Field Safety Notice related to exoplan

Customer information for patient safety 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 software in order to forward the information to end-users.
2) End-users to understand whether they are affected by the safety note and possible actions to take.

exoplan users that do not use a fully guided surgical treatment approach with Bicon implants are not affected.

Manufacturer	**exocad GmbH** Rosa-Parks-Str. 2 64295 Darmstadt Germany SRN DE-MF-000007341	
exocad product	**exoplan, versions**	**UDI-DI**
	2.3 Matera	4260521365002
	3.0 Galway	4260521365019
	3.1 Rijeka	4260521365026
Type of treatments	Planning of fully-guided cases using *Bicon implant, Bicon sleeve,* and *Bicon kit* libraries	
Affected library	The issue is an incorrect compatibility information contained in library *Bicon_sleeve* suggesting the usage of a drill that is 2mm too long.	
Involved dental parts and tools	Bicon® - MAX 2.5™ Integra-CP™ Ø 4mm, L 6mm implant, article number: 260-340-256 Bicon® - Guided Surgery Sleeves, Fully Guided, 4.0 Bicon® - 4.0mm Guided Surgical Kit, Ø 4mm, L 8mm, article number: 260-940-380	
Involved exoplan libraries with part from external manufacturers	Cases planned and designs of surgical guides with the following exocad libraries: • *Bicon_MAX25_plan_fda*, using implant Ø 4mm, L 6mm, article number 260-340-256 in combination with - *Bicon_sleeve*, and - *Bicon_4.0mm_kit* The version of the library can be identified by the tag <SignatureDate> in file config.xml with signature date before 5 April 2023, <SignatureDate>2023-04-05T09:03:35.9880966Z</SignatureDate>	
What have we 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 drill in a surgical kit can result in a hole being drilled for the implant 2mm too deep.	
What might go wrong?	In case an implant 260-340-256 of Bicon with a 4mm diameter and 6mm length is used in a fully-guided surgery procedure using a 4mm diameter Bicon sleeve it should only be possible to select a drill with 6mm length. But erroneously uses an 8mm length drill (instead of 6mm length drill) from the surgical kit. See figures 1 and 2. Possible impact on patient health: During surgical alveolar implant preparation and positioning 2mm 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 2mm is essential to avoid these risks. Since the literature safety distance of 2mm 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	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.*
Impact on other implant component combinations	Other combinations of libraries, surgical kits and implants than the above-mentioned are not affected by the found issue, nor is any other issue known for other combinations.
Patient injury	exocad has no known information relating to any patient injury that has happened in such case.
Actions	Users that are affected by the described issue are to be notified that: **1)** The subject *Bicon Sleeve* library containing erroneous compatibility information about implant, drill and sleeve was "blacklisted" on the exocad server on 3 April 2023. By that, the library defect is not available for new designs of surgical guides for existing and future installations. The user receives a message indicating that a library in the planning is "unsigned" (see figure 3). **Users notified by this warning should click "cancel" and not "continue".** 2) The library defect was corrected by exocad. 3) The corrected library was made available on exocad's download portal, see https://exocad.com/integration/exoplan-library-integration **End users that want to use the above libraries or plan Bicon implants in a fully guided procedure should download the corrected versions of the following library packages:** - Bicon GuideCreator FDA cleared parts libraries exocad Or use this download link: https://exocad.com/downloads/exoplanlibraries/BI_Bicon-GuideCreator-FDA-cleared-parts-libraries-exocad.zip (see also figure 4)
Internal reference (exocad)	#257029

Annex – Figures

Figure 1: Display of critical combination of items at the exoplan user interface

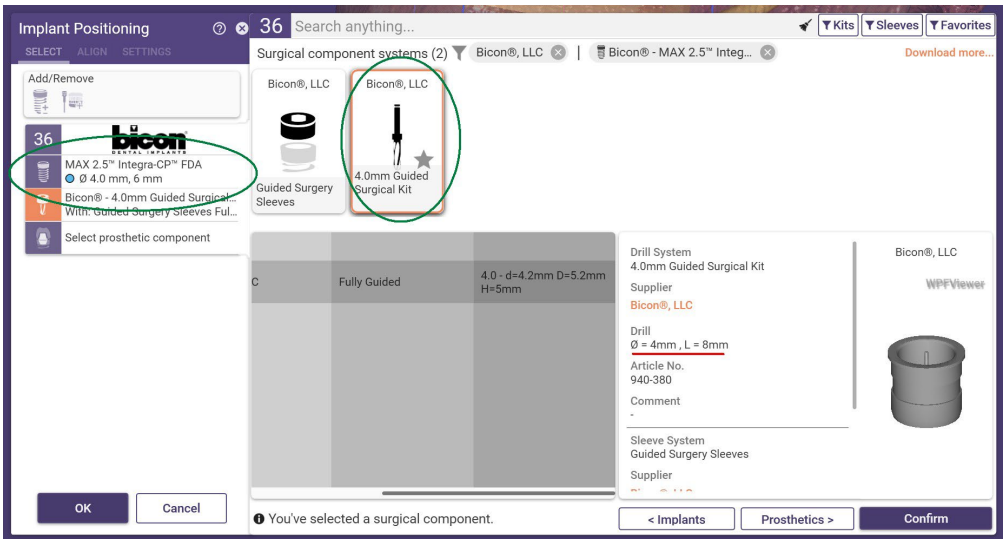
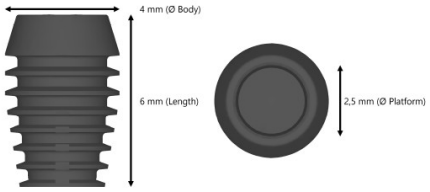


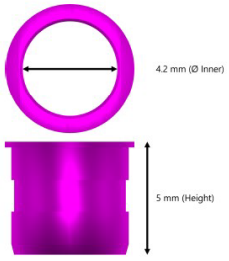
Figure 1: Critical combination of items, 4.0mm, L 6mm Implant using a 4.0mm Guided Surgical Kit, results in an automatic selection of a drill with 8mm length.

Figure 2: Extract from a Surgical Report

Surgical Report

Patient: Doe, John
Project: 2023-02-06_00001-004

Implant Information	
Tooth Number:	36
Implant Model:	Bicon® - MAX 2.5™ Integra-CP™ FDA
Manufacturer:	Bicon®, LLC
Article Number:	260-340-256
Length:	6 mm
Body Diameter:	4 mm
Platform Diameter:	2.5 mm
Library Integrity:	This library is signed.[1]
Image:	Color code: Bone Level (Library) 

Sleeve Information	
Library Information:	Bicon® - Guided Surgery Sleeves : Fully Guided : 4.0 - d=4.2mm D=5.2mm H=5mm
Sleeve Model:	Bicon® Sleeve Ti6Al4V - 4.0mm H5
Manufacturer:	Bicon®, LLC
Article Number:	260-940-005
Height:	5 mm
Inner Diameter:	4.2 mm
Sleeve Offset to Implant Platform / to Bone Level:	To platform: 12 mm / to bone level: 9.5 mm
Library Integrity:	This library is signed.[1]
Image:	Color code: 

Surgical Kit and Drill Information	
Library Information:	Bicon® - 4.0mm Guided Surgical Kit : Ø 4 mm : 8 mm | 260-940-380
Drill Model:	Ø = 4mm L = 8mm
Drill Manufacturer:	Bicon®, LLC
Article Number:	940-380
Drill Length:	8 mm
Drill Diameter:	4 mm
Drill Color Code:	
Library Integrity:	This library is signed.[1]

[1]The presence of an electronic signature only confirms that the library entry has been verified for certain mesh and/or data characteristics. If the library contains meshes, it does NOT imply correctness of their shape under technical, medical or other aspects.

Figure 2: Display in a Surgical Report, combination of items, 4.0mm, L 6mm implant using a 4.0mm Guided Surgical Kit, results in an automatic selection of a drill with 8mm length

Figure 3: Unsigned library message to user

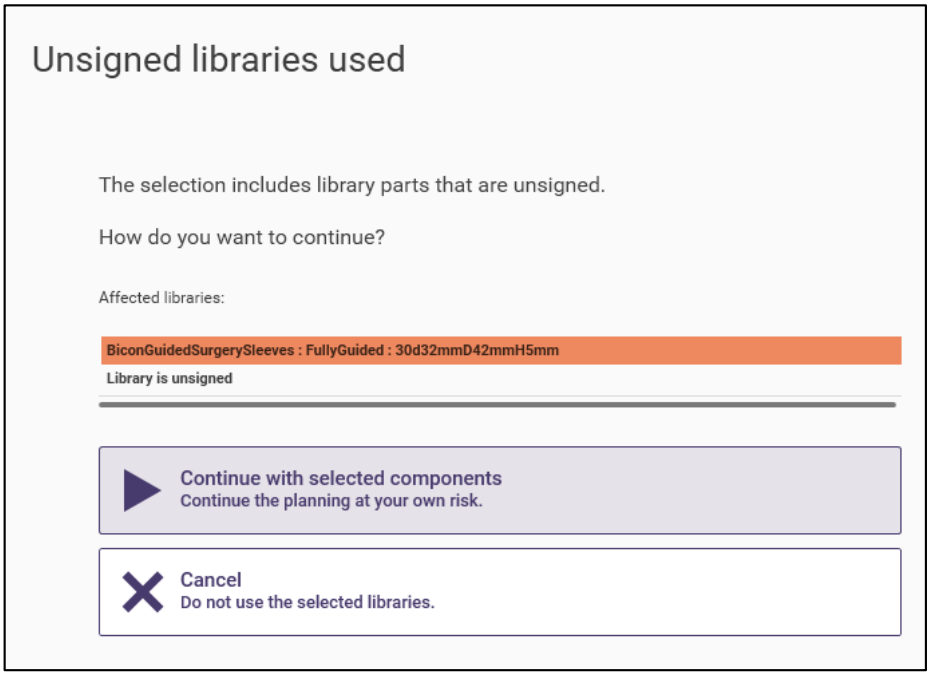


Figure 3: Unsigned message to user. Users notified by this warning should click "cancel" and not "continue".

Figure 4: Downloading an updated library

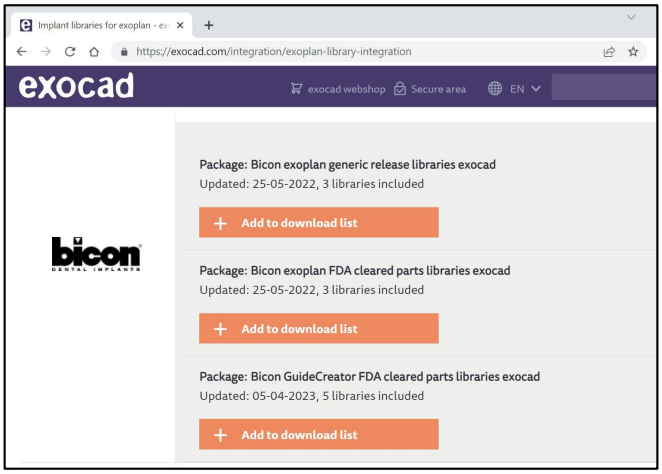


Figure 4: Downloading libraries with corrections from the exocad download portal.

Document History

Revision	Editor	Description of changes
2023-04-24	…	Initial revision