SICAT Surgical Guides

- Fabrication of Radiographic Templates
- Conebeam/CT scanning parameters
- 3-D Implant planning
- Ordering Surgical Guides

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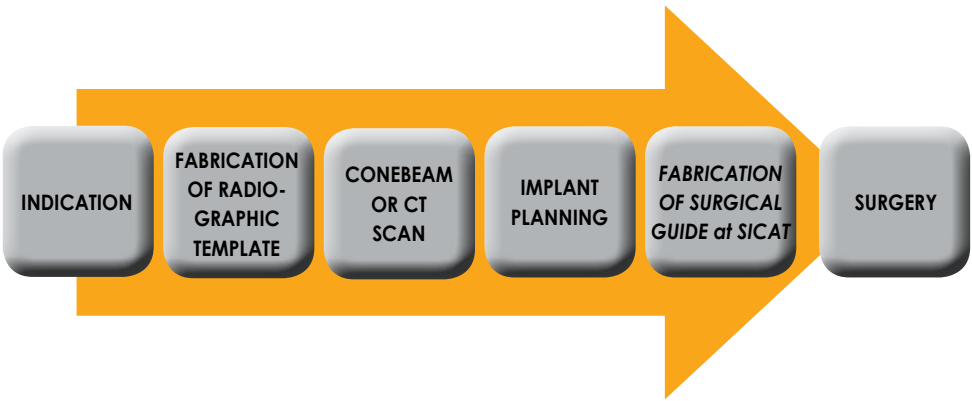
1. SICAT Surgical Guides

1.1 Important information about SICAT Surgical Guides

SICAT Surgical Guides support you in the execution of your implant plan that you have created with a SICAT planning software (GALILEOS Implant or SICAT Implant). SICAT Surgical Guides are custom-made for the respective patient and guide your drill with the help of guiding sleeves to the planned positions in the patient's jaw.

SICAT Surgical guides are available teeth- or mucosa supported with the option for fixation with anchor pins, fixation screws or microimplants. The sleeve systems offered are pilot sleeves, a generic sleeve-in-sleeve system and master sleeves for fully guided surgical systems. These fully guided surgical systems offer a complete procedure from the initial drilling all the way to implant insertion. Some of the currently supported guided surgical systems are Astra Tech, Biomet 3i, Camlog, Dentaurum, Klockner, Straumann, Nobel Biocare and Zimmer. See the SICAT website www.sicat.com for an updated list of all currently supported systems.

1.2 SICAT Workflow



1.3 Definitions of terms

1.3.1 Biteplate with radiographic markers
The biteplate serves as basis for the radiographic template and includes radiographic markers (fiducial markers). SICAT biteplate kits consist of a biteplate for the fabrication of radiographic templates, a CD-ROM for storing the implant planning data and a small padded shipping package. Please use only SICAT biteplate kits for the fabrication of your radiographic template.

1.3.2 Radiographic template
The patient wears the radiographic template during the 3D scanning process. The radio-opaque prosthetic proposal (Figure 1.3.2), is visible in the 3D scan and serves as orientation for virtual implant planning.

1.3.3 Surgical guide
The radiographic template is later modified to be transformed into a precise surgical guide by SICAT.

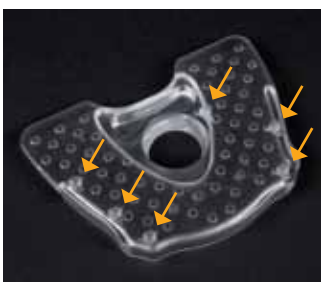


Figure 1.3.1

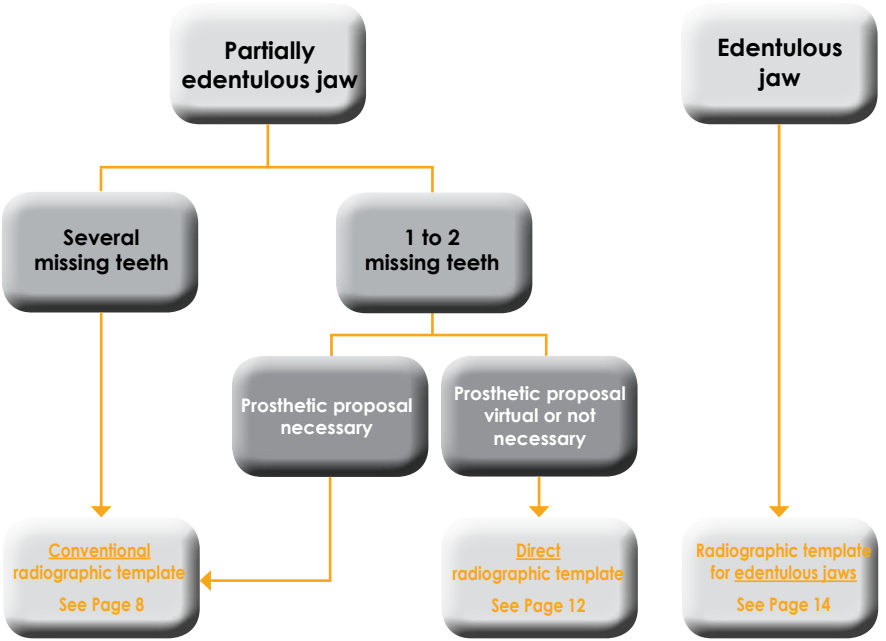
Figure 1.3.2

Figure 1.3.3

2. Fabrication of radiographic templates

Radiographic templates overview

Use this graphic overview to choose the workflow most applicable to your case for the fabrication of a radiographic template.



2.1 Conventional radiographic templates

The surgical guide is generated by SICAT by transforming the original radiographic template. A high-quality radiographic template is therefore essential to assure accuracy and precision of the surgical guide. For the fabrication of a radiographic template with a radio-opaque prosthetic proposal, your dental laboratory will need the following:

- Stone model (type 4 plaster) of the patient's jaw
- Biteplate with fiducial markers (available through www.sicat.com)
- Hard-elastic, transparent thermoforming sheet that bonds to PMMA (min. thickness 1.5 to max. 2.0 mm)
- Vacuum/Thermoforming device
- Cold-curing acrylic (PMMA)
- Radio-opaque acrylic or barium sulfate powder to be mixed with cold-curing acrylic

Recommendations for approved materials can be found at www.sicat.com.

! Use only current impressions or stone models of the patient's jaw. Changes in anatomical situations or old/inaccurate stone models of the patient's jaw potentially lead to a poorly fitting surgical guide!

! To ensure a stable bond of biteplate, thermoformed stent and prosthetic proposal, use only thermoforming sheets that bond to acrylic (PMMA). Isolating sheets must be removed after the thermoforming process.

Instructions for fabricating a conventional radiographic template

2.1.1 Produce a stone model of super hard plaster (type 4) and build a a prosthetic tooth wax-up in the edentulous area. The height of the stone model should not exceed 4 cm, as the shipping parcel has been designed for this maximum height.

2.1.2 Create a thermoformed stent on the stone model (min. thickness 1.5 mm to max. 2.0 mm) and remove the wax-up afterwards from the thermoformed stent.

2.1.3 Block out undercuts and isolate the endentulous areas on the stone model with varnish.

! Quality and actuality of impression and stone model are essential for a precise radiographic template and surgical guide and therefore crucial for precise implant placement.

Figure 2.1.1

Figure 2.1.2

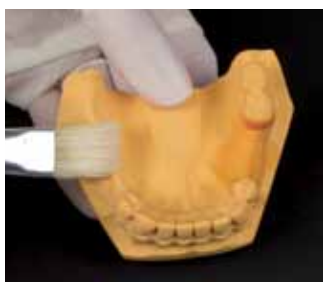


Figure 2.1.3

2.1.4 After mounting the vacuum formed stent onto the stone model, pour radio-opaque acrylic into the edentulous area of the vacuum formed stent (where the wax-up used to be).

If you do not have radio-opaque acrylic to use, mix cold-curing acrylic with 15% barium sulfate, in relation to weight of the PMMA powder until it has a viscous consistency. Make sure that the PMMA powder mixes smoothly and thoroughly with the barium sulfate without clots.

2.1.5 The prepared prosthetic proposal must seat flush on the gingiva outline of the stone model (see Figure 2.1.5)

2.1.6 For small jaws, the biteplate can be shortened in the areas marked green (see Figure 2.1.6). All other regions should not be altered.

! Regions not marked green (see Figure 2.1.6) should not be altered. Fiducial markers must not be altered or covered with acrylic! The orange-marked triangle must not be altered or covered with acrylic, as this area serves as fixture location for the fabrication of the surgical guide!

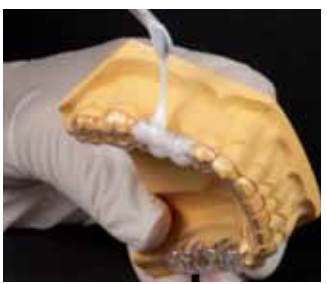


Figure 2.1.4

Figure 2.1.5

Figure 2.1.6

2.1.7 Mix cold-cure resin (without barium sulfate) until it has a viscous consistency. To etch the surface apply some of the cold-cure resin fluid to the outer side of the vacuumformed stent and the biteplate (side without fiducial markers). Pour the acrylic onto the biteplate (side with out fiducial markers). Use sufficient acrylic, as it serves for both, the bond of biteplate and thermoformed stent and for overall rigidity and stabilization of the radiographic template.

2.1.8 Position the thermoformed stent in the frontal area of the biteplate, on the side that does not contain the fiducial markers.

2.1.9 Press the thermoformed stent, seated on the stone model, onto the biteplate until the acrylic has cured. Control the firm and stable fit of the radiographic template on the stone model.

Figure 2.1.7

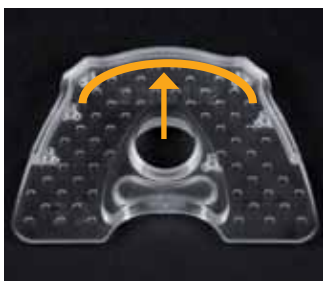


Figure 2.1.8

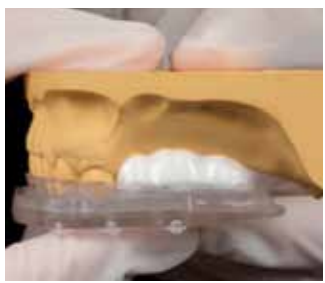


Figure 2.1.9

2.2 Direct radiographic templates

The direct radiographic template should **only be used for one or two missing teeth** when the visualization in the 3D scan of a prosthetic proposal via radio-opaque acrylic is not necessary or done via a virtual prosthetic proposal (CEREC-Crown).

The utilization of a bite registration allows the immediate fabrication of a radiographic template directly in the patient's mouth. The preparation of a stone model to fabricate a radiographic template is eliminated for now, however, a stone model still needs to be prepared at a later time and sent to SICAT for each case. It is necessary for the surgical guide manufacturing process and to verify the fit of the surgical guide after fabrication.

Only bite registration materials approved by SICAT should be used (for example, Kettenbach Futar® scan, R-Dental Metal Bite, Heraeus Kulzer Flexitime® bite). See www.sicat.com for a full list of all recommended materials as it will be updated over time.

The radiographic template is the basis for the surgical guide. A firm and stable fit on the patient's jaw is therefore of critical importance.

! It is mandatory to send a corresponding stone model to SICAT with every direct radiographic template.

Instructions for the fabrication of a direct radiographic template

2.2.1 Drill 4 holes (Ø4 mm) in predetermined positions in the SICAT biteplate. Biteplates can also be ordered from SICAT with pre-drilled holes for the direct radiographic template process.

2.2.2 Apply bite registration material over the entire inner surface of the bite plate (side without fiducial markers). Holes are meant to assist with mechanical retention of the bite registration material on the biteplate.

2.2.3 Take an impression of the patient's jaw.

! Control the firm and stable fit of the radiographic template in the patient's jaw. If the fit is insufficient repeat the process.

! Apply only one layer of bite registration material. The bite registration material is not used for the stabilization of the surgical guide, but merely for reproducing an accurate position.

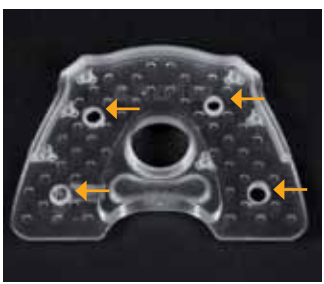


Figure 2.2.1

Figure 2.2.2

Figure 2.2.3

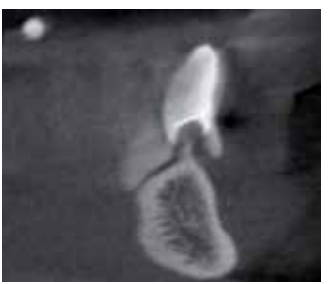
2.3 Fabrication of a radiographic template for the edentulous jaw

To accurately fabricate a radiographic template for the edentulous jaw, a total denture that roughly meets the desired final result in regard to aesthetics, occlusion and physical attributes relating to clarity of speach is necessary. The base for the radiographic template is a copy of the total denture made with acrylics of different radio-opacity so the teeth and mucosa surface can be visualized accordingly in the 3D scan.

If no denture is available that corresponds to the final result, a wax-up has to be prepared first or the existing denture can be improved by re-lining it to use as a model to be duplicated.

Original situation

Radiographic template



3-D X-ray image

Instructions for the fabrication of a radiographic template for the edentulous jaw

2.3.1 Control the fit of the total denture in the patient's mouth. If the denture does not seat form-fitted on the mucosa of the patient's jaw, it is necessary to mold the patient's mucosal situation using reline material. Use the denture like an impression tray and prepare an impression of the current mucosal situation using silicon lining material.

2.3.2 Fabricate a stone model from the total denture (lined if necessary) that represents the current mucosal situation of the patient's jaw.

! A good form-fitted seat of the total denture is essential, because the duplicated total denture is the basis for the radiographic template.

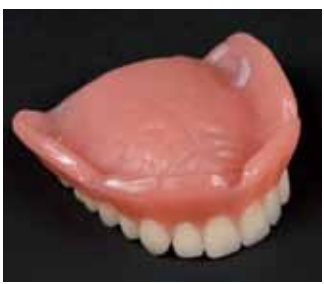


Figure 2.3.1 (a)

Figure 2.3.1 (b)

Figure 2.3.2

2.3.3 Remove excess material from the stone model.

2.3.4 Use a duplicating form to duplicate the total denture.
If there is no duplicating form available, you can also use silicone impression material (overcast material) for moulding the denture.

2.3.5 Fill the section of the duplicating form that represents the teeth with radio-opaque acrylic (equals a barium sulfate mix of approx. 15%). This is necessary to differentiate radio-opaque teeth from mucosal structure in the 3D scan.

Figure 2.3.3

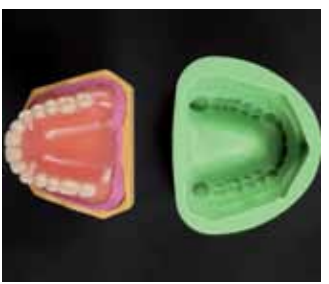


Figure 2.3.4

Figure 2.3.5

2.3.6 Now place the stone model, which represents the current mucosal situation, in the duplicating form, onto the still soft radio-opaque acrylic of the dental arch. The acrylic mix must be flush on the surface of the model so that the dental arch obtains the shape of the mucous membrane.

2.3.7 Allow the dental arch made of radio-opaque acrylic to cure.

2.3.8 Reduce the barium sulfate cast to separate the teeth of the dental arch. Separate the teeth, so that they can be visualized individually in the 3D scan and can be clearly distinguished.

2.3.9 Place the separated dental arch into the duplicating form.

Figure 2.3.6

Figure 2.3.8

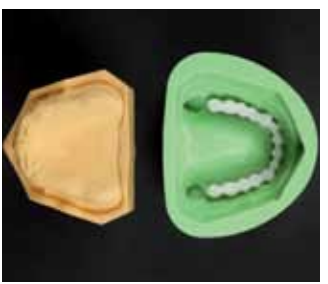


Figure 2.3.9

2.3.10 Place the stone model of the current mucosal situation into the duplicating form flush onto the dental arch.

2.3.11 Allow the radio-opaque acrylic (equals a barium sulfate mix of 8%) to flow into one of the holes of the duplicating form. The use of a mixture of 8% barium sulphate will help to differentiate mucosa and teeth clearly in the 3D scan later. If using ready-mixed material, use 50% of the material with 50% of neutral PMMA to dilute the solution to approx. 8%.

2.3.12 Once cured a duplicate of the denture made of different mixes of radio-opaque acrylic is obtained (see Figure 2.3.12).

2.3.13 For small jaws, the biteplate can be modified in the areas marked green.

Figure 2.3.10 / 2.3.11

Figure 2.3.12

Figure 2.3.13

2.3.15 Mix cold-cure resin (without barium sulphate) until it has a viscous consistency. To etch the surface, apply some of the cold-cure resin to the lower side of the biteplate (side without fiducial markers). Pour the acrylic onto the biteplate. The orange-marked area should not be covered with acrylic or removed. Use sufficient acrylic, as it serves for both, the bond of biteplate and duplicated denture and for stabilization of the radiographic template.

2.3.16 Position the duplicated total denture made of the acrylic/barium-sulfate mix onto the biteplate. Press the duplicated total denture onto the biteplate until the acrylic has cured. Control the firm and stable fit of the radiographic template on the stone model.

Figure 2.3.15

Figure 2.3.16 (a)

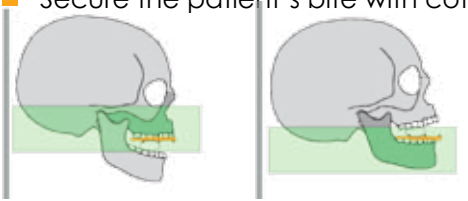
Figure 2.3.16 (b)

3. 3-D x-ray (Conebeam or CT)

3.1 General instructions

For optimal scanning results, please observe these general instructions:

- Double-check the stable and secure fit of the radiographic template
- Biteplate, thermoformed stent and prosthetic proposal must remain attached to one another, even under mechanical stress. The acrylic must be fully cured.
- Scan the patient wearing the radiographic template
- The radiographic template must seat gap-free, secure and stable in the patient's jaw
- Jaws should be scanned individually.
- Orientation of the occlusion plane should be parallel to the plane of image slice generated.
- Non-fixed metal parts in the opposing jaw should be removed (e.g. dentures, tongue piercings, etc.).
- Teeth of the opposing jaw should not touch the fiducial markers of the radiographic template.
- Secure the patient's bite with cotton pads.



Orientation of the occlusion plane parallel to the slice

3.2 3D x-ray with the GALILEOS 3D System

3.2.1 Prepare the 3D scan by selecting the correct biteplate holder (upper or lower jaw).

3.2.2 Let the patient try on the radiographic template. Check the secure and stable fit of the radiographic template in the patient's mouth.

3.2.3 Close the swivel arm and adjust the system height until the incisors and the ball of the biteplate holder are at approximately the same height.

3.2.4 Lead the patient carefully onto the biteplate holder. The patient should bite slightly onto the biteplate holder. The radiographic template should now be in a horizontal position.

3.2.5 Start the scanning process with your GALILEOS 3D System.

! If your GALILEOS 3D system has several scanning modes to choose from, please select mode VO1 and the largest patient kVmA setting.

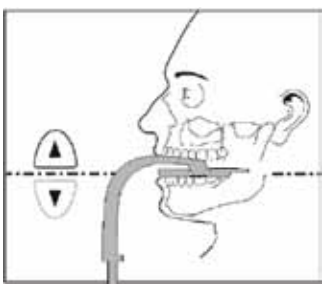


Figure 3.2.4 (a)

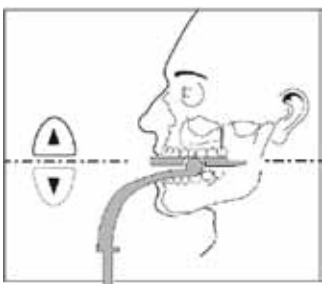


Figure 3.2.4 (b)

3.3 Scanning parameters for Conebeam and CT systems

- Gantry tilt = 0°
- Slice thickness < 0.7 mm
- Parallel slices only
- DICOM 3 format

For optimal scanning results, always read and follow the instructions for use of your Conebeam or CT radiographic system.

! In case the patients will be scanned without your presence, practice the correct insertion of the radiographic template with the patient!

! The radiographic template must not be modified after the 3D scan!

! All fiducial markers should be clearly visible in the 3D scan. No gap should be visible between the radiographic template and the mucosa or teeth that it is mounted to!

! Please instruct your patient that the radiographic template must sit gap-free, secure and stable on the jaw, and that no movement should take place during the scanning process!

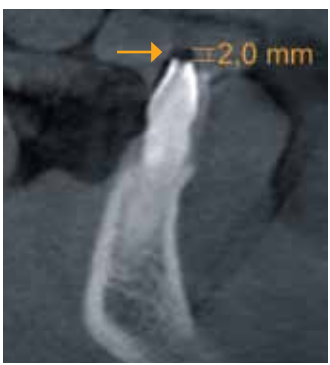
3.4 Preventing possible errors

3.4.1 Incorrect seat of the radiographic template

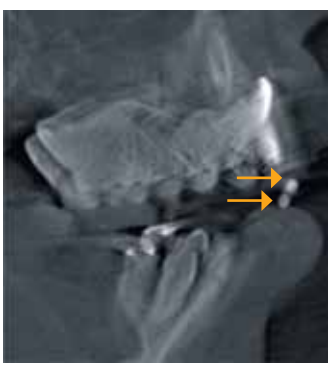
In this example, a gap of approximately 2 mm between the radiographic template and the tooth is shown. Since it cannot be guaranteed that the templates will sit in exactly the same way during the scanning process and the actual surgery, significant loss of precision is to be expected.

3.4.2 Patient movement

The patient's unintentional movement during the scanning process will cause movement artifacts which make the fiducial markers impossible to recognize. It is therefore important to tell the patient before the scanning process starts to not move during the procedure. Figure 3.4.2 shows double structures caused by the patient's movement. In this case the 3D scan has to be repeated as it is not possible to fabricate a surgical guide from this scan.



3.4.1 Incorrect fit



3.4.2 Patient movement

3.4.3 Unclear fiducial markers

For the fabrication of an accurate surgical guide, a distinct and error-free display of the fiducial markers is necessary. If the opposing jaw possesses structures which strongly absorb X-rays (e.g. gold or ceramic crowns) near the fiducial markers, it helps to open the bite of the patient with cotton rolls to avoid interference of scatter or artifacts.

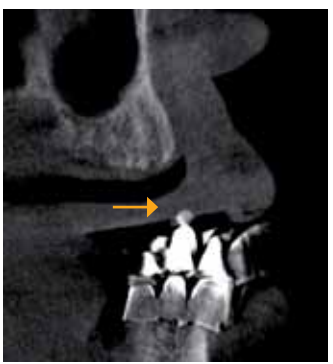


Figure 3.4.3 Unclear fiducial markers

4. Digital implant planning

4.1 Implant planning

To prevent planning errors, please read and follow these important tips for executing your implant plan:

4.1.1 Unsuitable drill path
In this implant plan, the drill path comes too close to the neighboring tooth and the drill sleeve would collide with the tooth.

4.1.2 Collision of drill sleeves
In this implant plan, the drill sleeves of both implants collide. Visualization of the drill path makes this clearly visible.

TIP: Right-click on the implant and select 'Visualize drill path' so the drill path of the pilot or the final drill can be shown. To visualize larger drill sleeves, set the diameter of the pilot drill path to the corresponding size (see “Settings” in your SICAT planning software).

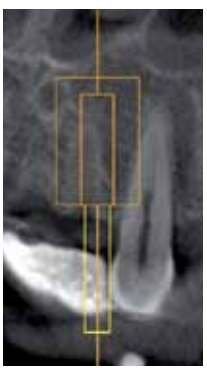


Figure 4.1.1 Unsuitable drill path

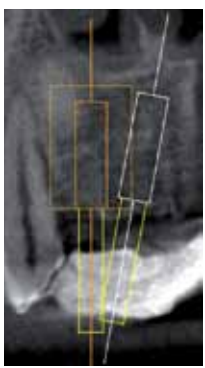


Figure 4.1.2 Collision of drill sleeves

4.2 Ordering of surgical guides

To properly order surgical guides, please follow the instructions of the order wizard in the SICAT planning program.

4.2.1 Under the 'Surgery' tab, click the surgical guide wizard icon to start "Order surgical guides based on the current plan".

4.2.2 Follow the instructions of the ordering wizard until completing the surgical guide ordering process.

! When selecting a fully guided implant system, such as Camlog Guide by Camlog, Navigator by Biomet 3i etc., a guided surgery kit of the implant manufacturer is necessary to perform surgery.

! Always read and follow your instructions for use for the respective planning program (GALILEOS Implant, SICAT Implant), which give you more useful tips for implant planning.

Figure 4.2.1

Figure 4.2.2

5. Shipment to SICAT

SICAT fabricates the patient-specific surgical guide for you. Please send the components listed below to SICAT, Attn. SGL (Surgical Guide Lab):

1. Planning data on CD, automatically generated by the order wizard in the SICAT planning program (GALILEOS Implant, SICAT Implant)

2. Order forms (2-sided) with signature of the dentist (generated from the SICAT planning program)

3. Radiographic template (disinfected and dry in the included Ziplock bag with silica gel pack)

4. Stone model

Label the CD and stone model with the patient's ID that appears on the surgical guide order form (include the name, date of birth or ID #).

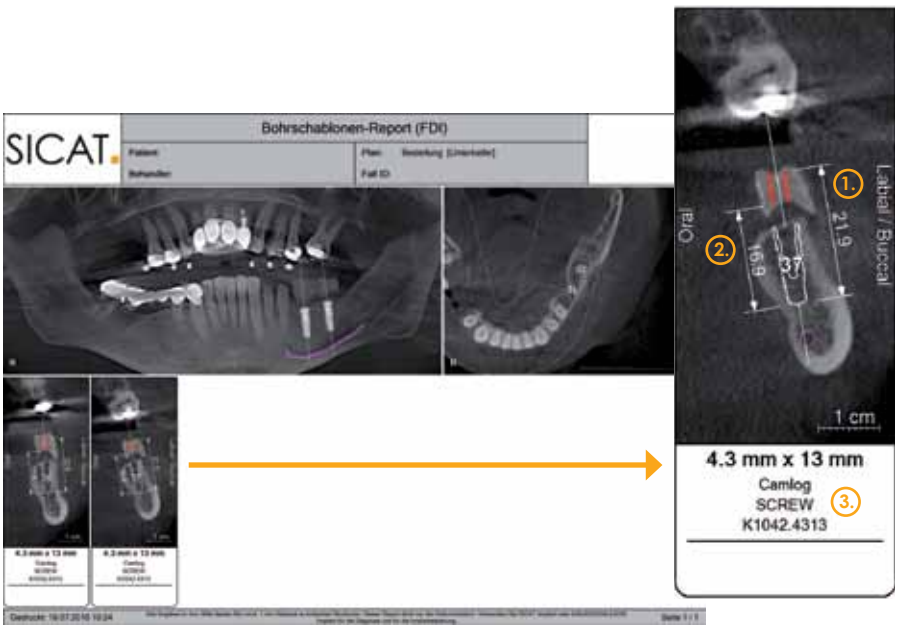
Make sure that there is enough padding to prevent the stone model or the radiographic template from breaking!

6. SICAT documentation

SICAT provides you with the customized surgical guide and the following documents:

6.1 Surgical guide report

An essential part of the report are the implant-specific depth specifications. Distances from the upper or lower end of the drill sleeve to the apical end of the implant are specified. These distances can be compared with the scale of the drill for planning and during the surgery.



1. Distance from the upper end of the drill sleeve to the apical end of the implant
2. Distance from the lower end of the drill sleeve to the apical end of the implant
3. Specifications of the planned implant

6.2 Accuracy report

The accuracy report states the deviations from the positions of the actual sleeves to the planned implant positions. SICAT guarantees a manufacturing deviation accuracy of 0.5 mm or less at the apical end of the implant.

6.3 Drill report

In case a guided sleeve system was chosen from an implant manufacturer that requires a drill protocol, SICAT will provide a drill protocol specifically for the guided system chosen with the fabricated surgical guide.

> **!** Please consider that individual arrangements with SICAT support are also noted on the surgical guide report.

7. Handling of the surgical guide

Before using the surgical guide, we recommend to observe the following:

- To prevent distortion of the surgical guide, please protect it from direct sunlight and high temperatures. Check the surgical guide before surgery.
- Make sure that the surgical guide seats gap-free, secure and stable on the stone model. Check the position of the drill sleeves inserted in the surgical guide to make sure they are according to your implant plan. Do not use the surgical guide if you find any discrepancies.
- Before surgery, make sure the surgical guide is positioned gap-free, secure and stable on the patient's jaw. Otherwise a reduction of accuracy can be expected.
- Before surgery, control all drills and drill sleeves that will be used and check for damage. To prevent mis-location of the drills during surgery, only use drills and sleeves in perfect condition.

! Verify that all necessary drills and sleeves according to your surgical plan and/or the surgical kit protocol are available!

! The drill should be inserted into the sleeve of the surgical guide before starting the rotation. When drills are inserted into the sleeves already rotating, a mis-location of the drill could occur!

! Disinfect the surgical guide only with disinfectants approved for this application!

! Do not employ heat-based methods for disinfection or sterilization (e.g. autoclaves) of the surgical guide as they may cause deformation!

! During the drilling process, please make accomodations for sufficient cooling of the surgical drills and the osteotomy area!

! Always read and follow the instructions for use of your guided surgical system!

Version E501/09-10

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SICAT.