**Field Safety Notice # 322799 related to exoplan Argon Rapid Surgery Sleeve library**
(affected part number 45009K3Pro.S)

**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 who use a fully guided surgical treatment approach with the **Argon Dental-K3Pro® Sure Implant ⌀ 4.0 mm P3.0 and 9 mm length (Part number 45009K3Pro.S)** using the Argon Dental - K3Pro® Rapid Surgery Sleeve with a **distance offset of 10 mm** are affected. When planning a fully guided case with the affected implant-sleeve combination and the offset of 10 mm, the resulting drilling would be 2 mm deeper than expected due to a dimensional error in the affected libraries.

*exoplan* users using other Argon Dental-K3Pro® implants or the affected implant (Part number 45009K3Pro.S) with another distance offset than 10 mm are NOT affected by this safety note.

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

**Manufacturer**

exocad GmbH
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64295 Darmstadt
Germany
SRN DE-MF-000007341

**Internal exocad Reference:** #322799

**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 Argon Dental-K3Pro® Sure Implant ⌀ 4.0 mm P3.0 and 9 mm length (part number 45009K3Pro.S) using the Argon Dental-K3Pro® Rapid Surgery Sleeve with an offset of 10 mm.

**Affected libraries:**

The issue is an incorrect specification in the Argon_Rapid_Surgery_sleeve libraries, suggesting the use of a surgical drill that results in a 2 mm deeper drill hole 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:

- Argon_K3Pro_Sure_plan_fda in combination with Argon_Rapid_Surgery_sleeve library that include components with the following article numbers are involved:

| Library name | Article number |
|---|---|
| Argon_K3Pro_Sure_plan_fda | **45009K3Pro.S** |
| Argon_Rapid_Surgery_sleeve | RS_BH3.0/3.5, RS_BH4.0/4.5, RS_BH5.0/6.0, |

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

| Library name | Library <Signature Date> |
|---|---|
| Argon_Rapid_Surgery_sleeve | <SignatureDate>2022-06-17T12:29:48.3313032Z</SignatureDate>, and older revisions without signature date |

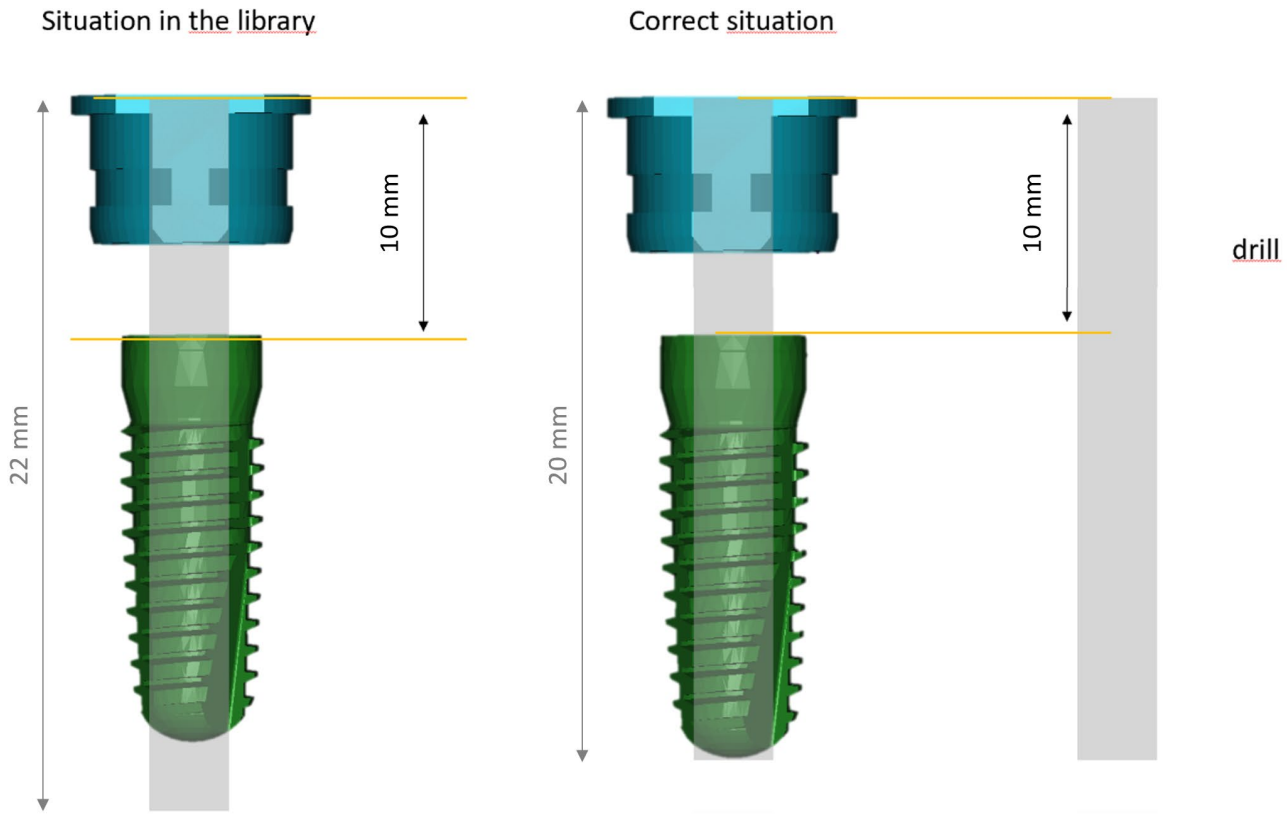


Figure 1: Sketch comparing the distance situation between sleeve, implant and drill for the wrongly entered drill (left) and the correct drill (right).

**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 2 mm deeper than expected.

**Possible impact on patient health**

The identified issue in the Argon Sleeve Library, where incorrect drill length information is reported, poses significant risks to patient health during dental implant surgeries. Specifically, the software indicates a drill length that is 2 mm longer than necessary. The software provides a default safety margin of 1.5 mm, which as a result of the incorrect drill length information, is insufficient, as it is also shifted by 2 mm. This error can lead to over drilling beyond the intended surgical boundary.

Primary risks Include:

1. Nerve damage: Over drilling may lead to partial or complete damage to the inferior alveolar nerve. This could result in adverse sensory effects such as numbness, tingling, or altered sensitivity in the lower lip, chin, teeth, and jaw on the affected side. In some cases, this may lead to chronic pain or paresthesia, which could be temporary or, rarely, permanent.

2. Perforation risks: There is an increased risk of perforating the maxillary sinus or nasal cavity due to the extended drill length. Such perforations could lead to complications like nasal bleeding, sinusitis, or the development of oral-sinus or oral-nasal fistulas, requiring surgical intervention to resolve.

3. Implant complications: Incorrect drilling depth may also compromise the stability of the implant, increasing the likelihood of implant failure, infection, or loss. Subsequent interventions might be necessary to remove or replace the compromised implant.

**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. There, 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 Argon® libraries (see above) were removed from the download server and "blacklisted" on the exocad server on May 7, 2024. 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 version of Argon_Rapid_Surgery_sleeve have been released
( <SignatureDate>2024-05-07T14:47:36.6611068Z</SignatureDate>).
Users can now download and install the new libraries.

**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 |
|---|---|---|
| 2024-05-08 | Stefan Walter, PRRC | Initial revision |

**Annex 1 - Figures**

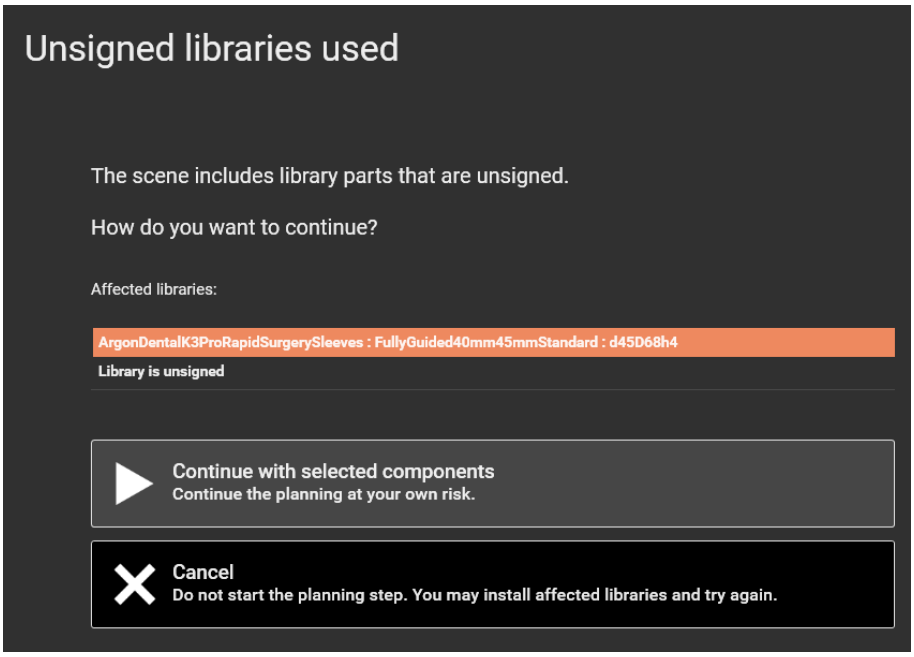


Figure 2: Unsigned library message of a blacklisted Argon® sleeve library to the user when selecting it in the software or when the planning and surgical guide output data is generated. Users notified by this warning should click “cancel” and not “continue”. If users click continue, they continue at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

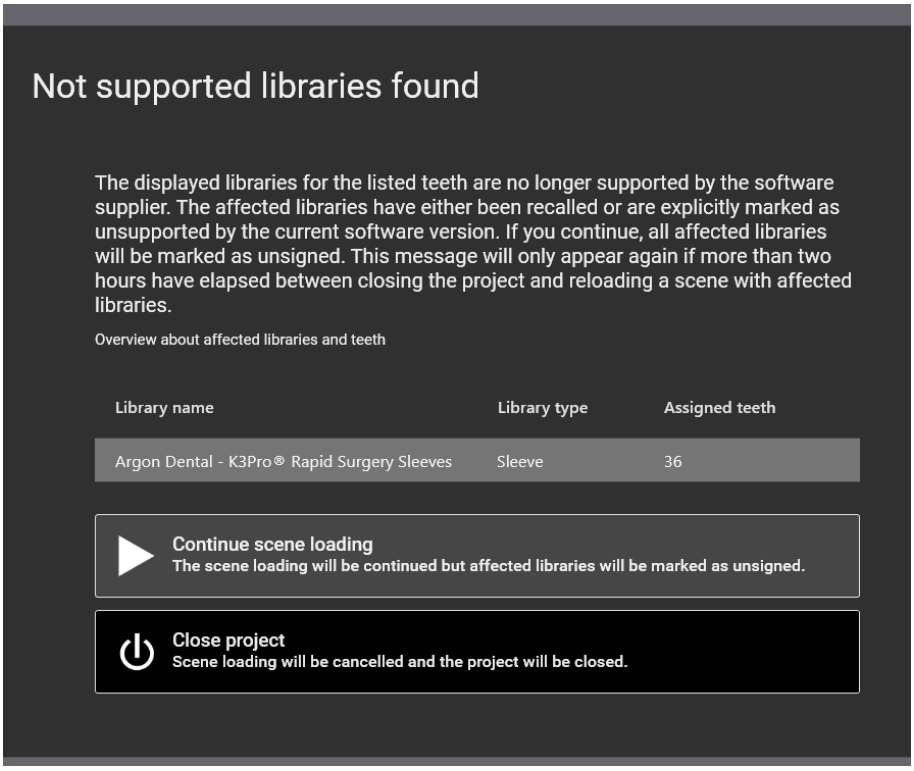


Figure 3: Unsigned library message of a blacklisted Argon® library to the user when loading a scene file that already contains the affected library.