Field Safety Notice #278955 related to *Camlog Sleeve Library*

Preface

This Field Safety Notice (FSN) contains important customer information for patient safety and for the safe use of *exoplan*, our software for implant planning and surgical guide design.

Who is affected by this Field Safety Notice:

exoplan users that do use a fully guided surgical treatment approach with CAMLOG® Screw-Line Promote® guide-screw-mounted implants using the CAMLOG® Screw-Line Guide System or StecoGuide Sleeves for Screw-Line System are affected. When planning a fully guided case with an affected implant and sleeve library combination, the resulting drill hole will be 1 mm deeper than expected due to a dimensional error in the affected libraries.

exoplan users using CAMLOG® Screw-Line Promote Plus® guided implants, CAMLOG® Screw-Line Promote® Plus guide/screw mounted implant and other CAMLOG® implants are NOT affected by this Field Safety Notice.

exoplan users using any other library packages provided by exocad are NOT affected by this Field Safety Notice.

Manufacturer

exocad GmbH
Rosa-Parks-Str. 2
64295 Darmstadt
Germany
SRN DE-MF-000007341

Internal exocad Reference: #278955

exocad product, commercial name: *exoplan*

Affected versions / **Unique Device Identifiers (UDI):**
2.3 Matera - UDI: (01)4260521365002(10)A02B03E****

3.0 Galway - UDI: (01)4260521365019(10)A03B00E****

3.1 Rijeka – UDI: (01)4260521365026(10)A03B01E****

Basic UDI-DI: 426052136EXOPLAN21A6

Type of treatments/protocols: Planning of fully-guided cases using CAMLOG® Screw-Line Promote® guide-screw-mounted implant, CAMLOG® sleeve, Steco Guide Sleeves for Screw-Line System, and CAMLOG® kit libraries

Affected libraries: The issue is an incorrect distance information contained in libraries CAMLOG_sleeve and Steco_StecoGuide_Compatible_Camlog_sleeve suggesting the usage of a surgical sleeve that results in a drill hole that is 1mm deeper than expected due to a dimensional error in the affected libraries.

Involved dental parts and tools

Cases planned and designs of surgical guides with the following *exocad* libraries:

- CAMLOG_CAMLOG_SCREW-LINE_PROMOTE_GSM_plan_fda in combination with
  - CAMLOG_sleeve and CAMLOG_RegularBone_ScrewLine_kit or CAMLOG_PilotDrill_ScrewLine_kit or
  - Steco_StecoGuide_Compatible_Camlog_sleeve and CAMLOG_RegularBone_ScrewLine_kit or CAMLOG_PilotDrill_ScrewLine_kit

Component libraries that include components with the following article numbers are involved:

Library name	Article number
CAMLOG_CAMLOG_SCREW-LINE_PROMOTE_GSM_plan_fda	K1045.3311, K1045.3313, K1045.3316, K1045.3809, K1045.3811, K1045.3813, K1045.3816, K1045.4309, K1045.4311, K1045.4313, K1045.4316
CAMLOG_sleeve	J37X4.3303, J37X4.3803, J37X4.4303
Steco_StecoGuide_Compatible_Camlog_sleeve	M.27.15.D350, M.27.15.D450L3, M.27.15.D450

The affected libraries are the following CAMLOG®/CAMLOG® compatible libraries that can be identified by the "<SignatureDate>" in the library config.xml file as follows:

Library name	Library <Signature Date>
CAMLOG_sleeve	<SignatureDate>2021-09-16T16:27:43.8522077Z</SignatureDate> <SignatureDate>2022-06-17T09:04:20.7153658Z</SignatureDate> <SignatureDate>2022-07-15T07:46:52.2549721Z</SignatureDate>
Steco_StecoGuide_Compatible_Camlog_sleeve	<SignatureDate>2023-07-14T13:47:08.2617948Z</SignatureDate>

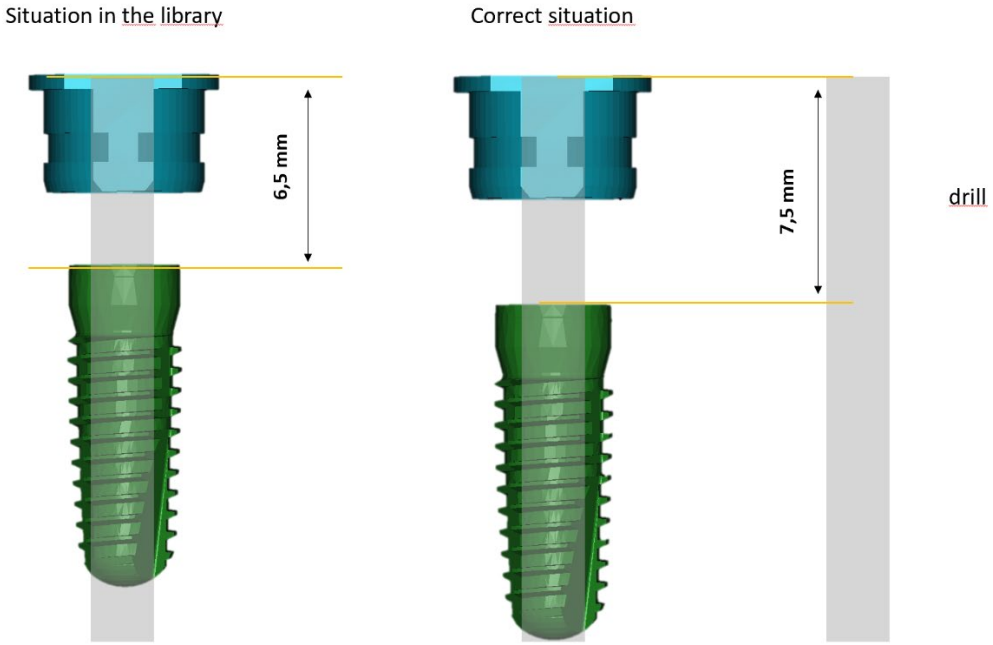

Figure 1: Sketch comparing the distance situation between sleeve, implant and drill for the wrongly positioned sleeve (left) and the correct position of the sleeve (right).

What (malfunction/nonconformity) has been found?
During an update of data used in a library shipped with *exoplan* or made available on the download portal of *exocad*, it was found that the use of a specific combination of an implant, sleeve and surgical drill can result in a hole being drilled 1 mm deeper than expected.

Possible impact on patient health
During surgical alveolar implant preparation and positioning 1 mm lower than planned and expected surrounding anatomical structures can be damaged, including nerves and blood vessels, causing bleeding, paresthesia, and other complications. Over-remodeling of the cervical implant can also occur during the healing process, possibly resulting in bone loss and esthetic concerns. Adhering to pertinent literature*, the recommended safe distance of 2 mm is essential to avoid these risks. Since the literature safety distance of 2 mm is recommended, the library will be within the boundaries limits of the safety distance. By using the above-mentioned library, there is a potential risk of harm to the patient.

* Ku JK, Lee J, Lee HJ, Yun PY, Kim YK. Accuracy of dental implant placement with computer-guided surgery: a retrospective cohort study. BMC Oral Health. 2022 Jan 16;22(1):8. doi: 10.1186/s12903-022-02046-z. PMID: 35034613; PMCID: PMC8762866.

Existing safety advice/measures

a) There is a disclaimer at the end of every Surgical Report to ensure that implantologists work diligently:

The surgeon bears full medical responsibility for the development and application of the surgical guide, the surgical instruments, implants, guiding sleeves, etc. to be used. This document should be considered as an addition to other documentation related to implantation, it does not replace or cancel other documents.

WARNING: This surgical report is a compilation of information to support the performance of the surgical procedure. It is based on information provided by the respective manufacturers of the implants, drill sleeves or surgical kits. In order to prevent patient injuries, it is required that the implantologist diligently ensures that the dental parts in this surgical report are the correct intended parts and that they correspond to the physical parts intended to be used for the surgery.

b) Safety features and warnings

Safety features, such as collision detection, density visualization, and safety distance, reduce the risk of harm to the patient to the lowest possible degree. The initial default setting for the safety distance around invasive parts (implants and anchor pins) is 1.5 mm. Based on the precision of the overall workflow, the safety distance can be adapted. exocad warns the user and does not recommend the usage of safety distances below 1.5 mm, within the software application and in the exoplan manual. In the exoplan manual, exocad recommends considering increased safety distances.

In case of detected collisions between invasive parts and/or between invasive parts and certain collision objects (e.g. the marked nerve canal or objects imported as collision objects) the implant positioning step and the planning in general cannot be completed. To additionally avoid misuse of the safety distance setting, the lowest distance that can be set is 1 mm.

Patient injury
exocad has no information relating to any patient injury that has happened in such case.

Actions carried out by exocad

1) The affected CAMLOG® and Steco libraries (see above) were removed from the download server and “blacklisted” on the exocad server on October 6, 2023. Users are no longer able to see or download the

affected libraries.

2) As a result of the blacklisting, if the user tries to select a component in the affected library, the user receives a message indicating that the selected sleeve library is marked as “unsigned” and should no longer be used. This message appears when the user selects the blacklisted library, as well as before the implant planning and surgical guide output data is generated. Users notified by this warning should click “cancel” and not “continue”. If users click continue, they continue at their own risk.

3) If an implant planning “scene file” (file containing all the information about a planning or design scene, e.g., workflow state, scene objects) is loaded into *exoplan* that previously used the blacklisted sleeve library in the implant placement planning, a warning message appears to inform the user about the unsigned library (see figure 3).

4) New library versions of CAMLOG_sleeve and Steco_StecoGuide_Compatible_Camlog_sleeve have been released. Users can now download and install the new libraries.

Note: Users who want to use CAMLOG® implants, related tools and kits can still do so. The issue relates only to the CAMLOG® Screw-Line Promote® guide-screw-mounted implants in combination with CAMLOG® Screw-Line Guide System or StecoGuide Sleeves for Screw-Line System. Other CAMLOG® libraries for other implants can still be used.

Required actions for end-users

1) Do not use the affected libraries - see section “Affected libraries” above.
2) Download the new libraries at https://exocad.com/integration/exoplan-library-integration or use exocad *Library Manager* from within *exoplan*.

Required actions for resellers/distributors

1) exocad distributors shall forward this Field Safety Note to their customers / end-users who are using *exoplan.*
2) If required, support your end customers with the installation of the updated libraries, available on our download portal or via exocad *Library Manager*.
3) Distributors should be aware that their national Competent/Regulatory Authorities might contact them and request additional information. As per local regulations, distributors are obliged to collaborate with Competent/Regulatory Authorities.

Document History

Revision	Editor	Description of changes
2023-10-06	Stefan Walter, PRRC	Initial revision

Annex 1 - Figures

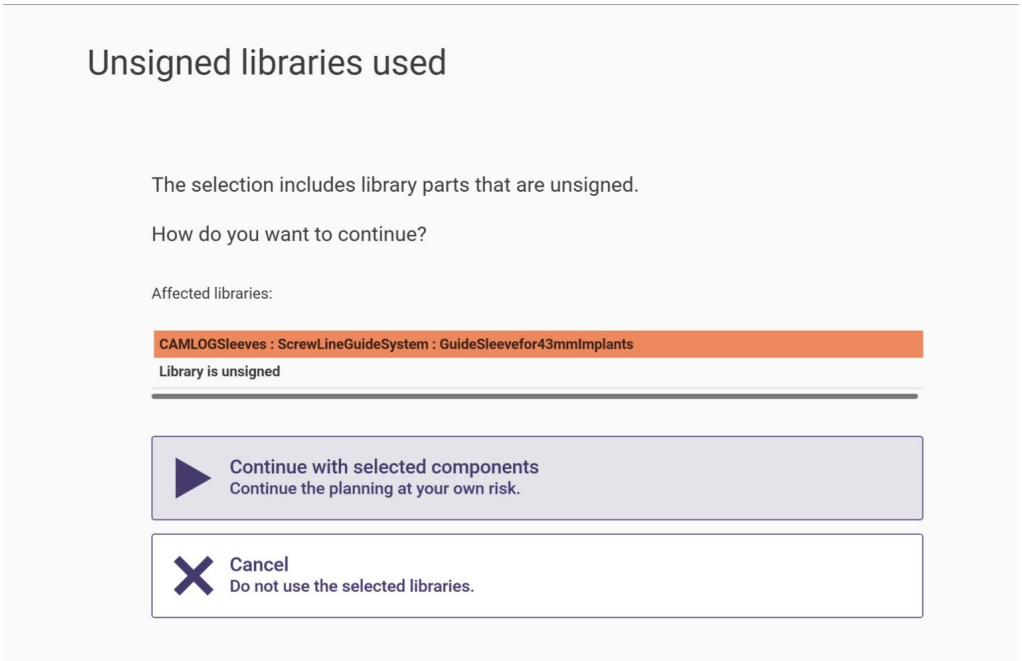

Figure 2: Unsigned library message of a blacklisted CAMLOG® / StecoGuide sleeve library to the user when selecting it in the software or when the planning and surgical guide output data is generated. Users notified by this warning should click “cancel” and not “continue”. If users click continue, they continue at their own risk.

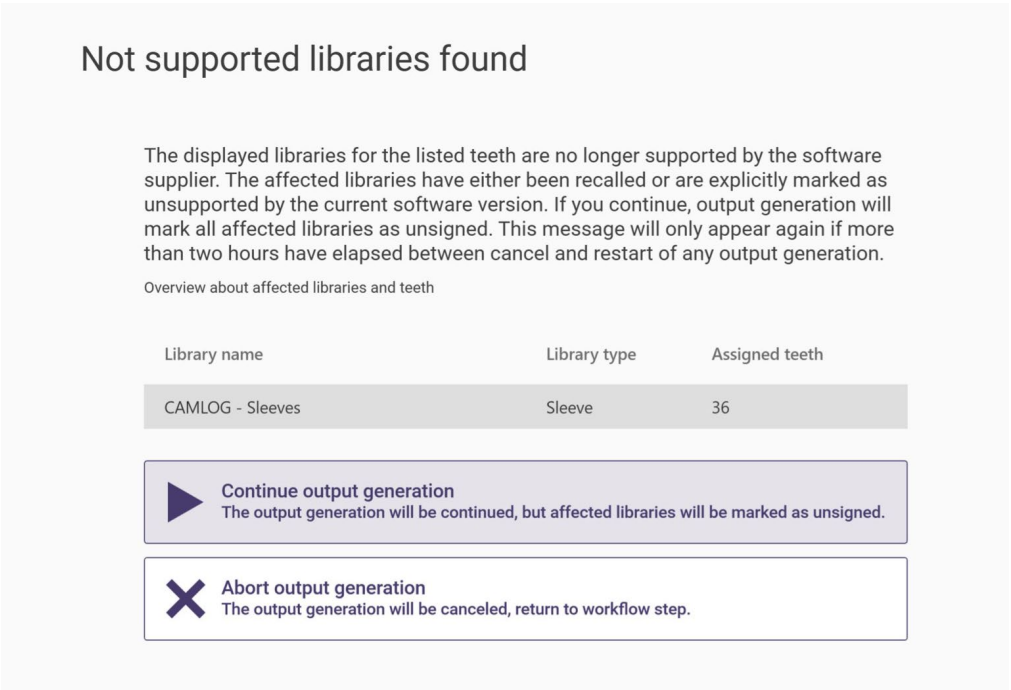

Figure 3: Unsigned library message of a blacklisted CAMLOG® / StecoGuide library to the user when loading a scene file that already contains the affected library.