



Simplant®

Simplant Editor 2.2

Instructions for Use

CE
0120

 Dentsply
Sirona
Implants

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Introduction

Product information

Simplant Editor is a software desktop application for reviewing, editing 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 and possibility for measurements
- 3D views of implants (transparent bone), esthetics and guide design for review and evaluation of the planned implant positions
- Adapting a proposed planning
- A comprehensive selection of implants for adapting the proposed planning
- 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 Editor 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 and any private data stored on his computer (like mySimplant account credentials) from harm and 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.

Indications for Use

Simplant Editor 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 Editor is intended for use as a pre-operative software program for generating and reviewing plans for dental implant placement and surgical treatment.

Contraindications

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

Warnings



Always check collision warnings, when reviewing a planning proposal and also when modifying planned implant positions. 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 Editor 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 Editor planning proposals must be verified and can be modified by the responsible clinician. The planning proposal must be verified by the responsible clinician on the 3D images as well as 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. Precise measurements should be done on the cross-sectional and axial slice images (2D). 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. As measurements of the anatomy in the software may be influenced by such factors as the initial scan settings, image artefacts and 3D reconstruction parameters, the user is recommended to take into account a safety zone of 0.2 mm relative to critical anatomical structures. Only scanned images with orientation RAB are allowed.

Adverse Reactions

There are no adverse reactions for treatment planning with Siplant Editor 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



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www.dentsplysirona.com

Technical support

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

Electronic instructions for use can be found on www.simplant.academy.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



Information is given to
the user



An action was successfully finished



A question is
asked to the user



An unexpected condition occurred

System requirements

The minimum system requirements for running Simplant Editor:

Windows:

- Operating system: Windows 7 32 bit SP1, Windows 8.1.
- Graphics card: Recent (2012 or better) Graphics card with OpenGL 3.1 support and 512 MB of video memory
- Processor: CPU Intel Core 2 Duo or AMD Athlon II with 2 or more CPU Cores
- Main memory: At least 4 GB of RAM
- Hard disk: At least 2 GB of free hard disk space
- Internet-connection
- Diagnostic monitor: at least 1440x900 pixels

Mac:

- Operating system: Mac OS X 10.10 "Yosemite"
- Graphics card: Recent (2012 or better) Graphics card with OpenGL 3.1 support and 512 MB of video memory
- Processor: CPU Intel Core 2 Duo or better with 2 or more CPU Cores
- Main memory: At least 4 GB of RAM
- Hard disk: At least 2 GB of free hard disk space
- Internet-connection
- Diagnostic monitor: at least 1440x900 pixels

The recommended system requirements for running Simplant Editor:

Windows:

- Operating system: Windows 7 64 bit SP1 , Windows 10 64 bit
- Graphics card: Recent (2012 or better) discrete AMD or NVIDIA graphics card with recent OpenGL 3.1 drivers and 1GB or above of video memory
- Processor: CPU Intel® Core i5 or AMD FX CPUs or better with 4 or more CPU Cores
- Main memory: At least 4 GB of RAM or above.
- Hard disk: At least 4 GB of free hard disk space.
- Internet connection
- Diagnostic monitor: at least 1440x900 pixels

Mac:

- Operating system: Mac OS X 10.11 "El Capitan"
- Graphics card: Recent (2012 or better) discrete NVIDIA graphics card with recent OpenGL 3.1 drivers and 1GB or above of video memory
- Processor: CPU Intel® Core i5 or better with 4 or more CPU Cores
- Main memory: At least 4 GB of RAM or above.
- Hard disk: At least 4 GB of free hard disk space.
- Internet connection
- Diagnostic monitor: at least 1440x900 pixels

Installation

Please make sure that you have administrator rights. Run the Simplant Editor setup file. It can be downloaded from the Simplant Help page on mySimplant.

During the installation process the following dialogs are shown:

Installation on Windows



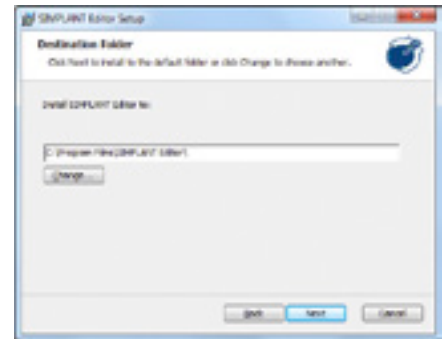
Step 1:

Click 'next' to start the installation. Depending on your operating system settings you might be asked to allow the program to make changes to your computer. Click 'yes'.



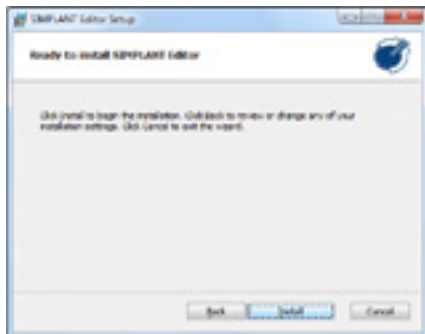
Step 2:

Read the license agreement and select 'I accept the terms in the License Agreement'. Click 'next' to proceed.



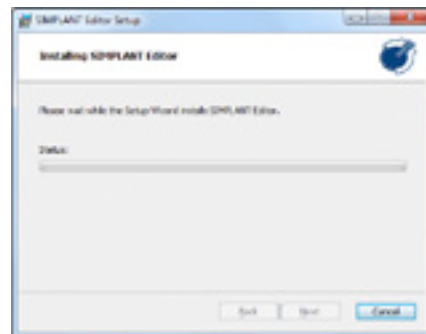
Step 3:

Simplant Editor is installed in a default folder 'Simplant Editor'. If you prefer another directory, use 'change' to select another directory. Click 'next' to proceed.



Step 4:

Click 'install' to begin the installation process.



Step 5:

Wait until the progress bar is finished.



Step 6:

Installation is complete. Click 'finish'. The shortcut of Simplant Editor is created on the desktop and in the Start Menu.

Installation on Mac



Step 1:
Click 'continue' to start the installation.



Step 2:
Read the license agreement and click 'continue' to proceed with the installation.



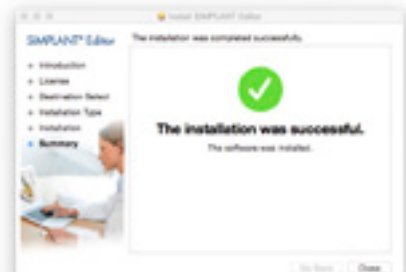
Step 3:
Click 'agree' to continue.



Step 4:
Click install to install Simplant Editor in a default folder 'Simplant Editor'. If you prefer another directory, use 'change install location' to select another directory.



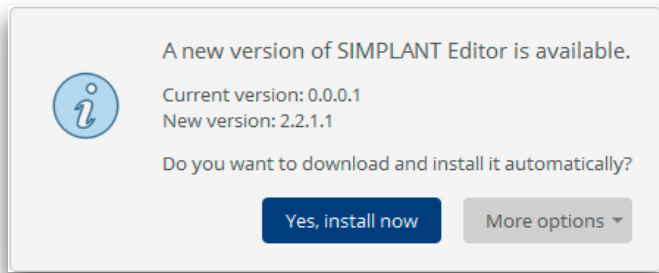
Step 5:
Wait until the progress bar is finished.



Step 6:
Installation is complete. Click 'close'. The Editor is added to list of installed applications.

Update Simplant Editor

If a new version of Simplant Editor is available, you will get a notification when opening a planning.

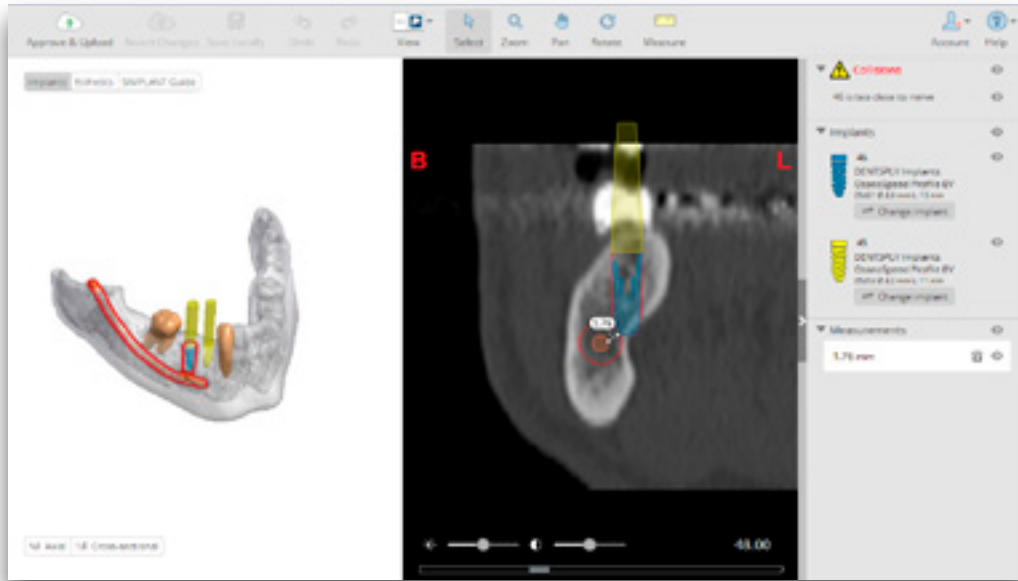


You can:

- Install now. The current project will be closed and the new version with the latest updates will be installed automatically.
- Via "More options" and "Download and install manually" you can download the latest installer manually and install it at any convenient time. In the meantime you can still work with the current version.
- Via "More options" and "Remind me later" you can postpone the update of Simplant Editor. In this case you will still use the current version of Simplant Editor, and the new features will not be available. You will be reminded next time when you open a plan in Simplant Editor.

Getting started

After opening a planing in Simplant Editor, the following layout shows in the software:



At the top:

- the toolbar, with tools to manipulate the active view

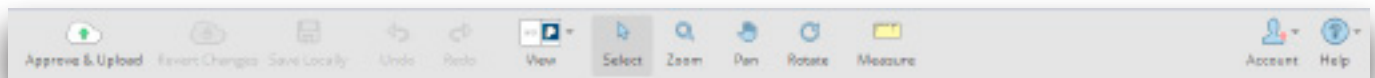
On the right:

- the task bar, with an overview of all collisions, implants and measurements

In the center:

- the active 3D view and 2D view

Toolbar



Approve & Upload: approve your planning by uploading the planning to mySimplant. After your approval, Dentsply Sirona Implants proceeds with the surgical guide manufacturing.



Revert changes: reopen the initial planning proposal from mySimplant. Changes that you made to the file (and saved locally) will be overwritten by the initial plan.



Save locally: save your file locally after applying changes.



Undo: undo your last action.



Redo: redo your last action.



View: choose an option from this dropdown to select the preferred view (3D view and cross-sectional images, 3D view and axial images, 3D view in full screen, axial images in full screen, cross-sectional images in full screen or panoramic X-ray view).



Select: select an object (for instance an implant, a measurement).



Zoom: zoom and unzoom the images and 3D objects using the left mouse button and dragging the mouse up and down.



Pan: translate the images or a 3D object using left mouse button.



Rotate: rotate the 3D objects using left mouse button.



Measure: create a measurement on the 3D or 2D images.



Account: the icon indicates if you are connected to mySimplant (green circle) or if you are logged off (red circle). Via the sub menu you can log in/out; and you can change the language of the application. Changes will take effect after restarting the application.

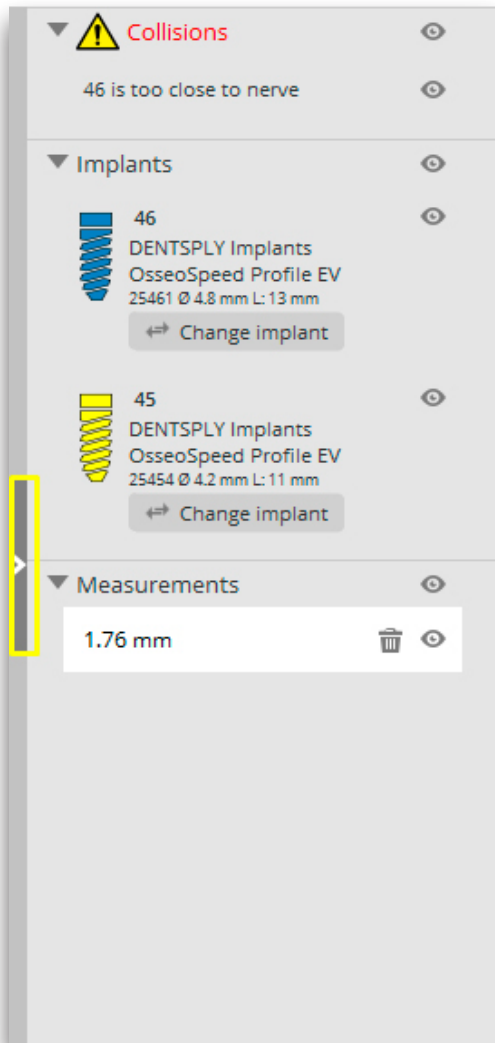


Help: The Help menu directs you to the Instructions for Use, to Technical support, and allows you to check the version of the software you are working with.

This Instruction for Use as well as additional electronic documentation can be found on **www.simplantacademy.org**. A paper copy of this Instructions for Use can be requested via technical support: **simplant-service@dentsplysirona.com**

Task bar

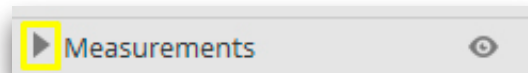
The task bar on the right includes three sections: **Collisions, Implants and Measurements.**




Collisions: This section shows you a list of all collisions currently present in the planning.


Implants: This section shows you a list of all implants that are currently present in the planning.

Measurements: This section shows you a list of all measurements that are currently present in the planning.



The task bar can be expanded/closed by clicking the arrow on the left side of the panel.

By clicking the  icon you can hide each of the objects; then this object will no longer be visible on the 2D and 3D images. By clicking the icon again the object becomes visible again.

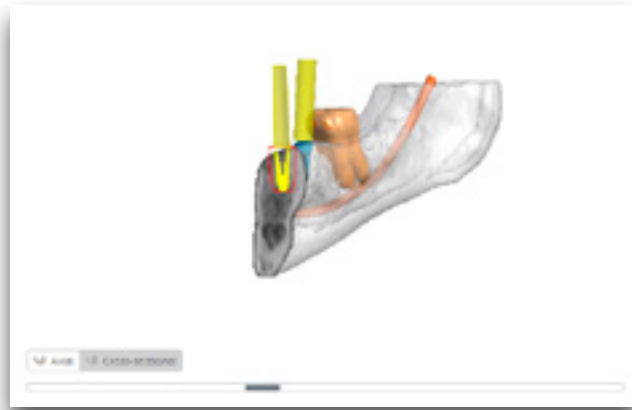
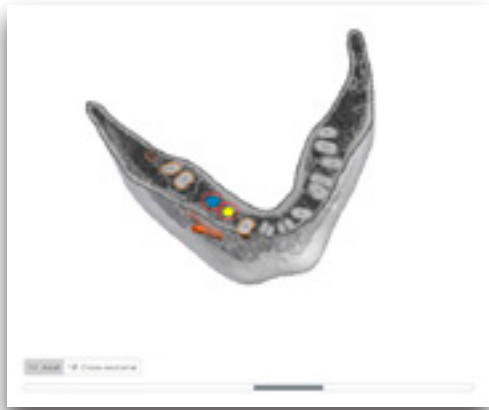
The measurements can be deleted from the planning file by clicking the  icon.

Each of the sections can be hidden/shown separately by clicking the arrow next to the titles **Collisions, Implants, Measurements.**

3D view

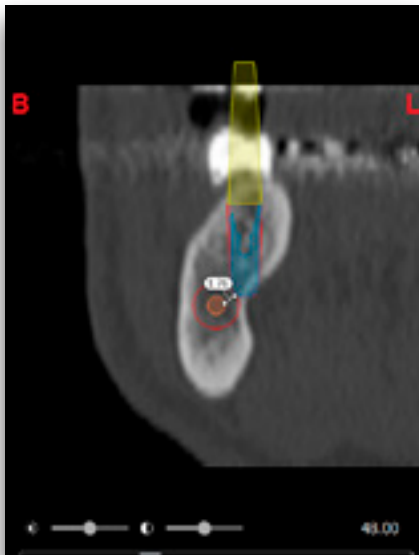


At the bottom of the 3D view you can activate the **axial or cross-sectional** clipping by clicking the **axial or cross-sectional** button. A slider bar becomes available at the bottom of the 3D view allowing you to scroll through the **axial or cross-sectional** clipped slices.



2D view

You can scroll through the 2D images by using the scroll wheel or by using the scrollbar that is shown at the bottom of the 2D images.



B and L marker: these markers indicate the buccal and lingual side of the jaw (only available on the cross-sectional image)

R and L marker: these markers indicate the right and left side of the jaw (only available on the axial image and panoramic X-ray view)

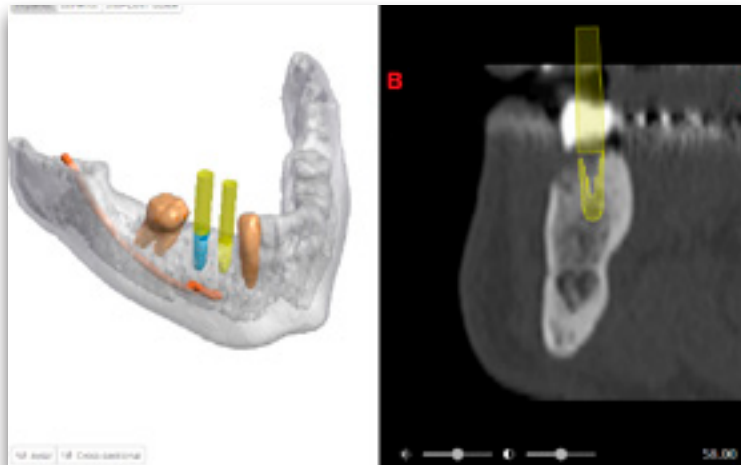
The brightness slider: this slider allows you to change the brightness of the images.

The contrast slider: this slider allows you to change the contrast of the images.

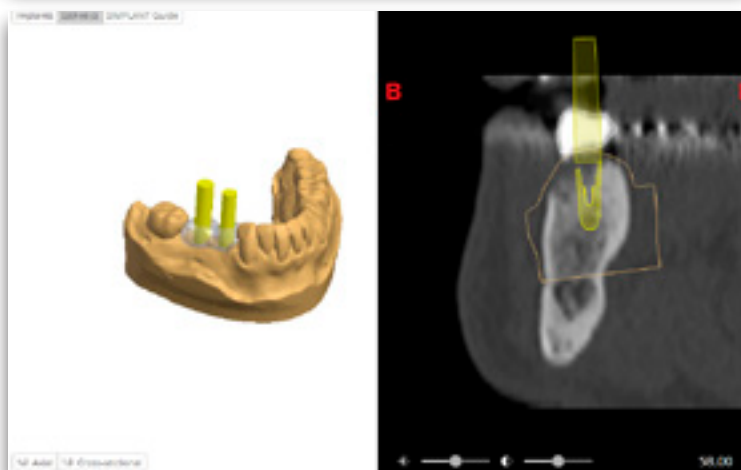
Object visibility

Implants Esthetics SIMPLANT Guide

At the top of the 3D or 2D view you can choose different view presets: **Implants, Esthetics and Simplant Guide.** Your choice will define what objects are visible on the 3D view and which contours are visible 2x on the 2D cross-sectional and axial images.



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, implants and fixation screws (if present) are visible.

Shortcuts

Icon	Name	Tool activation with mouse	Tool activation with keyboard (Windows)	Tool activation with keyboard (OS X)
	Select (implant or measurement)	LEFT mouse button on object	-	
	Pan	SHIFT + RIGHT mouse button (on 2D or 3D view)	CTRL+ ARROW keys (on 3D view)	CMD + ARROW keys
	Rotate	RIGHT mouse button (on 3D view)	ARROW keys (on 3D view)	ARROW keys (on 3D view)
	Zoom in/out	1. CTRL + RIGHT mouse button (on 2D or 3D view) + Move mouse up/down 2. Mouse wheel up/down (on 3D view, not clipping)	CTRL + "+" CTRL + "-"	CMD + "+" CMD + "-"
	Delete selected measurement	-	Delete	fn + Backspace
	Scroll images forward/back (2D view only)	Mouse wheel up/down	-	-
	Scroll clipping plane forward/back (3D view only)	Mouse wheel up/down	-	-
	Undo	-	CTRL + Z	CMD + Z
	Redo	-	CTRL+ Y	CMD +SHIFT+Z
	Brightness	RIGHT mouse button (on 2D view) + Move mouse horizontally	-	-
	Contrast	RIGHT mouse button (on 2D view) + Move mouse vertically	-	-
	Save planning locally	-	CTRL + S	CMD + S
	Exit	-	CTRL + Q	CMD + Q

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 and/or edited 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 needed for editing the planning proposal. This is free software that can be downloaded directly from mySimplant.

If you already have the Simplant Editor software, you can simply open a planning proposal by clicking "Open in Editor" on mySimplant. The planning proposal will automatically open in the Simplant Editor software on your computer. 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.

Open a case

From mySimplant

After order placement, you receive an e-mail notification when your planning proposal is available for review. This notification will direct you to the mySimplant order site where you can choose 'Open in Editor'. The Simplant Editor planning file is downloaded and opened automatically in the Simplant Editor software. Login using your mySimplant username and password and you can now review the implant plan.

When you open a plan via mySimplant the software checks if for this case a modified plan was saved locally on your computer. If so, then this modified plan is opened in Simplant Editor and you can proceed with modifying and approving this plan.

Locally

When starting Simplant Editor directly from your computer next page is shown:



It allows you to:

- Open mySimplant.com and select the case from the order list.
- Open an archived planning. The planning files for your orders are only kept for 6 months on mySimplant. By archiving the planning files on your computer, you can still access them after this period. Alternatively, archived files can also be opened by manually browsing to them.
- Login to Simplant Editor using your mySimplant username and password

Once you are logged in you can also open a recent planning for which you saved some changes locally on your computer. You can then proceed with modifying and approving the modified plan.



Save a case

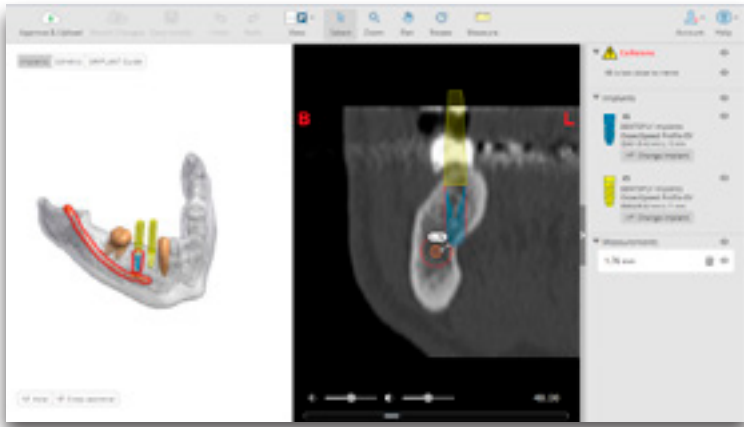
You can save a plan with your changes locally via the “Save Locally” button in Editor. You can then later on proceed with modifying and approving the modified plan.

Close a case

By closing Simplant Editor you can also close the case without saving the work.

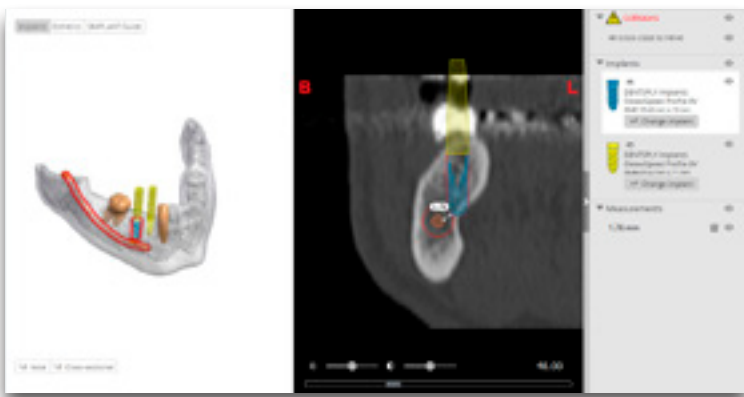
Review the proposed plan

The default view after opening a case in Siplant Editor is the 3D view on the left and the cross-sectional images on the right. By default the 'Implants' preset is activated. The 3D view shows the transparent bone, the implants and fixation screws with the restorative space, the nerve, and the real teeth. When scrolling through the 2D slide images a reference plane is visible on the 3D view clearly indicating the slice you are currently looking at.

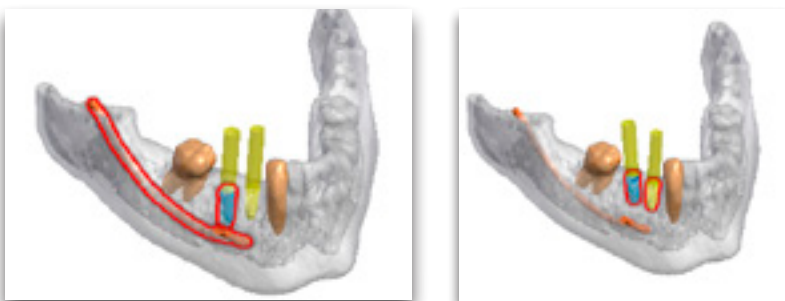


Collision detection between implant-implant and implant-nerve

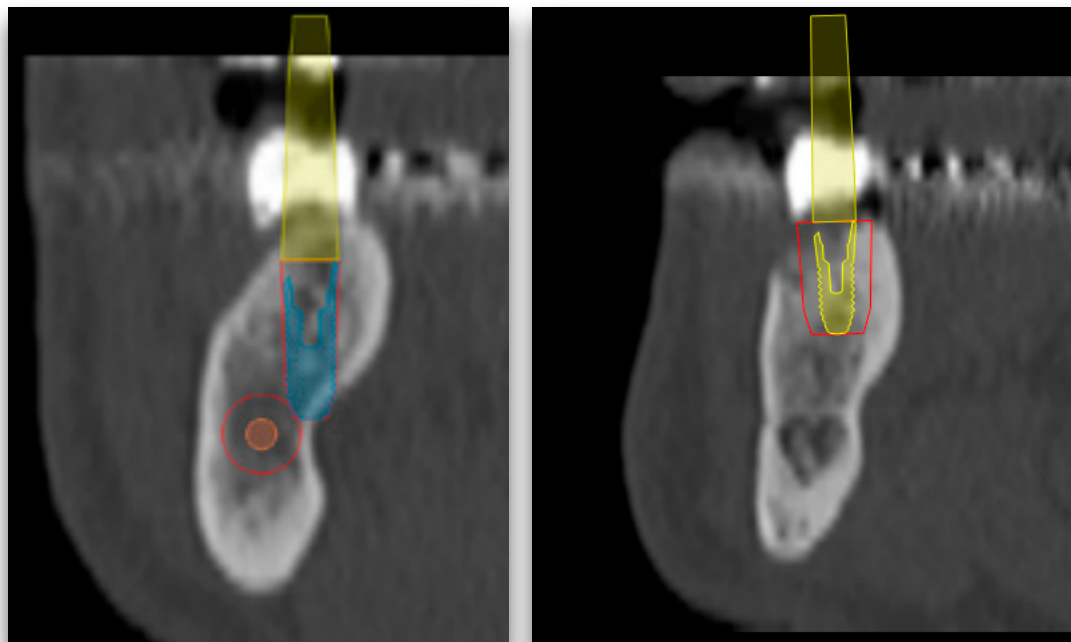
Safe implant placement even when close to the nerve is one of the key benefits of 3D implant planning. Siplant Editor automatically warns you when you place implants too close to nerves (2 mm) or to other implants (3 mm). Therefore it is very important to check the full list of collisions at the task bar on the right.



The 3D view shows the red contours of colliding objects. The left image shows an implant colliding with the nerve. The right image shows 2 colliding implants.



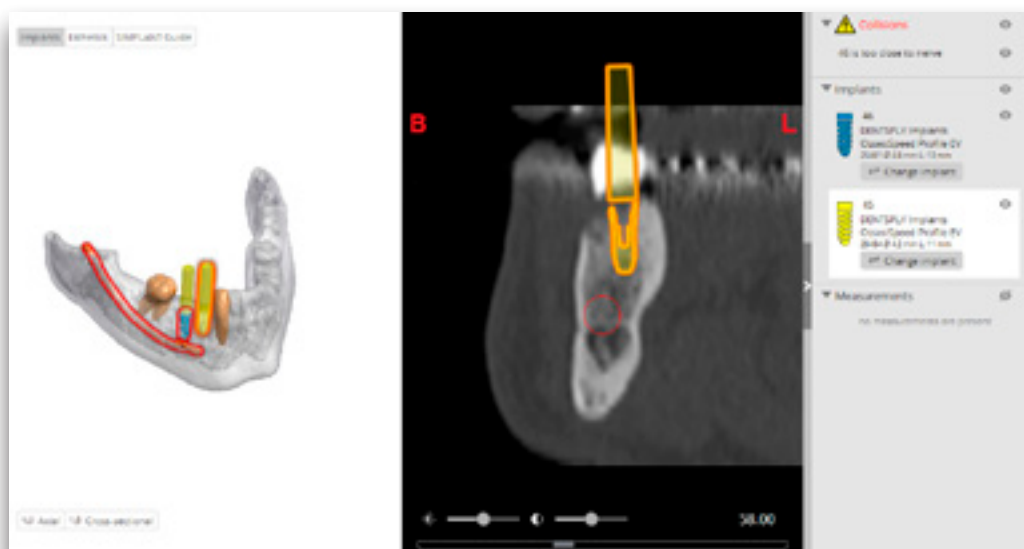
The 2D view shows the safety zones of the colliding objects. The left image shows the safety zone around the nerve when an implant is colliding with the nerve. The second image shows the safety zone around the implant when 2 implants are colliding.'



Implants review

Verify the implants that are present in the planning proposal by checking the implants section in the task bar at the right. You can see the implant manufacturer and product line, the implant ID, diameter and length.

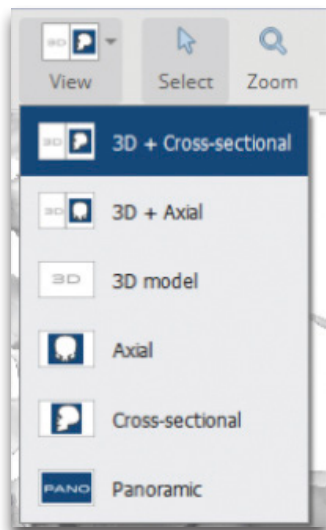
If you click on an implant in any of the views, the corresponding information gets highlighted in the Implants list. You can also select implants via the Implants list. Clicking an implant in the list will locate that implant in the 3D view, 2D views and Panoramic X-ray view.



Check the 'Modify a proposed plan' section if you want to change the implant position or if you want to change the implant diameter, length.

Review on the 2D views

Use the 2D views (cross-sectional and axial) to analyze the bone quality. Use the mouse wheel to scroll through the 2D slice images.



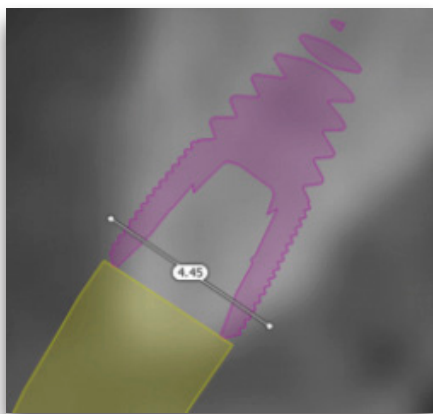
Using the View dropdown from the toolbar, you can choose to combine the 3D view with the cross-sectional or the axial images; or you can also visualize the cross-sectional, axial images or panoramic images in full screen.

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

Now select each of the implants in the list on the right and verify the position both on the 3D and 2D images.

Measure distance

By measuring the distance at a planned implant position, you can find out which implant diameter and length is suitable for the patient. Click on the “Measure” button and click on the left mouse button to position the first point. A measurement will be shown together with its length (expressed in mm). Click again to fix the other end of the measurement. Measuring accuracy for point-to-point distances: +/- 0,1mm.



You can adjust the measurement by dragging either end to a new location. Measurements can be made on the 3D image and on the 2D cross-sectional and axial images.



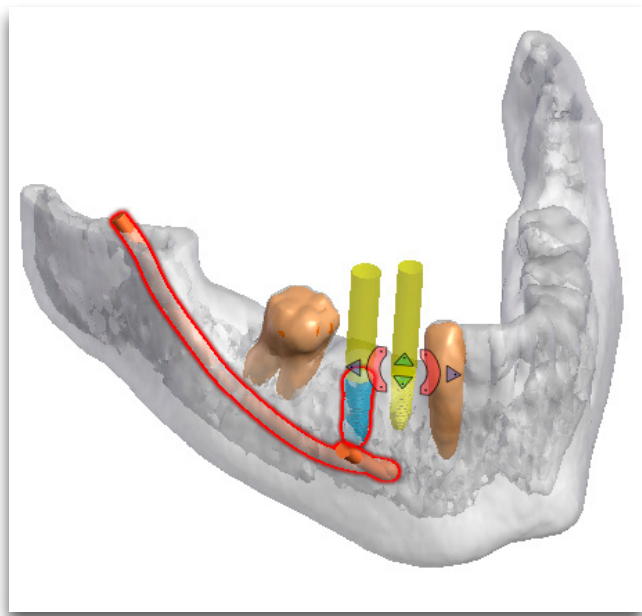
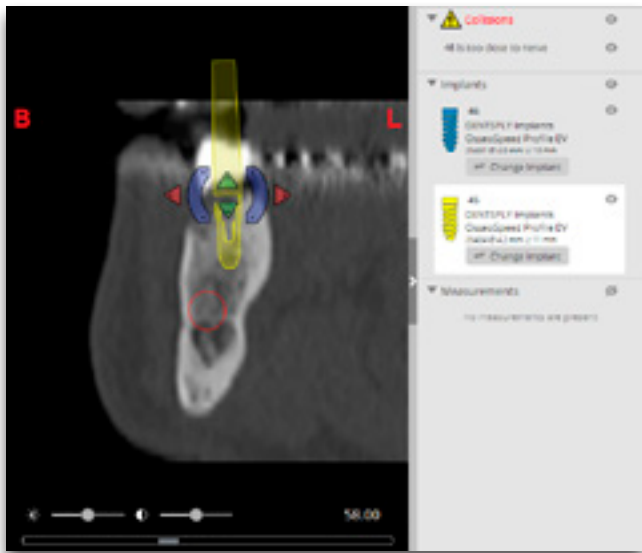
Precise measurements should be done on the slice images (2D). The quality of the images in the software depends on the quality of the scanned images. To obtain optimal results, please use the scan parameters specified in the Simplant scanning guidelines or as specified by the manufacturer of the scanning unit. 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.

As measurements of the anatomy in the software may be influenced by such factors as the initial scan settings, image artefacts and 3D reconstruction parameters, the user is recommended to take into account a safety zone of 0.2 mm relative to critical anatomical structures.

Modify the proposed plan

Moving implants

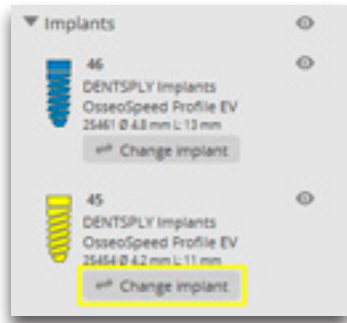
You can move the implant on any 3D or 2D view except the Panoramic X-ray view. It is advised to always check the implant position on the 2D cross-sectional and axial views. Select the implant which you want to move by selecting the implant on the view or in the task bar on the right. Then use the arrow and rotation controls to change the implant position.



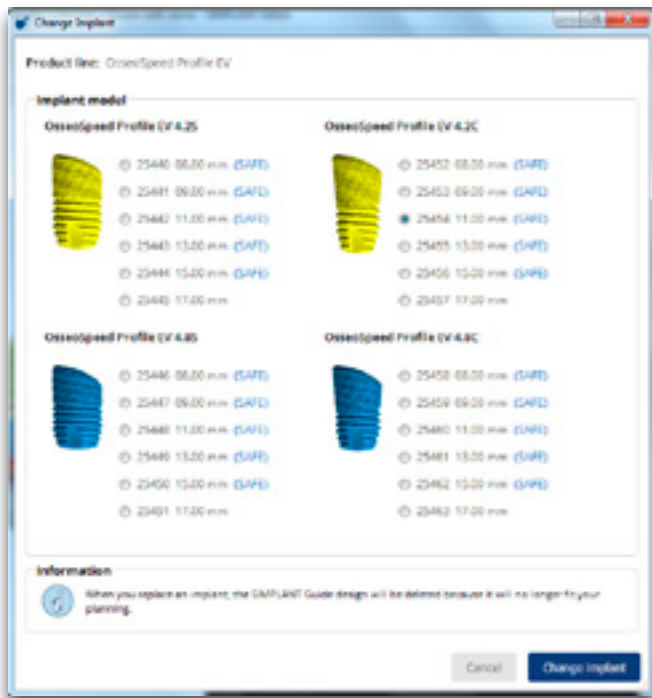
A plan for a fully edentulous patient will also contain fixation screws. Fixation screws can be moved in the same way as implants. As soon as you move an implant in the planning proposal, the Simplant Guide object will be removed from your plan. When approving a modified implant plan, a new Simplant Guide design will be created before manufacturing.

Changing the implant diameter, length

To change an implant from the planning proposal click on the 'Change implant' button in the task bar on the right.



The 'Change implant' dialog shows you the currently planned implant and other possible implant choices from the same product line.



In the 'change implant' dialog it is indicated which implants are compatible with the SAFE Guide. As soon as you change an implant in the planning proposal, the Simplant Guide object will be removed from your plan.

When you change an implant to an implant that is not compatible with the SAFE Guide you ordered, you will be informed that this implant is intended for use with a Simplant Pilot Guide. When approving such a modified implant plan, a new Simplant Guide design (Pilot Guide) will be created before manufacturing.

Approve a Simplant plan

After reviewing the planning proposal and making changes to the planning, click the 'Approve & Upload' button. By clicking 'Approve & Upload' you confirm that you have verified the modified treatment plan on 3D images as well as on 2D slice images and that you agree with the plan.

After your approval, Dentsply Sirona Implants proceeds with the surgical guide manufacturing.

Please do not close the application before the upload is finished.

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.