

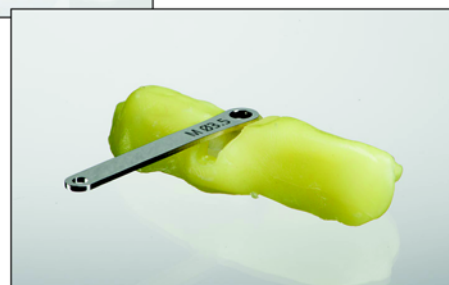
New as of:

06.2013

# Sirona Dental CAD/CAM System CEREC Guide

## Operating Instructions

**English (US)**



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# 1 General information

Please read this document completely and follow the instructions exactly.  
You should always keep it within reach.

Original language of the present document: German.

## 1.1 Structure of the document

### 1.1.1 Identification of the danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in this document. Such information is highlighted as follows:



#### **DANGER**

An imminent danger that could result in serious bodily injury or death.



#### **WARNING**

A possibly dangerous situation that could result in serious bodily injury or death.



#### **CAUTION**

A possibly dangerous situation that could result in slight bodily injury.

#### **NOTICE**

A possibly harmful situation which could lead to damage of the product or an object in its environment.

#### **IMPORTANT**

Application instructions and other important information.







**Tip:** Information on making work easier.

### 1.1.2 Formats and symbols used

The formats and symbols used in this document have the following meaning:

<ul style="list-style-type: none"> <li>✓ Prerequisite</li> <li>1. First action step</li> <li>2. Second action step</li> <li>or</li> <li>➤ Alternative action</li> <li>↪ Result</li> </ul>	Prompts you to do something.
See "Formats and symbols used [ → 4]"	Identifies a reference to another text passage and specifies its page number.
• List	Designates a list.
"Command/menu item"	Identifies commands, menu items or quotations.

## 1.2 Symbols used

Symbol	Description
	<b>NOTICE!</b> Observe Operating Instructions!
	This product is a medical device in accordance with Council Directive 93/42/EEC.
Rx only	<b>CAUTION:</b> According to US Federal Law, this product may be sold only to or by instruction of physicians, dentists, or licensed professionals.
 ABC123	Article number
 ABC123	Batch number
	This product is intended for single use only
	non-sterile

## 1.3 Intended use

The CEREC Guide concept is designed for the manufacture of individual implant surgical guides by specialist dental staff/technicians. The surgical guide is designed as an auxiliary device for dental surgery.

The CEREC Guide requires the CEREC system and a 3D X-ray system from Sirona, such as GALILEOS or ORTHOPHOS XG 3D

### 1.3.1 Further use of Sirona Dental CAD/CAM system

The Sirona Dental CAD/CAM system is also an endosseous dental implant accessory according to 21 CFR 872.3980. The system is used to produce a part that the user can manually incorporate together with other 3rd party components into a dental surgery guide, a temporary accessory used with endosseous dental implants with tissue contact for less than 1 hour (exempt). Such a device is exempt from the premarket notification procedures.

## 1.4 Indications

The CEREC Guide is used for dental implants that are completed with supported and managed surgical systems (refer to Materials [ → 7]).

## 2 Safety instructions

### Exclusion of liability

The surgical guide created with the CEREC Guide is an auxiliary device that is manufactured by a qualified dentist or dental technician. The user therefore bears full responsibility for the shape, suitability, and application of the template.

Observe the processing instructions provided by the implant and drill manufacturers.

### Limitations

The CEREC Guide enables you as a clinician or technician to create your own surgical guide using a MC XL milling machine. The CEREC Guide is not a fully automatic solution. It cannot be compared to a surgical guide that has been manufactured centrally based on your design.

The CEREC Guide must not be used to manufacture templates that are bigger than a quadrant.

No more than two implants should be set per template.

The thermoplast process is only approved for the extraoral creation of the scan template (on a model).

### Prerequisites

- CEREC or inLab MC XL milling unit
- GALILEOS or ORTHOPHOS XG 3D
- CEREC SW 4.0.2 or higher
- Open GALILEOS Implant license
- Implant planning software "GALILEOS Implant", V1.9 with SP1 or higher
- If you work with inLab software in parallel, the inLab SW 4.0.2 service pack must be installed as a minimum.



### CAUTION

#### Errors when setting the tooth numbering

When setting the tooth numbering to the American (ADA) pattern, an error in GALILEOS Implant V1.9 can cause invalid export data. This can cause the tooth number to be mixed up and hence injure the patient.

➤ Version 1.9 with SP1 is mandatory!

### Alternative SICAT OptiGuide

If there is any uncertainty at any time or the situation is deemed to be critical, the surgery must not be completed under any circumstances.

In such cases an optical impression (CEREC) of the situation must be imported into the X-ray volume. This can then be used to order a SICAT OptiGuide; refer to the "GALILEOS Implant" manual from version 1.9.

## 3 Product description

### 3.1 Description of the CEREC Guide surgical guide

Using the CEREC Guide, you can create a precise surgical guide in your practice/laboratory. The process is fast and incurs comparatively low costs.

The individually manufactured surgical guide is part of the integrated implant plan and surgical implementation using CAD/CAM and 3D X-ray systems from Sirona.

### 3.2 Materials

#### Thermoplast

Thermoplast is a rigid plastic. When heated with hot water it becomes soft and easily pliable.

Recommended materials:

- Hydroplastic from TAK Systems
- Luxaform from DMG Dental

**Important:** When handling these materials, please observe the relevant application descriptions from the manufacturers.

#### CEREC Guide Blocs



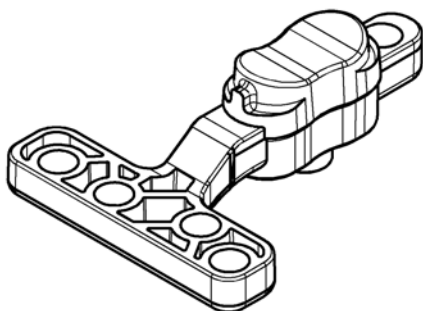
Product name	Size	REF
Sirona CEREC Guide Blocs S*	Small	63 75 054
Sirona CEREC Guide Blocs M*	Medium	63 75 062
Sirona CEREC Guide Blocs L	Large	63 75 070

In each case, two unsterile CEREC Guide Blocs and two unsterile CEREC Guide reference units (refer to Materials [ → 8]) are supplied. These parts are intended for single use only.

CEREC Blocs are made of clear Plexiglas® GS 0F00.

\* The Sirona CEREC Guide Blocs S and M are not suitable for use with CAMLOG®.

### CEREC Guide reference units



Size	Color	Width (mesial/distal)	Shifting mesial/distal
Small (S)	Orange	6mm	max. 1.5mm
Medium (M)	White	7.3mm	max. 2mm
Large (L)	Gray	11mm	max. 4mm

The reference units can only ever be used with a CEREC Guide Bloc of the same size. The basal surface of the reference unit corresponds to the basal surface of the drill bit, from which the CEREC Guide Bloc is created. As the drill channel must be fully within the basal surface, the plan states a maximum value by which the implant can be shifted in the mesial-distal direction.

CEREC Guide reference units are made of Hostaform® MT 12U01 plastic and are supplied unsterile. Seven glass soda balls are located in the reference units as radio-opaque markers.

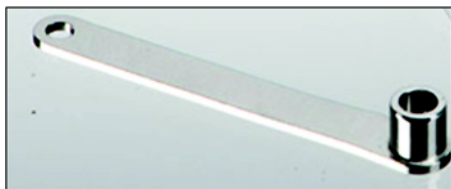
### Drill key sets

The drill keys provided by the implant manufacturers are not compatible with CEREC Guide. Use the Sirona CEREC Guide drill keys instead of the original drill keys.

Various CEREC Guide drill key sets are available which are only suitable for use with the following surgery kits from the respective implant manufacturer.

Guided insertion of implants using CEREC Guide is not supported.

CEREC Guide drill keys are made of grade 1.4301 stainless steel and are supplied unsterile.



Designation	REF	Suitable for surgical kit
Sirona CEREC Guide Drill Key Set ST	63 73 711	Straumann®: Guided Surgery Kit
Sirona CEREC Guide Drill Key Set NB	63 73 943	Nobel Biocare:* <ul style="list-style-type: none"> <li>• Branemark® System Guided Surgery Kit</li> <li>• NobelReplace® Straight Guided Surgery Kit</li> <li>• NobelReplace® Tapered Guided Surgery Kit</li> <li>• NobelActive Guided Surgery Kit</li> </ul>



Designation	REF	Suitable for surgical kit
Sirona CEREC Guide Drill Key Set AT	6373950	AstraTech: Facilitate®
Sirona CEREC Guide Drill Key Set B	6373968	Biomet 3i: Navigator®

\*Noble Biocare: The drills for WP and 6.0 implants are not supported.

Each drill key is labeled

- The size specifications S, M, and L indicate which respective drill key is suitable for each CEREC Guide Bloc.  
If, for example, a scan template with a white reference unit is generated (size M), then a CEREC Guide Bloc M is used for the drill bit. In this case, only drill bits labeled with an M are suitable.
- The numerical value specified corresponds to the inside diameter of the drill key in mm. This value does not correspond to the drill diameter in all systems.  
The following table specifies which original manufacturer drill key corresponds to the respective drill key from the Sirona drill key set.

### Overview of drill keys

Drill set	Original key designation	Ø drill = Ø inside tray	S (Ø ≤ 3.5)	M (Ø ≤ 4.3)	L (Ø ≤ 5.0)
<b>Straumann</b>					
The set contains 11 drive keys in 2 sterilized boxes.					
Guided drills	Ø 2.2 mm	2.2	X	X	X
	Ø 2.8 mm	2.8	X	X	X
	Ø 3.5 mm	3.5	X	X	X
	Ø 4.2 mm	4.2		X	X
<b>Nobel Biocare</b>					
The largest drill diameter for the insertion of WP and 6.0 implants is not supported.					
The set contains 25 drive keys in 3 sterilized boxes.					
Branemark System Guided Surgery Kit	NP Ø 2	2.0	X	X	X
	RP Ø 2				
NobelReplace Straight Guided Surgery Kit	6/WP Ø 2				
	NP Ø 2.8	2.8	X	X	X
NobelReplace Tapered Guided Surgery Kit	RP Ø 2.8				
	NP Ø 3	3.0	X	X	X
NobelActive Guided Surgery Kit	RP Ø 3				
	6/WP Ø 3				
	RP Ø 3.2	3.2	X	X	X
	NP Ø 3.2				
	RP Ø 3.4	3.4	X	X	X
	RP Ø 3.6	3.6		X	X
	6/WP Ø 3.6				
	6/WP Ø 3.8	3.8		X	X
	RP - NP	4.1		X	X
	6/WP - NP				
	6/WP Ø 4.2	4.2		X	X
	RP Ø 4.2				
	6/WP Ø 4.6	4.6			X
	6/WP Ø 5	5.0			X
	6/WP - RP				

Drill set	Original key designation	Ø drill = Ø inside tray	S (Ø ≤ 3.5)	M (Ø ≤ 4.3)	L (Ø ≤ 5.0)
<b>Astra Tech</b>					
The set contains 17 drive keys in 2 sterilized boxes.					
Facilitate	2.0	2.0	X	X	X
	3.2	3.2	X	X	X
	3.35	3.35	X	X	X
	3.7	3.7		X	X
	3.85	3.85		X	X
	4.2	4.2		X	X
	4.7	4.7			X
	4.85	4.85			X
<b>Biomet 3i</b>					
The set contains 16 drive keys in 2 sterilized boxes.					
Navigator	2.0	2.0	X	X	X
Navigator	2.75	2.75	X	X	X
Navigator	3.0	3.0	X	X	X
Navigator	3.25	3.25	X	X	X
Navigator	3.85	3.85		X	X
Navigator	4.25	4.25		X	X

## 4 Application

### 4.1 Application information

- The CEREC Guide must only be used in cases that have been planned by a qualified dentist using the implant planning software GALILEOS Implant or SICAT Implant.
- The drill keys listed in the Materials [ → 7] section are mandatory for every drilling process. Under no circumstances must the drill be controlled with just the drill bit, without the use of a drill key.
- The drill must only be operated once a suitable drill key is tightly fitted in the drill bit and the tip of the drill is fully inserted through the drill key in the apical direction.
- The drill must only be removed from the drill key or drill bit once it has come to a complete standstill.  
**Important:** Always observe the size specifications on the drill keys, reference units, blocks, and drill.  
Example: The MØ2.2 mm drill key is only permissible for 2.2 mm drills following the application of a medium-sized reference unit.
- The area around the implant must be amply sprayed and cooled during the drilling process. The temperature in the drill channel must be maintained to a minimum to prevent the hard tissue from denaturing. No remnants of tissue must remain in the area around the implant.
- All materials that are used intraorally must be disinfected before use and safeguarded against aspiration when being used.
- The materials Thermoplast, CEREC Guide Blocs, and CEREC Guide reference units (refer to "Materials [ → 7]") are intended for single use only and are not supplied in sterile packaging; also refer to "Disinfection/sterilization of the surgical guide [ → 20]".
- Please protect the surgical guide from direct sunlight and high temperatures to prevent it from deforming. Check the surgical guide before the operation. Do not use any heat-based methods to disinfect or sterilize (e.g. autoclaves), as this can cause the surgical guide to deform.

## 4.2 Preparation of the scan template

The heated Thermoplast is used to create an imprint of the implant area. The Thermoplast fixes the reference unit inserted on the required drilling position. The 3D X-ray can then be taken.

✓ The "implant" indication is then completed; refer to Indications [→ 5].

1. Optional: Where applicable, complete an initial CEREC scan to plan the prosthetics.



### IMPORTANT

#### Observing the undercuts

Check the location of the implant for any problematic undercuts.

- If necessary, manually even these out, for example, by using silicone-based material. Do not use wax as it can melt when it comes into contact with warm Thermoplast.
- The template must be able to be fitted and removed again with justifiable force.

2. Create a plaster model and block off any critical areas such as undercuts using a suitable material. This material must not be heat sensitive.



3. Prepare a reference unit for use. Select a size that is in accordance with the location of the implant.

### IMPORTANT

#### Reference units - sizes available

Always use the largest possible reference unit that will fit in the gap. The reference unit selected must also correspond to the maximum drill diameter to be used.



4. Place the Thermoplast material in a sufficiently large glass bowl.
5. Bring the water to the boil and pour the water directly over the Thermoplast so that it is fully covered.
  - ↪ Thermoplast melts at 90°C (195°F) and becomes a transparent, easily pliable mass.
  - ↪ The Thermoplast is completely transparent after two to three minutes (depending on the manufacturer).
6. **CAUTION!** Risk of burning! Do not place your hands in the water bath. Use a tool to remove the material from the water. Remove the material from the water, for example, using metal tweezers.

### IMPORTANT

#### Processing time

Thermoplast hardens as it cools and also loses its transparency. After removing it from the water bath you will have one to three minutes to process the Thermoplast.

Hardened Thermoplast can be reheated in the water bath.

7. Depending on the type of plaster: Moisten the plaster model so that the Thermoplast can be removed easily. CEREC Stone BC generally does not need to be moistened as Thermoplast does not connect with the material.
8. In accordance with the location of the implant, shape a 2-3 mm thick plate using the Thermoplast.
9. Shape it over the location of the implant in such a way that at least the distal and mesial adjacent teeth are covered with Thermoplast.
10. Optional: Before placing the Thermoplast on the model, you can use the reference unit to create a hole in the Thermoplast. This facilitates the later removal of the residual material between the reference unit and gingiva.
11. Position the Thermoplast on the prepared area. Create an imprint by applying light pressure.
  - ✎ The Thermoplast must be pressed closely on the location of the implant and enclose it fully. Following the casting process, the template must have a stable fit.
12. Press the reference unit into the required drilling position in the Thermoplast that is still soft.



### IMPORTANT

#### Positioning the reference unit

The reference unit must be pushed **as far in to the apical direction as possible** so that it rests on the gingiva. The template and the reference unit must not be able to be moved. The risk of any displacement caused by the tongue/cheek must be avoided.

The Thermoplast must not cover the reference unit. However, it must surround the reference unit up to the small undercut on the shoulder.

If the Thermoplast moves too far in a buccal or lingual direction when the reference unit is pushed in, it must be pushed back on to the reference unit.

If two implants are to be located next to each other, align a scanbody orally and according to the vestibular.

13. To accelerate the hardening process of the Thermoplast, you can cool it with water or a spray.
14. Remove the scan template from the model once it is completely hardened.

**Tip:** You can prevent the opposite jaw from moving during the X-ray. Insert additional Thermoplast to the side of the position of the implant to create a surface for the antagonist. Apply slight pressure to the soft mass. Once the material has hardened, the patient can bite down on it during the X-ray. Remove this Thermoplast again after the X-ray.

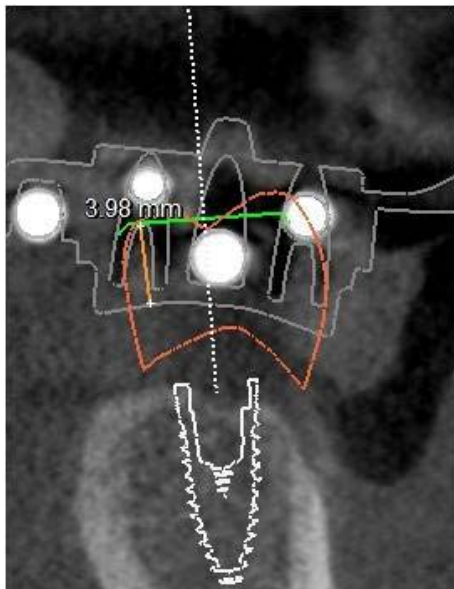


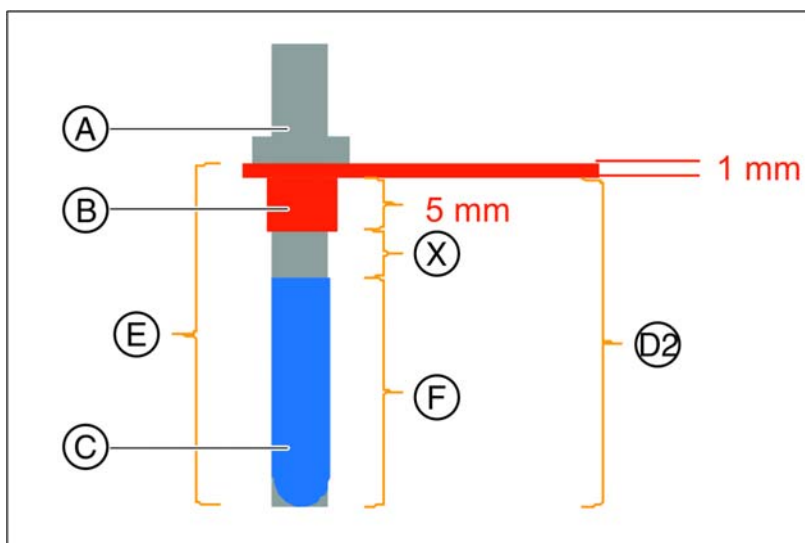
## WARNING

Before using the scan template in the mouth, it must first be disinfected with a suitable disinfectant. Please also observe the cleaning specifications provided by the Thermoplast manufacturer. Thermoplasts can generally not be autoclaved.

### 4.3 Planning the implant and exporting the data

1. Insert the first scan template into the patient's mouth. Check that the seating of the template is stable and accurate. Ensure that the template and reference unit cannot move during the X-ray.
2. Take an X-ray of the patient with the scan template in place. Please refer to the operating instructions for your Sirona 3D X-ray device.
3. Remove the scan template from the patient's mouth immediately after the X-ray.
4. Open the software **GALILEOS Implant** or **SICAT Implant** and load the patient's data record.
5. To plan the implant and localize the reference unit follow the instructions provided in the "GALILEOS Implant" operator's manual. Follow the instructions provided in the chapter "Exporting plan for third-party processing".  
Estimate the drill length necessary. It should be longer than the combined lengths:  
implant length + 6 mm + X (clearance between implant shoulder and bottom edge of the drill key).  
Enter the value for D2. It is calculated from the length of the longest drill used, subtracting 1 mm. ( $D2 = \text{drill length} - 1 \text{ mm}$ ).  
The D1 value can be ignored.
6. Finally, check whether the clearance (orange line) between the bottom side of the reference unit (gray outline) and the top of the drill bit (green line) is  $\geq 5 \text{ mm}$ . If the value is less than 5 mm, select a longer drill and adjust the D2 value accordingly.





<b>A</b>	Drill
<b>B</b>	Drill key
<b>C</b>	Implant
<b>D2</b>	D2 = implant length + 5 mm + clearance between implant shoulder and bottom edge of the drill key <b><math>D2 = F + 5\text{ mm} + X</math></b>
<b>E</b>	Drill length
<b>F</b>	Implant length
<b>X</b>	Clearance between implant shoulder and bottom edge of the drill key

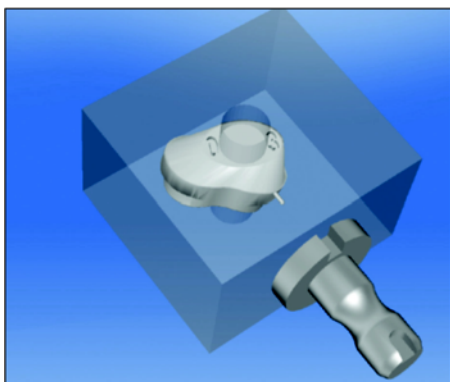
- Export the data for CEREC. Follow the instructions provided in the chapter "Exporting the plan" in the "GALILEOS Implant" operator's manual.



## 4.4 Milling the drill bit

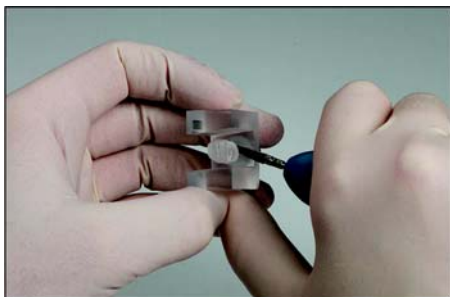
- ✓ The CEREC SW software has been started.
- ✓ Open GALILEOS Implant license is available.
- 1. Import the data in to CEREC SW. To do so, click on *"Import Case..."* in the system menu. Ensure that the file type filter in the bottom right corner of the *"Open"* dialog is set to CEREC Guide cases.
- 2. Select the file that you have just exported from GALILEOS Implant.  
**Tip:** In standard mode, GALILEOS Implant exports CEREC Guide cases to C:\ThirdPartyExport

➤ The milling preview is opened.



- 3. Select the desired milling unit as required.  
The Step Bur 20 and Cylinder Pointed Bur 20 millers are used.
- 4. Insert the correct CEREC Guide Bloc into the milling chamber.
- 5. Start the milling process.

➤ The drill bit is created.



- 6. Remove the drill bit from the block. Ensure that the sprue position on the drill bit is as flush as possible when disconnected. The best results are achieved by using cross-toothed plastic milling tools at a low speed.

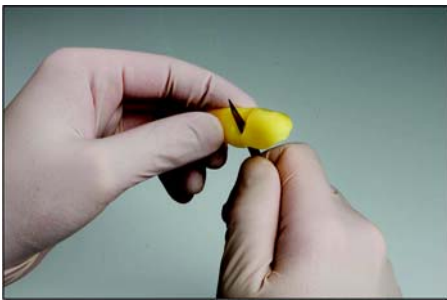
## 4.5 Creating the surgical guide

The scan template is now used to create a surgical guide, by removing the reference unit(s) and replacing it/them with the suitable drill bit(s).

**Tip:** In the event of several implants, the drill bits can be distinguished by the tooth number that is engraved on the drill bit.



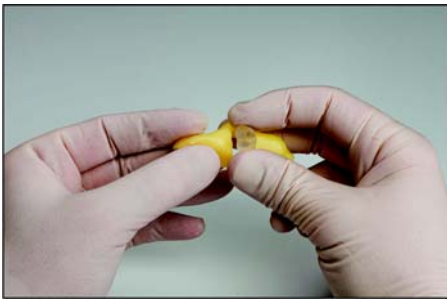
1. Carefully twist the reference unit to remove it from the scan template.



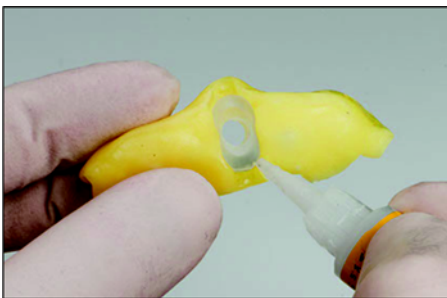
2. Ensure that there is no Thermoplast residue under the drill bit. The drill channel must not be blocked. Use a sharp scalpel.

**Tip:** Thin areas of the hardened Thermoplast can be cut using a scalpel. Stronger parts can be processed with a very slow turning handpiece, such as a three-edged cutter for processing thermoforming films.

When processing, use a water spray for cooling purposes. If the instrument causes the Thermoplast to become too warm, the plastic will become liquid again, deform, and block the instrument. Therefore only use the handpiece in areas that are too thick for the scalpel.



3. Use the model to ensure that adequate drainage of the rinsing liquid is guaranteed during the operation. Adapt the template, if necessary, by adding holes for rinsing purposes.



4. Insert the drill bit into the template. Attach the drill bit with adhesive that is approved for intraoral applications (e.g. LOCTITE® 4601).
5. Reinsert the template into the patient's mouth.



6. Select the drill key required which corresponds to the drills specified by the manufacturer of the guided system.  
Also adhere to the drill key assignment table in the chapter regarding Materials [ → 7]).

**⚠ CAUTION**

This checklist must be fully verified before the drilling process:

- Drill bit is fixed in the template.
- Surgical guide clicks into the correct position
- Once in place, the surgical guide is secured tightly (no "play" or "wobbling")
- The drill channel guide corresponds to the implant plan
- ↪ If one of these points does not apply, an optical impression (CEREC) of the situation must be imported into the X-ray volume and a SICAT OptiGuide must be ordered; refer to the "GALILEOS Implant" manual.

7. Start the implantation in accordance with the instructions provided by your drill supplier.

## 5 Disinfection/sterilization of the surgical guide

### Disinfecting

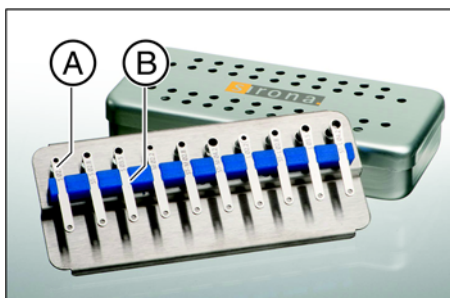
The materials used for the drill key (including its drill sleeve) are supplied unsterilized and must be disinfected along with standard practice equipment.

Recommended disinfectant e.g.

"Dentavon® Liquid" from Schülke & Mayr

Please also observe the cleaning specifications provided by the Thermoplast manufacturer.

### Sterilizing



The drill key (A) and terminal strip (B) are supplied unsterilized and must be steam sterilized using a standard practice sterilization device.

The drill keys must be sterilized before being used in the mouth. Furthermore, the locally applicable legal regulations and the hygiene standards applicable for a dental practice must be observed. Only use the approved sterilization procedures specified below to sterilize the drill keys. Observe the sterilization parameters.

Steam sterilization can be performed with the fractionated vacuum or the gravitation method. The sterilization time is 5 minutes at 132°C / 270°F and 15 minutes at 121°C / 250°F. Steam sterilization may be performed only using devices that comply with EN 13060 or EN 285 standards. Sterilization methods must be validated in compliance with EN ISO 17664.

The responsibility for the sterility of the drill keys lies with the user. It must be ensured that only suitable devices, materials and product-specifically validated methods are used to perform sterilization. It must be ensured that the methods used have been validated. The equipment and devices must be properly maintained and serviced at regular intervals.

The manufacturer (dentist/dental technician/dental assistant) must inform the user about the required sterilization process before insertion in the patient's mouth!



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We reserve the right to make any alterations which may be required due to technical improvements.

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**Sirona Dental Systems GmbH**

**in the USA:**

Fabrikstraße 31  
64625 Bensheim  
Germany  
[www.sirona.com](http://www.sirona.com)

Sirona Dental Systems LLC  
4835 Sirona Drive, Suite 100  
Charlotte, NC 28273  
USA

Order No

**63 96 100 D3587**