



Simplant®

Simplant Viewer 2.1

Instructions for Use

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 **Dentsply
Sirona**
Implants

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Introduction

Product information

Simplant Viewer is a web-based software for reviewing and approving implant plans provided by the service provider

Functionality includes:

- Review of the implant planning proposal on the (CB) CT slice images (2D) and reconstructions (3D)
- Assessment of collisions
- 3D views of implants (transparent bone), esthetics and guide design for review and evaluation of the planned implant positions
- Approving a plan for surgical guide manufacturing

Caution



US federal law restricts this product for sale by or on order of a dentist or physician. Simplant Viewer software can only be used by technicians / clinicians who have had the appropriate education and training.

User must take appropriate measures and steps to protect his computer or mobile device and any private data stored on it (like mySimplant account credentials) from harm or uncontrolled access by other people. Therefore it is strongly advised to use firewall and anti-virus software appropriate for the environment of use; and to close all open planning files when you leave your computer or mobile device.

Indications for Use

Simplant Viewer is indicated for use as medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. Simplant Viewer is intended for use as a pre-operative software program for reviewing plans for dental implant placement and surgical treatment.

Contraindications

There are no absolute contraindications for using Simplant Viewer besides the ones that are applicable for implant treatment in general.

Warnings



Always check collision warnings, when reviewing a planning proposal. When two implants are placed too close to each other or too close to a nerve, a collision warning is shown.

The 3D reconstructions and slice images (2D) in the Siplant planning proposal are the result of image processing operations such as reformatting and cropping of original CT images. The responsible clinician should always refer to the original CT images for a full radiological assessment, such as evaluating presence of tumours or infections outside the implant placement region.

While accuracy with Siplant guided surgery is higher than for non-guided surgery, linear and angular deviations are to be expected when using either non-guided or guided surgery, as linear and angular deviations have been reported in experimental and in clinical studies. Therefore, it is important to keep a safety distance also when using guided surgery.

Precautions



With Siplant Viewer planning proposals must be verified by the responsible clinician on the 3D image as well on the slice images (2D) before approval. The clinician must exercise his/her professional judgment in any decision to follow or to not follow the Siplant treatment plan. The quality of the images in the software depends on the quality of the scanned images. To obtain optimal results, please use the scan parameters specified in the Siplant scanning guidelines. For scans taken with an inter-slice distance of 1 mm the accuracy of the 3D reconstructions in the software varies between 0.1 to 0.2 mm. The use of larger inter-slice distances is not recommended. Only scanned images with orientation RAB are allowed

Adverse Reactions

There are no adverse reactions for treatment planning with Siplant Viewer software besides the ones that are applicable for implant treatment in general.

Step-by-Step Instructions

Step-by-step instructions can be found in the next chapters of this document.

Manufacturer



DENTSPLY Implants NV,
Research Campus 10,
3500 Hasselt, Belgium
Phone +32 16 84 14 00 fax +32 16 84 14 01
e-mail: Simplant-info@dentsplysirona.com
www.dentsplysirona.com

Technical support

Technical support and information on known software bugs and anomalies can be found on www.simplantacademy.org or can be requested via technical support: simplant-service@dentsplysirona.com

Electronic instructions for use can be found on www.simplantacademy.org and a paper copy can be requested via technical support: simplant-service@dentsplysirona.com

Identifications of symbols used



CE Mark



Consult Instruction for Use
(available in electronic format at website)



Manufacturer



Caution, warning



US Federal law restricts
this device for sale by or
on order of a physician
or clinician



Date of manufacture



Catalogue number




System requirements

The minimum system requirements for running Simplant Viewer:



- iPhone 5s and later versions are supported.
- iPad Air, iPad Mini 2 and later versions are supported.
- Safari for IOS 10.x and above on iPhone or iPad.

Touch interactions

Next interactions are possible on the 3D view:

- Rotating using 1 finger 
- Zooming using 2 fingers 
- Panning using 2 fingers 
- Zoom in /out to max /min zoom factor Double tap

Next interactions are possible on the 2D images:

- Panning using 1 finger 
- Zooming using 2 fingers 
- Zoom in / out to max / min zoom factor Double tap

Working with a case

Order a planning service



To order a Simplant planning proposal and surgical guide, you must register to gain access to the mySimplant order site.

Fill out the order details for your patient by going through the subsequent order pages. You will be asked to indicate implant positions and restorative positions.



Indicate the type of surgery and the Guide type and then upload the scans to the mySimplant website. You can use the Simplant Scan Finder to help you find the scan images on your computer and to upload them.

When all case data are available to Dentsply Sirona Implants, the planning proposal will be ready for review in the next 48 hours. Each planning proposal and guide design has to be reviewed by the clinician before being produced by Dentsply Sirona Implants. After order placement, you receive an e-mail notification when your proposed plan and guide design images are available for review.

- On iPhone and iPad Simplant Viewer can be used to review and approve the planning proposal.
- The Simplant Editor software is used for advanced reviewing tools and for editing the planning proposal. This is a free software for Windows and Mac desktop systems that can be downloaded directly from mySimplant.

Open a case

When the planning proposal is ready for your approval you receive an email notification. This notification will direct you to mySimplant where you can see all the case details. The planning proposal will automatically open in the Simplant Viewer software on your mobile device. The proposal must be verified on 3D images as well as on 2D slice images. After your approval, Dentsply Sirona Implants proceeds with the surgical guide manufacturing.

Review the proposed planning

Overview of the proposed planning

When viewing the planning proposal on your mobile device, the following layout shows in the software:

- The panoramic X-ray
- The list of implants and fixation screws
- The notifications
- The 3D view
- The approval section
- The order details

The panoramic X-ray

The panoramic X-ray together with the list of implants and fixation screws gives you an overview of the proposed planning. By clicking on the panoramic X-ray you can see it in full screen. We advise to use landscape mode while reviewing the panoramic X-ray.

The X-ray is a flat reconstruction of panoramic 3D image data. To assess exact implant relations or collisions, the 3D and 2D cross-sectional images should be used.

The list of implants and fixation screws

The list of implants and fixation screws contains all implants and fixation screws that are present in the planning.

Next info is shown about the implant:

- Tooth number
- Implant manufacturer
- Implant Product line
- Implant ID
- Implant diameter
- Implant length

If fixation screws are present, next info is shown:

- Tooth number
- Screw manufacturer
- Screw diameter
- Screw ID
- Screw length

Note: for the case in the screenshot no fixation screws are present.



Notifications

This section is only present if important remarks were made by the Simplant team when preparing the case. Please carefully read through these comments.

Note: for the case in the above screenshot no remarks were added by the Simplant team.

The 3D view

The 3D view immediately gives an overview of the planning proposal that was made. By clicking on the image you can see it in full screen.

Next interactions are possible on the 3D view:

- Rotating
- Zooming
- Panning
- Zoom in/out to max/min zoom factor

The approval button

2 buttons are present allowing you to approve the planning & guide; or to indicate that you want to make changes to the planning.

The order details

This section contains the details that you indicated when creating the order on mySimplant. It includes:

1. Ordered products
2. Bill & Ship
3. Treatment
4. Digital Data
5. History

Help

This directs you to the Instructions for Use.

Electronic instructions for use can be found on www.simplantacademy.org and a paper copy can be requested via technical support: simplant-service@dentsplysirona.com.

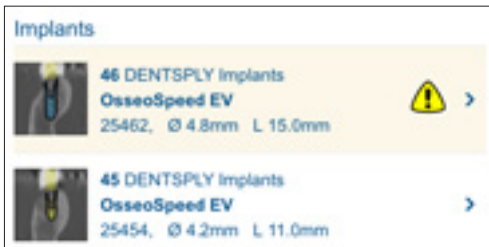
About

This directs you to the software label, allowing you to check the version of the software you are using.

Collision detection between implant-implant and implant-nerve

Safe implant placement even when close to nerve is one of the key benefits of 3D implant planning. Simplant Viewer automatically warns you when implants/fixation screws were placed too close to nerves (2 mm) or other implants/fixation screws (3 mm).

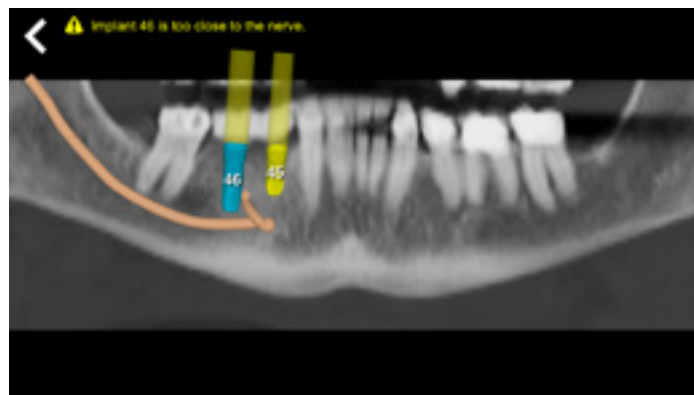
- A warning icon is shown in the list of implants/fixation screws in case the implant/fixation screw is too close to the nerve or neighbouring implant.



- The collision is part of the notifications



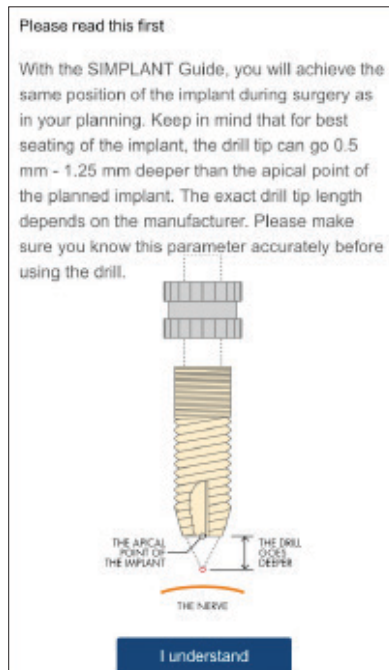
- On the 2D images it is indicated in case collisions are present.
- 2D cross-sectional image
- Panoramic X-ray



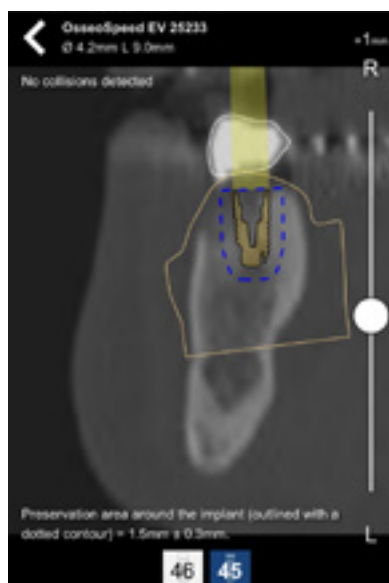
Please carefully review these collision warnings.

Review on 2D view

Verify the implants that are present in the planning proposal by checking the implants list. You can see the implant manufacturer and product line, the implant ID, diameter and length. Select an implant from the list to see the 2D cross-sectional view.



When clicking on an implant from the list the first time, you will see the 'Please read this first' information. This screen informs you that for the best seating of the implant the drill tip can go 0.5 - 1.25mm deeper than the apical point of the planned implant. Please carefully read this information and click the 'I understand' button to indicate that you understood this message.



The 2D cross-sectional images show the implant with restorative space. Besides that, depending on the type of case, the contours of the plaster cast with wax-up (like in the screenshot); or the prosthesis with wax-up are present. In case no wax-up is present, then the contour of the virtual teeth will be visible.

The preservation area, indicated with a blue dotted line around the implant, is the area of 1.5mm + - 0.3mm around the implant. This preservation area is the minimum space around the implant that needs to be clear: the nerve/sinus and other implants may not be within this preservation area; and it also allows evaluating the thickness of the bone wall.

At the top of the 2D cross-sectional image you can see the details (product line, diameter and length) of the implant that you are currently looking at. It is indicated if collisions were detected for this implant.

The scroll bar allows you to scroll through the images; and to verify if the implant is correctly positioned. While scrolling, the slice indicator (= +1mm in the screenshot) informs you about the distance from the middle of the implant till the current slice. This gives you an idea about the mesio-distal distances between objects.

Select each of the implants and verify the position on the 2D cross-sectional images. You can easily switch to the next implant by using the buttons at the bottom of the screen.

A plan for a fully edentulous patient will also contain fixation screws. Fixation screws can be reviewed in the same way as implants.

Review on 3D view

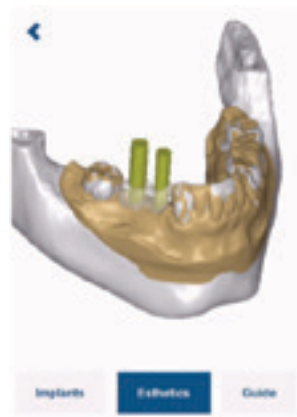


By clicking on the image you can see it in full screen.

At the bottom of the 3D you can choose different view presets: Implants, Esthetics and Simplant Guide. Your choice will define what objects are visible on the 3D view.



The 'Implants' preset allows you to clearly see how the implants and fixations screws (if present) are positioned in the bone. The implants and fixation screws are shown with their restorative space in the transparent bone. Also the nerve and neighboring teeth are visible (if present for your case).

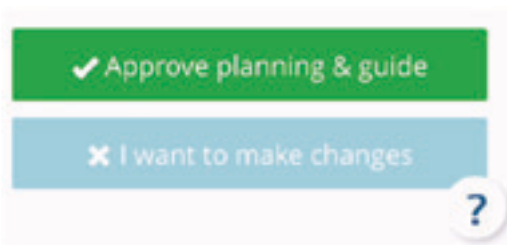


The 'Esthetics' preset allows you to clearly see how the implants and fixations screws (if present) relate to the esthetic information. The wax-up, prosthesis with soft tissue or virtual tooth is shown besides the bone or plaster cast, and the implants and fixation screws (if present) with their restorative space.

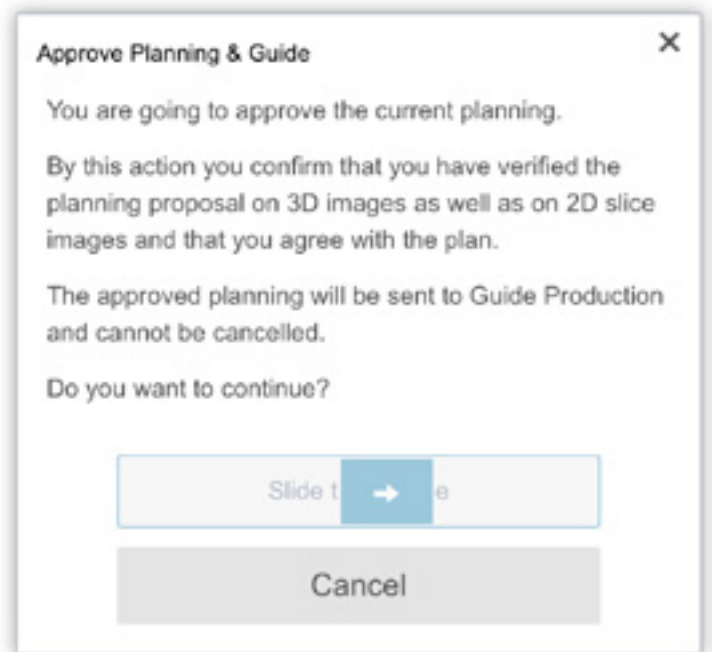


The 'Simplant Guide' preset allows you to review the Simplant Guide design. The guide design, the bone or plaster cast depending on the type of guide and the fixation screws (if present) are visible.

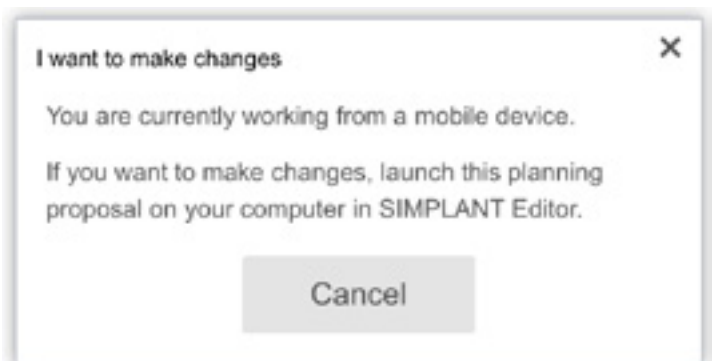
Approve the proposed planning



When clicking 'Approve Planning & Guide' you confirm that you have verified the planning proposal on 3D images as well as on 2D slice images and that you agree with the plan. Approve the planning and Guide by moving the slider to the right. After your approval, Dentsply Sirona Implants proceeds with the surgical guide manufacturing and the order will get the status 'approved' on mySimplant.



If you want to make changes or if you need more advanced reviewing tools, you need to open the case in Simplant Editor on your computer.



About Dentsply Sirona Implants

Dentsply Sirona Implants offers comprehensive solutions for all phases of implant therapy, including Ankylos®, Astra Tech Implant System® and Xive® implant lines, digital technologies, such as Atlantis® patient-specific solutions and Siplant® guided surgery, Symbios® regenerative solutions, and professional and business development programs, such as STEPPS™. Dentsply Sirona Implants creates value for dental professionals and allows for predictable and lasting implant treatment outcomes, resulting in enhanced quality of life for patients.

About Dentsply Sirona

Dentsply Sirona is the world's largest manufacturer of professional dental products and technologies, with a 130-year history of innovation and service to the dental industry and patients worldwide. Dentsply Sirona develops, manufactures, and markets a comprehensive solutions offering including dental and oral health products as well as other consumable medical devices under a strong portfolio of world class brands. As The Dental Solutions Company™, Dentsply Sirona's products provide innovative, high-quality and effective solutions to advance patient care and deliver better, safer and faster dentistry. Dentsply Sirona's global headquarters is located in York, Pennsylvania, and the international headquarters is based in Salzburg, Austria. The company's shares are listed in the United States on NASDAQ under the symbol XRAY.

Visit www.dentsplysirona.com for more information about Dentsply Sirona and its products.