Field Safety Notice #271391 related to *exoplan 3.1 Rijeka*

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:

1) Distributors of exocad's *exoplan 3.1 Rijeka* software should forward the information to their end-users.
2) Only *exoplan 3.1* users that use or are planning to use a guided surgical treatment approach with Straumann® BLX/TLX implants and **Straumann® BLX/TLX/VeloDrill libraries with step-by-step full drill protocol export** are affected by this Field Safety Notice and recommended actions.

exoplan 3.1 users using other Straumann® library packages without full drill protocol export (e.g. Straumann® Guided Surgery for other implants, "Legacy" Straumann® BLX/TLX Guided Surgery) are not affected by this Field Safety Notice.

exoplan 3.1 users using any other library packages are not affected by this Field Safety Notice.

Users of previous releases of *exoplan* (e.g. *exoplan 3.0 Galway,* etc.) 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: #271391

exocad product, commercial name: *exoplan 3.1 Rijeka*

Affected versions ("Builds"):

- 8423 (initial release, non-US)
- 8439 (US release)
- 8587 (SR1, non-US)
- 8588 (SR1 US)
- 8606 (SR1 US Offline)

Unique Device Identifiers (UDI):

UDI-DI: 4260521365026,
Basic UDI-DI: 426052136EXOPLAN21A6

(01)4260521365026(10)A03B01E8423 (non-US)
(01)4260521365026(10)A03B01E8439 (US)
(01)4260521365026(10)A03B01E8587 (SR1, non-US)
(01)4260521365026(10)A03B01E8588 (SR1 US)
(01)4260521365026(10)A03B01E8606 (SR1 US offline)

Type of treatments/protocols: Planning of fully guided cases, including full drill protocol export using certain Straumann® implants, Straumann® sleeve, Straumann® kit and Straumann® full drill protocol libraries.

Affected libraries: The affected libraries are the following Straumann® BLX/TLX/VeloDrill step-by-step full drill protocol libraries that can be identified by the "<SignatureDate>" in the library config.xml file as follows:

Library name	Library <Signature Date>
Straumann_BLX_protocol	*<SignatureDate>2023-03-09T13:21:16.6513194Z</SignatureDate>*
Straumann_TLX_protocol	*<SignatureDate>2023-03-09T13:21:01.5173457Z</SignatureDate>*
Straumann_VeloDrill_PartiallyGuided_protocol	*<SignatureDate>2023-03-09T13:21:14.3991315Z</SignatureDate>*
Straumann_VeloDrill_Pilot_protocol	<SignatureDate>2023-03-09T13:21:16.1955065Z</SignatureDate>

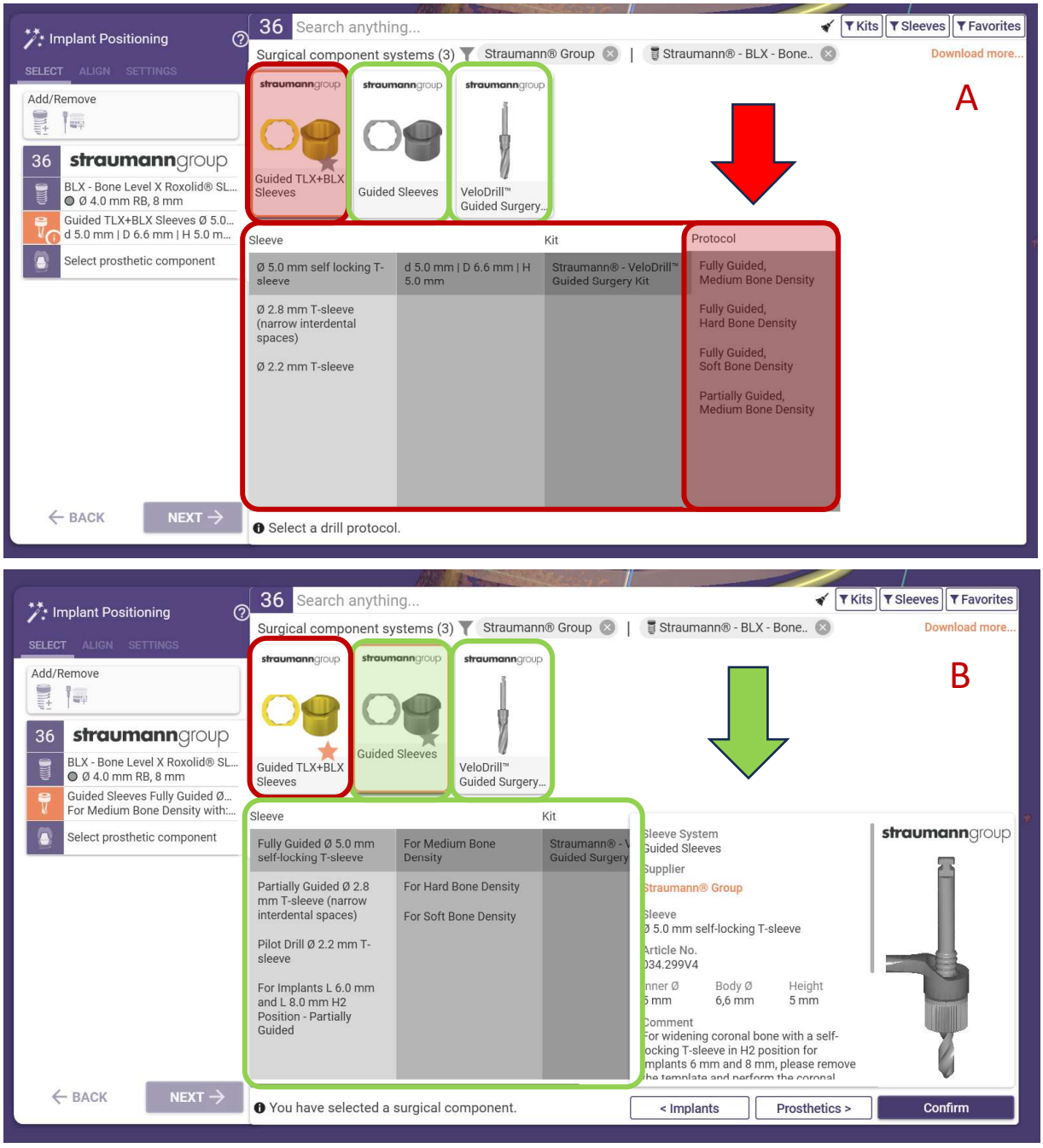

Figure 1: Examples comparing between selecting a "protocol" library (case A) and selecting libraries without protocol (case B). The picture shows all entries that should not be used in red. Those that can be used without interference are marked in green. If no "Protocol" column is present, the library is not affected by this FSN.

What (malfunction/nonconformity) has been found?

The issue is a software malfunction incorrectly filtering compatibility information contained in the library Straumann® BLX/TLX implants and the affected Straumann® **step-by-step full drill protocol** libraries where multiple sub-full drill protocols exist, e.g., hard-, medium- and soft-bone protocols. The software does not filter out unsupported sleeve height positions for a particular sub-full drill protocol and instead shows ALL possible sleeve height positions for all sub-full drill protocols.

Please note: It is NOT a library issue but a software issue in which the information in the full drill library is incorrectly managed by the *exoplan* software.

The issue also occurs when the user adjusts the initial sleeve height position to a supported height position (e.g. 9 mm) and moves it back to the unsupported height position of 7 mm by manually typing in the value in the "Sleeve Edit Control" window. The usage of other methods of changing the support height position is not affected (e.g. changing the position with the sleeve widget results in the correct protocol selection).

What might go wrong?

When a Straumann® BLX/TLX implant with 6 mm or 8 mm length in combination with a Straumann® BLX/TLX sleeve and the Straumann® VeloDrill-kit with full drill protocols is used, the software places the sleeve for the initially selected full drill protocol "Fully Guided Medium Bone Density" to a height position of 7 mm (see figure 2). For this protocol, however, only 9mm and 11 mm are allowed. Internally, the software selects the full drill protocol for a sleeve height position of 9 mm and shows this also in the surgical protocol (see figure 3). If a user follows the full drill protocol sequence from the surgical report when printing and using this guide with that wrong sleeve position, the drill depth would be 2 mm deeper than planned and might damage anatomical risk structures close to the implant apical positions (e.g., nerves, or neighbored tooth roots).

Patient injury

exocad has no information relating to any patient injury that has happened in such case. The software issue was found during internal testing by exocad's specialists.

Possible impact on patient health

Perforation of the dental implant deeper than planned can lead to damage to the surrounding bone, nerve structures, maxillary sinus, or blood vessels, resulting in complications such as infection, intense pain, implant failure, and even permanent damage to the oral structure. The main advantage of guided surgery is precisely to avoid possible problems like this. If a user who is unfamiliar with the guided surgery protocol follows the steps represented in the surgical report protocol, a patient could be injured and for this reason we are taking the necessary measures to contain this issue.

Actions carried out by exocad

1) The affected Straumann® libraries (see above) allowing the advanced full-drill protocols (see above) were removed from the download server and "blacklisted" on the exocad server on August 7, 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 full drill protocol library is marked as "unsigned" (see figure 4) and should no longer be used. This message appears when the user selects the blacklisted protocol 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 full drill protocol library in the implant placement planning, a warning message appears to inform the user about the unsigned library (see figure 5).

4) The malfunction in the *exoplan* application has been identified and corrected. A new version will be released as soon as validation activities are completed, along with updated libraries for the Straumann® full-drill protocols. A tag in the libraries ensures that they can only be used with the corrected, new version. Users who want to use the Straumann® BLX/TLX /VeloDrill full step-by-step drill protocols can then download and install the new libraries and the corrected software package.

Note: Users who want to use Straumann® implants, related tools and kits can still do so. The issue relates only to the Straumann® BLX/TLX /VeloDrill full step-by-step drill protocols. The Straumann® Guided Surgery libraries for other implants and Straumann® "Legacy" BLX/TLX Guided Surgery libraries without step-by-step drill protocol can still be used.

Required actions for end-users

1) Do not use the affected libraries - see section "Affected libraries" above - with *exoplan 3.1 Rijeka* until a new *exoplan 3.1 Rijeka* version and updated libraries are released and made available for download at https://exocad.com/integration/exoplan-library-integration.
2) Complete the End-User Medical Device Recall Return Response (see Annex 2) attached to the FSN and return to exocad by email based on reseller market region:
    - US & Canada: info@us.exocad.com
    - Europe: service@exocad.com

Required actions for resellers/distributors

1) exocad distributors shall forward this Field Safety Note to their customers / end-users who are using *exoplan 3.1 Rijeka*.
2) Complete the Distributor/Reseller Report Report including information in both tables, as applicable (see Annex 3) attached to the FSN and return to exocad by email based on reseller market region, **within fourteen days of this notification:**
    - US & Canada: info@us.exocad.com
    - Europe: service@exocad.com
3) Distributors should also request and report information to exocad from end-users.
    a. Are they using the Straumann® BLX/TLX /VeloDrill step-by-step drill protocols and surgical guides designed for that treatment, or not (which means that they are not concerned by this issue)?
    b. If they do, have they had issues with such a case?
4) 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.
5) exocad must provide a final report to the contacted Competent/Regulatory Authorities including the information sent back from the distributors. We kindly ask for your support on this matter.

Existing safety advice

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. 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.

Document History

Revision	Editor	Description of changes
2023-08-09	Stefan Walter, PRRC	Initial revision

Annex 1 - Figures

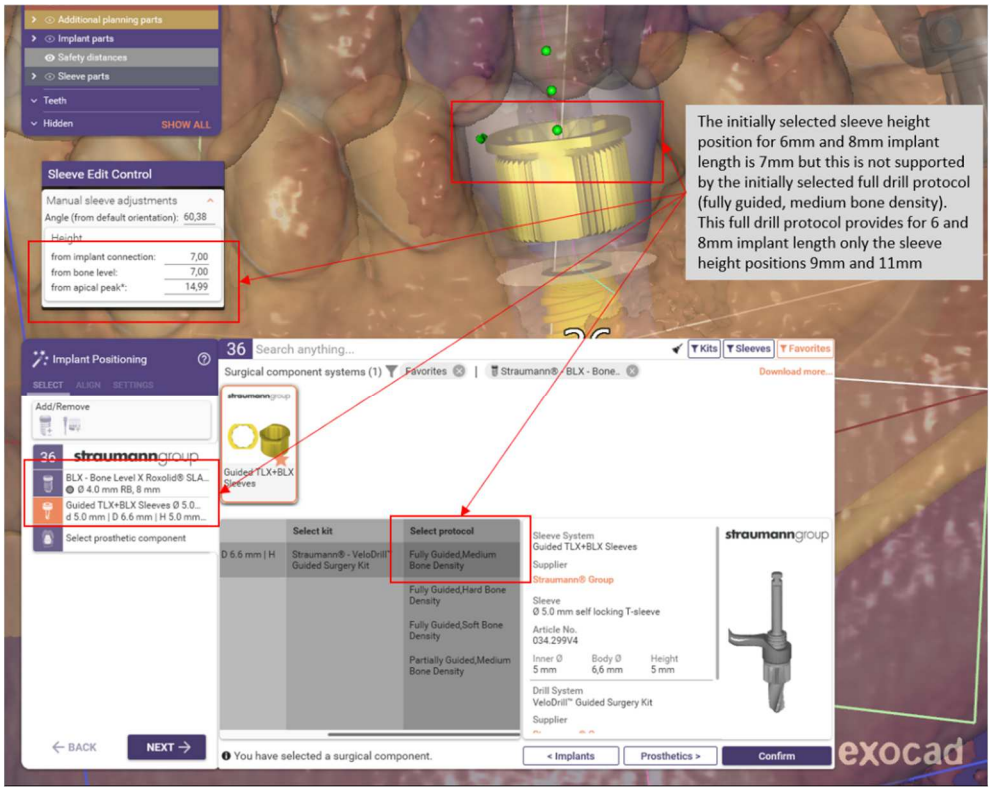

Figure 2: Example of one critical combination between unsupported sleeve height position for the selected full drill protocol. See explanation in the image.

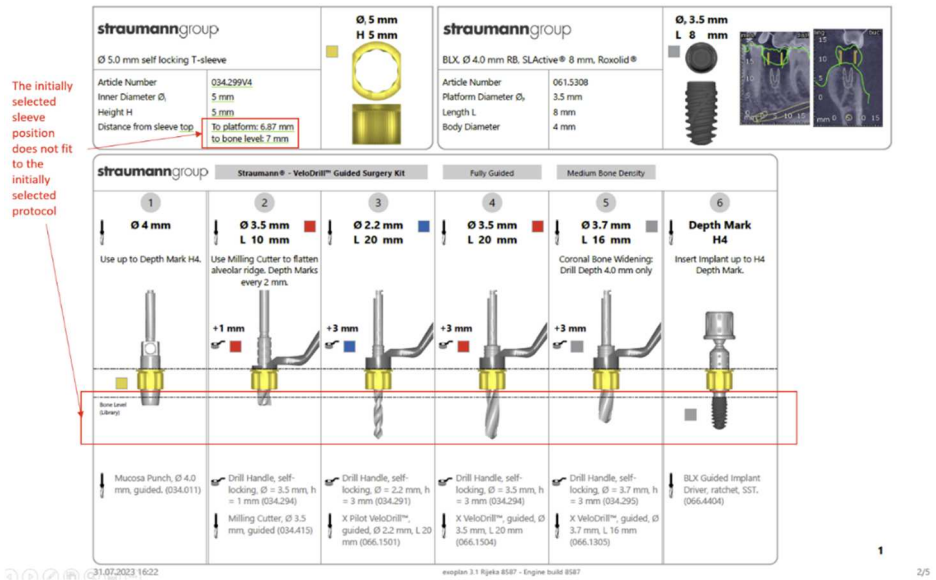

Figure 3: Extract from the surgical report that depicts the mismatch between the initial sleeve height position and the full step-by-step drill protocol where the distance from sleeve top to implant shoulder is incorrect.

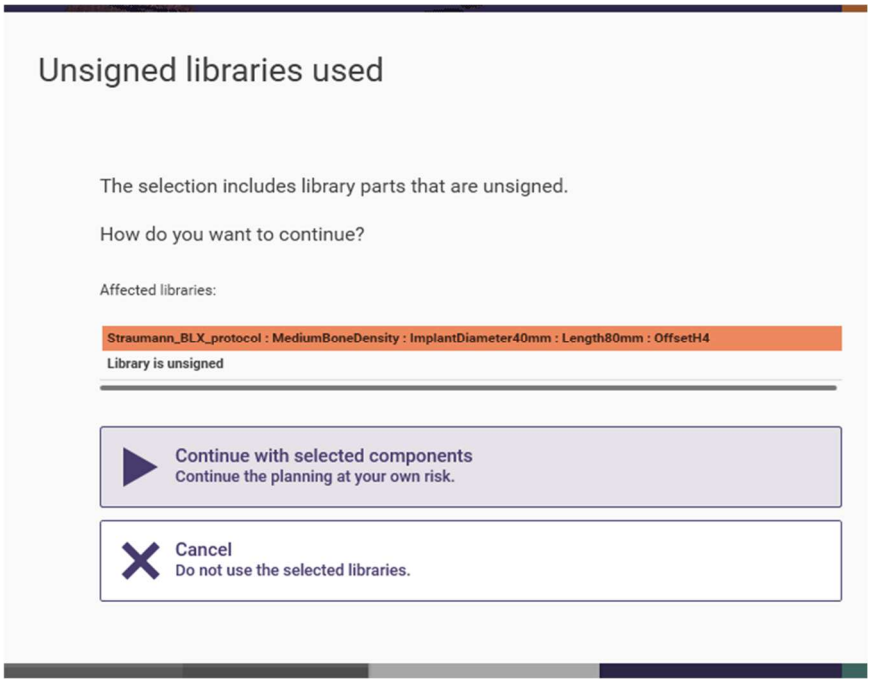

Figure 4: Unsigned library message of a blacklisted Straumann® full drill protocol library to the user when selecting it in the software or when the planning and surgical guide output data is generated. Users notified by this warning should click “cancel” and not “continue.” If users click continue, they continue at their own risk.

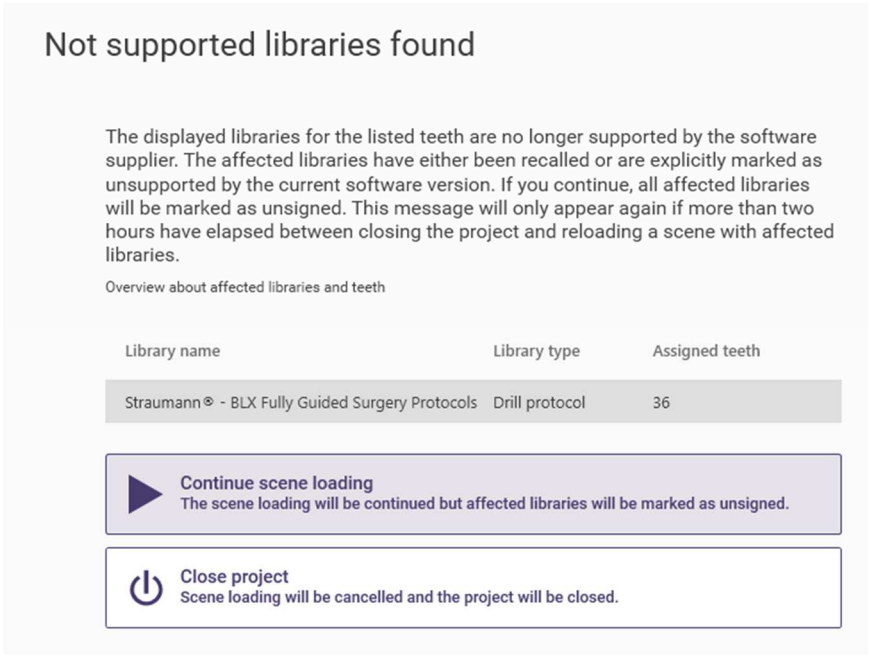

Figure 5: Unsigned library message of a blacklisted Straumann® full drill protocol library to the user when loading a scene file that already contains the affected library.

Annex 2 - End User Medical Device Recall Return Response Acknowledgement and Receipt Form

Response is Required

Return to exocad by email based on reseller market region:

- US & Canada: info@us.exocad.com
- Europe: service@exocad.com

Customer Information:
Customer Name:
Street Address:
City, State, Zip Code:

exoplan dongle serial number:_____

Instructions/Adverse Events:
I have read and understand the recall instructions provided in the August 16, 2023 letter. Yes _ No_
Did you encounter any adverse events associated with recalled product? Yes _ No _
If yes, please explain:
_____
_____
_____

Return Response Box:

Please provide any additional information, if applicable.

Annex 3 - Distributor/Reseller Report

Return to exocad by email based on reseller market region:

- US & Canada: info@us.exocad.com
- Europe: service@exocad.com

Distributor Name:
Street Address:
City, State, Zip Code:

Vigilance / regulatory Contact Name:
Regulatory Contact e-mail:

I have identified and notified the following customers that were shipped or may have been shipped this product:

exoplan s/n	Customer Name	Customer Location (City/State)	Customer Contact Name	Customer Contact email	Method of Contact	Date of Contact	Actions taken (none – library not installed, or library removed)	Using Affected Library (Y / N)	Encountered Issues with Affected Library?

Below is a list of customers who received/may have received this product but have not responded to my notification for this Recall/Correction/FSN. Please notify my customers directly.

exoplan s/n	Customer Name	Customer Address	Customer Contact Name	Customer Contact email	Customer Phone Number	Method/Date of Last Contact Attempt