance must be supervised by qualified personnel.

⚠ **CAUTION!** Failure to inform the patient about consulting you in the case of unwanted movement of teeth or unwanted changes to the dental occlusion may pose a health hazard to the patient. Instruct the patient that he or she must immediately contact you if he or she notices unwanted movement of teeth or unwanted changes to the dental occlusion.

⚠ **CAUTION!** Failure to inform the patient about consulting you about pain in or problems with the TMJ may pose a health hazard to the patient. Instruct the patient that he or she must immediately contact you in case of pain in or problems with the TMJ.

⚠ **CAUTION!** Failure to inform the patient about consulting you about loose teeth may pose a health hazard to the patient. Instruct the patient that he or she must immediately contact you if he or she notices loose teeth.

Usage

⚠ **WARNING!** A failure to check the severity of the obstructive sleep apnea (OSA) could lead to health implications or incorrect treatment. Prior to using the therapeutic appliance, you should have the patient checked if he or she is suffering from minor to medium obstructive sleep apnea (OSA).

⚠ **WARNING!** The use of the therapeutic appliance could lead to breathing problems or a blockage of the respiratory path. Remove the therapeutic appliance if breathing problems occur.

⚠ **CAUTION!** The use of the therapeutic appliance could result in excessive salivation. If problems persist due to excessive salivation, contact your attending dentist.

15 SAFETY INSTRUCTIONS

Changes to the therapeutic appliance

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

Treatment

⚠ **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 having the setting and position of the therapeutic appliance in the patient's mouth checked by qualified personnel could pose a health hazard to the patient or lead to an incorrect treatment. Ensure that only qualified personnel check the setting and position of the therapeutic appliance in the patient's mouth.

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

⚠ **WARNING!** Failure to take into account the medical history of the patient could pose a health hazard to the patient. Dentists should consider the medical history of patients, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device. Examine the patient during the treatment regularly to diagnose health problems and allergic reactions.

⚠ **WARNING!** Failure to observe the patient with regard to respiratory problems and blockages of the respiratory tract could result in negative health implications for the patient. Observe the patient with regard to respiratory problems and blockages of the respiratory tract.

⚠ **CAUTION!** Failure to observe the patient with regard to unwanted tooth movements and unwanted changes to dental occlusion may pose a health hazard to the patient. Observe the patient during treatment to detect any unwanted tooth movement or unwanted changes in dental occlusion.

⚠ **CAUTION!** Failure to observe the patient with regard to pain in the gingiva, oral mucosa, or teeth may pose a health hazard to the patient. Observe the patient with regard to pain in the gingiva, oral mucosa, or teeth.

15 SAFETY INSTRUCTIONS

⚠ **CAUTION!** Failure to monitor the patient's treatment with regard to cranio-mandibular dysfunction may pose a health hazard to the patient. Regularly monitor the patient's treatment with regard to craniomandibular dysfunction.

⚠ **CAUTION!** Failure to monitor the patient's treatment with regard to loose teeth may pose a health hazard to the patient. Observe the patient with regard to loose teeth.

⚠ **CAUTION!** The use of the therapeutic appliance could result in pain of the TMJ. Remove the therapeutic appliance if pain of the TMJ occurs.

⚠ **CAUTION!** The use of the therapeutic appliance could result in pain of the gingiva, oral mucosa, or teeth. Remove the therapeutic appliance if pain of the gingiva, oral mucosa, or teeth occurs.

⚠ **CAUTION!** Use of the therapeutic appliance may result in loose teeth. Remove the therapeutic appliance if loose teeth occur.

⚠ **CAUTION!** The use of the therapeutic appliance could result in tooth movements or changes in dental occlusion. Remove the therapeutic appliance if unwanted movement of teeth or changes in the dental occlusion occur.

Cleaning

⚠ **WARNING!** The use of inappropriate disinfectants and the application of an incorrect disinfection process for the therapeutic appliance could result in damage to the appliance. Only use disinfectants and/or disinfection processes that are suitable for PMMA (Polymethyl methacrylate) materials and polyamide materials.

⚠ **WARNING!** Failure to clean or disinfect the therapeutic appliance before first use could pose a health hazard to the patient. Clean and disinfect the therapeutic appliance before first use.

⚠ **WARNING!** The use of hot or boiling water to clean the therapeutic appliance may result in damage to the therapeutic appliance. Never clean the therapeutic appliance with hot or boiling water.

⚠ **WARNING!** The use of denture cleaners containing oxygen to clean the therapeutic appliance may result in damage to the therapeutic appliance. Never clean the therapeutic appliance with denture cleaners containing oxygen.

15 SAFETY INSTRUCTIONS

Damage

⚠ **WARNING!** A damaged therapeutic appliance may pose a health hazard to the patient. Never insert a damaged therapeutic appliance into the mouth. Examples of such damages include deformations, cracks, fractures, gaps, and loose parts.

Service life

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

16 MANUFACTURER AND SUPPORT



Manufacturer:

SICAT GmbH & Co. KG

Brunnenallee 6

53177 Bonn, Germany

www.sicat.com

SICAT OPTISLEEP Support

Telephone: +49 228 85469712

Fax: +49 228 85469799

E-Mail: support@sicat.com

Further information for patients online:

www.optisleep.com

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Print information

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CONTACT



MANUFACTURER:

SICAT GMBH & CO. KG

BRUNNENALLEE 6

53177 BONN, GERMANY

WWW.SICAT.COM

**FURTHER INFORMATION FOR
PATIENTS ONLINE:**

WWW.OPTISLEEP.COM

SICAT OPTISLEEP SUPPORT

TELEPHONE: +49 228 85469712

FAX: +49 228 85469799

E-MAIL: SUPPORT@SICAT.COM

