Field Safety Notice #423314 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:

All *exoplan 3.1* users of a legacy software version with engine build (EB) 8657 or lower who use or are planning to use a guided surgical treatment approach with step-by-step drill protocol export.

Who is not affected by this Field Safety Notice:

1. Users of recent *exoplan* software versions (*exoplan 3.1 Rijeka* EB 8752 or higher) are not affected by this Field Safety Notice, as multiple warning messages are displayed if a blacklisted library is selected during the design and planning process
2. Users of legacy *exoplan 3.1 Rijeka* versions when using only drill protocol workflows other than the step-by-step drill protocol (example: see Figure 1) are not affected by this Field Safety Notice.
3. Users of *exoplan 3.0 Galway* are not affected by this Field Safety notice.

What should distributors do?

Distributors of exocad's *exoplan 3.1 Rijeka* software should forward the information to their end users and update their clients to the latest *exoplan* version (3.1 EB 9627 (non-US), EB 9628 (US) EB 9629 (US offline) or later), provided on our download server.

Manufacturer

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

Internal exocad Reference: #423314

exocad product, commercial name: *exoplan 3.1 Rijeka*

Affected versions of *exoplan 3.1*
Engine Builds (EB):

- EB 8633 (US)
- EB 8634 (US Offline)
- EB 8657 (non-US)

Unique Device Identifiers (UDI):
Basic UDI-DI: 426052136EXOPLAN21A6

- (01)4260521365026(10)A03B01E8633 (US)
- (01)4260521365026(10)A03B01E8634 (US Offline)
- (01)4260521365026(10)A03B01E8657 (non-US)

Type of treatments/protocols: Planning of protocol guided cases, including step-by-step drill protocol/sequence export using certain Straumann® implants and Straumann® drill protocol libraries or other step-by-step drill protocols.

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

Protocol library name	Library <Signature Date>
Straumann_BLXTLX_PartiallyGuided_protocol	<SignatureDate>2025-08-13T14:20:35.0910793Z</SignatureDate> and <SignatureDate>2025-09-01T07:38:18.5490060Z</SignatureDate>
Straumann_BLXTLX_PartiallyGuided_tsleeve_protocol	<SignatureDate>2025-09-23T08:48:41.9777196Z</SignatureDate>

Implant library name	Library <Signature Date>
Straumann® - BLX - Bone Level X Roxolid® SLActive®	<SignatureDate> earlier than 2025-05-01
Straumann® - TLX SP - Tissue Level X Standard Plus SLA® FDA	
Straumann® - TLX S - Tissue Level X Standard SLA® FDA	
Straumann® - TLX SP - Tissue Level X Standard Plus SLActive® FDA	
Straumann® - TLX S - Tissue Level X Standard SLActive® FDA	

What (malfunction/nonconformity) has been found?
A complaint for *exoplan 3.1 Rije*ka (EB 8657) was reported to exocad by an end user (a dentist based in India) in which the generated surgical report did not contain the complete and correct drill sequence for the selected Straumann® implant, sleeve, and surgical kit system.

The displayed drill/tool sequence in the generated surgical report included drills with insufficient length for the planned implant position (see figure 1 below). The dentist did not notice this discrepancy prior to treatment. As a result, the prepared osteotomy was too shallow to place the implant as planned.

The dentist addressed the situation by using a longer drill in combination with a drill handle with a smaller offset in order to achieve the required implant depth while using the same surgical guide.

The patient was not harmed, and no adverse effects were reported. No further incidents of this nature have been reported by the dentist. This was an isolated case. The described issue, however, might happen to all users of the affected *exoplan 3.1 Rijeka* (EB 8657) version with the mentioned Straumann® libraries or other step-by-step drill protocols.

It is confirmed that it is a software issue and not a library issue that was already addressed in subsequent *exoplan 3.1 Rijeka* (EB 8752) or later.

Implant – Reference code: 061.4310
Straumann® - BLX - Bone Level X Roxolid® SLActive® FDA, BLX, Ø 3.75 mm RB, SLActive® 10 mm, Roxolid®

Surgical sleeve - Reference code: 034.299V4
Straumann® – Guided iExcel Sleeves : Ø 5.0 mm self-locking T-sleeve · d 5.0 mm | D 6.6 mm | H 5.0 mm, Ø 5.0 mm self-locking T-sleeve

Surgical drill kit - Reference code: 066.1305
Straumann® - VeloDrill™ Guided Surgery Kit, X VeloDrill™, guided, Ø 3.7 mm, L 16 mm

Drill sequence protocol
Straumann® - BLX Fully Guided Surgery Protocols, Fully Guided | Medium Bone Density, Full Drill Sequence

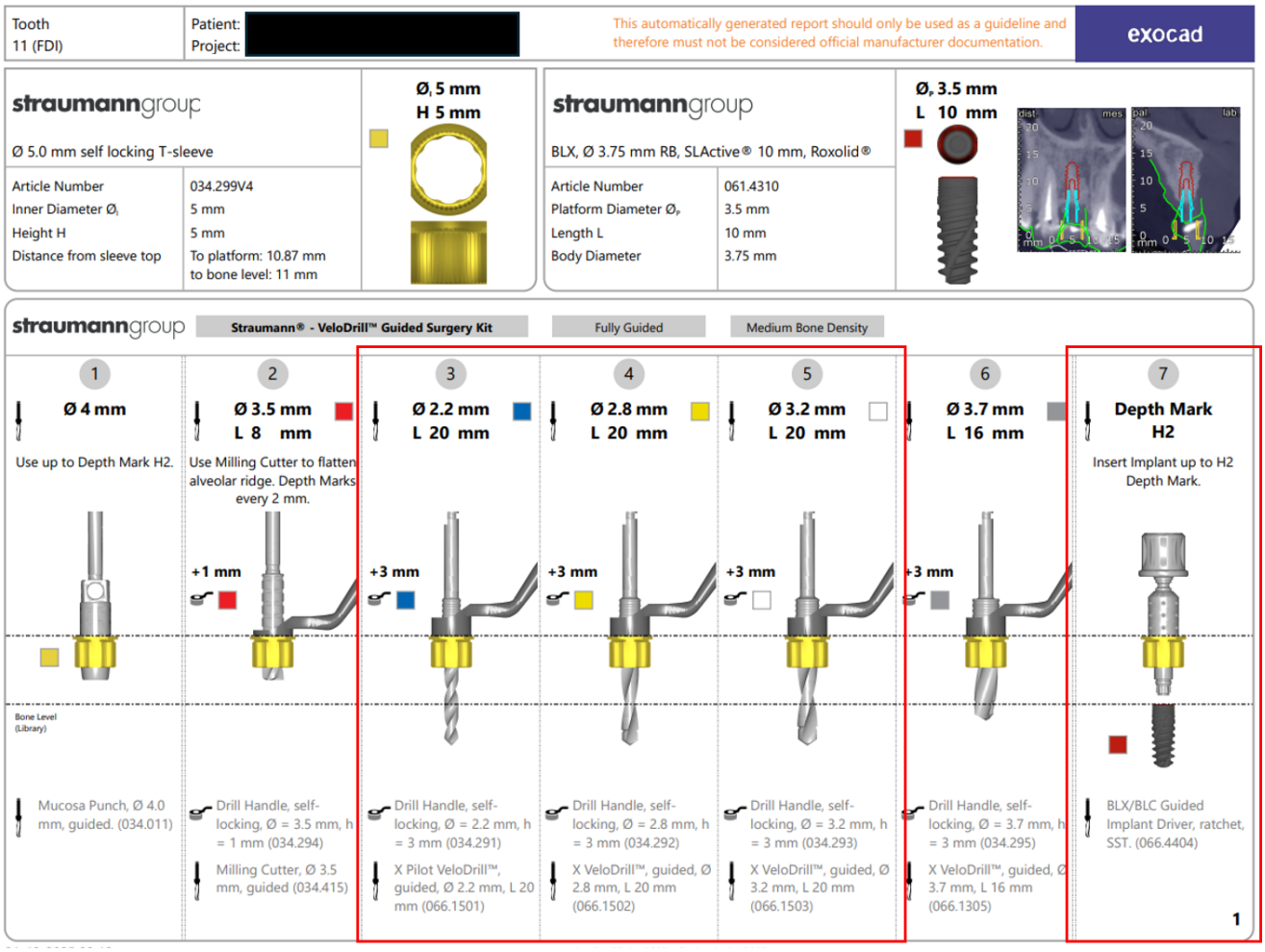

Figure 1: Report from the end user who has reported the issue with the too shallow drilling. The red marked drill/tool sequence steps (no. 3-5,7) depicts the steps with the wrong (drill/tool length) information.

exocad can confirm that this issue only occurred with the legacy version *exoplan 3.1 Rijeka* (EB 8657, 8633 US, 8634 US-offline) and is resolved in *exoplan 3.1 Rijeka* (EB 8752) or later.

Additional finding (library issue)
During internal testing of libraries an error was identified within specific Straumann® surgical protocol libraries, developed by exocad. In certain workflows, the protocol output displays an incorrect instrument combination in the final drilling steps. After several correct steps, in two consecutive protocol steps, an incorrect drill handle is displayed (h=1 mm instead of h=3 mm), which may result in a drilling depth up to 2 mm deeper than intended. This may lead to unintended injury depending on anatomical conditions and clinical use.
After selecting the implant, the user is prompted to choose a bone density (medium, hard, or soft) and an offset (7, 9 or 11 mm) which describes the distance from the top of the sleeve to the upper platform of the implant. The incorrect drill handle is displayed if the user chooses the following combination:

1. TLX/BLX implants with diameters of 5.5 mm and 6.5 mm and length of 6 mm (see “Affected implants” table below)
2. Ø 5.0 mm –T-sleeves (see “Affected surgical sleeves” table below)
3. Partially guided protocol, hard bone density
4. Sleeve offset 7 mm (closest of three available distances – marked as blue sphere in the figure 2 below)

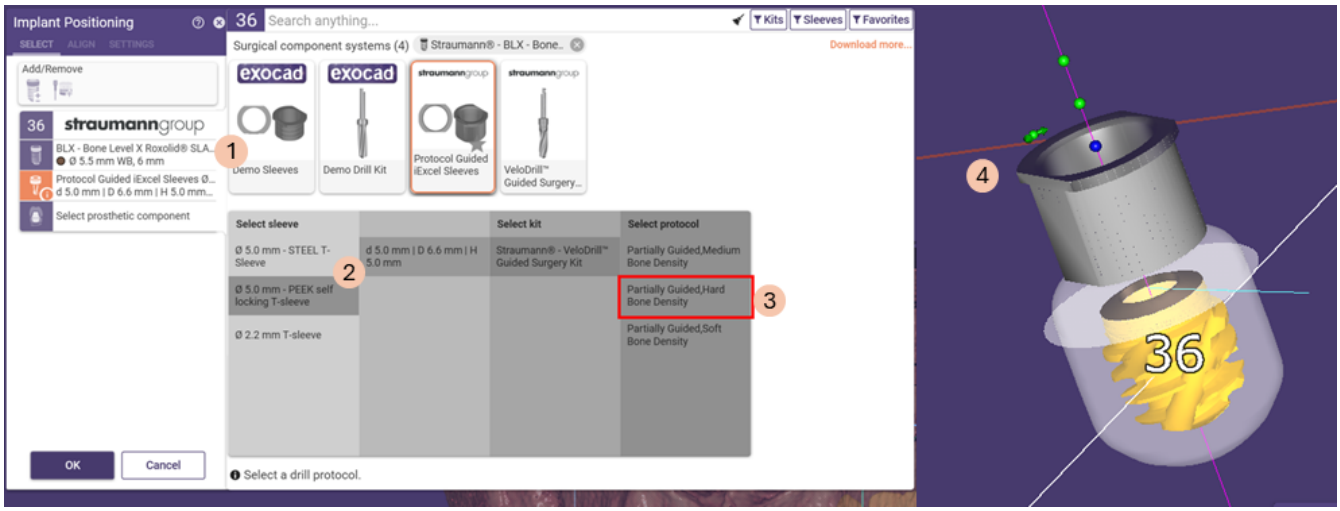

Figure 2: Example of a library selection during implant planning that leads to a wrong library entry. (1) Choose one of the affected implants (see table below); (2) Select one sleeve with diameter 5.0 mm; (3) choose protocol “Partially Guided, Hard Bone Density”; (4) Choose closest distance between sleeve and implant.

The deviation is limited to specific implant/sleeve/workflow selections and does not affect all configurations. The affected components are:

Affected implants	Diameter	Length	Reference code
Straumann® BLX - Bone Level X Roxolid® SLActive®	5.5 mm	6.0 mm	061.8306
	6.5 mm	6.0 mm	061.9306
Straumann® TLX SP - Tissue Level X Standard Plus SLA® FDA	5.5 mm	6.0 mm	035.2706S
	6.5 mm	6.0 mm	035.2806S
Straumann® TLX S - Tissue Level X Standard SLA® FDA	5.5 mm	6.0 mm	035.0706S
	6.5 mm	6.0 mm	035.0806S
Straumann® TLX SP - Tissue Level X Standard Plus SLActive® FDA	5.5 mm	6.0 mm	035.3706S
	6.5 mm	6.0 mm	035.3806S
Straumann® TLX S - Tissue Level X Standard SLActive® FDA	5.5 mm	6.0 mm	035.1706S
	6.5 mm	6.0 mm	035.1806S

Affected surgical sleeves	Dimensions	Reference code
Straumann® – Guided iExcel Sleeves - Ø 5.0 mm PEEK self-locking T-sleeve	d 5.0 mm | D 6.6 mm | H 5.0 mm	034.299V4
Straumann® – Guided iExcel Sleeves - Ø 5.0 mm - STEEL T-Sleeve	d 5.0 mm | D 6.3 mm | H 5.0 mm	034.053V4

In this case, protocol steps 4 and 5 display the incorrect height of the drill handles for the used drills (marked red in figure 3 below):

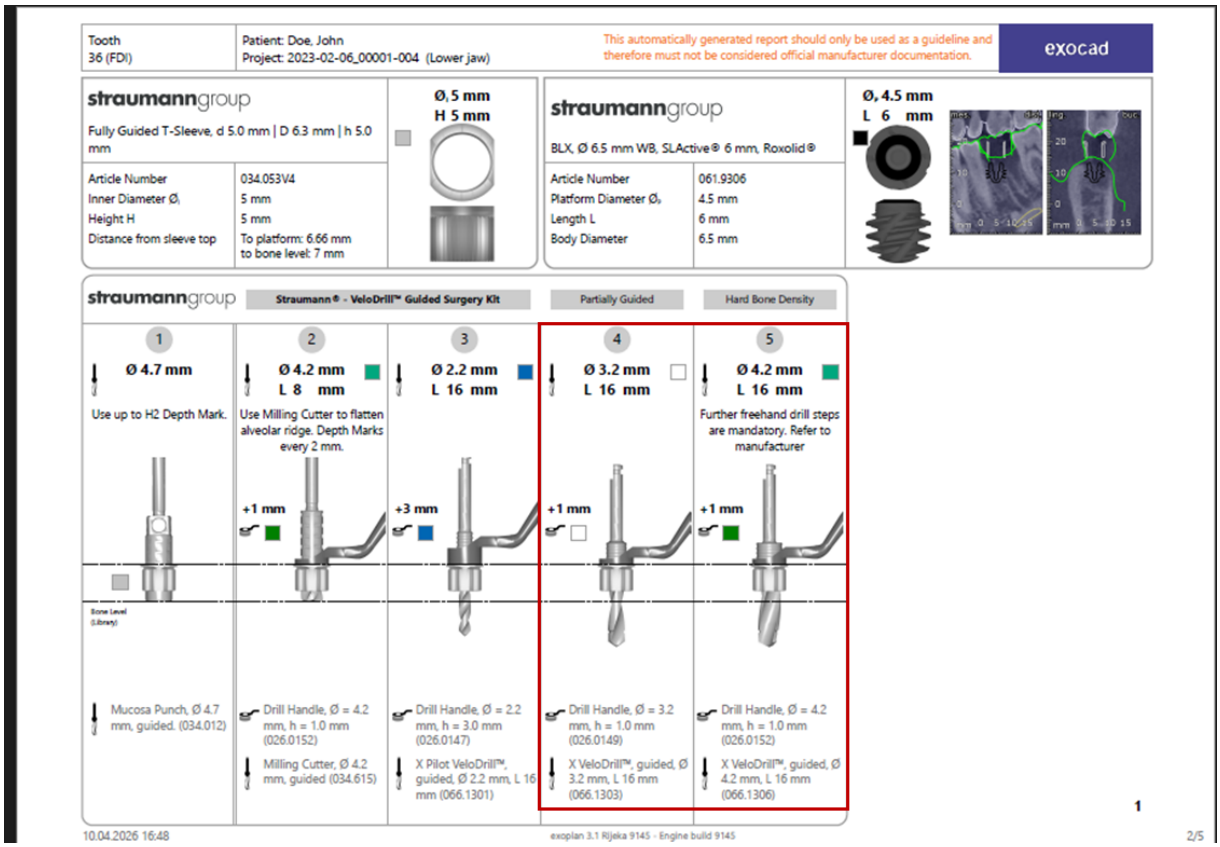

Figure 3: Example step-by-step drill protocol output of *exoplan*. The drill step number 4 and 5 display the wrong drill handle (h1.0, marked red), step 3 displays the correct drill handle (h3.0).

The usage of other Straumann® components is not affected. No other implant sizes, offset distances, surgical sleeves or protocol selections are affected. This chart showcases affected workflows. The red marked workflows are not to be used. Green workflow options are safe to use.

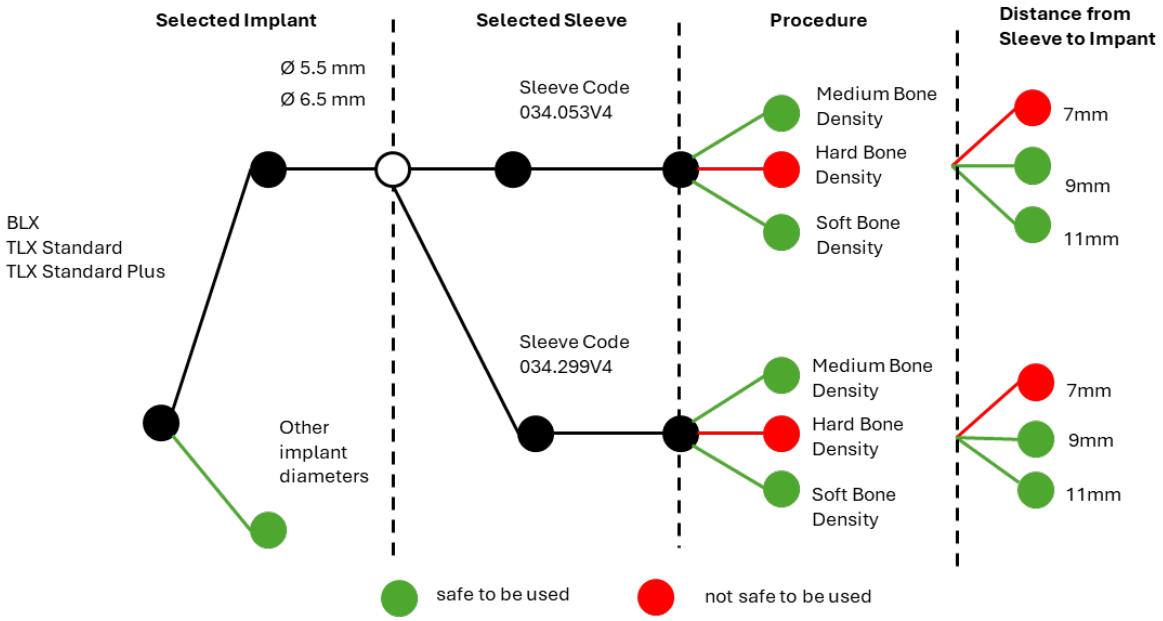

Figure 4: Combination of parameters available for affected Straumann® implant lines. The red circles indicate options that are not to be used. All green workflow options are safe to use.

What might go wrong with the additional finding?
When a Straumann® BLX/TLX implant with a diameter of 5.5 or 6.5 mm and a length of 6 mm is planned in combination with a Straumann® BLX/TLX sleeve and the Straumann® VeloDrill-, *exoplan* will show an incorrect handle position for the selected full drill protocol "Partially Guided with Hard Bone Density." The incorrect information is displayed for the fourth and fifth drill step.
If the incorrectly displayed protocol steps are followed, the user may select the wrong drill handle in steps four and five. This can cause the osteotomy depth to deviate 2 mm from the intended preparation depth.

Possible patient injury
exocad has no information related to any patient injury that has happened in such case.

exocad has only information of one isolated case where a patient was treated with an *exoplan* drill protocol. The dentist addressed the situation by using a longer drill in combination with a drill handle with a smaller offset in order to achieve the required implant depth while using the same surgical guide.

The patient was not harmed, and no adverse effects were reported. No further incidents of this nature have been reported by the dentist. This was an isolated case. The described issue, however, might happen to all users of the affected *exoplan 3.1 Rijeka* (EB 8657) version with the mentioned Straumann® libraries.

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. For this reason, we are taking the necessary measures to contain this issue.

Possible impact of the reported clinical case on patient health (under-drilling):
In the documented clinical case, the depth error was identified intraoperatively by the treating clinician. While no permanent patient injury was reported, the immediate intraoperative management of this error carries its own procedural risks. If the clinician attempts to reverse-torque the implant to remove it and re-drill to the correct depth, there is a risk of fracturing the implant or the implant mount/carrier during retrieval. Alternatively, if the clinician attempts to advance the implant further into an insufficiently prepared osteotomy without re-drilling, the implant may spin without engaging bone, resulting in loss of primary stability and failure to achieve the planned insertion torque.

Actions carried out by exocad

1. The affected Straumann® libraries (see above) were removed from the download server and blacklisted on the exocad server on **April 16, 2026**. Consequently, these libraries are no longer visible or available for download by users.
2. New, corrected versions of the affectedlibraries have been made available for download at https://exocad.com/integration/exoplan-library-integration#/all/tag-str
3. As a result of the blacklisting, any attempt to select a component from an affected library will trigger a system message indicating that the selected protocol library is "unofficially extended/changed" and must no longer be used.
   This warning is displayed both at the time the blacklisted protocol library is selected and prior to the

generation of implant planning or surgical guide output data.
Users receiving this message are warned that correct operation of the software cannot be assured when continuing with the selected library. Selection of **"Continue"** constitutes use at the user's own risk.

4. If an implant planning *scene file* (i.e., a file containing all information related to a planning or design scene, such as workflow state and scene objects) is opened in *exoplan* and previously relied on a blacklisted protocol library for implant placement planning, a warning message will be displayed to inform the user that an "unofficially extended" library is present. The warning message is the same as described in point three above.
5. In addition, all affected implant libraries have been blacklisted for the US market (FDA-cleared library versions) to ensure that these libraries cannot be used.
6. A new service release *exoplan **3.1*** **EB 9627 and 9628 (US), 9629 (US-offline)** will be made available by **2026-05-29**. This release includes additional safeguards against the use of blacklisted libraries. Libraries that do not contain a valid signature issued by exocad or that have been explicitly blacklisted will no longer be permitted for use (refer also to points 3 and 4).
7. To ensure implementation of these safety measures, all *exoplan 3.1* releases with EB 8657 or earlier will be disabled by **2026-05-22**. Users are recommended to update to *exoplan **3.1*** **EB 9627 and 9628 (US), 9629 (US-offline)** in order to facilitate the possibility to withdraw blacklisted libraries completely as described in point six above.
8. Following the deactivation of earlier versions on the license server, users who have not yet updated to *exoplan* version **3.1 EB 8752 or later** will be informed upon application startup by the following message:
   "This software version has been recalled. Please update to the latest exoplan version, available from your reseller."
9. exocad strongly recommends installing software updates promptly upon release to ensure continued safety, performance, and regulatory compliance.

Required actions for end-users

1) Do not use the affected libraries – see section "Affected libraries" above – with *exoplan 3.1 Rijeka.*
2) If you are intending to use the affected Straumann® libraries, update all of them with the new, corrected versions available for download at https://exocad.com/integration/exoplan-library-integration#/all/tag-str .
3) Upgrade to the latest *exoplan 3.1 Rijeka* version.

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) If required, resellers shall support their end customers with the installation of the *exoplan 3.1 Rijeka* software version **EB 8752** or later, available on our download server. exocad recommends to use **EB 9627** or **9628 (US) and 9629 (US-offline)**, once they have been released**.**
3) Distributors should be aware that their national competent/regulatory authorities might contact them and request additional information. Per local regulations, distributors are obliged to collaborate with competent/regulatory authorities.

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.