



MANUFACTURING CONDITIONS

SICAT Surgical Guides and Therapeutic Appliances

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Consent to the manufacturing conditions, in particular to the modification of the production order for SICAT surgical guides and therapeutic appliances

Revision: 2023-09-01

1. SICAT SURGICAL GUIDES (CLASSICGUIDE, OPTIGUIDE, DIGITALGUIDE, RAPID DIGITALGUIDE, ACCESSGUIDE, RAPID ACCESSGUIDE)

- 1.1 The customer is responsible for the quality of the data and objects that are transmitted to SICAT GmbH & Co. KG (hereinafter SICAT) as part of a purchase order. The quality can have a direct influence on the accuracy of the surgical guide. SICAT reserves the right to optimize the data and objects, if necessary, so that they have a positive influence on the accuracy of the surgical guide.
- 1.2 The customer uses the products according to the corresponding instructions for use.
- 1.3 The customer agrees that SICAT may
 - a) correct minor defects and artefacts in optical models if they exist,
 - b) shorten the guide if there is a distal delay in the optical model,
 - c) carry out a new registration with the aim of optimizing the registration, in the event of an insufficient registration between optical scan and conbeam,
 - d) adjust the height of sleeves for implant surgical guides according to the protocol of the implant manufacturer in order to avoid a collision with anatomical structures.
- 1.4 The customer is aware that
 - a) the delivery time for a **CLASSICGUIDE**, **OPTIGUIDE** or **ACCESSGUIDE** may be up to six working days plus shipping time starting at the point in time when all queries have been clarified,
 - b) artefacts in conbeam make an all-encompassing assessment of the superimposition of optical scan and conbeam impossible and that the correct fit of the guide, which is impaired by undiscovered deficiencies of the optical model, can therefore not be guaranteed. In any case, the customer must verify the correct fit of the guide on the patient's jaw before the operation. The guide must not be used if the fit is incorrect,
 - c) she or he will only receive a drill protocol for an implant surgical guide manufactured according to the protocol of the implant manufacturer. For all conversions deviating from the manufacturer's protocol (e.g. selection of a smaller sleeve or modified sleeve spacing) no drill protocol can be created,
 - d) SICAT uses drill sleeves for implant surgical guides from implant manufactures as well as drill sleeves which are compatible with them and functionally identical.
 - e) when manufacturing a **DIGITALGUIDE**, **RAPID DIGITALGUIDE** or **RAPID ACCESSGUIDE** himself, he bears the responsibility for compliance with local regulatory requirements as well as for manufacturing quality and is the manufacturer.
 - f) **RAPID DIGITALGUIDE** and **RAPID ACCESSGUIDE** cases will be not checked, corrected or optimized by SICAT. The **RAPID DIGITALGUIDE** as well as the **RAPID ACCESSGUIDE** are fabricated automatically based on the submitted original data only. The customer is responsible for the final check of the digital surgical guide design.

2. OPTISLEEP

- 2.1 In order to fabricate an **OPTISLEEP**, the transmitted data must facilitate an occlusal appliance thickness of at least 1 mm. SICAT reserves the right to carry out a production-orientated optimization of the data based on the transmitted data without consultation and in particular to changing the blocking in such a way that the design of a therapeutic appliance becomes possible.
- 2.2 Unless otherwise specified, SICAT uses the longest connector with which the selected therapy position can be implemented. The advantage of starting therapy with a longer connector is the availability of a larger number of shorter connectors, which can be used to further increase the degree of protrusion.
- 2.3 The optimization is carried out and checked by specially trained and experienced dental technicians.

3. OPTIMOTION

- 3.1 Due to manufacturing, **OPTIMOTION** therapeutic appliances must have a minimum thickness of 1.5 mm. This applies over the entire arch of the jaw. If the transmitted data does not allow an appliance thickness of at least 1.5 mm, SICAT will carry out a production-orientated optimization of the data based on the transmitted data without consultation and in particular to changing the vertical clearance in such a way that a therapeutic appliance can be designed.
- 3.2 To design the **OPTIMOTION** therapeutic appliances, the patient-specific data is transferred into a digital design. SICAT reserves the right to adjust the transmitted data during the transfer without prior consultation, for example, in order to prevent or minimize the penetration of the teeth after merging the data.
- 3.3 The optimization is carried out and checked by specially trained and experienced dental technicians.

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