Field Safety Notice #442582 related to Alpha-Bio Tec and DSP Biomedical® Sleeve Libraries

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

The issue affects *exoplan* users performing fully guided surgical treatments with Alpha-Bio Tec Master Sleeve SLL ⌀ 5.5 mm (art. 66013) in combination with any of the following implants:
- ICE™ IH Implants ⌀ 4.2 mm (art. 1056), ⌀ 4.65 mm (art. 1036), ⌀ 5.3 mm (art. 1046) each with 6.0 mm length
- ATID Implant ⌀ 5.0 mm with 6.0 mm length (art. 1446*);* Implant phased out, library no longer available

It also affects *exoplan* users performing fully guided surgical treatments with the DSP Biomedical® CMI Biofit implant (⌀ 3.5 mm, length 11.5 mm, art. 70.3511B) using the Long Fitguide Guided Drill Kit and the drilling workflow for bone densities III and IV with the Long Twist Drill D 2.7 mm (art. 27.8027L).

Who is 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.

exoplan users using other Alpha-Bio Tec implants or surgical sleeves (e.g., SLS ⌀ 4.1 mm) are NOT affected by this Field Safety Notice.

exoplan users using other DSP Biomedical® implants or other bone density workflows (e.g., bone densities I and II) are NOT affected by this Field Safety Notice.



Internal exocad references: #442582

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

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Type of treatments/protocols

Planning fully guided cases using
- Alpha-Bio Tec implants with a length of 6.0 mm with the Alpha-Bio Tec Master Sleeve SLL ⌀ 5.5 mm or
- DSP Biomedical® implant ⌀ 3.5 mm and 11.5 mm length in drilling workflows for bone densities III and IV.

Affected libraries

The Alpha-Bio_Tec_sleeve and DSP_Biomedical_Fitguide_sleeve libraries contain dimensional errors affecting the implant-to-sleeve distance. In both cases, the incorrect distance results in an osteotomy that is 2.0 mm deeper than intended.

The affected library can be identified by the "<SignatureDate>" in the library config.xml file as follows:

Library name	<SignatureDate> in config.xml
Alpha-Bio_Tec_sleeve	2020-05-07T11:28:00.9120040Z 2022-06-14T10:23:45.5493198Z 2022-06-20T07:19:12.6768449Z 2025-06-10T08:25:52.8598314Z 2026-06-08T07:50:45.0841027Z 2026-09-29T11:10:03.0520951Z
DSP_Biomedical_Fitguide_sleeve	2022-03-23T10:19:39.8874167Z 2022-06-14T13:11:35.3114767Z 2023-02-03T09:50:47.7582598Z 2025-07-21T09:34:13.3490624Z

Involved libraries, dental components and tools

Library name	Dental component	Article number
Alpha-Bio Tec		
Alpha-Bio_Tec_sleeve	Master Sleeve SLL ⌀ 5.5 mm	66013
Alpha-Bio_Tec_ICE_IH_plan	ICE™ IH implant ⌀ 4.2 mm L 6.0 mm	1056
	ICE™ IH implant ⌀ 4.65 mm L 6.0 mm	1036
	ICE™ IH implant ⌀ 5.3 mm L 6.0 mm	1046
Alpha-Bio_Tec_ATID_plan	ATID implant ⌀ 5.0 mm L 6.0 mm	1446 *(phased out)*
Alpha-Bio_Tec_kit	CD3.2-8 Surgical drill ⌀ 3.2 mm L 8.0 mm	65017
	CD3.65-8 Surgical drill ⌀ 3.65 mm L 8.0 mm	65022
	CD4.1-8 Surgical drill ⌀ 4.1 mm L 8.0 mm	65027
	CD4.5-8 Surgical drill ⌀ 4.5 mm L 8.0 mm	65032
DSP Biomedical®		
DSP_Biomedical_CMI_Biofit_plan	CMI Biofit implant ⌀ 3.5 mm L 11.5 mm	70.3511B
DSP_Biomedical_Fitguide_Long_kit	Long Twist D 2.7 mm drill	27.8027L

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What (malfunction/nonconformity) was found?

One of our official exocad resellers informed us of a finding by the treating dentist that the use of a specific combination of implants, sleeve and surgical drill can result in an osteotomy being drilled 2.0 mm deeper than expected. During internal review, a second finding was identified.

Possible impact on patient health

Two library errors result in the same apical overdepth:

- Alpha-Bio Tec: In the Alpha-Bio_Tec_sleeve library, the sleeve-to-bone-level distance for the ICE™ IH implants ⌀ 4.2 mm, ⌀ 4.65 mm and ⌀ 5.3 mm, and the ATID implant ⌀ 5.0 mm, each with a length of 6.0 mm, is stored as 9.0 mm instead of the 11.0 mm specified by the supplier. As a result, these implants are prepared with the drilling depths of the corresponding 8.0 mm implants.
- DSP Biomedical®: For the CMI Biofit implant ⌀ 3.5 × 11.5 mm, the drilling workflow for bone densities III and IV specifies drilling with the Long Twist Drill D 2.7 mm to the 17 mm depth marking instead of the required 15 mm depth marking.

In both cases, every osteotomy planned with an affected configuration extends 2.0 mm beyond the planned implant apex. This exceeds the default safety distance of 1.5 mm in *exoplan*. A plan that respects the safety distance to a critical anatomical structure may therefore still reach that structure. The software generates no warning.

In the Alpha-Bio Tec finding, the drills of the Alpha-Bio Guided Surgery Tool Kit have integrated stops and no depth-offset handles are available, so the overdepth cannot be compensated for during surgery. Because 6.0 mm implants are typically selected where bone height is limited, the deviation occurs where the distance to critical structures tends to be smallest. In the DSP Biomedical® finding, the protocol for bone densities III and IV is used mainly in soft bone. There, the overdepth also reduces apical bone engagement and primary stability.

Potential health consequences

Depending on the anatomical location of the planned implant, use of the affected libraries may result in the following potential health consequences:

Injury to the inferior alveolar or mental nerve

In the mandible, overdrilling may cause the drill to enter the mandibular canal or the region of the mental foramen and injure the inferior alveolar or mental nerve. Potential consequences include numbness, altered sensation or paraesthesia affecting the lower lip, chin, teeth and gingiva.

- **Reversible nerve injury:** Severity Moderate.
- **Irreversible nerve injury resulting in permanent impairment of nerve function:** Severity Critical.

Available clinical evidence indicates that most neurosensory disturbances are expected to be transient and followed by recovery. However, permanent nerve injury cannot be excluded.

Implant complication pertinent to the DSP Biomedical® finding

The overdrilling removes apical bone engagement. In soft bone (bone densities III and IV), where primary stability is already limited, this may increase the risk of failed osseointegration or implant loss (Severity Moderate).

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Blood vessel injury

If overdrilling reaches blood vessels within the mandibular canal or passes through a cortical plate, vascular injury may occur (Severity Marginal).

Maxillary sinus or nasal floor perforation

For implants planned in the maxilla, the incorrect drilling depth may result in perforation of the maxillary sinus or nasal floor (Severity Marginal).

Cortical perforation and bone injury

When an osteotomy is planned close to a cortical bone boundary, the incorrect drilling depth may result in cortical perforation and associated bone injury (Severity Marginal).

For the DSP Biomedical® case, an affected osteotomy reaching the mandibular canal is considered clinically unlikely. The maxilla is the most likely affected region, where the expected harm is reversible.

Detectability of the issue

The additional drilling depth may not be reliably detected during the surgical procedure.

During fully guided implant insertion, the implant mount stops the implant at its planned position, although the osteotomy extends 2.0 mm beyond the planned implant apex. The implant may therefore be inserted at the planned position without providing a reliable tactile indication that the osteotomy was prepared too deeply.

If the implant is inserted freehand following guided drilling, it may be advanced deeper than planned. Recognition depends on the clinician's visual control of the implant platform relative to the alveolar crest and may be limited during flapless surgery.

The discrepancy can be identified before treatment by reviewing the drilling information in the surgical report and comparing it with the applicable implant manufacturer's drilling protocol. For the Alpha-Bio Tec finding, a 6.0 mm implant is incorrectly associated with a drilling depth intended for an 8.0 mm implant. For the DSP Biomedical® case, the workflow specifies drilling with the Long Twist Drill D 2.7 mm to the 17 mm depth marking instead of the required 15 mm depth marking. No software warning is generated for either affected configuration.

Clinical experience

For the Alpha-Bio Tec finding, one near miss has been reported. The healthcare professional identified the discrepancy before performing the osteotomy. In both findings, no patient harm occurred.

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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. 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 avoid misuse of the safety distance setting, the lowest distance that can be set is 1.0 mm.

Patient injury

exocad has no information relating to any patient injury that has occurred in such a case.

Because the deviation was systematic and did not generate a software warning, exocad cannot exclude that adverse clinical outcomes may previously have been attributed to surgical, anatomical, or other causes rather than to the planning libraries.

Actions carried out by exocad

1) The affected libraries (see above) were removed from the download server and “blacklisted” on the exocad server on September 29, 2026 (Alpha-Bio Tec finding) and October 14, 2026 (DSP Biomedical® finding). 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 do so 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 2).

4) New library versions of Alpha-Bio_Tec_sleeve (<SignatureDate>2026-09-30T15:30:12.3831425Z</SignatureDate>) and DSP_Biomedical_Fitguide_sleeve (<SignatureDate>2026-10-16T07:46:55.2258008Z</SignatureDate>) have been released.
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*.
3) Consider reviewing previously treated cases planned with the affected libraries if unexpected clinical findings or complications were observed and no alternative explanation was identified at the time. If you discover any such cases, please report them to your distributor or directly to exocad (regulatory@exocad.com).

Required actions for resellers/distributors

1) exocad distributors should forward this Field Safety Notice 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*.

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
2026-10-26	Stefan Walter, PRRC	Initial revision

Annex 1 – Figures related to Alpha-Bio Tec

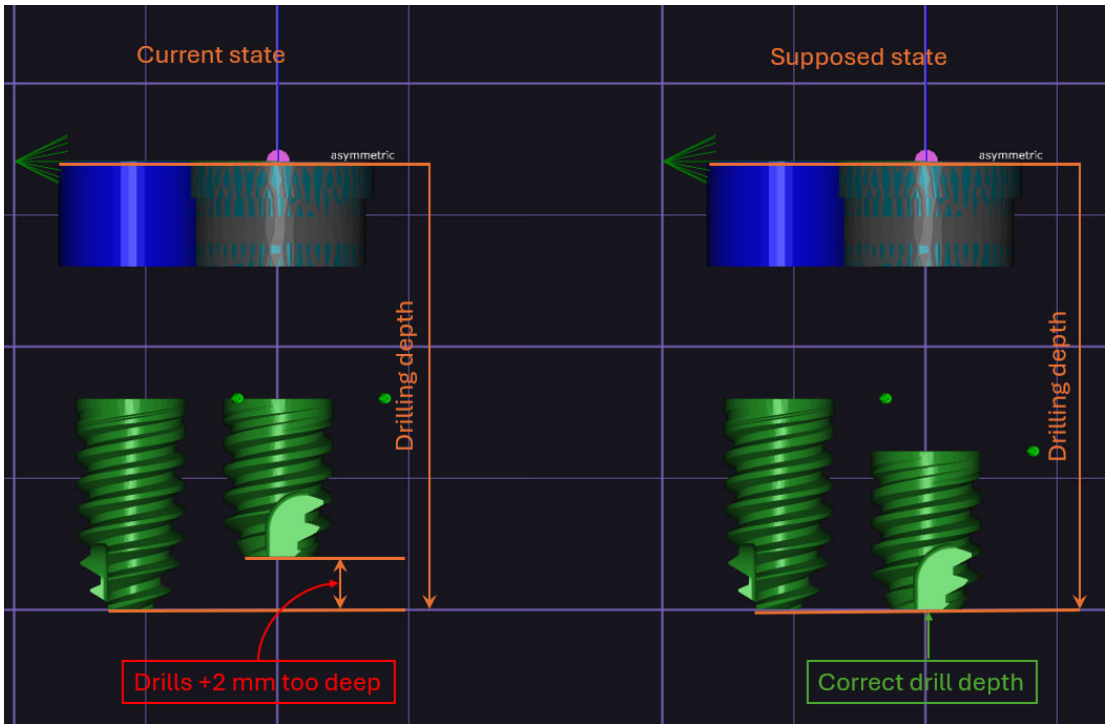


Figure 1: Comparison between incorrect and correct situation between sleeve, implant and drilling depth for an 8.0 mm reference implant (left) and the affected 6.0 mm implant (right).

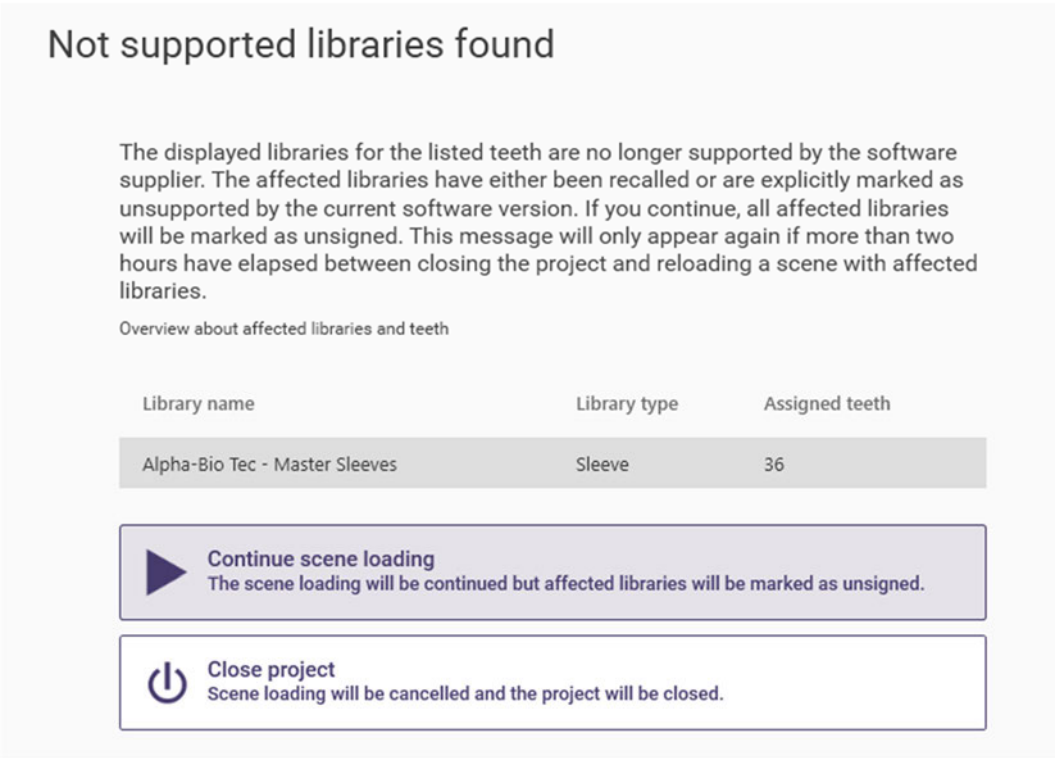


Figure 2: Unsigned library message of a blacklisted Alpha-Bio Tec library to the user when loading a scene file that already contains the affected library.

Annex 2 – Figures related to DSP Biomedical®

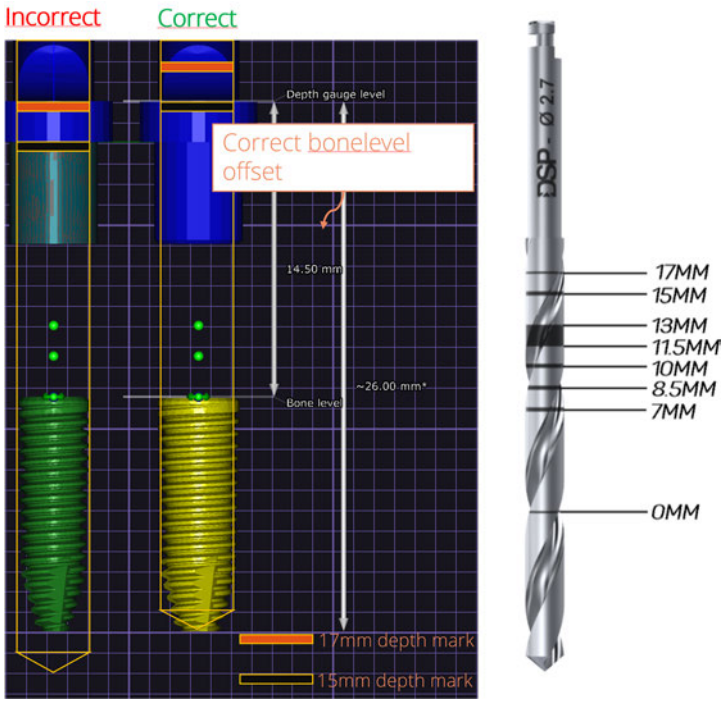


Figure 3: Comparison between incorrect and correct situation between sleeve, implant and drilling depth for the wrong 17.0 mm drilling depth (left) and the correct 15.0 mm drilling depth (right).

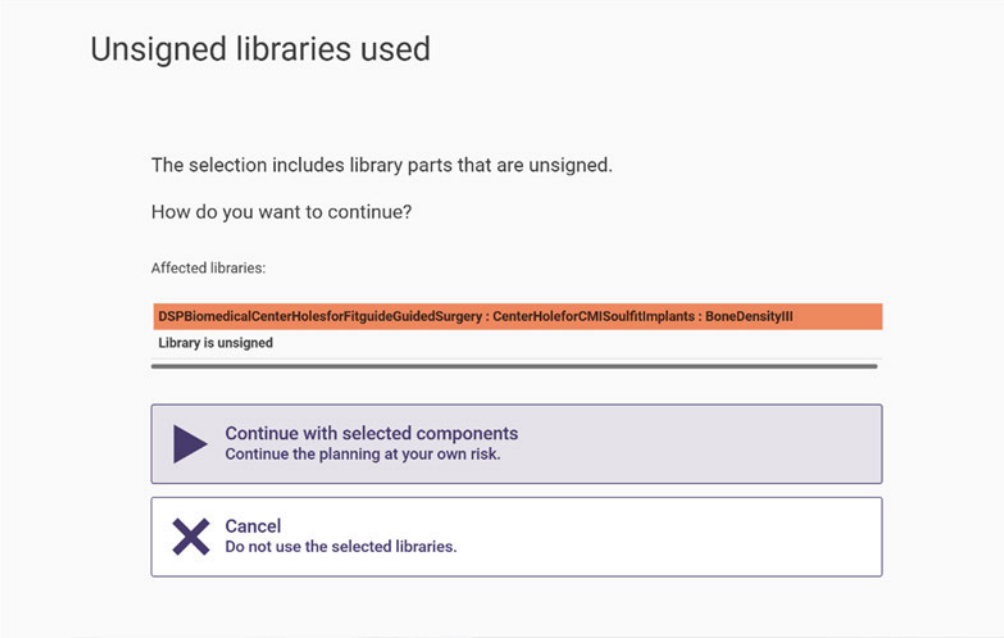


Figure 4: Unsigned library message of the blacklisted DSP Biomedical® library to the user when loading a scene file that already contains the affected library. Users notified by this warning should click “Cancel” and not “Continue.” If users click “Continue”, they do so at their own risk.