



Instructions for use for the treating dentist
English



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1 THE SICAT OPTIMOTON THERAPEUTIC APPLIANCE

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Intended use, clinical benefit and target group

SICAT OPTIMOTION is a state-of-the-art intra-oral therapeutic appliance for use with functional problems in the orofacial region. The manufacturer digitally designs the therapeutic appliance based on individual patient data granting a high accuracy of fit.

SICAT OPTIMOTION is an intraoral device to protect teeth and restorations from injury due to bruxism. It is used for temporary treatment of Temporomandibular Disorder (TMD) along with the relief of associated headaches and pains. SICAT OPTIMOTION is able to provide temporary relief of Temporomandibular Disorder (TMD) and bruxism by reducing muscle tension. SICAT OPTIMOTION is to be worn at night and removed in the morning. In the presence of severe pain, typically only within the first days of use, it may be worn during the day with daily interruptions for eating, drinking, and cleaning of the device.

Thanks to the digital design an identical appliance can be re-ordered at any time.



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

1 THE SICAT OPTIMOTON THERAPEUTIC APPLIANCE

1.1 INDICATIONS FOR USE

- Protection of teeth and restorations from injury due to bruxism.
- Temporary treatment of Temporomandibular Disorder (TMD) along with the relief of associated headaches and pains.
- Temporary relief of Temporomandibular Disorder (TMD) and bruxism by reducing muscle tension.

1.2 CONTRAINDICATIONS

SICAT OPTIMOTION therapeutic appliances are not to be used:

- As an athletic mouth guard
- By persons under the age of 18
- In case of insufficient dentition
- In case of severe respiratory problems

1 THE SICAT OPTIMOTON THERAPEUTIC APPLIANCE

1.3 DESIGN AND MANUFACTURING

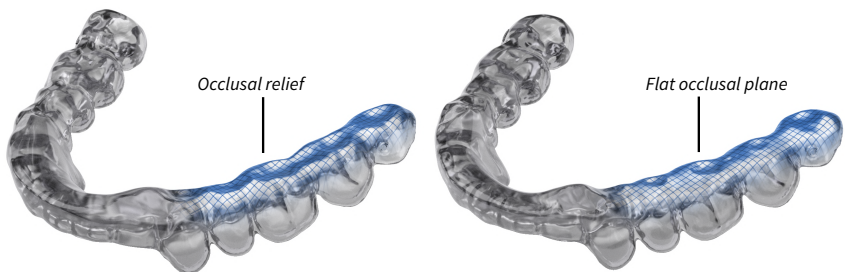
Each SICAT OPTIMOTION therapeutic appliance is custom-made for each patient. The appliance is prescribed and ordered individually for each patient by a dentist with the necessary medical expertise. SICAT designs the therapeutic appliance based on this order.

The following options are available when ordering the SICAT OPTIMOTION:

1. Selection of upper jaw or lower jaw for the patient
2. Selection of cuspid guidance or anterior guidance



3. Selection of occlusal relief or flat occlusal plane



2 SICAT OPTIMOTION WORKFLOW

2 SICAT OPTIMOTION WORKFLOW

CREATE 3D X-RAY SCAN WITH SICAT FUSION BITE

RECORD JAW MOTION TRACKING DATA

OPEN 3D X-RAY SCAN

REGISTER JAW MOTION TRACKING DATA

REGISTER OPTICAL IMPRESSIONS

DETERMINE TREATMENT POSITION IN SICAT FUNCTION

ORDERING AND MANUFACTURING OF THERAPEUTIC APPLIANCE

**HAND-OVER OF THE THERAPEUTIC APPLIANCE TO THE PATIENT AND
INSTRUCTION ON HOW TO USE IT**

**REGULAR CHECK-UP APPOINTMENTS AND POSSIBLE ADJUSTMENTS OF THE
TREATMENT POSITION**

3 NOTES ON EXPOSURES

3D X-ray scan

- Ensure that all the necessary image information is contained in the CBCT scan (please see image 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 patient does not move during the scan in order to avoid movement artifacts (see figure 2).
- Ensure that at least four teeth per quadrant do not have any metal artifacts (please see figure 3).

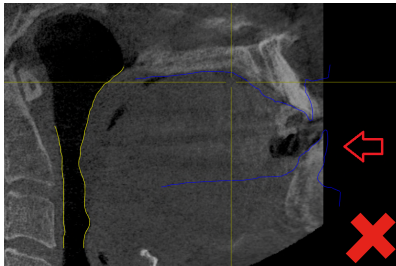


Figure 1: Missing areas in the CBCT data

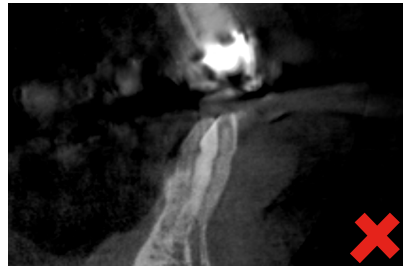


Figure 2: Patient movement

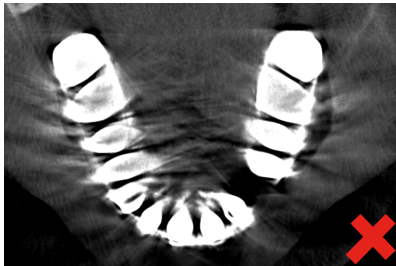


Figure 3: Metal artifacts

3 NOTES ON EXPOSURES

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.
- When registering optical impressions, ensure that they match the 3D X-ray scan in terms of the exposure time (please see figure 4). A guiding value here is a maximum of 90 days in between the time of the exposure and the optical impression.
- Make sure that the optical impressions do not contain any errors. Examples of errors:
 - 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)

3 NOTES ON EXPOSURES



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

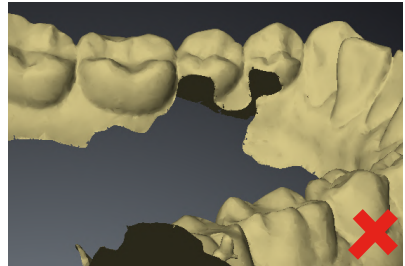


Figure 5: Holes in the surface data

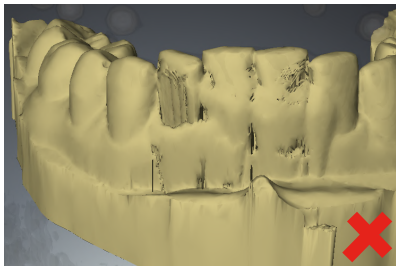


Figure 6: Distortions in the surface data

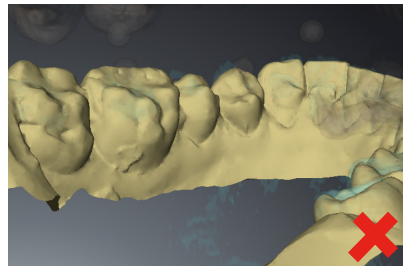


Figure 7: Misalignment in the surface data

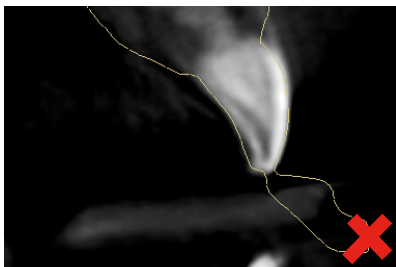


Figure 8: Artifacts

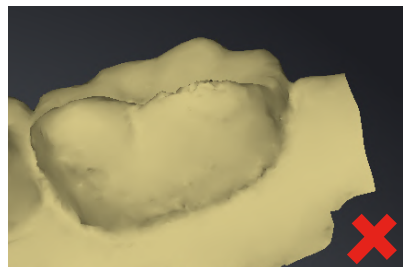


Figure 9: Noise

4 INFORMATION ON TEETH STATUS

4 INFORMATION ON TEETH STATUS

- 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.

5 UNPACKING THE SICAT OPTIMOTON THERAPEUTIC APPLIANCE

The manufacturer provides the SICAT OPTIMOTION with the following components:

- SICAT OPTIMOTION therapeutic appliance
- Storage container
- Gift bag to be handed over to the patient
- Application and care information for the patient
- Instructions for use for the treating dentist

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. For further information on the cleaning agents to be used see *Cleaning the SICAT OPTIMOTON therapeutic appliance* [► Page 15].

6 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 OPTIMOTON therapeutic appliance* [► Page 13] and *Removing the SICAT OPTIMOTON therapeutic appliance* [► Page 14].
- Inform the patient about possible risks associated with using the therapeutic appliance.

7 TREATMENT

7 TREATMENT

7.1 PRIOR TO TREATMENT

Prior to treatment, please pay attention to the following:

- Inform the patients that the therapeutic appliance needs to be worn every night while sleeping.
- Inform the patients that the therapeutic appliance only works as long as it is worn.

7.2 DURING THE TREATMENT

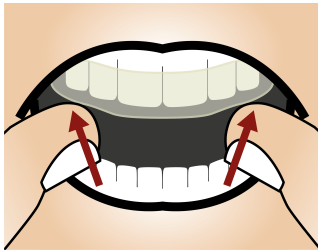
Make regular check-up appointments with your patients. Check the course of treatment at regular intervals.

8 INSERTING THE SICAT OPTIMOTON THERAPEUTIC APPLIANCE

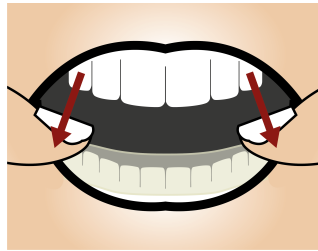
8 INSERTING THE SICAT OPTIMOTON THERAPEUTIC APPLIANCE

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

1. Insert the appliance into the mouth.
2. Place the appliance on the teeth in the patient's side teeth region by applying little pressure.



Inserting of upper-jaw appliance



Inserting of lower-jaw appliance

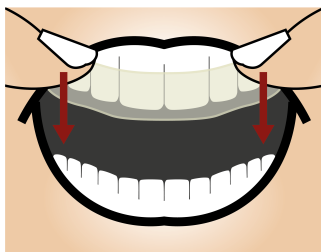
The appliance should remain safely on the teeth due to retention. If more pressure is to be applied, it will be highly probable that the appliance does not fit correctly. The reason may be outdated patient data.

9 REMOVING THE SICAT OPTIMOTON THERAPEUTIC APPLIANCE

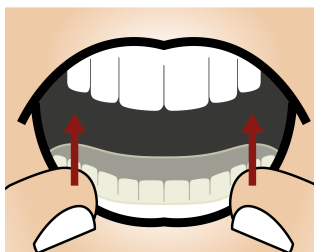
9 REMOVING THE SICAT OPTIMOTON THERAPEUTIC APPLIANCE

To remove the SICAT OPTIMOTION therapeutic appliance from the patient's mouth, proceed as follows:

1. Lift the appliance carefully in the region of the molars by moving it alternately to the left and right.
2. Remove the appliance from the mouth.



Removal of upper-jaw appliance



Removal of lower-jaw appliance

It should be possible to remove the appliance from the patient's teeth by exerting little force. Touch the appliance in the side teeth region.

10 CLEANING THE SICAT OPTIMOTON 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 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 any germs from forming.
- Inform the patient that the therapeutic appliance needs to be occasionally cleaned with a mild cleaning agent or a prostheses cleaner not containing oxygen.

11 DAMAGE AND REPAIR

11 DAMAGE AND REPAIR

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 if it is broken or damaged as there will be the risk of swallowing and inhaling small parts. Instruct the patient that a therapeutic appliance must not be worn in this case.

Repair after damage

You may not repair the therapeutic appliance after a break. In case of a break, please contact the support to order a replacement. If the patient does not use the appliance for a longer period, it may be required to record the most current data of the patient to ensure proper fitting of the appliance.

12 LIFE TIME

The SICAT OPTIMOTION therapeutic appliance has an expected life time of 2 years. We recommend to check the therapeutic appliance in regular intervals.

13 DISPOSAL

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

14 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.

15 SAFETY INSTRUCTIONS

Side effects

⚠ **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.

⚠ **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.

⚠ **CAUTION!** Using the therapeutic appliance could cause pain in the TMJ. Remove the therapeutic appliance if pain in the TMJ occurs.

Treatment planning

⚠ **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.

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.

15 SAFETY INSTRUCTIONS

⚠ **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.

Patient information

⚠ **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 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.

15 SAFETY INSTRUCTIONS

⚠ **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 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.

⚠ **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.

Treatment

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

⚠ **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.

Monitoring the patient

⚠ **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.

15 SAFETY INSTRUCTIONS

⚠ **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.

⚠ **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.

Changes to the 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.

Cleaning

⚠ **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.

What to do in case of 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.

15 SAFETY INSTRUCTIONS

Life time

⚠ **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.

16 MANUFACTURER AND SUPPORT



Manufacturer

SICAT GmbH & Co. KG

Friesdorfer Str. 131-135

53175 Bonn, Germany

www.sicat.com

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