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### **1 INTENDED USE AND INDICATIONS FOR USE**

SICAT **ACCESSGUIDE** is a customized drill guide for orthograde and retrograde root canal treatment specific for each patient. It aids as an accessory for executing a surgical plan depending on previously identified surgical pathways. SICAT **ACCESSGUIDE** is manufactured in two variants, the orthograde SICAT **ACCESSGUIDE** and the retrograde SICAT **ACCESSGUIDE**.

#### **Indications for use**

The SICAT **ACCESSGUIDE** is intended for guiding drills during endodontic treatment.

Opening of pathways in the intra-oral region

- Opening of pathways in the jawbone for endodontic treatments (retrograde variant)
- Opening of pathways in teeth for endodontic treatments (orthograde variant)

#### **Contraindications**

- Insufficient tooth status for stable support of the drill guide
- Allergies or hypersensitivity to chemical ingredients of used materials (Poly-methyl methacrylate “PMMA”, titanium) or materials used by the dentist during the treatment (e.g. stainless steel)

#### **Clinical benefit**

The SICAT **ACCESSGUIDE** maximizes the transfer accuracy of an endodontic planning into the apical dental situation, minimizing treatment risks.

#### **Patient target group**

For the patient target group there are no exclusion criteria.

However, SICAT **ACCESSGUIDE** 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.

## 1 INTENDED USE AND INDICATIONS FOR USE

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### Intended users

Intended users are qualified dental professionals such as dentists.

### Important notes

- Currently, SICAT **ACCESSGUIDE** is only available as orthograde variant. Opening of pathways in the jawbone for endodontic treatments will only be available with the retrograde variant.
- The device is a single-use device.

### 2 SAFETY INFORMATION

It is important that you read the following safety-related sections in order to prevent injuries to operating personnel or patients, as well as material damage.

#### 2.1 DEFINITION OF THE DANGER LEVELS

The following safety labeling is used in these instructions for use:



##### **WARNING**

**Indicates a dangerous situation, which could result in death or severe injuries if not prevented.**



##### **CAUTION**

**Indicates a dangerous situation, which could result in smaller injuries if not prevented.**

##### **NOTICE**

**Indicates information deemed important, but not relevant to safety.**

### 2.2 QUALIFICATIONS OF OPERATING PERSONNEL



#### **WARNING**

**Use of the surgical guides by unqualified personnel could pose a health hazard to the patient or lead to improper treatment.**

The surgical guides may only be used by qualified personnel.

You must meet the following requirements to use the surgical guide:

- You have read the instructions for use.
- You have familiarized yourself with the requirements for the use of the surgical guides.
- You are able to recognize the limits of usability and take suitable steps where necessary.



## 3 SICAT ACCESSGUIDE

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

SICAT **ACCESSGUIDE** surgical guides help you implement the root treatment plan you have created using SICAT Endo. SICAT **ACCESSGUIDE** surgical guides are custom-made creations for each individual patient and guide your drill to the planned positions in the patient's tooth using guide sleeves.



SICAT ACCESSGUIDE



### 3.1 DESIGN AND MANUFACTURING

The SICAT laboratory designs the SICAT **ACCESSGUIDE** surgical guides based on 3D X-ray scans, optical impressions and your planning in SICAT Endo.

If you do not have the equipment to produce optical impressions, you may also send the stone models to SICAT. They will produce the optical scans of the stone models for you.

You will receive one SICAT **ACCESSGUIDE** surgical guide for each planned drilling site.

### 3.2 DEFINITION OF TERMS

#### **EndoLine**

An EndoLine is a multi-functional measuring line, which serves to mark the root canal to be treated and to locate the root apex. Please refer to the SICAT Endo instructions for use for further information regarding the use of EndoLines.

#### **Drill canal**

Drilling path planned on the basis of the EndoLine that can be visualized and edited in SICAT Endo.

#### **Drill depth**

The drill depth is the distance between the upper edge of the sleeve and the end of the drill canal. It will be indicated in SICAT Endo when you plan the drill canals. You will also find the planned drill depth on the surgical guide report, which SICAT will supply to you with the surgical guides.

#### **Guide ID**

The guide ID is a unique code that each surgical guide is provided with. The guide ID enables you to verify at any time that the supplied surgical guide matches your order. You will also find the guide ID on the surgical guide report.

#### **Diameter**

You will see the diameter for the planned drillhole when you plan the drill canals in SICAT Endo. The drilling diameter corresponds to the diameter of the used drill.

#### **Stone models**

Stone models are made by taking an impression of the teeth and are used to define the initial situation for treatment planning. They can be digitized using a 3D scanner. This makes it possible to create optical impressions which are used as basis for planning the SICAT **ACCESSGUIDE** surgical guide.

#### **Surgical guide**

A surgical guide based on a SICAT **ACCESSGUIDE** surgical guide model is customized for your patient. Once the surgical guide is placed on the patient's teeth, the guide and a sleeve accurately guide your drill to the position you have previously planned.

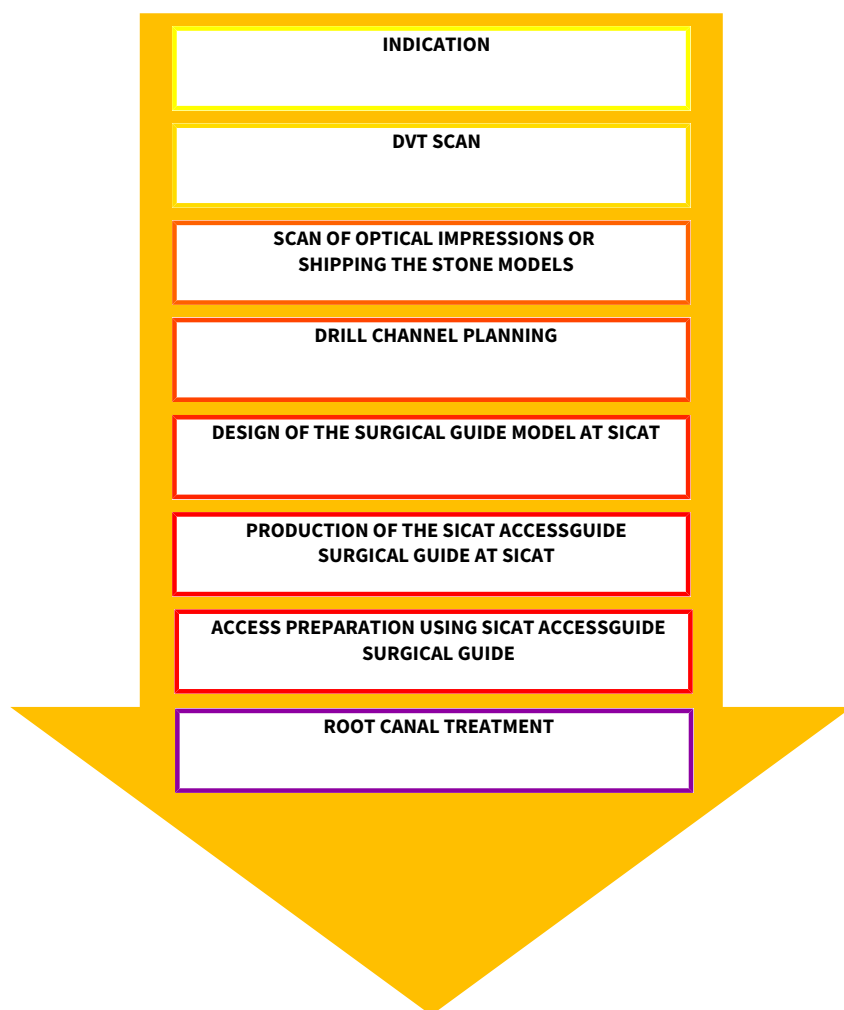
#### **Optical impressions**

You can obtain optical impressions by scanning the jaw with a 3D intraoral camera or by digitizing a stone model with a 3D scanner.

### ***4 PLANNING A SURGICAL GUIDE***

The SICAT **ACCESS**GUIDE surgical guide is based on the treatment planning that you have performed in SICAT Endo. Based on your planning and a suitable drill sleeve, SICAT designs a digital model of a surgical guide and produces the surgical guide.

### 4.1 SICAT ACCESSGUIDE WORKFLOW



### 4.2 PREPARATION OF A SICAT ACCESSGUIDE SURGICAL GUIDE

You can prepare a SICAT **ACCESSGUIDE** surgical guide as follows:

- Optionally, import intraoral scans into SICAT Endo and register the intraoral scans in the 3D X-ray scan.
- Import and register the optical impressions in SICAT Endo.
- Mark the root canals that are to be treated using EndoLines and plan the drill canals.

If you do not have the equipment to produce optical impressions, you may also send the stone models to SICAT. They will produce the optical scans of the stone models for you.

Please refer to the SICAT Endo instructions for use for more detailed information on registering intraoral scans and planning drill canals.

For important information on planning your drill canals, please refer to: *Planning instructions* [▶ Page 16].

For information on creating 3D X-ray scans and optical impressions, please refer to: *Scanning instructions for SICAT ACCESSGUIDE* [▶ Page 17].



#### **WARNING**

**Inaccurate or incorrect registration of the optical impression with the 3D X-ray scan may result in improper treatment.**

Ensure correct registration of the optical impression with the 3D X-ray scan.



#### **WARNING**

**Optical impressions or stone models that do not match the patient's anatomy may result in treatment mistakes.**

Ensure that the optical impressions or the stone model match the patient's anatomy.



#### **WARNING**

**Insufficient quality and precision of optical impressions and 3D X-ray scans for the purposes of this device may result in improper treatment.**

Only use optical impressions and 3D X-ray scans of sufficient quality and precision that is appropriate for the intended use and purpose.



##### **WARNING**

**Unwanted changes of the dental status could pose a health hazard to the patient.**

Ensure that the period of time from creation of the optical impressions or the stone model to treatment is as short as possible.



##### **CAUTION**

**An incorrect dental status in the stone model or in the optical model could pose a health hazard to the patient or result in improper treatment.**

Make sure that the stone model and the optical model reflect the correct dental status and are current when ordering and before you use the surgical guide.



##### **WARNING**

**Inadequate packaging of stone models could cause damage to the stone models.**

Use robust and adequately padded packaging to ship stone models.

### 5 PLANNING INSTRUCTIONS

Please follow the advice given below when planning your drill canals.

#### Collision with tooth that is to be treated

Figure 1 shows the collision between a drill sleeve and a tooth that is to be treated. Avoid such a scenario by restricting your planning to the area above the optical impressions in order to prevent overlaps. Otherwise the surgical guide will not fit onto the patient's jaw.

However, such a planning is generally possible even if there is not enough space. Before placing the SICAT **ACCESSGUIDE** surgical guide, the occlusal filling must be removed in this case.

#### Patient's mouth opening

Figure 2 shows the individual mouth opening which can differ greatly from one patient to another. Adjust the drill canal planning to the patient's individual situation as required.

Please note that it may not be possible to use SICAT **ACCESSGUIDE**, in particular in the posterior region, if the patient's mouth opening is not large enough to insert the drill into the sleeve.

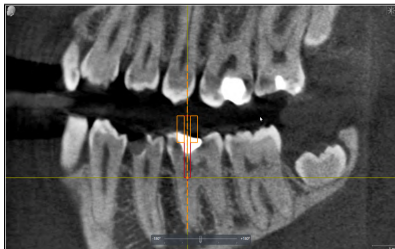


Figure 1: Collision between drill sleeve and tooth



Figure 2: Mouth opening



### 6 SCANNING INSTRUCTIONS FOR SICAT ACCESSGUIDE

The following pages contain instructions regarding the creation of 3D X-ray scans and optical impressions that are relevant for SICAT **ACCESSGUIDE** surgical guides.

#### 6.1 INSTRUCTIONS FOR 3D X-RAY SCANS

Please follow the instructions below to obtain optimum scanning results:

- Do not scan patients with the occlusion closed. Slightly obstruct bite, for example, by padding it with cotton pads or use a suitable holder.
- Remove non-fixed metal parts from patients' mouth, for example dentures.
- If possible, scan at least 75 % of the arch of the jaw. This increases the probability of you being able to use a sufficient number of artifact-free teeth for registration. With adequate positioning this is also possible in case of 3D X-ray scans having a volume of 5 cm x 5 cm.
- For better representation of the mucosa in the 3D scan, you can separate jaw and lip or cheek using cotton rolls.

#### 6.2 INSTRUCTIONS FOR OPTICAL IMPRESSIONS

If possible, scan at least 75 % of the arch of the jaw in order to ensure that the surgical guide is securely placed and to increase the probability of you being able to use a sufficient number of artifact-free teeth for registration.



##### **WARNING**

**Inaccurate or incorrect registration of the optical impression with the 3D X-ray scan may result in improper treatment.**

Ensure correct registration of the optical impression with the 3D X-ray scan.



##### **WARNING**

**Optical impressions or stone models that do not match the patient's anatomy may result in treatment mistakes.**

Ensure that the optical impressions or the stone model match the patient's anatomy.



### WARNING

**Insufficient quality and precision of optical impressions and 3D X-ray scans for the purposes of this device may result in improper treatment.**

Only use optical impressions and 3D X-ray scans of sufficient quality and precision that is appropriate for the intended use and purpose.



### WARNING

**Unwanted changes of the dental status could pose a health hazard to the patient.**

Ensure that the period of time from creation of the optical impressions or the stone model to treatment is as short as possible.



### CAUTION

**An incorrect dental status in the stone model or in the optical model could pose a health hazard to the patient or result in improper treatment.**

Make sure that the stone model and the optical model reflect the correct dental status and are current when ordering and before you use the surgical guide.

### 6.3 PREVENTING POTENTIAL ERRORS

#### Patient movement

Figure 1: If the patient inadvertently moves during the scanning process, movement artifacts are caused which will blur the scan. Artifacts like this make it hard to register optical impressions and 3D X-ray scans. Thus, it is important that you tell the patient before the 3D X-ray scan not to move throughout the entire scanning procedure. If a scan does contain movement artifacts, exact registration is not possible. SICAT is not able to manufacture surgical guides based on such 3D X-ray scans. It is necessary to make a new 3D X-ray scan.

#### Metal artifacts

Figure 2: The exact shape of a tooth that has been restored using metal or ceramic materials cannot be accurately reconstructed in the 3D X-ray scan due to metal artifacts. You can use these teeth, and in many cases the adjacent teeth as well, which are affected by such metal artifacts neither for registration nor for assessment of a registration.

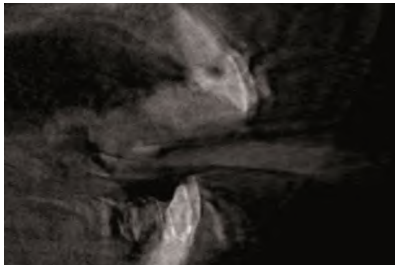


Figure 1: Patient movement



Figure 2: Metal artifacts

### Optical impressions do not match the jaw situation

Figure 3: SICAT manufactures the surgical guides based on optical impressions. Incorrect scan data can result in a surgical guide not fitting accurately onto the patient's jaw. It is therefore essential for you to ensure that the optical impressions exactly match the patient's situation.



Figure 3: Optical impressions do not match the jaw situation



#### WARNING

**Insufficient quality and precision of optical impressions and 3D X-ray scans for the purposes of this device may result in improper treatment.**

Only use optical impressions and 3D X-ray scans of sufficient quality and precision that is appropriate for the intended use and purpose.



#### WARNING

**Unwanted changes of the dental status could pose a health hazard to the patient.**

Ensure that the period of time from creation of the optical impressions or the stone model to treatment is as short as possible.



#### WARNING

**Optical impressions or stone models that do not match the patient's anatomy may result in treatment mistakes.**

Ensure that the optical impressions or the stone model match the patient's anatomy.



### **WARNING**

**Inaccurate or incorrect registration of the optical impression with the 3D X-ray scan may result in improper treatment.**

Ensure correct registration of the optical impression with the 3D X-ray scan.

### 7 ORDERING A SURGICAL GUIDE

The following pages provide a summary of all important shipping information for the surgical guide ordering process from SICAT Endo:

- SICAT **ACCESSGUIDE** (option 1), with integrated optical impressions
- SICAT **ACCESSGUIDE** (option 2), without integrated optical impressions

#### 7.1 ORDERING AN ACCESSGUIDE SURGICAL GUIDE (OPTION 1)

With integrated optical impressions:

SICAT manufactures the patient-specific **ACCESSGUIDE** surgical guide for you. Please use the order wizard in SICAT Endo only.

- You can transmit your order to SICAT online via the order wizard.
- You can view and edit your orders at all times in the SICAT Portal.

#### 7.2 ORDERING AN ACCESSGUIDE SURGICAL GUIDE (OPTION 2)

Without integrated optical impressions:

SICAT manufactures the patient-specific **ACCESSGUIDE** surgical guide for you. Please send the following components to:



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

1. **Stone model**
2. **Dispatch note for identification of the stone model**



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.



### CAUTION

**Missing and incorrect components in the order package may result in a faulty surgical guide.**

Make sure that the necessary and correct components are included in your order package.



### WARNING

**Inadequate packaging of stone models could cause damage to the stone models.**

Use robust and adequately padded packaging to ship stone 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.



### 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.

### NOTICE

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

### 8 UNPACKING THE SURGICAL GUIDE

When unpacking your surgical guide please check the following:

- Check the contents of the shipping box for completeness:
  - Surgical guide report
  - Instructions for use
  - Correct number of surgical guides
  - Correct number of drills (optional): When ordering via SICAT
- Check whether the number of surgical guides matches the number of planned drill canals. If the numbers do not match, please contact the SICAT surgical guide support.
- Ensure that the surgical guides are undamaged. Damaged surgical guides must not be used. They pose an increased risk of injury to the patient, which must be prevented under any circumstance.
- Check the information on the surgical guide report. Make sure that any information featuring there is correct and matches your planning. Check whether the information in the report matches the information of the patient who is to be treated.



#### **WARNING**

#### **A damaged surgical guide may pose a health hazard.**

Check the surgical guide for damage before using it. Examples of such damage include deformations, cracks, breaks, gaps, and loose parts.



### 9 HANDLING OF THE SURGICAL GUIDE

Before you use your surgical guide please observe the following instructions:

- Protect the guide from direct sunlight and high temperatures to prevent the surgical guide from deforming.
- Check the surgical guide before the treatment and before placing the rubber dam. Check that the surgical guide can be firmly and correctly placed using the stone model, if available, or in the patient's mouth. Ensure that the position of the drill sleeves matches your planning. If the surgical guide does not pass this check, you must not use it.
- Clean and disinfect the surgical guide according to the instructions given in the following chapter: *Cleaning and disinfection procedure* [▶ Page 36]
- Check the drills and drill sleeves that are to be used for damage before using the surgical guide. To prevent the drill from getting wedged in a sleeve, use only flawless drills and sleeves.
- Ensure, during the use of the surgical guide, that you are able to place the guide onto the teeth accurately and without play. Otherwise, a decrease in drilling accuracy is to be expected.



#### WARNING

**The reuse of the surgical guide may lead to a risk of infection for the patient and operator. Furthermore, it may negatively impact the performance and characteristics of the product.**

The surgical guide is a single-use device. Do not reuse or try to sterilize or re-disinfect the surgical guide.



#### WARNING

**Use of an unsuitable drill could pose a health hazard to the patient or result in improper treatment.**

Use a suitable drill.



#### WARNING

**Using a drill and a drill sleeve that are not meant to be combined could pose a health hazard to the patient.**

Ensure that the drill you want to use matches the drill sleeve of the surgical guide.



### WARNING

**Inadequate fixing of the surgical guide on the patient's teeth could pose a health hazard to the patient.**

Fix the surgical guide without exerting too much pressure. Ensure that the guide fits precisely such that the drill sleeve is positioned correctly as planned.



### WARNING

**Exerting too much pressure when placing the surgical guide or during drilling could pose a health hazard to the patient or result in improper treatment.**

Only use as much force as necessary when inserting the surgical guide and during drilling.



### WARNING

**A damaged surgical guide could pose a health hazard to the patient.**

Never use a damaged surgical guide. Examples of such damage include deformations, cracks, breaks, gaps, and loose parts.



### WARNING

**Exposure to direct sunlight could result in damage to the surgical guide.**

Protect the surgical guide from exposure to direct sunlight and high temperatures.



### WARNING

**Inadequate fitting of the surgical guide on the patient's teeth could pose a health hazard to the patient.**

Check that the surgical guide is correctly and firmly placed before starting to drill.



### WARNING

**Wrong cleaning and disinfection may lead to a risk of infection for the patient and operator. Furthermore, it may negatively impact the performance and characteristics of the product.**

Clean and disinfect the surgical guide according to the instructions given in this manual.



### **WARNING**

**A heat-based disinfection or sterilization method (e. g. autoclaving) could result in damage to the surgical guide.**

Never use a heat-based method for disinfection or sterilization of the surgical guide.

### 9.1 USING ORTHOGRADE SICAT ACCESSGUIDE SURGICAL GUIDES



#### **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.

In this chapter you will learn how to use an orthograde SICAT **ACCESSGUIDE** surgical guide. Some steps are optional and can be left out.

#### **Checking the placement of the surgical guide**

- Check that the surgical guide is correctly and firmly placed in the patient's mouth.
- Ensure that the position of the drill sleeve matches your planning.
- If the surgical guide does not pass this check, you must not use it.



*Figure 1: Placing the surgical guide*



*Figure 2: Checking the placement of the surgical guide*



#### **WARNING**

**If the patient has not enough teeth remaining in his or her mouth this could result in improper treatment.**

Check whether the patient has enough teeth remaining to ensure that the surgical guide can be correctly and firmly placed.



### **WARNING**

**Failure to take the patient's medical history into account could pose a health hazard to the patient.**

Consider the patient's medical history before treatment. Pre-existing conditions include, for example, allergies, especially to materials used in dental care, asthma or other relevant health problems.



### **WARNING**

**Inadequate fitting of the surgical guide on the patient's teeth could pose a health hazard to the patient.**

Check that the surgical guide is correctly and firmly placed before starting to drill.



### **WARNING**

**Exerting too much pressure when placing the surgical guide or during drilling could pose a health hazard to the patient or result in improper treatment.**

Only use as much force as necessary when inserting the surgical guide and during drilling.

## 9 HANDLING OF THE SURGICAL GUIDE

### Instructions on how to use a rubber dam

You can use the SICAT **ACCESSGUIDE** surgical guide with a rubber dam. Please follow the instructions below in this case:

- Before placing the rubber dam, check that the surgical guide is correctly placed in the patient's mouth.
- The rubber dam must be placed before you start the treatment.
- All teeth on which the appliance is resting must stand out from the rubber dam.
- The clamps for the rubber dam must be spaced as far apart that the surgical guide fits between them.
- Ensure that the surgical guide does not touch the clamps of the rubber dam.



Figure 1: Placing the surgical guide



Figure 2: Rubber dam with clamps



#### **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.

### Preparing the tooth

1. Check whether the spot marked by the surgical guide is the spot that you want to trepanize.
2. In addition, you can mark the corresponding spot on the enamel using a color marker (caries detector, jeweler's rouge) or a thin, rotating tool (e. g. fissure burs).



Figure 1: Marking the tooth



Figure 2: Checking the mark

3. Check the marked spot with the surgical guide placed.
4. Remove the enamel or the restorations at the marked spot down to the dentine in the axis of the drill sleeve using a diamond-coated tool. So as not to damage the sleeve you should not work through the sleeve.

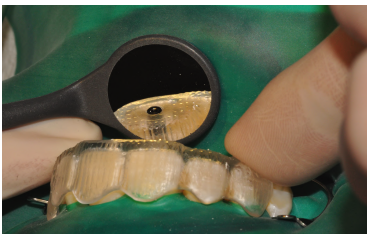


Figure 3: Checking mark with surgical guide



Figure 4: Ablating enamel



### WARNING

**Failure to prepare the surface of the tooth or the drill point could pose a health hazard to the patient.**

Before you start to drill, you must prepare the surface of the tooth for drilling, e. g. by removing enamel or restorations or creating a surface that is as orthogonal to the direction of drilling as possible.

### Preparing the drilling process

1. Place the surgical guide again and check that the surgical guide is correctly and firmly placed in the patient's mouth.
2. Transfer the drill depth that you have planned in SICAT Endo using a ruler and a rubber stop.
3. Insert the drill into the drill sleeve.
4. Ensure that the drill is not rotating when it is inserted as it might get wedged and damage the drill sleeve.
5. If you have trouble inserting the drill, insert the drill into the sleeve before attaching the drill to the tool holder.

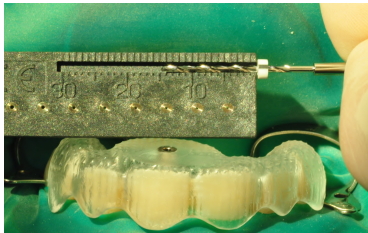


Figure 1: Transferring the drill depth



Figure 2: Inserting the drill into the drill sleeve





### WARNING

**Inadequate fitting of the surgical guide on the patient's teeth could pose a health hazard to the patient.**

Check that the surgical guide is correctly and firmly placed before starting to drill.



### WARNING

**Inadequate fixing of the surgical guide on the patient's teeth could pose a health hazard to the patient.**

Fix the surgical guide without exerting too much pressure. Ensure that the guide fits precisely such that the drill sleeve is positioned correctly as planned.



### WARNING

**Using a drill and a drill sleeve that are not meant to be combined could pose a health hazard to the patient.**

Ensure that the drill you want to use matches the drill sleeve of the surgical guide.



### WARNING

**Use of an unsuitable drill could pose a health hazard to the patient or result in improper treatment.**

Use a suitable drill.



### WARNING

**Improper use of the surgical guide could pose a health hazard to the patient.**

Use the surgical guide in accordance with the enclosed report and the following drilling instructions only:

- ▶ When the drill is first inserted into the sleeve it must not be rotating.
- ▶ Guided drilling must always be performed using an intermittent technique with continuous water cooling.
- ▶ Comply with the drill manufacturer's instructions.

### Instructions on how to use the drill

Please comply with the following instructions when using the drill:

- If required, start with a shorter drill before you change to a longer drill.
- Use a rubber stop to set the exact drill depth on the drill.
- The penetration depth that you have set using the rubber stop must not be exceeded.
- Comply with the manufacturer's recommendations regarding the frequency of use of the drill.

### Drilling

1. Fix the surgical guide in the patient's mouth.
2. Perform the drilling using continuous, slight pressure under permanent cooling. Use an intermittent technique.
3. Comply with the rotational speed indicated by the drill manufacturer during drilling.



Image 1: Drilling



Image 2: Flushing the drill channel

4. If the drill fails to advance when you exert a slight pressure, it might still be in the enamel or a restoration might be in contact with the tip of the drill. If this is the case, you have to repeat the steps described in section **Preparing the tooth**.

## 9 HANDLING OF THE SURGICAL GUIDE

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5. Remove any dentine residues on the drill and in the drill hole by flushing the drill canal at regular short intervals. Otherwise, they could impede the advance of the drill.
6. Regularly check that the drill and the drill sleeve remain undamaged.
7. Verify the correct position of the rubber stop on the drill before you have reached the final drilling depth.
8. Stop drilling as soon as the rubber stop touches the upper edge of the sleeve.



### **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.

### 10 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 Sensitive", 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)

## 10 CLEANING AND DISINFECTION PROCEDURE

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### Manual high-level disinfection

- **Equipment:** FDA-listed high-level disinfectant solution on basis of ortho-phthalaldehyde (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 Sensitive” as detergent for cleaning and “CIDEX OPA” for disinfection.

## 11 STORAGE

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### **11 STORAGE**

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

### **12 DISPOSAL**

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

### **13 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.

### **14 SICAT DOCUMENTATION**

The following documents will be included with your delivery of the custom-made surgical guide from SICAT:

#### **Report**

A main component of the report is information on the length of the planned drilling canals. The report includes the distances from the upper edge of the drill sleeve to the target point of the drill canal.

In addition, the report contains the following information:

- Interior diameter of the sleeve used
- Root canal description from SICAT Endo
- Order information

You will also find information on how to perform the drilling process in the report.

#### **Test certificate**

The test certificate states any deviations of the actual sleeve position compared to digital treatment planning. SICAT guarantees a manufacturing accuracy with a max. deviation of 0.5 mm at the apical end of the drilled hole.

#### **Declaration of Conformity**

### 15 SAFETY INSTRUCTIONS

#### Order



#### CAUTION

**Missing and incorrect components in the order package may result in a faulty surgical guide.**

Make sure that the necessary and correct components are included in your order package.



#### 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.



#### WARNING

**Inadequate packaging of stone models could cause damage to the stone models.**

Use robust and adequately padded packaging to ship stone models.



#### 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.

#### Drill



#### WARNING

**Using a drill and a drill sleeve that are not meant to be combined could pose a health hazard to the patient.**

Ensure that the drill you want to use matches the drill sleeve of the surgical guide.



## 15 SAFETY INSTRUCTIONS



### **WARNING**

**Use of an unsuitable drill could pose a health hazard to the patient or result in improper treatment.**

Use a suitable drill.

## **Surgical guide**



### **WARNING**

**Exposure to direct sunlight could result in damage to the surgical guide.**

Protect the surgical guide from exposure to direct sunlight and high temperatures.



### **WARNING**

**A damaged surgical guide may pose a health hazard.**

Check the surgical guide for damage before using it. Examples of such damage include deformations, cracks, breaks, gaps, and loose parts.



### **WARNING**

**Inadequate fitting of the surgical guide on the patient's teeth could pose a health hazard to the patient.**

Check that the surgical guide is correctly and firmly placed before starting to drill.

## **Changes to the surgical guide**



### **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.

## 15 SAFETY INSTRUCTIONS

### Cleaning



#### WARNING

**Wrong cleaning and disinfection may lead to a risk of infection for the patient and operator. Furthermore, it may negatively impact the performance and characteristics of the product.**

Clean and disinfect the surgical guide according to the instructions given in this manual.



#### WARNING

**A heat-based disinfection or sterilization method (e. g. autoclaving) could result in damage to the surgical guide.**

Never use a heat-based method for disinfection or sterilization of the surgical guide.

### Optical impressions



#### WARNING

**Inaccurate or incorrect registration of the optical impression with the 3D X-ray scan may result in improper treatment.**

Ensure correct registration of the optical impression with the 3D X-ray scan.



#### WARNING

**Insufficient quality and precision of optical impressions and 3D X-ray scans for the purposes of this device may result in improper treatment.**

Only use optical impressions and 3D X-ray scans of sufficient quality and precision that is appropriate for the intended use and purpose.

## 15 SAFETY INSTRUCTIONS



### WARNING

**Optical impressions or stone models that do not match the patient's anatomy may result in treatment mistakes.**

Ensure that the optical impressions or the stone model match the patient's anatomy.



### WARNING

**Unwanted changes of the dental status could pose a health hazard to the patient.**

Ensure that the period of time from creation of the optical impressions or the stone model to treatment is as short as possible.



### CAUTION

**An incorrect dental status in the stone model or in the optical model could pose a health hazard to the patient or result in improper treatment.**

Make sure that the stone model and the optical model reflect the correct dental status and are current when ordering and before you use the surgical guide.

## Qualification of the user



### CAUTION

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



### WARNING

**Use of the surgical guides by unqualified personnel could pose a health hazard to the patient or lead to improper treatment.**

The surgical guides may only be used by qualified personnel.

### Usage



#### WARNING

**The reuse of the surgical guide may lead to a risk of infection for the patient and operator. Furthermore, it may negatively impact the performance and characteristics of the product.**

The surgical guide is a single-use device. Do not reuse or try to sterilize or re-disinfect the surgical guide.



#### WARNING

**Failure to take the patient's medical history into account could pose a health hazard to the patient.**

Consider the patient's medical history before treatment. Pre-existing conditions include, for example, allergies, especially to materials used in dental care, asthma or other relevant health problems.



#### WARNING

**If the patient has not enough teeth remaining in his or her mouth this could result in improper treatment.**

Check whether the patient has enough teeth remaining to ensure that the surgical guide can be correctly and firmly placed.



#### WARNING

**Improper use of the surgical guide could pose a health hazard to the patient.**

Use the surgical guide in accordance with the enclosed report and the following drilling instructions only:

- ▶ When the drill is first inserted into the sleeve it must not be rotating.
- ▶ Guided drilling must always be performed using an intermittent technique with continuous water cooling.
- ▶ Comply with the drill manufacturer's instructions.



### WARNING

**Failure to prepare the surface of the tooth or the drill point could pose a health hazard to the patient.**

Before you start to drill, you must prepare the surface of the tooth for drilling, e. g. by removing enamel or restorations or creating a surface that is as orthogonal to the direction of drilling as possible.



### WARNING

**Inadequate fixing of the surgical guide on the patient's teeth could pose a health hazard to the patient.**

Fix the surgical guide without exerting too much pressure. Ensure that the guide fits precisely such that the drill sleeve is positioned correctly as planned.



### WARNING

**Exerting too much pressure when placing the surgical guide or during drilling could pose a health hazard to the patient or result in improper treatment.**

Only use as much force as necessary when inserting the surgical guide and during drilling.

## Damage



### WARNING

**A damaged surgical guide could pose a health hazard to the patient.**

Never use a damaged surgical guide. Examples of such damage include deformations, cracks, breaks, gaps, and loose parts.

### Service life



#### **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.

### 16 EXPLANATIONS OF LABELING



Caution! Observe the accompanying documents.



Case number



Observe the instructions for use.



Manufacturer



Date of manufacture



Medical device



Do not re-use



Keep away from sunlight



Prescription use only (USA specific symbol)

### **17 MANUFACTURER AND SUPPORT**



**Manufacturer**

#### **SICAT GmbH & Co. KG**

Friesdorfer Str. 131-135

53175 Bonn, Germany

[www.sicat.com](http://www.sicat.com)

#### **Support**

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The information in this document was correct at the time of publication, but may be subject to change without notice.



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# CONTACT



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