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1 General data

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 Contact information

Customer Service Center

In the event of technical queries, please use our online contact form at the following address:

http://srvcontact.sirona.com

Manufacturer's address

Sirona Dental Systems GmbH
Fabrikstrasse 31
64625 Bensheim
Germany

Tel.: +49 (0) 6251/16-0
Fax: +49 (0) 6251/16-2591
e-Mail: contact@dentsplysirona.com
www.dentsplysirona.com

1.2 Structure of the document

1.2.1 Identification of the danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in these instructions for use. 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.

⚠️ NOTE
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 for simplifying work.
1.2.2 Formats and symbols used

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔️</td>
<td>Prerequisite Requests you to do something.</td>
</tr>
<tr>
<td>1.</td>
<td>First action step</td>
</tr>
<tr>
<td>2.</td>
<td>Second action step</td>
</tr>
<tr>
<td>or ➢</td>
<td>Alternative action</td>
</tr>
<tr>
<td>➢</td>
<td>Result Individual action step</td>
</tr>
</tbody>
</table>

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" Indicates commands / menu items or quotations.

1.3 Symbols used

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOTE!</td>
<td>Observe operating instructions!</td>
</tr>
<tr>
<td>☑️</td>
<td>This product is a medical device in accordance with Council Directive 93/42/EEC.</td>
</tr>
<tr>
<td>CAUTION: According to US Federal Law, this product may be sold only to or by instruction of physicians, dentists, or licensed professionals.</td>
<td></td>
</tr>
<tr>
<td>☑️</td>
<td>Article number</td>
</tr>
<tr>
<td>☑️</td>
<td>Batch number</td>
</tr>
<tr>
<td>☑️</td>
<td>This product is intended for single use only</td>
</tr>
<tr>
<td>☑️</td>
<td>unsterile</td>
</tr>
<tr>
<td>☑️</td>
<td>Protect against direct sunlight.</td>
</tr>
</tbody>
</table>
1.4 **Indications for use**

CEREC Guides are intended to support the dentist or oral surgeon when drilling for placement of dental implants. CEREC Guides are intended to be designed and fabricated using the Sirona Dental CAD/CAM System’s CEREC Chairside software and CAM equipment, Galileos Implant dental implant planning software.
2 Safety instructions

2.1 Exclusion of liability

The CEREC Guide surgical 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.

2.2 Limitations

A CEREC Guide 2 can be manufactured by you as a clinician or technician by means of an MC X / MC XL milling and grinding unit or an inLab MC X5. The CEREC Guide 2 is not a fully automatic solution. It cannot be compared to a surgical guide that has been manufactured centrally based on your design.

A CERED Guide 2 must always be supported by the residual teeth. It is not possible to support the guide through the mucous membrane alone.

When working on a MC X or MC XL milling and grinding unit, no more than one implant can be created per template.

2.3 Prerequisites

To create the optical impression and export a prosthetic proposal:
- CEREC SW ≥ 4.3.1 or inLab SW ≥ 15.0 incl. implant module
- CEREC only: Open GALILEOS Implant license

To create a 3D X-ray volume and for implant planning:
- GALILEOS, ORTHOPHOS XG 3D or ORTHOPHOS SL 3D
- Sidexis XG or Sidexis 4
- Galaxis 1.9.2
- Implant planning software "GALILEOS Implant", V1.9.2

To develop the CEREC Guide 2:
- CEREC SW ≥ 4.6.1 or inLab SW ≥ 18.1 incl. implant module
- CEREC only: Open GALILEOS Implant license
- MC X milling and grinding unit or MC XL with milling function or inLab MC X5.

2.4 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 2

CEREC Guide 2 is a precise surgical guide which is individually created in your practice or laboratory. The manufacturing process is fast and incurs comparatively low costs.

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

It is a prerequisite that the location of one or more implants has been planned using the 3D X-ray scan (DVT) and that location is to be transferred to the actual jaw. CEREC Guide 2 is a device that supports the dentist when setting implants. CEREC Guide 2 functions as a surgical guide, which is placed on the residual teeth or another supporting structure in the mouth and acts as a mechanical guide for the drills used. Together with CEREC Guide 2, drill keys are also used as reducing bushes, which enable the use of drills with smaller diameters.

The key steps for manufacturing and using a CEREC Guide 2 are as follows:

1. Optical scan
   An optical scan of the situation in the mouth is created (either intraoral or using a model). A suitably large area is encompassed, on which the drilling template can later support itself. A restoration is designed, which initially enables the subsequent implant planning in terms of prosthetic aspects. This information is exported as a *.SSI file.

2. DVT exposure
   A DVT scan is performed, which forms the basis for the implant planning.

3. Implant planning
   Optical scan (Import of the *.SSI file) and DVT scan are superimposed in GALILEOS Implant using striking features, which are present in both scans (such as the residual teeth). The implant planning is performed based on all of this information. Therefore the location of the guide bushing of the drill is also defined in relation to the residual teeth (or other supporting structures). The planning data is exported as a *.CMG.DXD file.

4. Creating the drilling template
   After importing the *.CMG.DXD file in CEREC or inLab, a drilling template is designed, which can be placed on suitable supporting structures and has an opening at a planned location, through which the drill is to be fed. The single-piece template is create from PMMA, for example by milling.

5. Surgery
   The drilling template is placed in the patient’s mouth. According to the drilling protocol of the manufacturer of the implant, different bores with drills with different guide diameters. Drill keys are used for this and serve as reducing bushes for the respective drill diameter.
The mechanical guide of the drill, with a prescribed direction and depth, enables the treating physician to change the planned implant into reality.
3.2 Materials

Check all materials prior to their initial use for intactness of packaging and correctness of contents.

CEREC Guide Blocs

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

The CEREC Guide Blocs medi/maxi and inCoris PMMA guide disc 22 are intended to manufacture a CEREC Guide 2. These materials are processed in a milling process on the machinery provided for this.

All parts are provided unsterilized and are intended for single use only.

<table>
<thead>
<tr>
<th>Designation</th>
<th>REF</th>
<th>Contents</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEREC Guide Bloc medi</td>
<td>64 66</td>
<td>1x CEREC Guide Bloc medi</td>
<td>Length: 55 mm, Width: 40 mm, Height: 22 mm</td>
</tr>
<tr>
<td></td>
<td>564</td>
<td></td>
<td>MC X only</td>
</tr>
<tr>
<td>CEREC Guide Bloc maxi</td>
<td>64 47</td>
<td>1x CEREC Guide Bloc maxi</td>
<td>Length: 85 mm, Width: 40 mm, Height: 22 mm</td>
</tr>
<tr>
<td></td>
<td>093</td>
<td></td>
<td>MC XL only</td>
</tr>
<tr>
<td>inCoris PMMA guide disc 22</td>
<td>65 51</td>
<td>1x inCoris PMMA guide disc 22</td>
<td>Ø 98.5 mm, height 22 mm</td>
</tr>
<tr>
<td></td>
<td>324</td>
<td></td>
<td>only inLab MC X5</td>
</tr>
</tbody>
</table>
Drill key sets

The drill keys provided by the implant manufacturers are not compatible with CEREC Guide 2. Use the CEREC Guide Drill Keys in place of the original drill key from the implant manufacturer.

CEREC Guide Pilot Drill Keys are only suitable for guiding pilot drills. CEREC Guide Drill Keys Sets also contain additional drill keys to guide the drills for widening drilled holes. Guided insertion of implants using CEREC Guide 2 is not supported.

All CEREC Guide Drill Keys are only suitable for use with the following surgical kits from the respective implant manufacturers.

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

<table>
<thead>
<tr>
<th>Designation</th>
<th>REF</th>
<th>Suitable for surgical kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEREC Guide Pilot Drill Keys 2.0</td>
<td>64 62 530</td>
<td>AstraTech: Facilitate®, pilot drill only Biomet 3i: Navigator®, pilot drill only</td>
</tr>
<tr>
<td>CEREC Guide Pilot Drill Keys 2.2</td>
<td>64 62 563</td>
<td>Straumann®: Guided Surgery Kit, pilot drill only</td>
</tr>
<tr>
<td>Sirona CEREC Guide Drill Key Set ST</td>
<td>63 73 711</td>
<td>Straumann®: Guided Surgery Kit</td>
</tr>
<tr>
<td>Sirona CEREC Guide Drill Key Set ST A</td>
<td>63 73 950</td>
<td>AstraTech: Facilitate®</td>
</tr>
<tr>
<td>Sirona CEREC Guide Drill Key Set B</td>
<td>63 73 968</td>
<td>Biomet 3i: Navigator®</td>
</tr>
<tr>
<td>Sirona CEREC Guide Drill Key Set C</td>
<td>63 73 729</td>
<td>Camlog guided drills*</td>
</tr>
</tbody>
</table>

*drills for 3.3mm implants are not supported

Each drill key is marked with the information for the sleeve diameter and drill diameter:

- Sizes S, M and L state the compatibility with the planned sleeve diameter.
  When planning the sleeve in GALILEOS Implant, a determination is made as to whether the drill key size S, M or L is used.
- 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

<table>
<thead>
<tr>
<th>Drill set</th>
<th>Original key designation</th>
<th>Ø drill = Ø inside tray</th>
<th>S (Ø ≤ 3.5)</th>
<th>M (Ø ≤ 4.3)</th>
<th>L (Ø ≤ 5.0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEREC Guide Pilot Drill Keys 2.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The set contains three drill keys</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Astra Tech Facilitate</td>
<td>2.0</td>
<td>2.0</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Biomet 3i Navigator</td>
<td>2.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEREC Guide Pilot Drill Keys 2.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The set contains three drill keys</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Straumann</td>
<td>Ø 2.2 mm</td>
<td>2.2</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CEREC Guide Drill Key Set ST (for Straumann)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The set contains 11 drill keys in 2 sterilized boxes.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guided drills</td>
<td>Ø 2.2 mm</td>
<td>2.2</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Ø 2.8 mm</td>
<td>2.8</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Ø 3.5 mm</td>
<td>3.5</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Ø 4.2 mm</td>
<td>4.2</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CEREC Guide Drill Key Set AT (for Astra Tech Facilitate)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The set contains 17 drill keys in 2 sterilized boxes.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facilitate</td>
<td>2.0</td>
<td>2.0</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>3.2</td>
<td>3.2</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>3.35</td>
<td>3.35</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>3.7</td>
<td>3.7</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>3.85</td>
<td>3.85</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>4.2</td>
<td>4.2</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>4.7</td>
<td>4.7</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>4.85</td>
<td>4.85</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>CEREC Guide Drill Key Set B (for Biomet 3i Navigator)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The set contains 16 drill keys in 2 sterilized boxes.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Navigator</td>
<td>2.0</td>
<td>2.0</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>2.75</td>
<td>2.75</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>3.0</td>
<td>3.0</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>3.25</td>
<td>3.25</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>3.85</td>
<td>3.85</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>4.25</td>
<td>4.25</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CEREC Guide Drill Key Set C (for Camlog)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The set contains 3 of the same drill keys in 1 sterilized box.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Camlog</td>
<td>4.5 (sleeve)</td>
<td>4.5</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
</tbody>
</table>

* Not suitable for use for 3.3 mm implants.
4 Application

4.1 Creating a CEREC Guide 2

4.1.1 Optical impression

1. Scan the situation in the mouth either intraorally or using a model. The following applies at least to all areas which are intended to later serve as a support for the CEREC Guide 2. The surface scan is also used for the overlay of the x-ray volume.

   **NOTE**
   
   Note that the drilling template cannot be bigger than the scanned area.
   
   Avoid holes in the scan. Otherwise, no locating surface for the CEREC Guide 2 can be determined at these points.

2. Design a restoration at the planned implant position. Mark the emergence profile of the tooth on the gingiva in manual entry mode.

3. Export the data record using in *.SSI format.
4.1.2 3D x-ray and implant planning

A DVT exposure can be performed before or after the optical impression. Make sure that there are no metal artifacts in the scan, as these may hinder the overlay of optical data with the x-ray volume or even make it impossible. Do not scan the patient at the final bite position, but rather with a slightly opened jaw. Remove all removable metal parts in the opposing jaw (e.g. prosthetics). If possible, record 3/4 of the arch of the jaw. This increases the likeliness that teeth free from artifacts can be used for registration.

To produce a CEREC Guide 2, the import of the previously created *.SSI data record in GALILEOS Implant is necessary. The optical surface scan is superimposed over the X-ray volume. This makes it possible to determine the implant location while also considering the soft tissue and prosthetic planning.

⚠️ CAUTION
Check that the optical impression is correctly aligned with the X-ray data record.

If multiple implants are to be planned, multiple *.SSI data records must be imported.

To plan the implant follow the instructions provided in the "GALILEOS Implant 1.9.2" operator's manual. As a general rule, follow the instructions provided in Appendix C.2 "Exporting plans for third-party processing using optical impressions”.

Select Sirona - CEREC Guide Drill Keys as the sleeve system (CEREC Guide 2, SICAT Surgical Guides). You then have three sleeves available to choose from, which match the CEREC Guide drill keys S, M or L respectively.

If, for example only one pilot hole is to be created, the selection of size S is sufficient (apart from Camlog).

The specification of a depth stop is oriented on the length of the drill used. The planned position is reached when drilling once the mechanical stop of the drill reaches the drill key or (if the drill does not have a stop) the length marking on the drill is lowered to the upper side of the drill key.
In the GALILEOS Implant software, the depth stop is to be entered using the D2 value. The D2 value is defined as the distance from the side of the drilling template to the apical top of the implant. As the drill strikes the 1 mm thick drill key, the D2 value to be set results from the length of the drill minus one millimeter (D2 = drill length – 1 mm).

The statement of the D1 value is to be ignored.

After entering the D2 value, the sleeve is visualized above the implant at the relevant height.

**NOTE**

When selecting the bushing, ensure that it does not collide with neighboring teeth and the drill key and the drill itself can be introduced without a collision.

Note that selecting a smaller sleeve may limit the use of larger drill diameters.

The Camlog Guided System is only compatible with sleeve L.

If the representation of the underside of the sleeve cuts the scan shown as the yellow line, this indicates that the position of the drill key is at least partially subgingival.

Multiple implants and sleeve positions are planned in the same way. It is possible to export this as a file. Export the plan for “processing by third-party providers by way of optical impressions” as a .CMD.DXD file.

**NOTE**

Maintain a minimum distance of at least 2 mm between the implant and critical anatomic structures (e.g., nerve, roots, sinus).
4.1.3 **Design and development of the CEREC Guide 2**

By selecting "Import", you can switch the directly load the *.CMG.DXD file.

**Phase ADMINISTRATION**

If the plan contains multiple implants, these will be treated as multiple separate restorations.

Select the machine type for development. This determines the possibilities for further processing.

**Phase MODEL**

If the original scan is presented, which was also the basis for the implant planning. All areas, which are not intended to serve as a support for the CEREC Guide 2 should be cut. This includes, for example, larger areas of gingiva outside the planned implant position.

Parts of the residual teeth may also be discarded if they are not required for support.

Note that a longer template is easier to hold in position with one finger and ensures secure support. This applies to free-end situations in particular.

**Phase DESIGN**

The position and shape of the sleeve cannot be changed using general design tools.

If a sleeve is shown in red, parts of it are subgingival. Determine whether these areas are to be cut away (e.g. to enable the unhindered placement on a model) or are to be left as they are. They color of the sleeve then turns green.

Optionally, you can create side access to introduce the drill from the side. This is only recommended for reasons of stability where required due to a lack of space.

After calculating the template element and if necessary orienting it in the block, you have the option of creating viewing panels, which you can use to check the fitting of the template even during the surgical intervention.

You can then still adapt the design of the template by cutting away any problematic areas.

**Phase MANUFACTURE**

Where necessary, ensure that you have activated "Configuration" the option "MC XL Milling".

So that the milling process runs without interruption, ensure where necessary that milling tools with a sufficient service life are used, the water filter has been cleaned and there is sufficient water in the tank.

After milling, ensure that no shavings enter into the tank during the cleaning process, as these can quickly clog the water filter.
4.1.4 Application information

- All materials that are used intraorally must be disinfected before use and safeguarded against aspiration when being used.
- The materials “CEREC Guide Blocs” (see “Materials [→ 9]”) are intended for single use only and are not supplied in sterile packaging; also refer to “Cleaning, disinfection and sterilization [→ 16]”.

**NOTE**

**Risk of deformation to the surgical guide**

Please protect the drilling template from direct sunlight and high temperatures (> 35°C/95°F) and high humidity (> 80%) 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 Cleaning, disinfection and sterilization

4.2.1 Cleaning and disinfection

CEREC Guide 2 must be cleaned and disinfected prior to clinical use.

**Cleaning**

Follow the steps below for cleaning:

- Clean with a cotton gauze moistened with tap water and neutral soap until no more contaminants are visible on the unit.
- Rinse under running water for at least 30 seconds.
- Dry the CEREC Guide 2 using a lint-free cloth.

**Disinfecting**

To disinfect use the product Sporox II disinfectant:

- Place the CEREC Guide 2 in a bath containing the undiluted disinfection solution.
- Leave the CEREC Guide 2 immersed in the solution for 30 minutes.
- Wash the remaining disinfectant for 30 seconds with water of at least drinking water quality.
- Dry the CEREC Guide 2 using a sterile lint-free cloth.

4.2.2 Cleaning the CEREC Guide Drill Keys

A machine-based method can be used to clean the drill keys. Use the cleaning agent neodisher® forte (Dr. Weigert, Germany) with a concentration of 0.5% or a comparable cleaning agent.

For example, use the device WD BHT Innova® M3 and program 03 for thermal disinfection:

1. Stage 1: Clean for 1 minute at 30 °C with 0.5% neodisher® forte.
2. Stage 2: Clean for 6 minutes at 55 °C with 0.5% neodisher® forte.
3. Stage 3: Rinse with completely demineralized water for 1 minute.
4.2.3 **Sterilization of the CEREC Guide Drill Keys**

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. The sterilization time is 3 minutes at 135°C / 275°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.

**Tip:**
In order to facilitate handling, following cleaning insert the drill keys into the terminal strip of the tray, which was provided with the CEREC Guide Drill Keys Set and sterilize the entire set (see Figure).

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!
4.3 Surgical intervention

- CEREC Guide 2 must only be used in cases that have been planned by a qualified dentist using the implant planning software "GALILEOS Implant".
- The drill keys listed under the “Materials [→ 9]” 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 and drill.
  Example: The MØ2.2 mm drill key is only permissible for 2.2 mm drills.
- The area around the implant must be amply sprayed and cooled during the drilling process. Please bear in mind that there may be abraded material from the components used in the osteotomy or the collected bone material. 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.

**CAUTION**

Remove burrs and round sharp corners on the template element. Always check that the template fits correctly in the mouth beforehand where necessary using a model. The template element must be completely slid open and must not wobble. Clean and disinfect the CEREC Guide 2 as described in the previous chapter. 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. Ensure that the drill key can fully enter the drill hole and stops there without wobbling. If you wish to use several surgical guides in an operation, ensure that the drills and drill keys are correctly assigned to the respective templates.

1. Perform the implantation according to the implant manufacturer’s instructions.
2. Fix the template in the mouth, holding it in position with your finger if necessary.

**Tip:** If you have created access to the drill from the side due to a lack of space, first place the CEREC Guide 2 into the patient’s mouth. Then guide the drill key through the drill and push it upwards. Now guide the drill through the side into the sleeve position and lower the drill key to the stop point. Then start drilling.
We reserve the right to make any alterations which may be required due to technical improvements.