SURGICALGUIDES

SICAT SURGICAL GUIDES

Instructions for preparation of SICAT **CLASSIC**GUIDE, SICAT **OPTI**GUIDE and SICAT **DIGITAL**GUIDE

Table of contents

1. SICAT Surgical Guides

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

Intended use

The SICAT surgical guide is a customized surgical guide specific for each patient to aid implantological treatment. It is a tool for helping to guide previously planned implants into the patient's jaw. It is used to enable precise guidance of surgical tools.

Indications

The SICAT surgical guide aids implantological rehabilitation.

Contraindications

Allergies or hypersensitivity to chemical ingredients of used materials (Polymethyl methacrylate "PMMA", titanium) or materials used by the dentist for the preparation of a radiographic template or during the surgery (e.g. stainless steel).

SICAT Surgical Guides

Clinical benefit

The SICAT surgical guide maximizes the transfer accuracy of an implant plan into the patient's jaw, minimizing surgical and prosthetic risks.

Patient target group

For the patient target group there are no exclusion criteria.

However, the SICAT surgical guide is used within an entire treatment workflow, that requires the use of different medical devices. For those devices, the indications including patient target group according to the corresponding manufacturer’s Instructions for Use must be observed.

Intended users

Intended users are qualified dental professionals such as dentists.

Important note

The device is a single-use device.

WARNING

The SICAT surgical guide is a single-use device. Do not reuse or try to sterilize or re-disinfect the SICAT surgical guide. The reuse may lead to a risk of infection for the patient and operator. Furthermore, it may negatively impact the performance and characteristics of the product.

WARNING

The SICAT bite plate is a single-use device. Do not reuse or try to sterilize or re-disinfect the SICAT bite plate. The reuse may lead to a risk of infection for the patient and operator. Furthermore, it may negatively impact the performance and characteristics of the product.

1.1. SICAT Surgical Guide types

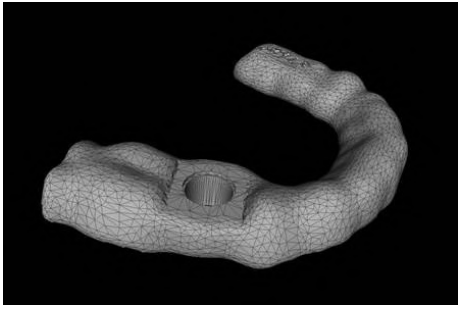
Three types of surgical guides are available: **CLASSIC**GUIDE, **OPTI**GUIDE and **DIGITAL**GUIDE.

*SICAT **CLASSIC**GUIDE*

*SICAT **OPTI**GUIDE*

The SICAT laboratory converts **CLASSIC**GUIDEs directly into accurate surgical guides on the basis of radiographic templates and 3D X-ray data. **CLASSIC**GUIDEs are available tooth and gingiva supported with optional fixation using anchor pins, fixation screws, or mini implants.

OPTIGUIDEs are fabricated directly in the SICAT laboratory on the basis of optical surface scan data and 3D X-ray data. Radiographic templates do not need to be used with **OPTI**GUIDE. **OPTI**GUIDEs are available tooth-supported or mucosa-supported.



*SICAT **DIGITAL**GUIDE*

DIGITALGUIDEs are designed in the SICAT laboratory on the basis of optical surface scan data and 3D X-ray data. In this process, a digital model of a surgical guide is created. You can produce it with your own 3D printer or you can have it printed in a laboratory of your choice. Radiographic templates do not need to be used with **DIGITAL**GUIDE. **DIGITAL**GUIDEs are available tooth-supported.

If you order the fabrication of a surgical guide yourself, please make sure that your laboratory has the desired sleeves available.

The sleeve systems available for **CLASSIC**GUIDE and **OPTI**GUIDE are pilot sleeves, a generic sleeve-in-sleeve system, and master sleeves for guided surgical systems. These guided surgical systems generally offer a complete procedure, from the initial osteotomy all the way to implant insertion.

Among others, the guided systems by the following manufacturers are supported by SICAT:

- Alphatech
- Anthogyr
- Astra Tech
- BEGO Implant Systems
- Bicon Dental Implants
- BioHorizons
- Biomet **3i**™
- Bredent
- CAMLOG® Biotechnologies
- Dentaurum
- DENTSPLY Friadent
- Hiossen
- Implant Direct
- Kentec
- Klockner
- Leone
- Medentis Medical

- MEISINGER
- Neoss
- Nobel Biocare™
- SIC invent
- Straumann®
- Sweden&Martina
- TRI Dental Implants
- Zimmer® Dental

Visit SICAT's website ***www.sicat.com*** to find the guided systems currently supported.

NOTICE	Please note that under certain circumstances, the use of **OPTI**GUIDE and **DIGITAL**GUIDE is limited or that in some cases, the use of **CLASSIC**GUIDE is recommended. Please see the following chapter: *Decision-making aid: CLASSICGUIDE, OPTIGUIDE or DIGITALGUIDE? [▶ Page 14]*.

1.2. Definition of terms

1. Bite plate with radiographic markers (CLASSICGUIDE)

The bite plate serves as a basis for the radiographic template and has radiographic markers (fiducial markers- see marking). Please use only SICAT bite plate kits. SICAT bite plate kits consist of a bite plate for fabricating a radiographic template, a blank CD for storing implant planning data and a small padded shipping package.

2. Radiographic template (CLASSICGUIDE)

The patient wears the radiographic template during the 3D scanning process. The radio-opaque prosthetic proposal, which may be incorporated in the radiographic template (see marking), is visible in the 3D X-ray and serves the dentist in charge of treatment as a basis for implant planning. Afterwards, SICAT manufactures a precise surgical guide out of the radiographic template.

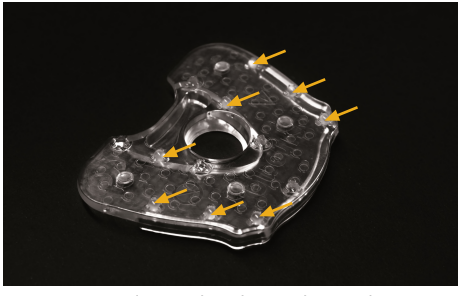


*Figure 1: Bite plate with radiographic markers **(CLASSIC**GUIDE)*

*Figure 2: Radiographic template **(CLASSIC**GUIDE)*

3. Surgical guide

A surgical guide (**CLASSIC**GUIDE, **OPTI**GUIDE) or a surgical guide based on a **DIGITAL**GUIDE is a customized device specific for your patient. Once the surgical guide is placed on the patient's jaw, it uses sleeves to help guide your surgical instruments and, if appropriate, your implant, accurately to the position you have previously planned.

4. Optical impressions

Optical impressions are obtained by scanning a stone model with a 3D scanner or by scanning the jaw with a 3D intraoral camera.

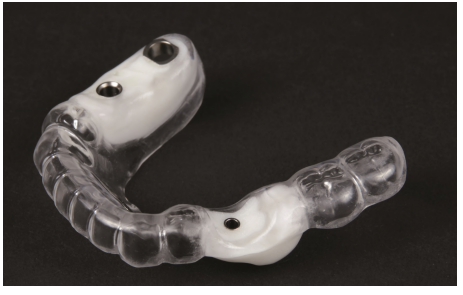


Figure 3: Surgical guide

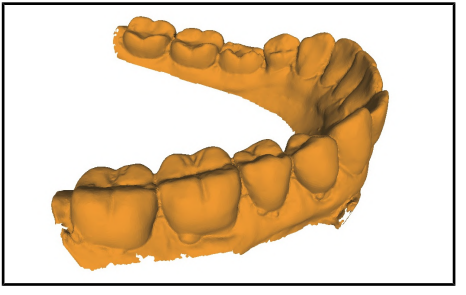
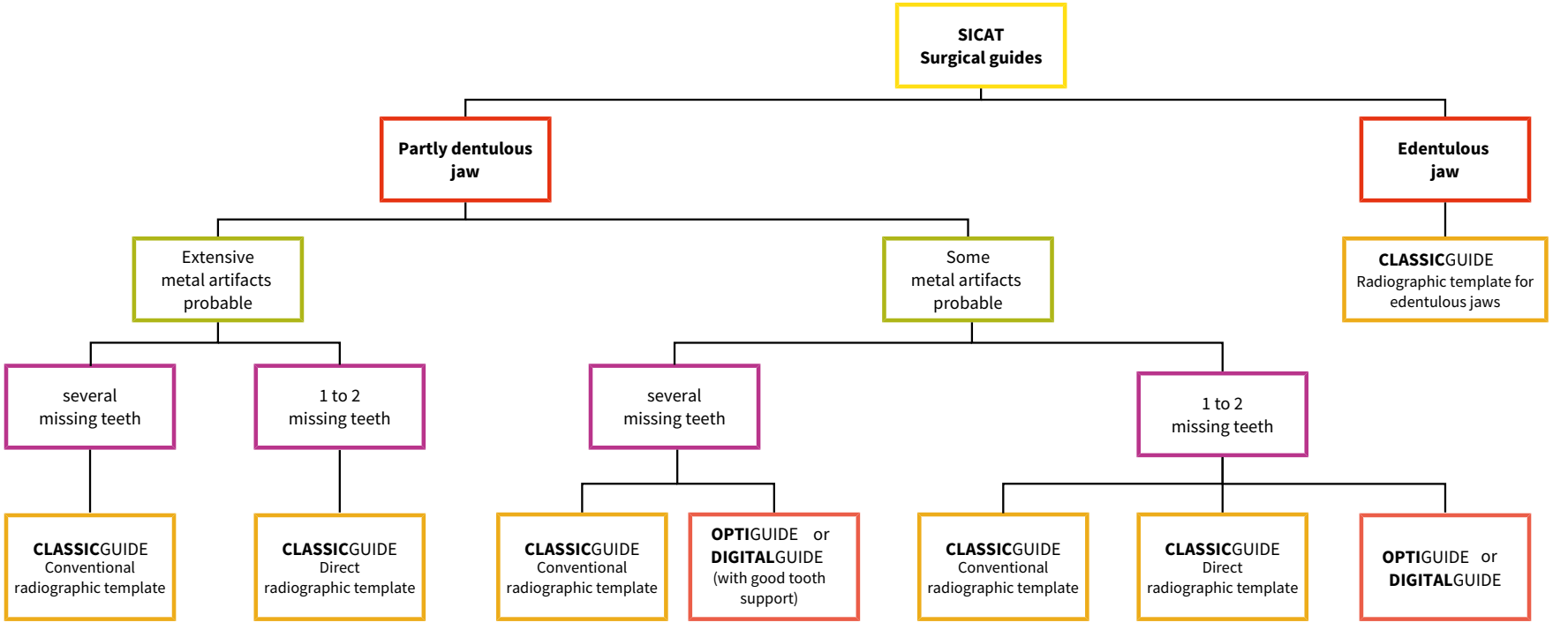


Figure 4: Optical impressions

1.3. Decision-making aid: CLASSICGUIDE, OPTIGUIDE or DIGITALGUIDE?



2. SICAT CLASSICGUIDE

SICAT **CLASSIC**GUIDE is based on a patient-specific radiographic template, which can be prepared in one of three different ways, depending on the indication:

- Conventional radiographic template with thermoforming technique - for partially edentulous jaws utilizing barium sulfate prosthetic proposals.
- Direct radiographic template with bite registration material - for one to two missing teeth and prosthetic proposals through optical scan data.
- Edentulous radiographic template for a fully edentulous jaw - utilizes a duplicate copy of an acrylic denture.

CLASSICGUIDEs are directly transformed in the SICAT laboratory from the radiographic template. A high-quality radiographic template is therefore essential for the quality of the surgical guide.

For additional information to the previously mentioned topics go to *Conventional radiographic template [▶ Page 19]*, *Direct radiographic template [▶ Page 24]* and *Radiographic template for the edentulous jaw [▶ Page 28]*.

WARNING

Clean and disinfect the bite plate according to the instructions given in this manual. Wrong processing may lead to a risk of infection for the patient and operator. Furthermore, it may negatively impact the performance and characteristics of the product.

WARNING

Please protect the bite plate from direct sunlight and elevated temperatures to prevent it from deforming.

WARNING

Never use a damaged bite plate (e.g. a bite plate showing deformations, cracks, fractures, fissures, lost or loose parts). Before use, please check the bite plate for damages.

WARNING

Use of the bite plate after the end of its service life may pose a health hazard to the patient. Ensure that the bite plate is not used after the end of its service life.

WARNING

Use of the bite plate by unqualified personnel could pose a health hazard to the patient or lead to improper treatment. The bite plate may only be used by qualified personnel.

WARNING

Ensure that there are still eight radio-opaque markers on the bite plate after the cleaning or disinfection procedure. If not, use a new bite plate.

WARNING

The use of incorrect materials for the preparation of the radiographic template can lead to health risks for the patient. It can also negatively influence the performance and characteristics of the product. Only use materials that have been validated by SICAT for preparation. A list of materials can be found here in the instructions for use.

WARNING

Modify the bite plate only at areas specified for modification. When modifying the bite plate avoid sharp edges and damages such as deformations, cracks or fractures.

WARNING

Do not utilize heat-based methods (e.g. autoclaves) for disinfecting or sterilizing the bite plate. The bite plate could become deformed.

2.1. SICAT CLASSICGUIDE Workflow

2.2. Conventional radiographic template

Your dental laboratory will need the following materials to fabricate a radiographic template with a radio-opaque prosthetic proposal:

- stone model (type 4 plaster) of the patient's jaw
- bite plate with fiducial markers (available at ***www.sicat.com***)
- hard-elastic, transparent thermoforming sheet* which bonds to PMMA (thickness min. 1.5 mm to max. 2.0 mm)
- thermoforming device
- cold-curing acrylic (PMMA)*
- radio-opaque acrylic*

*A list of the materials validated by SICAT can be found in the following chapter: *Materials to be used [▶ Page 25]*

WARNING

Only use current impressions/stone models. A modified anatomical situation will result in a poorly-fitting surgical guide.

NOTICE

Only use thermoforming sheets which bond to PMMA. Intermediate sheets must be removed after the thermoforming process. This is the only way to ensure a durable bond between bite plate, thermoformed stent and prosthetic proposal.

WARNING

Only use thermoforming sheets with material thickness of 1.5 mm and 2.0 mm.

NOTICE

Manufacturing a conventional radiographic template and a radiographic template for fully edentulous jaws requires dental technician experience and is preferably made by certified dental technicians.

2.3. Fabricating a conventional radiographic template

NOTICE	The quality and currency of the impression and stone model are essential for the precise fit of the radiographic template and the surgical guide and are therefore crucial for accurate implantation.

WARNING	Do not modify the radiographic template after the 3D X-ray scan.

1. Produce a stone model made of super-hard plaster (type 4) with a wax-up. The height of the stone model may not exceed 4 cm, as the shipping parcel has been designed for this maximum height.
2. Prepare a thermoformed stent (thickness min. 1.5 mm to max. 2.0 mm) on the stone model with wax-up and then remove the wax-up from the thermoformed stent.
3. Block out undercuts. Isolate the stone model from the acrylic.

Figure to point 1

Figure to point 2

Figure to point 3

4. Pour radio-opaque acrylic into the area of the thermoformed stent where the wax-up was previously located.
5. The prosthetic proposal prepared in this way must sit flush on the gingiva.
6. For small jaws, the bite plate can be shortened in the **areas marked in green**. The **area shown in orange** should not be altered or covered with acrylic.

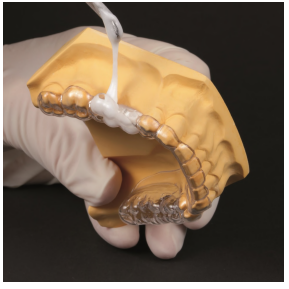


Figure to point 4

Figure to point 5

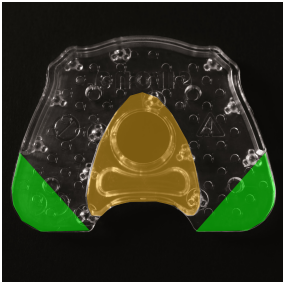


Figure to point 6

7. Clean and disinfect the bite plate according to the instructions given in the following chapter: *Cleaning and disinfection procedure [► Page 67]*
8. Mix cold-cure acrylic (without barium sulfate) until it has a viscous consistency. To etch the surfaces, apply cold-cure acrylic to the top of the thermoformed stent and bite plate (side without the fiducial markers). Pour the acrylic onto the bite plate (side without the fiducial markers). Make sure you use sufficient acrylic, as this serves both to bond the bite plate and the thermoformed stent and to stabilize the radiographic template.
9. Position the thermoformed stent in the frontal area of the bite plate on the side without the fiducial markers.
10. Press the thermoformed stent, situated on the stone model, onto the bite plate until the acrylic has cured. Check that the radiographic template fits securely and stably on the stone model.

Figure to point 7

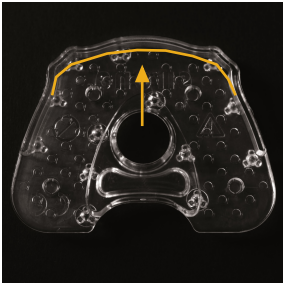


Figure to point 8

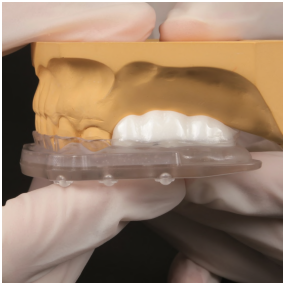


Figure to point 9

2.4. Direct radiographic template

The direct radiographic template should **only be used with one or two missing teeth** when visualization of a prosthetic proposal in the 3D X-ray scan is not necessary or is displayed by a virtual prosthetic proposal (e.g. CEREC AC from Dentsply Sirona).

Utilization of bite registration material allows immediate fabrication of a radiographic template directly in the patient's mouth. There is no need to make a radiographic template based on a stone model with the aid of thermoforming for the time being.

Only bite registration materials validated by SICAT should be used. For a complete list of all validated materials see the following chapter: *Materials to be used [▶ Page 25]*.

The radiographic template is the basis for the subsequent **CLASSIC**GUIDE. A firm and stable fit on the patient's jaw is therefore of critical importance.

NOTICE	For reasons of quality assurance, please ensure that the corresponding stone model is sent to SICAT with every radiographic template.

2.5. Materials to be used

The following materials have been validated by SICAT:

Material	Name	Manufacturer	Internet
Bite registration material	Metal bite	r-dental	***https://r-dental.com/***
Cold-curing acrylic	2-component material: ■ Probase Cold Monomer ■ ProBase Cold Polymer	ivoclar	***https://www.ivoclar.com***
Radio-opaque acrylic	2-component material: ■ Acryline X-Ray Powder (25% BaSO4) or Acryline X-Ray Powder DVT (10% BaSO4) ■ Acryline Liquid	Anaxdent	***https://www.anaxdent.com/***
Thermoforming sheet 1,5 mm - 2 mm	Erkodur	Erkodent	***https://www.erkodent.com***

2.6. Fabricating a direct radiographic template

WARNING

Check that the radiographic template fits securely and stably in the patient's mouth. If the fit is inadequate, repeat the process.

NOTICE

Apply only one layer of bite registration material. The bite registration material is not used to stabilize the surgical guide, but only to reproduce an accurate position.

NOTICE

Apply the bite registration material only onto the side of the bite plate which does not show the fiducial markers.

WARNING

Do not modify the radiographic template after the 3D X-ray scan.

1. Drill 4 holes (Ø4 mm) in the SICAT bite plate in the pre-specified positions.
2. Clean and disinfect the bite plate according to the instructions given in the following chapter: *Cleaning and disinfection procedure [▶ Page 67]*
3. Apply bite registration material over the whole inner surface area of the bite plate (side without the fiducial markers). The holes ensure that the registration is retained on the bite plate.
4. Take the impression in the patient's mouth.

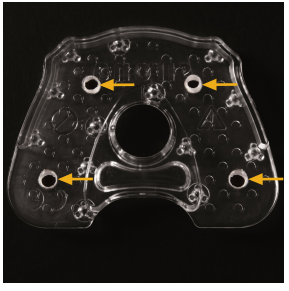


Figure to point 1

Figure to point 2

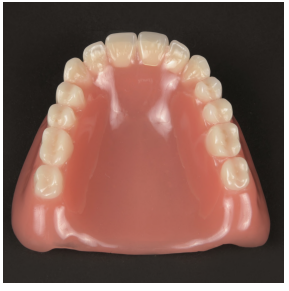
Figure to point 3

2.7. Radiographic template for the edentulous jaw

A full denture of approximately the desired final result with regard to aesthetics, occlusion and physical attributes is necessary to fabricate a radiographic template for the edentulous jaw.

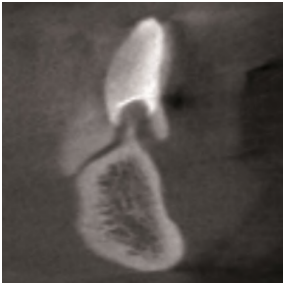
The basis for the radiographic template is a copy of the full denture, made with acrylics of different radio-opaque concentrations, so that the teeth and gingival surface can be visualized accordingly in the X-ray.

If no denture corresponding to the final result is available, a wax-up should be prepared beforehand.



Original situation

Radiographic template



3D X-ray scan

NOTICE	Manufacturing a conventional radiographic template and a radiographic template for fully edentulous jaws requires dental technician experience and is preferably made by certified dental technicians.

2.8. Fabricating a radiographic template for the edentulous jaw

NOTICE	A good form-fit of the denture is very important, as the duplicated denture serves as a basis for the radiographic template.

WARNING	Do not modify the radiographic template after the 3D X-ray scan.

1. Check the fit of the full denture in the patient's mouth. If the denture does not have a form-fit on the gingiva, it will be necessary to reline the denture to ensure proper fit over the gingiva. To reline the denture, use the existing denture as an impression tray to prepare an impression of the current mucosal situation (as when performing a soft-reline). Use silicone reline material.
2. Create a stone model from the full denture (relined if necessary), which represents the current mucosal situation of the patient's jaw.

Figure to point 1

Figure to point 1

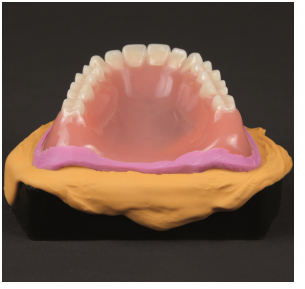


Figure to point 2

3. Remove excess material from the stone model.
4. Use a duplication form to duplicate the full denture with the model. If there is no duplication form available, you can use silicone impression material (overcast material) as an alternative to mold the denture situation.
5. Fill the section of the duplication form which represents the teeth with radio-opaque acrylic (corresponding to a barium sulfate mix of approx. 25%) to enable the teeth to be visualized subsequently in the 3D X-ray scan.

Figure to point 3

Figure to point 4

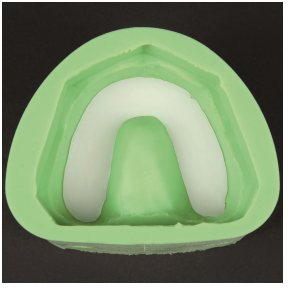


Figure to point 5

6. Now place the stone model representing the current mucosal situation in the duplication form, situating it on top of the radio-opaque acrylic dental arch, which should still be soft. The acrylic mix must contact the surface of the model so that the dental arch acquires the shape of the mucosal situation.
7. Allow the dental arch made of radio-opaque acrylic to cure.
8. Then, reduce the barium sulfate cast to obtain a separated dental arch. Separate the teeth so that these can be visualized individually in the X-ray and are clearly visible.
9. Place the separated dental arch into the duplication form.

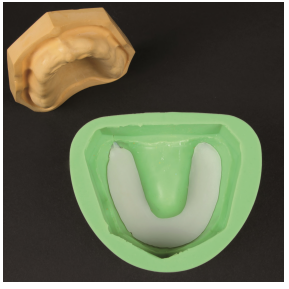


Figure to point 6

Figure to point 8

Figure to point 9

10. Place the stone model representing the current gingival situation in the duplication form, flush with the dental arch.
11. Allow the radio-opaque acrylic with a barium sulfate mix of 10% to flow into one of the holes of the duplication form. Using an 10% barium sulfate mix will help differentiate gingiva and teeth clearly in the X-ray later.
12. Once curing is complete, a duplicate of the denture made of different mixes of radio-opaque acrylic will be obtained.
13. Clean and disinfect the bite plate according to the instructions given in the following chapter: *Cleaning and disinfection procedure [▶ Page 67]*
14. Mix cold-cure acrylic (without barium sulfate) until it has a viscous consistency. To etch the surfaces, apply cold-cure acrylic to the underside of the bite plate (side without fiducial markers). Pour acrylic onto the bite plate. Make sure you use sufficient acrylic, as this serves both to bond the bite plate and the copy of the denture and to stabilize the radiographic template.

Figure to point 10 and 11

Figure to point 12

Figure to point 13

15. Position the duplicated denture made of the acrylic/barium sulfate mix on the bite plate. Press the duplicated denture onto the bite plate until the acrylic has cured. Make sure that the radiographic template is located securely and accurately on the stone model.

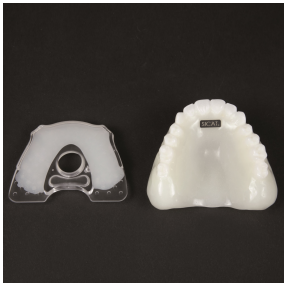
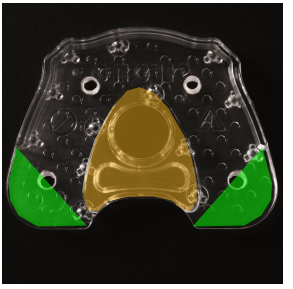


Figure to point 14

Figure to point 14



Bite plate

The **area shown in orange** should not be covered with acrylic or removed.

For small jaws, the bite plate can be shortened in the **areas marked in green**.

WARNING

Do not modify the radiographic template after the 3D X-ray scan.

2.9. 3D X-ray (Conbeam or CT)

General notes for the use of radiographic templates (CLASSICGUIDE)

For optimum scanning results, please observe the general instructions below:

- Check that the radiographic template is securely located and stable.
- Bite plate, thermoformed stent and any prosthetic proposal must remain firmly bonded to one another, even under mechanical load. The acrylic must be fully cured.
- Scan the patient wearing the radiographic template.
- Jaws should be scanned individually.
- Align the occlusion plane in parallel with the slice.
- Slightly pad bite (e.g. with cotton wool pads).
- Remove non-fixed metal prostheses from the opposing jaw, e.g. dentures.
- Make sure that the teeth of the opposing jaw do not touch the fiducial markers of the radiographic template.

WARNING

The acrylic must be fully cured prior to the 3D X-ray scan.

WARNING

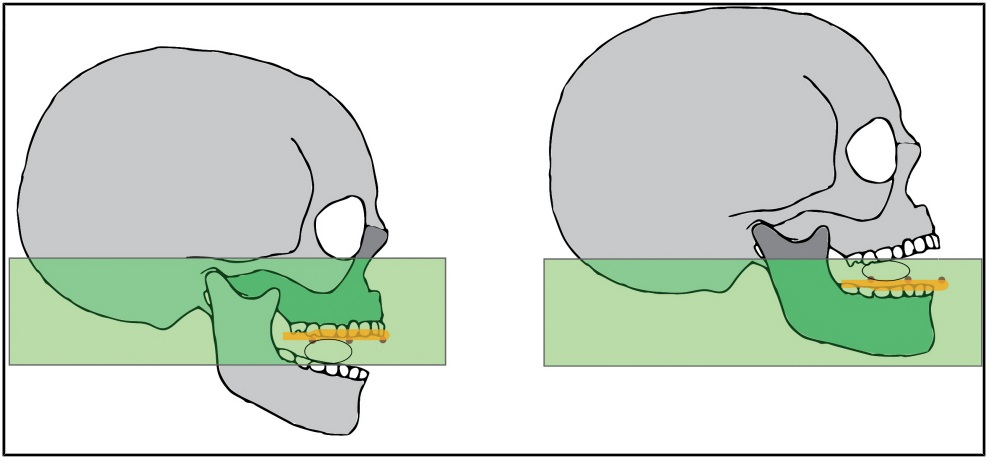
Make sure that the radiographic template is seated on the jaw **without gaps**, and that the fit is **secure** and **stable**.

WARNING

Practice the correct seating of the radiographic template with the patient in case he is scanned in your absence.

WARNING

Please advise your patient that the radiographic template must be positioned **without gaps** and **must sit securely** on the jaw. The patient must not move during the scan.



Alignment of the occlusion plane in parallel with the slice

2.10. 3D X-ray (Dentsply Sirona system)

1. Prepare the scan by selecting the appropriate bite plate holder (upper or lower jaw).
2. Let the patient try on the radiographic template. Check that the radiographic template is secure and stable.
3. Close the swivel arm and adjust the system height until the incisors and the ball of the bite plate holder are at the same level.
4. Now guide the patient carefully onto the bite plate holder. The patient should bite gently on the bite plate holder. The radiographic template should now be in a horizontal position.
5. Start the scanning process on your Conebeam system.

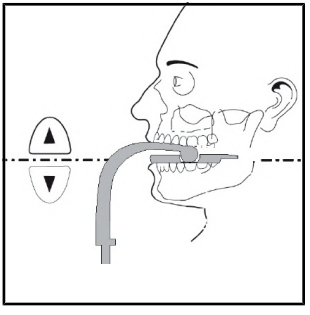


Figure to point 4

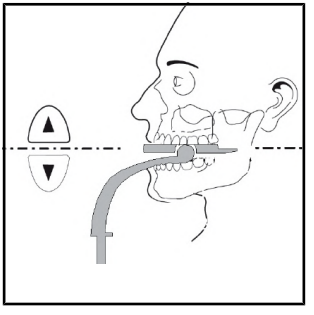


Figure to point 4

2.11. Scanning parameters for CT and Conebeam systems

For optimum scanning results, please observe the following parameters of your 3D X-ray system:

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

For optimum scanning results, always follow the instructions of use of your Conebeam or CT radiographic system.

WARNING

For a SICAT CLASSICGUIDE at least four fiducial markers must be visible in the 3D X-ray scan.

WARNING

Please advise your patient that the radiographic template must be positioned **without gaps** and **must sit securely** on the jaw. The patient must not move during the scan.

WARNING

If the thermoformed stent detaches from the bite plate after the CBCT scan, it must be reattached with radiolucent acrylic, followed by a new CBCT scan.

WARNING

Only qualified persons should initiate the x-ray scan.

WARNING

The 3D X-ray scan must not contain significant artifacts.

2.12. Preventing potential errors

1. Incorrect positioning of the radiographic template

In this example, a gap of approximately 2 mm can be seen between the radiographic template and the tooth. If you cannot ensure that the position of the radiographic template during the scanning procedure is exactly the same as the position of the surgical guide during the surgery, a significant decrease in accuracy of the osteotomy is possible.

2. Patient movement

If the patient inadvertently moves during the scanning process, this will cause movement artifacts. The artifacts make the fiducial markers and important anatomical structures difficult to detect. It is therefore important to tell the patient not to move during the scanning procedure. This 3D X-ray scan shows double structures. Production of a surgical guide is not possible with a 3D X-ray scan of this type. A new 3D X-ray scan is required.

3. Unclear fiducial markers

In order to be able to fabricate an accurate **CLASSIC**GUIDE surgical guide, the fiducial markers must appear clearly and without errors. If the opposing jaw has structures which absorb X-rays to a significant extent (for example gold or ceramic crowns) and these structures are located close to the fiducial markers, it helps to pad the patient's bite with cotton rolls.

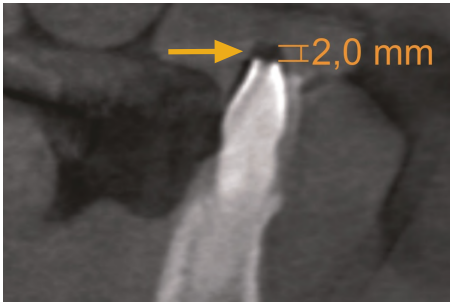


Figure 1: Incorrect fit

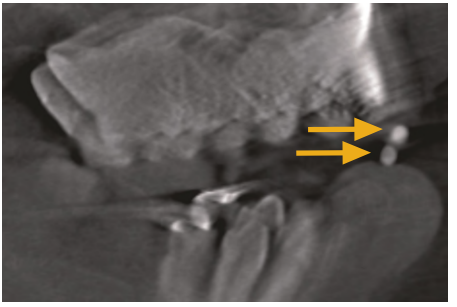


Figure 2: Patient movement

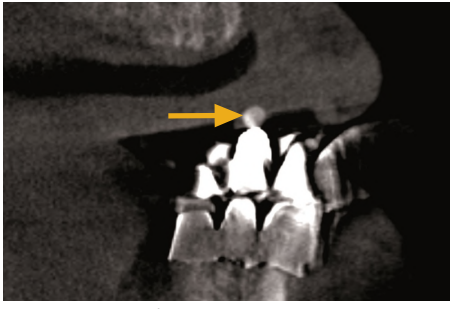


Figure 3: Unclear fiducial marker

WARNING

Make sure that you use only current 3D X-ray scans for implant planning. Otherwise tooth situation, gingiva situation and bone situation can significantly deviate from reality.

WARNING

Send the exact radiographic template that the patient was wearing during the CBCT scan.

WARNING

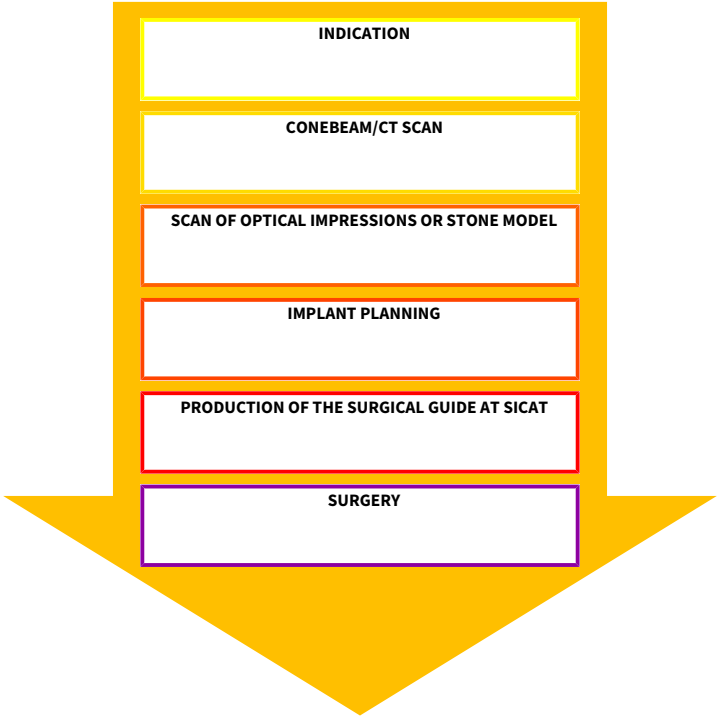
Do not modify the radiographic template after the 3D X-ray scan.

3. SICAT OPTIGUIDE

SICAT **OPTI**GUIDE is based on the superimposition of optical impressions of a jaw and the corresponding 3D X-ray data. Together with implant planning and the desired selection of sleeves, SICAT fabricates an accurate surgical guide. Production of a radiographic template based on a bite plate is not required for **OPTI**GUIDE.

NOTICE	If you are uncertain whether a case is suitable for **OPTI**GUIDE or **DIGITAL**GUIDE, before taking the 3D X-ray scan, follow the CLASSICGUIDE workflow. Alternatively, please contact SICAT Support.

3.1. SICAT OPTIGUIDE Workflow



3.2. Preparation of an OPTIGUIDE surgical guide

You can prepare an **OPTI**GUIDE in two different ways:

- Import optical impressions directly into GALILEOS Implant or SICAT Implant and superimpose the optical impressions with the 3D X-ray scan. You can find additional information on superimposing optical scan data with 3D X-ray data in our GALILEOS Implant or SICAT Implant software manuals.
- Send accurate stone models with your order for SICAT to digitize and superimpose with 3D X-ray data.

WARNING

For **OPTI**GUIDE or **DIGITAL**GUIDE, ensure that the patient has sufficient remaining teeth to provide reliable support for the surgical guide. If this is not the case, follow the **CLASSIC**GUIDE workflow.

WARNING

For **OPTI**GUIDE or **DIGITAL**GUIDE, ensure that the optical impressions correspond **exactly** to the current situation in the jaw. Otherwise, it will be impossible to fit the surgical guide accurately, and this may lead to a deviation from the planned implant position.

WARNING

Verify and confirm accurate superimposition of optical impressions with 3D X-ray data. Inaccurate registrations may lead to deviations in the implant planning process.

NOTICE	Do not use alginate impressions to create accurate stone models.

For information about 3D X-ray scans and optical impressions go to: *Scan notes (OPTIGUIDE and DIGITALGUIDE) [▶ Page 51]*

4. SICAT DIGITALGUIDE

SICAT **DIGITAL**GUIDE is based on the superimposition of optical impressions of a jaw and the corresponding 3D X-ray data. Together with implant planning and the desired selection of sleeves, SICAT designs a digital model of a surgical guide. SICAT uploads the digital surgical guide design file to your personal SICAT Portal account. You can produce it with your own 3D printer or you can have it printed in a laboratory of your choice. If a SICAT partner laboratory is available in your country, you can choose this option and SICAT will forward the digital surgical guide model directly to the partner laboratory. Production of a radiographic template based on a bite plate is not required for **DIGITAL**GUIDE.

NOTICE	If you are uncertain whether a case is suitable for **OPTI**GUIDE or **DIGITAL**GUIDE, before taking the 3D X-ray scan, follow the CLASSICGUIDE workflow. Alternatively, please contact SICAT Support.

4.1. SICAT DIGITALGUIDE Workflow

4.2. Preparation of a DIGITALGUIDE surgical guide

Follow the steps to prepare a **DIGITAL**GUIDE:

- Import optical impressions directly into GALILEOS Implant or SICAT Implant and register the optical impressions with the 3D X-ray scan. You can find additional information on registering optical scan data with 3D X-ray data in our GALILEOS Implant or SICAT Implant software manuals.

WARNING

For **OPTI**GUIDE or **DIGITAL**GUIDE, ensure that the patient has sufficient remaining teeth to provide reliable support for the surgical guide. If this is not the case, follow the **CLASSIC**GUIDE workflow.

WARNING

For **OPTI**GUIDE or **DIGITAL**GUIDE, ensure that the optical impressions correspond **exactly** to the current situation in the jaw. Otherwise, it will be impossible to fit the surgical guide accurately, and this may lead to a deviation from the planned implant position.

WARNING

Verify and confirm accurate superimposition of optical impressions with 3D X-ray data. Inaccurate registrations may lead to deviations in the implant planning process.

If the surgical guide is not printed in a SICAT partner laboratory, make sure that you or your laboratory have the desired sleeves available.

For information about 3D X-ray scans and optical impressions, see: *Scan notes (OPTIGUIDE and DIGITALGUIDE) [▶ Page 51]*

5. Scan notes (OPTIGUIDE and DIGITALGUIDE)

Below, you can find notes regarding 3D X-ray scans and scanning optical impressions that are relevant for **OPTI**GUIDE and **DIGITAL**GUIDE.

5.1. Instructions about 3D X-ray scans

For optimum scanning results, please observe the general instructions below:

- Do not scan patient with the occlusion closed. Slightly pad bite (e.g. with cotton pads).
- Remove non-fixed metal prostheses from the opposing jaw, e.g. dentures.
- If possible, scan at least 3/4 of the curve of the jaw. This increases the likelihood of being able to use sufficient artifact-free teeth for registration.
- For better representation of the gingiva, it is helpful to separate jaw and lip or cheek using cotton rolls.

5.2. Instructions about scanning optical impressions

If possible, scan at least 3/4 of the curve of the jaw in order to ensure that the surgical guide is stable and to increase the likelihood of being able to use sufficient artifact-free teeth for registration.

WARNING

Complete optical impressions of at least 3/4 of the curve of the jaw must be available.

WARNING

If it is likely that a 3D X-ray scan will have several metal artifacts (for example numerous gold or ceramic crowns), follow the **CLASSIC**GUIDE workflow. When severe metal artifacts are involved, it is not possible to manufacture an **OPTI**GUIDE or **DIGITAL**GUIDE.

5.3. Preventing potential errors

1. Patient movement

If the patient inadvertently changes position during the scanning process, this will cause movement artifacts which causes the image to be blurred. These artifacts make it hard to register optical impressions with 3D X-ray scans. Therefore, it is important to tell the patient not to move during the scanning procedure. It is not possible to accurately superimpose optical scan data if there are movement artifacts in the 3D X-ray scan. SICAT cannot manufacture a surgical guide based on such 3D X-ray scans. A new 3D X-ray scan is required.

2. Metal artifacts

The precise shape of a tooth, that has been restored using metal or ceramic, cannot be verified accurately in the 3D X-ray scan due to metal artifacts. These teeth, and in many cases the adjacent teeth, cannot be used for successful registration or verifying the registration of an optical impression. This is why **OPTI**GUIDE and **DIGITAL**GUIDE are not indicated in cases with many metal artifacts. In contrast, **CLASSIC**GUIDE is relatively insensitive to metal artifacts.

3. Optical impressions do not correspond to jaw situation

SICAT manufactures this surgical guide based on optical impressions. Faulty scan data can lead to a surgical guide not fitting the patient's jaw correctly. It is therefore essential to ensure that the optical impressions correspond precisely to the patient’s situation.

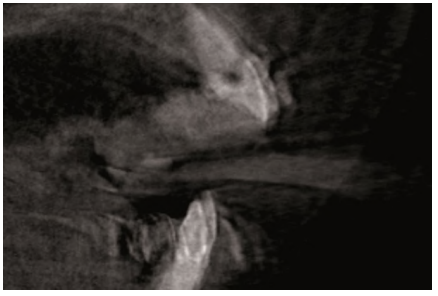


Figure 1: Patient movement

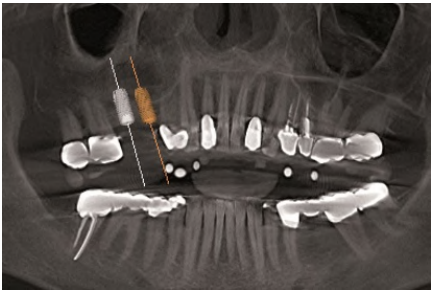


Figure 2: Metal artifacts

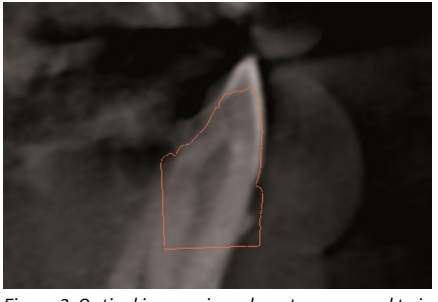


Figure 3: Optical impressions do not correspond to jaw situation

6. Preventing planning errors

To prevent planning errors, please follow the important tips below when executing your implant plan.

Unsuitable drill path

Figure 1 shows a drill path that is too close to an adjacent tooth. The drill sleeve and the final drill would collide with the adjacent tooth.

Collision between drill sleeve and drill sleeve

Figure 2 shows the collision of the drill sleeve of two implants. The visualization of the drill sleeves shows this clearly. Production of the surgical guide is not possible.

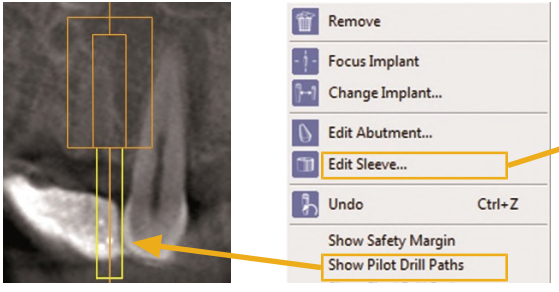


Figure 1: Unsuitable drilling path

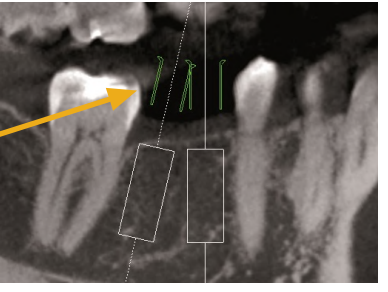


Figure 2: Collision between drill sleeve and drill sleeve

Collision between drill sleeve and neighboring tooth

Figure 3 shows the collision between a drill sleeve and a neighboring tooth. Avoid this scenario by allowing enough space between sleeves and neighboring teeth because the surgical guide will not fit the patient's jaw when such collisions are involved.

Collision between drill sleeve and gingiva

Figure 4 shows the collision between a drill sleeve and the gingiva. If you reflect a gingival flap during surgery, this will not be a problem. However, if you are planning a flapless surgery, the surgical guide will not fit on the jaw of the patient. Avoid this scenario by planning the sleeve on top the gingiva.

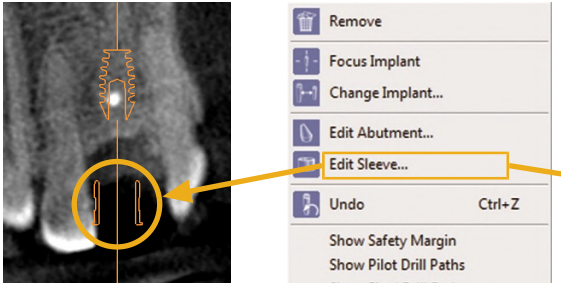


Figure 3: Collision between drill sleeve and adjacent tooth

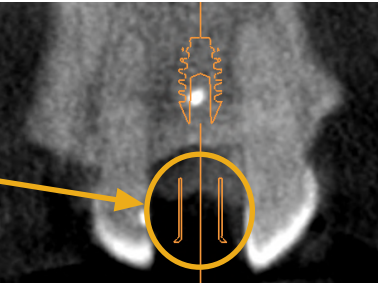


Figure 4: Collision between drill sleeve and gingiva

Right-click on the implant and select "Visualize drill path" to display the drill path of the pilot or the final drill. Select the corresponding sleeve system within the implant dialog in order to visualize drill sleeves.

WARNING

Please take into account the feasibility of using a surgical guide, while creating your implant plan.

7. Handling of the surgical guide

Please pay close attention to following description before using the surgical guide:

- Please protect the surgical guide from direct sunlight and elevated temperatures to prevent it from deforming.
- Check the surgical guide before surgery. Make sure that the surgical guide can be positioned without gaps and is secure and stable on the stone model, if available, or in the patient's mouth. Ensure that the position of the drill sleeves is in line with your implant plan. Do not use the surgical guide if the inspection is unsuccessful.
- Clean and disinfect the surgical guide according to the instructions given in the following chapter: *Cleaning and disinfection procedure [▶ Page 67]*
- Before using the surgical guide, check all drills and drill sleeves which are going to be used for damages. Use only drills and sleeves in perfect condition in order to prevent drills from tilting in a sleeve.
- Ensure that the surgical guide is secure and stable on the jaw during use. Otherwise the holes are likely to be less accurate.

WARNING

The SICAT surgical guide is a single-use device. Do not reuse or try to sterilize or re-disinfect the SICAT surgical guide. The reuse may lead to a risk of infection for the patient and operator. Furthermore, it may negatively impact the performance and characteristics of the product.

WARNING

Ensure that you have the correct drills and surgical components to fit the sleeves.

WARNING

The drill should be inserted into the sleeve of the surgical guide before rotation begins. If the drills are rotating before being inserted into the sleeve, the drill could scratch and damage the inside surface of the sleeve, and/or the drill angle might deviate.

WARNING

Prior to surgery, check that the surgical guide is secure and stable on the patient's jaw.

WARNING

Clean and disinfect the surgical guide according to the instructions given in this manual. Wrong processing may lead to a risk of infection for the patient and operator. Furthermore, it may negatively impact the performance and characteristics of the product.

WARNING

Please protect the surgical guide from direct sunlight and elevated temperatures to prevent it from deforming.

WARNING

Never use a damaged surgical guide (e.g. a surgical guide showing deformations, cracks, fractures, fissures, lost or loose parts). Before use, please check the surgical guide for damages.

WARNING

Use of the surgical guide after the end of its service life may pose a health hazard to the patient. Ensure that the surgical guide is not used after the end of its service life, i.e. 3 months after manufacture.

WARNING

Use of the surgical guide by unqualified personnel could pose a health hazard to the patient or lead to improper treatment. The surgical guide may only be used by qualified personnel.

WARNING

Changes to the surgical guide may pose a health hazard to the patient or result in improper treatment. Do not make any changes to the surgical guide.

WARNING

Do not utilize heat-based methods (e.g. autoclaves) for disinfecting or sterilizing the surgical guide. The surgical guide could become deformed.

NOTICE Ensure adequate cooling during drilling.

NOTICE Always follow the manufacturer's instructions for use of your guided surgical system.

WARNING

The force of the drill, can cause the guide to move during surgery. It is important to stabilize the guide properly during use.

WARNING

Ensure that excessive force is not exerted on the drill sleeve during the drilling process; this prevents the sleeve from separating from the guide. Sleeves planned too closely to adjacent teeth, will be surrounded by a limited amount of acrylic material.

WARNING

Ensure that excessive force is not exerted on the surgical guide during use; this will prevent it from breaking.

NOTICE

In the unlikely event that it should become apparent during surgery that the surgical guide cannot be used, please ensure that you can still perform surgery safely without it.

Storage

If stored, the device should be stored in a clean environment at usual room conditions and protected from direct sunlight.

Disposal

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

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.

8. Cleaning and disinfection procedure

Personal protective equipment: gloves, water repellent protective skirt, face protection mask or protective glasses and mask

Manual cleaning and drying

Equipment: mild detergent (e.g. "Denkmit Spülmittel Ultra Sensitve", dm, ingredients: water, sodium laureth sulfate, cocamidopropyl betaine, alcohol, sodium chloride, MEK, citric acid, pH-value: 5.3), soft toothbrush, ultrasonic unit, frequency 35 kHz

- Clean the complete device thoroughly using a soft toothbrush with one drop of mild detergent on it with running tap water* (20 – 25 °C/68°F - 77°F).
- Continue until no more contaminants are visible on the device, but for at least 1 minute. Pay particular attention to corners, edges and lumens.
- Place the pre-cleaned medical device completely in an ultra-sonic unit filled with cleaning solution (1 teaspoon (5 ml) /5 liter tap water*, 20-25°C/68°F - 77°F) for 10 minutes. Make sure that all surfaces are completely moistened with cleaning solution.
- Rinse under running tap water* for at least 1 minute. Take special care to thoroughly flush the drill sleeves.
- Dry with compressed air or allow the device to air-dry thoroughly or dry with a clean and lint-free single use wipe.

Visual inspection: After cleaning and drying, inspect the device for unacceptable deterioration (such as cracks, breaks) and properly dispose any devices that fail the inspection. If the device is not visibly clean, remove soil manually and repeat the cleaning steps above.

*Drinking water quality according to the country regulations e.g. EU drinking water regulations (total germ count max. 100 cfu/ml)

Manual high-level disinfection

- **Equipment**: FDA-listed high-level disinfectant solution on basis of ortho-phthaladehyde (e.g., ASP CIDEX OPA Solution #20391, active ingredients: 0.55% ortho- phthalaldehyde), disinfectant tank, sterile water
- Immerse device completely by slightly moving (forward and backward) it in order to fill all lumens and eliminate air pockets, in CIDEX OPA solution for 10 minutes at 20°C - 25 °C (68°F - 77°F) to destroy all pathogenic microorganisms. Brush the device with a soft toothbrush in the disinfectant for 1 min. Pay particular attention to corners, edges and lumens.
- Remove the device from the solution and directly rinse following the rinsing instructions below.

Rinsing procedure

Following removal from the CIDEX OPA solution, thoroughly rinse the device by immersing it completely in a large volume (minimum of 1 L) of sterilized deionized water.

- Keep the device totally immersed for a minimum of 1 minute. Manually flush all lumens with help of slight movements (forward and backward) within the rinse water for a minimum of 15 seconds.
- Remove the device and discard the rinse water. Always use fresh volumes of sterilized deionized water for each rinse. Do not reuse the water for rinsing or any other purpose.
- Repeat the procedure two (2) additional times, for a total of three (3) rinses, with large volumes of fresh sterilized deionized water to remove CIDEX OPA residues.

Residues may cause serious effects. Refer to the CIDEX OPA instructions for use for more details.

Drying after disinfection

- Dry with compressed air or allow the device to air-dry thoroughly or dry with a clean and lint-free single use wipe.

The instructions given above were successfully validated in an accredited laboratory using the product “Denkmit Spülmittel Ultra Sensitve” as detergent for cleaning and “CIDEX OPA” for disinfection.

9. Ordering a surgical guide

Depending which surgical guide workflow option you have selected, there are various options for sending your order to SICAT.

The following pages summarize all of the methods for the surgical guide ordering process:

- SICAT **CLASSIC**GUIDE
- SICAT **OPTI**GUIDE with registered optical impressions
- SICAT **OPTI**GUIDE with stone model
- SICAT **DIGITAL**GUIDE with registered optical impressions

NOTICE	A guided surgery kit from the implant manufacturer is essential when selecting a guided implant system - e.g. CAMLOG® Guide from CAMLOG, Navigator® from Biomet **3i**™, etc.

NOTICE	It is essential to follow the instructions for use for the planning program in question (GALILEOS Implant, SICAT Implant) for further helpful tips on implant planning.

NOTICE	Please note that in the event of the patient's jaw opening being limited, it can be more difficult, if not impossible, to insert the drill into the sleeve, especially in posterior position.

NOTICE	Please ensure that you send patient-specific data in anonymised form.

Using the order wizard

To order surgical guides, please follow the order wizard in the software.

1. Under **Surgery**, click on the **surgical guide wizard** icon to start.
2. Select the type of surgical guide you would like to order.
3. Follow the instructions of the order wizard until the surgical guide ordering process is complete.

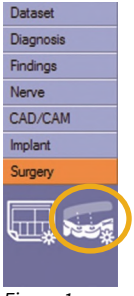


Figure 1

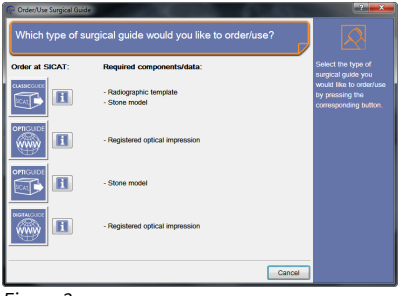


Figure 2

WARNING

Make sure that you use only current 3D X-ray scans for implant planning. Otherwise tooth situation, gingiva situation and bone situation can significantly deviate from reality.

9.1. Ordering SICAT CLASSICGUIDE

WARNING

Send the exact radiographic template that the patient was wearing during the CBCT scan.

WARNING

Do not modify the radiographic template after the 3D X-ray scan.

SICAT produces the patient-specific **CLASSIC**GUIDE for you. Please send the following materials:

SICAT GmbH & Co. KG
Digital Manufacturing
Friesdorfer Str. 131-135
53175 Bonn, Germany

1. **3D planning data on CD**,
2. **Signed payment form**
3. **Radiographic template**
4. **Stone model**

The 3D planning data on CD generated with the order wizard in a SICAT planning program (GALILEOS Implant, SICAT Implant). You only need the signed payment form if you have not authorized a direct debit. The radiographic template is the basis for the production of a **CLASSIC**GUIDE (disinfected and dry in the polyethylene bag with a silica gel pack).

WARNING

Label the CD, the stone model and the radiographic template (the latter only for **CLASSIC**GUIDE) with the corresponding patient ID in the surgical guide order.

The easiest way to send a case is to use the SICAT Online Pick-Up Service. To arrange the pick-up, please visit our SICAT Portal by opening ***http://www.sicat.com*** and clicking the link to the SICAT Portal. If you have not registered yet, you can set up an account there.

WARNING

Please ensure sufficient padding when packing to prevent the stone model or radiographic template from breaking.

WARNING

Send the exact radiographic template that the patient was wearing during the CBCT scan.

WARNING

Ensure that the radiographic template is disinfected before sending it.

WARNING

Ensure that the radiographic template is placed inside the polyethylene bag before sending it.

WARNING

Ensure that a silica gel pack is placed inside the polyethylene bag before sending the radiographic template.

9.2. Ordering SICAT OPTIGUIDE (Option 1)

With registered optical impressions:

SICAT produces the patient-specific **OPTI**GUIDE for you. Please only use the order wizard in the software (SICAT Implant, GALILEOS Implant).

- You can digitally upload the order to SICAT, via the software order wizard.
- Alternatively, you can physically ship the order, burned onto a CD, to SICAT. In this case, please label the CD with the patient name and/or ID that corresponds with the information in the order, and ship it to:

SICAT GmbH & Co. KG
Digital Manufacturing
Friesdorfer Str. 131-135
53175 Bonn, Germany

- If you have not authorized a reoccurring credit card payment, please fax the **signed payment form** to SICAT separately or enclose it with your package.

9.3. Ordering SICAT OPTIGUIDE (Option 2)

With stone model:

SICAT produces the patient-specific **OPTI**GUIDE for you. Please send the following materials:

SICAT GmbH & Co. KG
Digital Manufacturing
Friesdorfer Str. 131-135
53175 Bonn, Germany

1. **3D planning data on CD**, generated with the order wizard in a SICAT planning program (GALILEOS Implant, SICAT Implant).
2. **Signed payment form** if you have not authorized a direct debit.
3. **Stone model**

WARNING

Label the CD, the stone model and the radiographic template (the latter only for **CLASSIC**GUIDE) with the corresponding patient ID in the surgical guide order.

The easiest way to send a case is to use the SICAT Online Pick-Up Service. To arrange the pick-up, please visit our SICAT Portal by opening ***http://www.sicat.com*** and clicking the link to the SICAT Portal. If you have not registered yet, you can set up an account there.

WARNING

To prevent the stone model from breaking, please ensure sufficient padding when packing.

9.4. Ordering SICAT DIGITALGUIDE

With registered optical impressions:

SICAT designs a patient-specific digital 3D model of a **DIGITAL**GUIDE surgical guide. You can produce it with your own 3D printer or you can have it printed in a laboratory of your choice. Please only use the order wizard in GALILEOS Implant (v1.9.2 or higher).

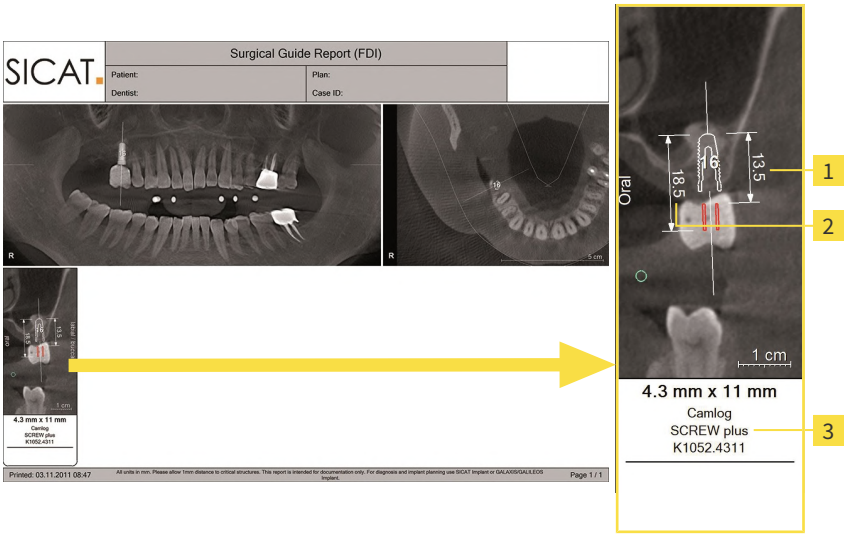
- You can digitally upload the order to SICAT, via the software order wizard.
- If you have not authorized a reoccurring credit card payment, please fax the **signed payment form** to SICAT separately.

10. SICAT documentation

You will receive the following documents from SICAT, along with your customized surgical guide (**CLASSIC**GUIDE, **OPTI**GUIDE) or your surgical guide design file (**DIGITAL**GUIDE):

Surgical guide report

The main component of the report is the implant-specific depth information. The report quotes the distances between the top of the sleeves and the apical end of the implants. You can compare these distances by measuring the drill during surgery.



1 Distance from the bottom of the drill sleeve to the apical end of the implant

2 Distance from the top of the drill sleeve to the apical end of the implant

3 Specifications of the planned implant

NOTICE	Please note that individual arrangements with SICAT Support are also noted on the surgical guide report.

Drill protocol

If you are using a sleeve system from an implant manufacturer which requires a drill protocol, SICAT will send the protocol generated, accordingly, along with your surgical guide.

Accuracy report (only for CLASSICGUIDE and OPTIGUIDE)

The accuracy report states the deviations of the positions of the actual sleeves in relation to the digital implant plan. For **CLASSIC**GUIDE and **OPTI**GUIDE, SICAT guarantees manufacturing deviation accuracy of max. 0.5 mm at the apical end of the implant.

11. Explanations of labeling

 Caution! Observe the accompanying documents.

SN Case No.

 Observe the instructions for use.

 Manufacturer

 Date of manufacture

MD Medical device

 Do not re-use

 Keep away from sunlight/heat

Rx only Prescription use only (USA specific symbol)

 Use-by date

LOT Lot number

CONTACT

Manufacturer

SICAT GmbH & Co. KG

Friesdorfer Str. 131-135

53175 Bonn, Germany

www.sicat.com

Additional marking for bite plate:

CE UKCA

Support

Telephone: +49 228 286206600

E-mail: sgl@sicat.com

DOCUMENT ID: DD30IFU002
MATERIAL NUMBER: 10370EN
CHANGE NUMBER: 500209

SICAT

REVISION: 2023-12-12