

Customer Information Letter

Subject:	Software bug
Product affected:	3Shape Implant Studio software versions from 2.17.3.0 to R1.2.15 (2.17.3.0 and R1.2.15 included)
Function affected:	Failure in collision detection logic
Date:	04-03-2022
3Shape reference:	CAS-547866-N5S8G5 and Bug BM-3203
Type of action:	Information regarding use of the software

Dear 3Shape Customer,

We are writing to inform you about an issue with Implant Studio software versions from 2.17.3.0 to R1.2.15 (2.17.3.0 and R1.2.15 included) that could affect the implant and anchor pin collision detection feature embedded in the software.

Background

During virtual implant planning it is important to ensure that anchor pins and implants placement is planned with enough distance from the patient's mandibular nerve and between other implants/anchor pins. To ensure that anchor pins and implants do not pressure on the mandibular nerve and do not collide with each other, the Implant Studio software provides a feature that detects and prevents approval of the virtual implant planning until the implant/anchor pin is more than 1.5 mm away from the marked nerves or another implant/anchor pin. However, due to a software bug this feature is not working correctly for certain Implants IDs, namely:

Implant ID	Type of implant
43000_IPGS_Nobel_Biocare_Branemark_System_Zygoma_TiUnite_RP_4.0_30.0_Implant3351.stl	Zygoma
43000_NobelBiocare_AnchorPins_15_NA_20_Pin4605.stl	Anchor Pin
51370_IPGS_JDental_Care_JDZYGOMA_4.5_4.3_45.0.stl	Zygoma
51370_IPGS_JDental_Care_JDZYGOMA_4.5_4.3_52.5.stl	Zygoma
51370_IPGS_JDental_Care_JDZYGOMA_4.5_4.3_57.5.stl	Zygoma
51370_IPGS_JDental_Care_JDZYGOMA_4.5_4.3_60.0.stl	Zygoma
59444_GM_ZIGOMATIC_4x35_Implant.stl	Zygoma
59444_Implant3669_PR-F4437.stl	Zygoma
93973a_IPGS_Nobel_Biocare_Branemark_System_Zygoma_Machined_RP_4.4_47.5.stl	Zygoma
93973a_Southern_Implants_ZYGEX_ZYGE_4.0_47.5.stl	Zygoma

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3Shape's actions

The issue has been fixed with software release R1.2.16, which has been deployed on March 4th, 2022.

Your actions

Please inform your Implant Studio software customers to:

- 1) Update to Implant Studio software version R1.2.16 as soon as possible and, in the meantime
- 2) Stop using the Implant IDs mentioned above
- 3) Always follow the instruction for use and be sure to mark the nerve correctly
- 4) Confirm finalization of the planning only when sure that all important anatomical elements have been taken into consideration

In addition, we ask you to:

- Inform the appropriate personnel working in your customer's clinic/laboratory of the contents of this letter
- Acknowledge receipt of this letter by sending an email to regulatory@3shape.com

We sincerely apologize for any inconvenience caused by this issue. If you require further clarification, please contact support@3shape.com.

Kind Regards,

Antje Marquardsen
Senior Director of Regulatory Affairs
3Shape