

15.07.2020

URGENT – FIELD SAFETY NOTICE

SICAT IMPLANT V2.0

Dear customer,

As the manufacturer of the SICAT IMPLANT V2.0 software, we are informing you as user about an error which may lead to a risk for patients. This field safety notice has been prepared based on a user's report and informs

- what exactly the problem is, and under which circumstances it can occur,
- what the potential risk to the patient is,
- which measures should be taken by the customer/user to avoid endangering the patients,
- what measures are planned by SICAT to remedy the problem.

What is the problem?

An **error** was detected in **the export functionality for a CEREC Guide (“CMG.DXD export”)** in SICAT IMPLANT V2.0. SICAT surgical guides and the planning report are not affected by the error.

In certain cases (see figure 1), the error leads to the planned implant-sleeve combination being exported shifted by a positive or negative offset along the implant axis. The offset is the difference between the **nominal implant length**¹ and the **realistic implant length**². The sign of the offset also depends on the format of the import data (SSI, SIXD) (see figure 1). The exported CMG.DXD file is incorrect in these cases.

Implants whose nominal length corresponds to the realistic length are **not affected** by the error (e.g. many bone level implants). Implants whose nominal length deviates from the realistic length are **affected** by the error (e.g. many tissue level implants and many one-piece implants). They are the more affected the greater the difference between the nominal implant length and the realistic implant length. Generic implants are **not affected** by the error.

Ultimately, the error for the affected implants means that when a CEREC Guide is used, the **drilling is predominantly not deep enough** or the **drilling is too deep**. In the latter case, anatomical structures in the jaw such as nerves, maxillary sinuses, roots or bone can be damaged.

¹ Nominal implant length = length of the implant according to the manufacturer's catalog (usually corresponds to the insertion depth into the bone) = length displayed in SICAT IMPLANT V2.0, e.g. in the **selection window** or in the **Properties** area for the implant

² Realistic implant length = total length of the implant, i.e. distance between the highest point and the lowest point of the implant

Figure 1 provides an overview of the cases in which the error occurs and the consequences.

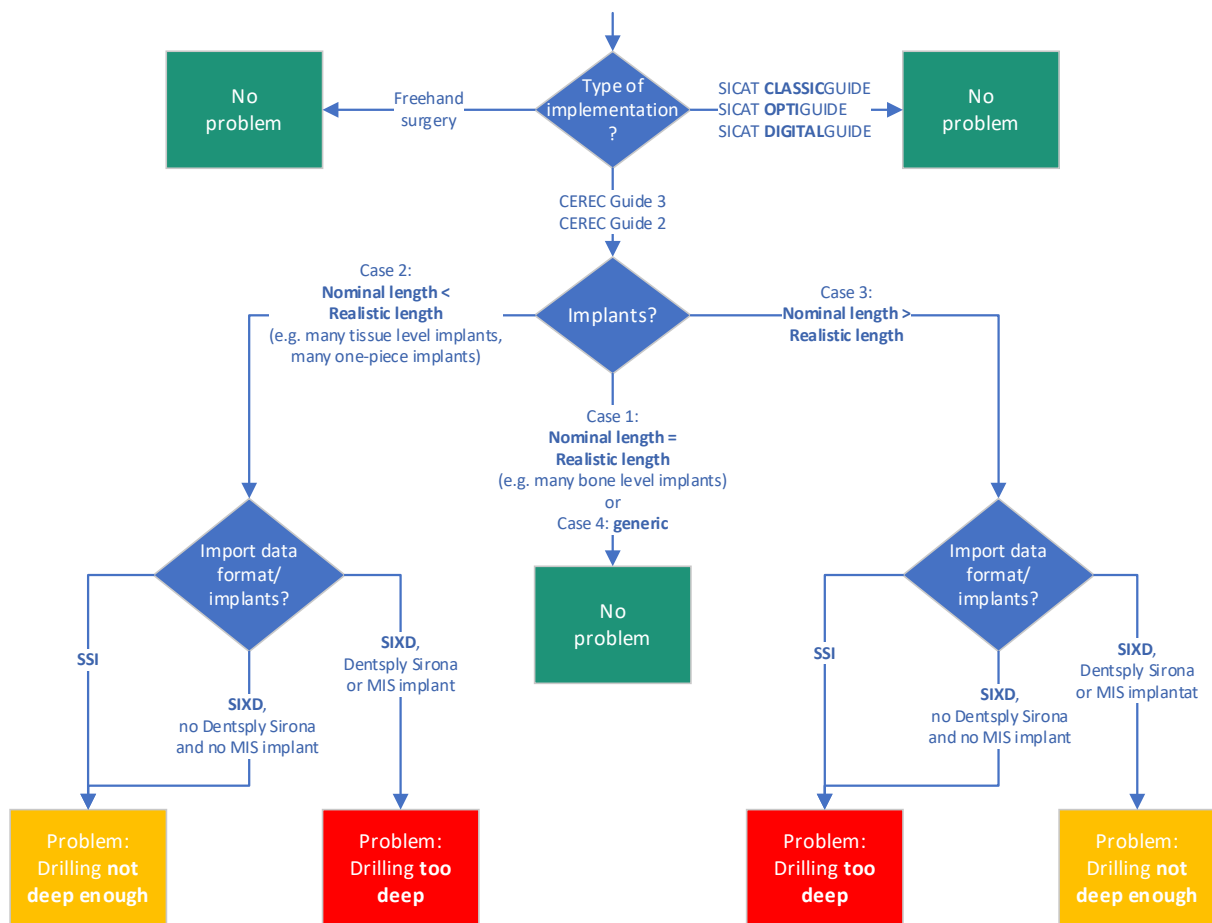


Figure 1: In which cases does the error occur and with what consequences?

Table 1 provides an overview of which implant systems currently supported by the CEREC Guides are affected by the problem and to what extent.

| Implant systems currently supported by the CEREC Guides | | Affected by the problem? | How and to what extent are they affected by the problem? |
|---|--|--------------------------|--|
| CEREC Guide 3 | | | |
| Dentsply Sirona | Ankylos C/X | No (Case 1) | n/a |
| | AT OsseoSpeed EV | No (Case 1) | n/a |
| | Xive S plus - Ø3mm | No (Case 1) | n/a |
| | Xive S plus - Ø3.4mm, Ø3.8mm, Ø4.5mm, Ø5.5mm | Yes (Case 2) | Drilling 0.2 mm not deep enough (when using the import data format SSI) or drilling 0.2 mm too deep (when using the import data format SIXD) |
| CEREC Guide 2 | | | |
| BIOMET 3i | Certain | Yes (Case 3) | Drilling 0.4 mm too deep |
| | External Hex | Yes (Case 2) | Drilling 0.3 mm not deep enough |
| Camlog Biotechnologies | CAMLOG | No (Case 1) | n/a |
| | CONELOG | No (Case 1) | n/a |
| Dentsply Sirona | AT OsseoSpeed TX | No (Case 1) | n/a |
| Nobel Biocare | Branemark System | Yes (Case 2) | Drilling 0.3 mm not deep enough |
| | NobelActive | Yes (Case 3) | Drilling 0.5 mm too deep |
| | NobelReplace Straight Groovy, Replace Select Straight | Yes (Case 3) | Drilling 0.8 mm too deep |
| | NobelReplace Tapered, NobelReplace CC, NobelReplace PS, Replace Select Tapered | Yes (Case 2) | Drilling 0.6 mm not deep enough |
| Straumann | Bone Level | Yes (Case 2) | Drilling 0.3 mm not deep enough |
| | PURE Ceramic | Yes (Case 2) | Drilling 1.8 mm not deep enough |
| | PURE Ceramic Monotype | Yes (Case 2) | Drilling 7.3 mm not deep enough |
| | Standard | Yes (Case 2) | Drilling 3.3 mm not deep enough |
| | Standard Plus, Tapered Effect | Yes (Case 2) | Drilling 2.3 mm not deep enough |

Table 1: Which implant systems currently supported by the CEREC Guides are affected by the problem and how?

What is the potential risk?

There is no significant likelihood that the use of the software containing the error will result in serious health consequences or death.

There is a reasonable probability that temporary health consequences will be caused (drilling not deep enough, cancellation of a surgical procedure).

There is a non-significant probability of serious adverse health consequences (injury to structures in the jaw, such as nerves, maxillary sinuses, roots or bones due to drilling too deep).

Measures by the user

The export for a CEREC Guide ("CMG.DXD export") in SICAT IMPLANT V2.0 may only be used for the unaffected implants (Case 1 from Table 1), otherwise the patient may be harmed.

CMG.DXD files already exported from SICAT IMPLANT V2.0 may only be used for the unaffected implants (Case 1 from Table 1), otherwise the patient may be harmed.

Measures by SICAT

The license system has been adapted to prevent new installations of SICAT IMPLANT V2.0 from being activated. Users who have already activated SICAT IMPLANT V2.0 will receive this field safety notice.

It is expected that a patch fixing the error will be available for download for all customers in July 2020 in the form of a SICAT SUITE V2.0.1 with SICAT IMPLANT V2.0.1. As soon as this patch is available, all affected customers will be informed. Customers who want to use SICAT IMPLANT must download and install SICAT SUITE V2.0.1 with SICAT IMPLANT V2.0.1 and activate SICAT IMPLANT V2.0.1.

Please make this information available to all users in your practice who need to be informed.

You will find all important information again in an overview starting on page 5. Please especially note and follow the information in the section "NECESSARY MEASURES OF THE CUSTOMERS / USERS" as well as the detailed information regarding the subject of the problem.

As a user of the SICAT IMPLANT V2.0 software, it is imperative that you take the measures described in this field safety notice and that you acknowledge receipt of this letter.

If you require further information or assistance in connection with this field safety notice, please contact the following person:

SICAT Software Support

Telephone: +49 (0)228 / 286206-610

E-mail: softwaresupport@sicat.com

We hereby confirm that this notification has been sent to the competent national authority.

We thank you for your attention to this matter and regret any inconvenience it may cause.

Sincerely yours,

Your SICAT Team

| | |
|----------------------------|---|
| AFFECTED PRODUCTS | SICAT IMPLANT V2.0 |
| PROBLEM DESCRIPTION | <p>The export functionality for a CEREC Guide contains an error. The error causes the planned implant-sleeve combination to be exported shifted by a positive or negative offset along the implant axis in certain cases. The offset is the difference between the nominal implant length and the realistic implant length. The sign of the offset also depends on the format of the import data.</p> <p>Possible cases:</p> <ol style="list-style-type: none"> Nominal length = realistic length (e.g. many bone level implants): no problem Nominal length < realistic length (e.g. many tissue level implants and many one-piece implants): <ol style="list-style-type: none"> For SSI as import data format → Drilling not deep enough For SIXD as import data format + no Dentsply Sirona and no MIS implant → Drilling not deep enough For SIXD as import data format + Dentsply Sirona or MIS implant → Drilling too deep Nominal length > realistic length <ol style="list-style-type: none"> For SSI as import data format → Drilling too deep For SIXD as import data format + no Dentsply Sirona and no MIS implant → Drilling too deep For SIXD as import data format + Dentsply Sirona or MIS implant → Drilling not deep enough Generic implants: no problem |
| POTENTIAL RISK | <p>There is no significant likelihood that the use of the software containing the error will result in serious health consequences or death.</p> <p>There is a reasonable probability that temporary health consequences will be caused (drilling not deep enough, cancellation of a surgical procedure).</p> <p>There is a non-significant probability of serious adverse health consequences (injury to structures in the jaw, such as nerves, maxillary sinuses, roots or bones due to drilling too deep).</p> |

| | |
|--|--|
| NECESSARY MEASURES OF THE CUSTOMERS / USERS | <p>The export for a CEREC Guide ("CMG.DXD export") in SICAT IMPLANT V2.0 may only be used for the unaffected implants (Case 1 from Table 1), otherwise the patient may be harmed.</p> <p>CMG.DXD files already exported from SICAT IMPLANT V2.0 may only be used for the unaffected implants (Case1 from Table 1), otherwise the patient may be harmed.</p> |
| MEASURES PLANNED BY SICAT | <p>The license system has been adapted to prevent new installations of SICAT IMPLANT V2.0 from being activated. Users who have already activated SICAT IMPLANT V2.0 will receive this field safety notice.</p> <p>It is expected that a patch fixing the error will be available for download in July 2020 in the form of a SICAT SUITE V2.0.1 with SICAT IMPLANT V2.0.1. As soon as this patch is available, all affected customers will be informed. Customers who want to use SICAT IMPLANT must download and install SICAT SUITE V2.0.1 with SICAT IMPLANT V2.0.1 and activate SICAT IMPLANT V2.0.1.</p> |
| FURTHER INFORMATION AND SUPPORT | <p>If you require further information or assistance in connection with this field safety notice, please contact:</p> <p>SICAT Software Support Telephone: +49 (0)228 / 286206-610 E-mail: softwaresupport@sicat.com</p> |