

SIMPLANT®

SIMPLANT Editor

Instructions for Use



CE
0120

DENTSPLY
IMPLANTS

Contents

Introduction	3
Product information	3
Caution	3
Indications for use	3
Contraindications	3
Warnings	3
Precautions	4
Adverse reactions	4
Step-by-Step Instructions	4
Manufacturer	5
Identifications and symbols used	5
 Order a planning service	 6
 System requirements	 7
 Installation	 8
 Getting started	 9
Toolbar	10
Task bar	11
3D view	12
2D view	12
Object visibility	13
Shortcut keys	14
 Working with a case	 15
Opening, saving and closing a case	15
 Review the proposed plan	 15
Collision detection between implant-implant and implant-nerve	16
Implants review	17
Review on the 2D views	18
Measure distance	18
 Modify the proposed plan	 19
Moving implants	19
Changing the implant diameter, length	20
 Approve a SIMPLANT plan	 21

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. These are intended for use as pre-operative software programs for simulating/evaluating dental implant placement and surgical treatment options.

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 SIMPLANT 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.

Accuracy with SIMPLANT guided surgery is clearly higher than for non-guided surgery. However, linear and angular deviations are to be expected also when applying guided surgery, which is reported in experimental as well as clinical studies, thus, underlining the importance of keeping a safety distance also when using guided surgery.

Precautions



With SIMPLANT 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 SIMPLANT treatment plan. 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. 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.

Adverse Reactions

There are no adverse reactions for treatment planning with SIMPLANT 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



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@dentsply.com
www.dentsplyimplants.com

Identifications of symbols used



CE Mark



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



Manufacturer



Caution, warning

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.

The screenshot shows the 'Patient' and 'Treatment' sections of the mySIMPLANT website. The 'Patient' section includes fields for Name, Birth date (Year, Month, Day), and Gender (Male, Female). The 'Treatment' section includes fields for Clinical indication, Implants, Implant positions (with a diagram of a dental arch), Restorative positions (with a diagram of a dental arch), and Teeth to be extracted (with a diagram of a dental arch). There are also dropdown menus for 'Partially edentulous', 'Select a manufacturer', 'Select a product line', 'Select an option', and 'Tooth numbering'.

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 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 in SIMPLANT Editor before being produced by DENTSPLY Implants.

After order placement, you receive an e-mail notification when your proposed plan and guide design images are available for review. The SIMPLANT Editor software is needed for reviewing 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". The planning proposal will automatically open in the SIMPLANT Editor software on your computer. Login using your mySIMPLANT username and password and you can now review the implant plan. The proposal must be verified on 3D images as well as on 2D slice images.

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

The screenshot shows the 'Surgery' and 'Scans' sections of the mySIMPLANT website. The 'Surgery' section includes a 'Surgery type' dropdown menu and a 'Guide type' dropdown menu. Below these are four diagrams illustrating different surgical guide types: 'Tooth supported guide', 'Bone supported guide, then tooth support needed', 'SIMPLANT SAFE Guide', and 'SIMPLANT Max Guide with computerized system'. The 'Scans' section includes a note about the need for digital files and three diagrams illustrating different scan types: 'CT or Cone Beam scan', 'Stone model optical scan or intra oral scan', and 'Stone model to set up optical scan (optional)'. Each diagram has a corresponding 'Upload' button.

System requirements

The minimum system requirements for running SIMPLANT Editor:

- Operating system:
 - Windows 7 Home/Professional SP1 32 bit and 64 bit
 - Windows 8 Home/Professional 32 bit and 64 bit
 - Windows 8.1 Home/Professional 32 bit and 64 bit
 - Windows 10 Home/Professional 64 bit
- 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 2 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:

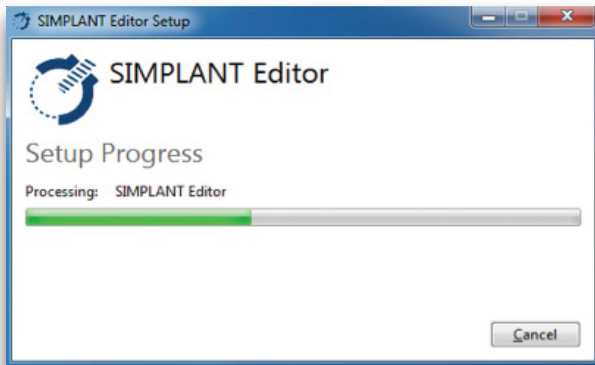
- Operating system:
 - Windows 7 Home/Professional 64 bit SP1
 - Windows 8 Home/Professional 64 bit
 - Windows 8.1 Home/Professional 64 bit
 - Windows 10 Home/Professional 64 bit
- Graphics card: Recent (2012 or better) discrete ATI or NVIDIA graphics card with recent OpenGL 3.1 drivers and 1GB or above of video memory
- Processor: CPU Intel® Core i5 or AMD Phenom II or AMD FX CPUs or above 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

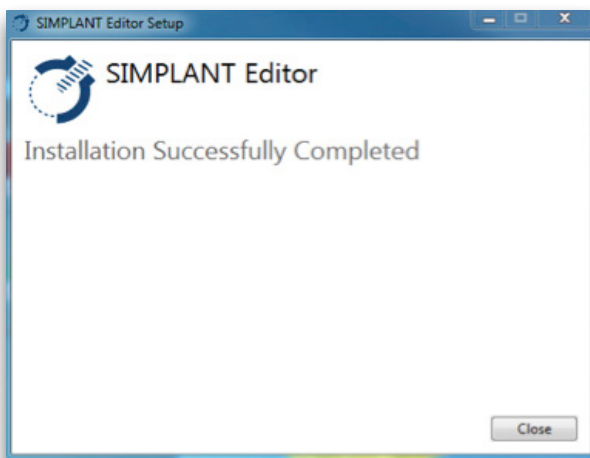
1. You need administrator rights to install SIMPLANT Editor. Run the SIMPLANT Editor setup file. It can be downloaded from the SIMPLANT Help page on mySIMPLANT.



2. Read the license agreement and select 'I agree with the terms and conditions'. Click on the "Install" button to start the installation.



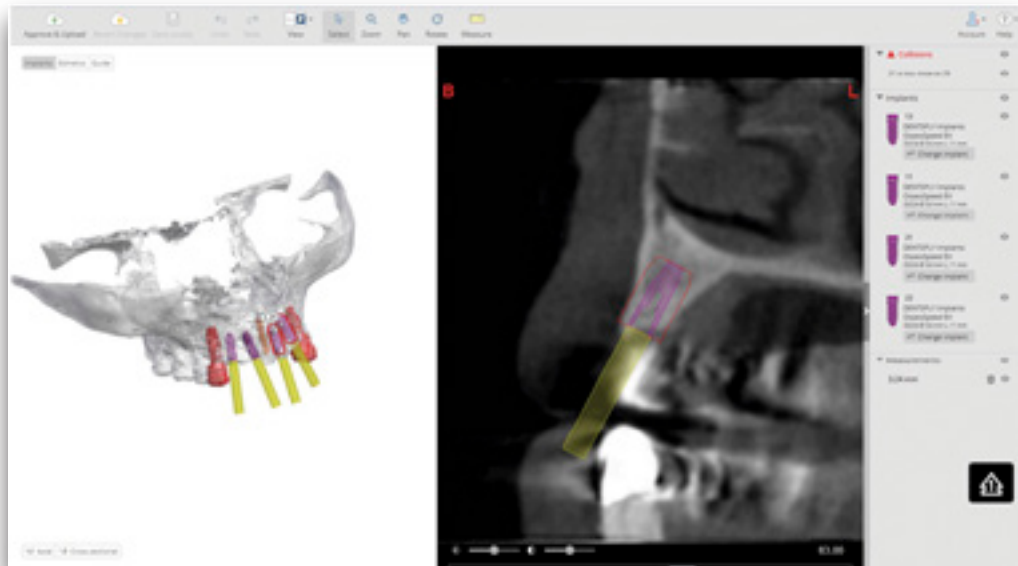
3. Wait until the progress bar is finished. You will be asked to allow the program to make changes to your computer. Click 'yes'.



4. Installation is complete. The shortcut of SIMPLANT Editor is created on the desktop and in the Start Menu.

Getting started

After opening a case in SIMPLANT Editor, the following layout shows in the software:



At the top:

- the toolbar, with tools to manipulate the active view

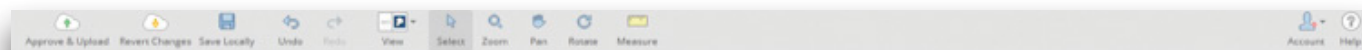
On the right:

- 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, DENTSP-
LY 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.



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).



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 working offline (red circle).

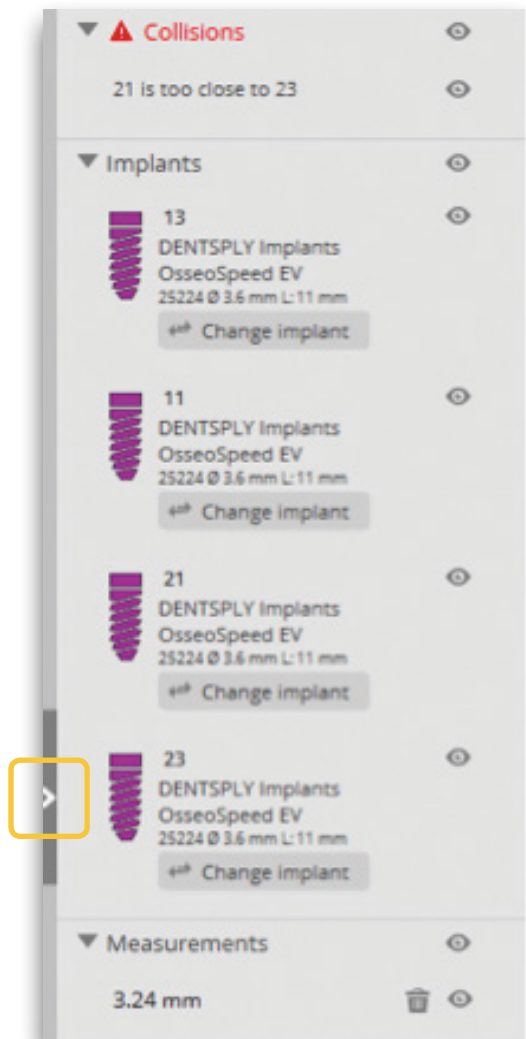


Help: The Help menu in SIMPLANT Editor directs you to the instructions for use, and allows you to check the software
version that you are working with.

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@dentsply.com

Task bar

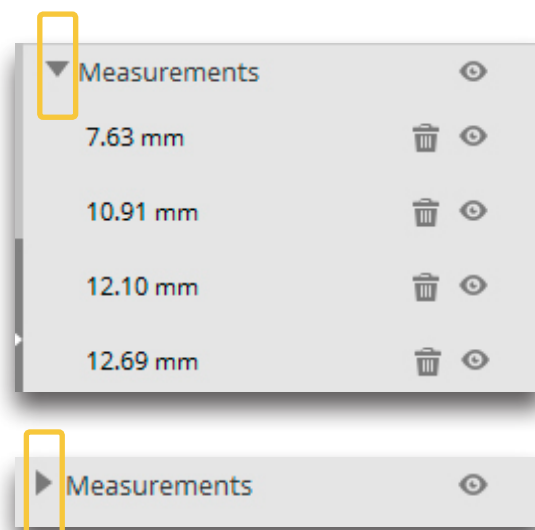
The task bar on the right includes three sections: **Collisions**, **Implants** and **Measurements**.




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 these 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.

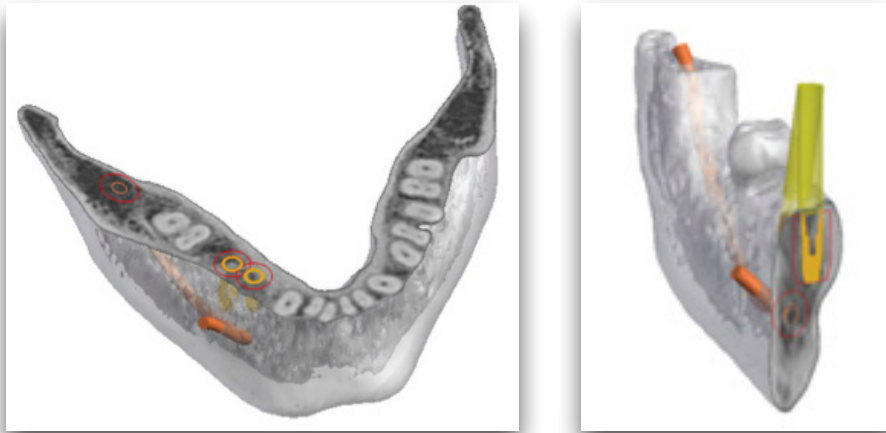
The measurements can be deleted from the planning file by clicking the  icon.

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

3D view

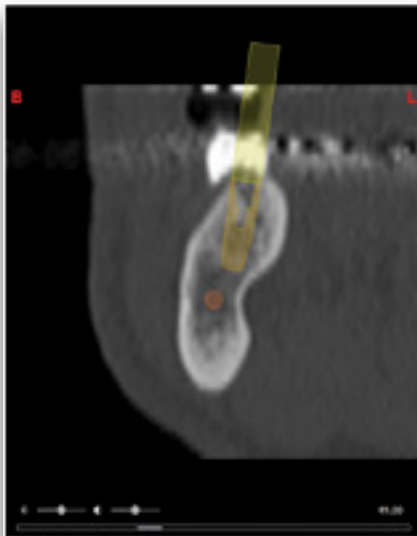


At the bottom of the 3D view you can activate the **axial** or **cross-sectional** clipping by clicking the axial or cross-sectional button. A slider bar becomes available at the bottom of the 3D view allowing you to scroll through the **axial** or **cross-sectional** clipped slices.



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)

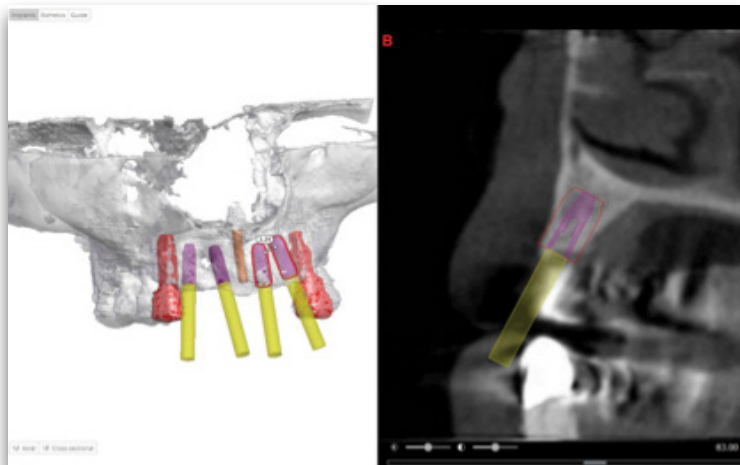
The brightness slider: this slider allows you to change the brightness of the images.

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

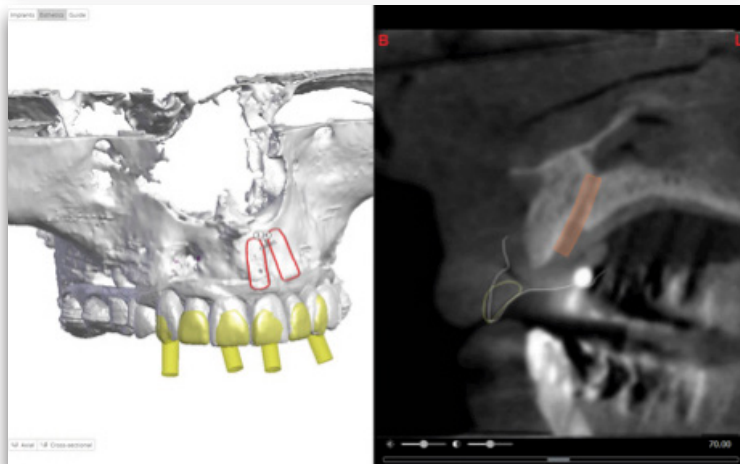
Object visibility

Implants Esthetics Guide

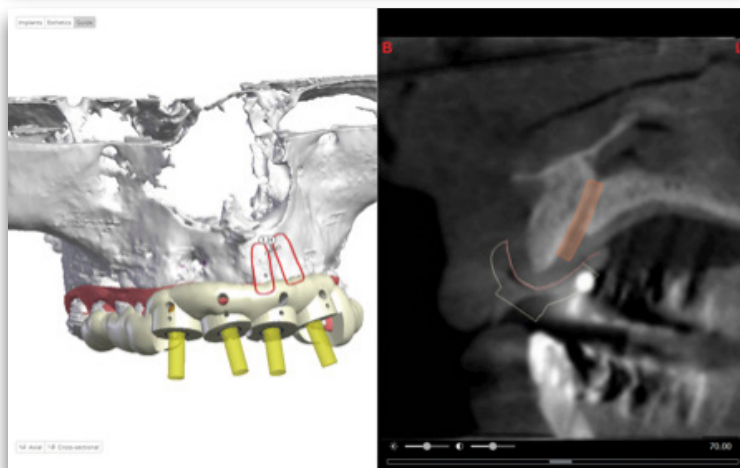
At the top of the 3D or 2D view you can choose different view presets: **Implants, Esthetics and Guide**. Your choice will define what objects are visible on the 3D view and which contours are visible on the 2D cross-sectional and axial images.



When selecting **Implants** the bone is transparent allowing you to clearly see the implants and fixation screws (if present). Also the nerve and real teeth are visible (if present for your case).









When selecting **Esthetics** the esthetic information (wax-up, virtual teeth or prosthesis) is shown besides the bone, nerve, implants and fixation screws (if present).






When selecting **'Guide'** the stone model and SIMPLANT Guide are visible besides the bone, nerve, implants and fixation screws (if present).

Shortcuts for the Left toolbar – Keyboard and Mouse

	Select:	LEFT mouse button (on implant)
	Pan:	SHIFT + RIGHT mouse button (on 2D or 3D view)
	Rotate:	RIGHT mouse button (on 3D view)
	Zoom:	CTRL + CMD + RIGHT mouse button (on 2D or 3D view)
	Brightness:	RIGHT mouse button (on 2D view) Move mouse horizontally
	Contrast:	RIGHT mouse button (on 2D view) Move mouse vertically

Shortcuts for the Left toolbar – Keyboard only

	Pan:	CTRL + CMD + arrow keys (on 2D or 3D view)
	Rotate:	Arrow keys (on 3D view)
	View Presets:	Spacebar

Shortcuts for file management – Keyboard only

Open Case	CTRL + CMD + O
Save Case	CTRL + CMD + S
Save Case As	CTRL + CMD + Shift + S
Close Case	CTRL + CMD + W

Common shortcuts – Keyboard only

Undo	CTRL + CMD + Z
Exit	CTRL + CMD + Q

Working with a case

Opening, saving and closing a case

When choosing **Open in Editor** on mySIMPLANT, the SIMPLANT planning file will download and open automatically in the SIMPLANT Editor software. Login using your mySIMPLANT username and password and you can now review the implant plan.

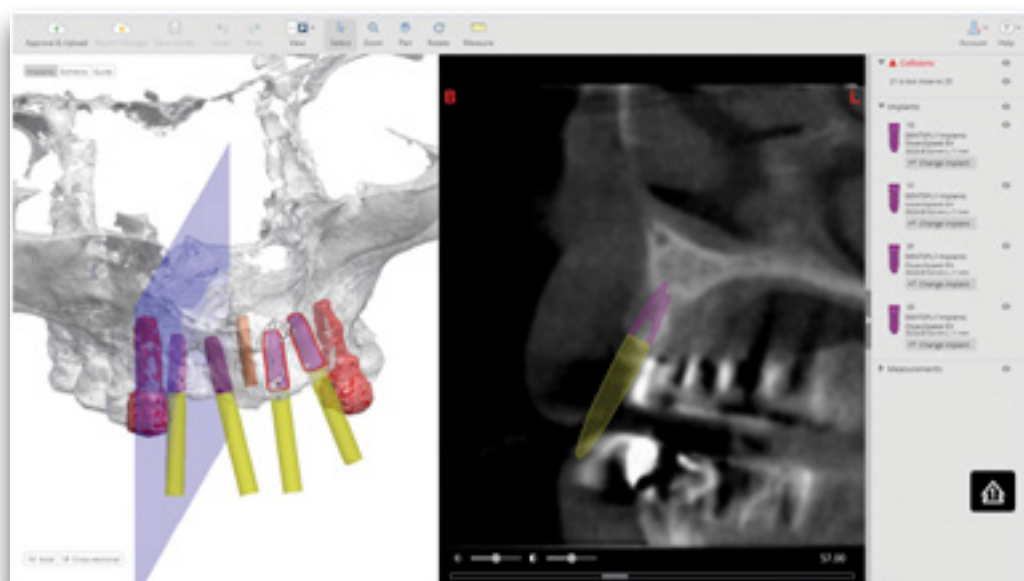
You can **save** a plan anytime **locally**. By opening SIMPLANT Editor directly from your computer this locally saved file will open automatically in the SIMPLANT Editor software. You can then proceed with modifying the proposed plan and approving the modified plan.

By closing the SIMPLANT Editor application you can also close the case without saving your work.

Review the proposed plan

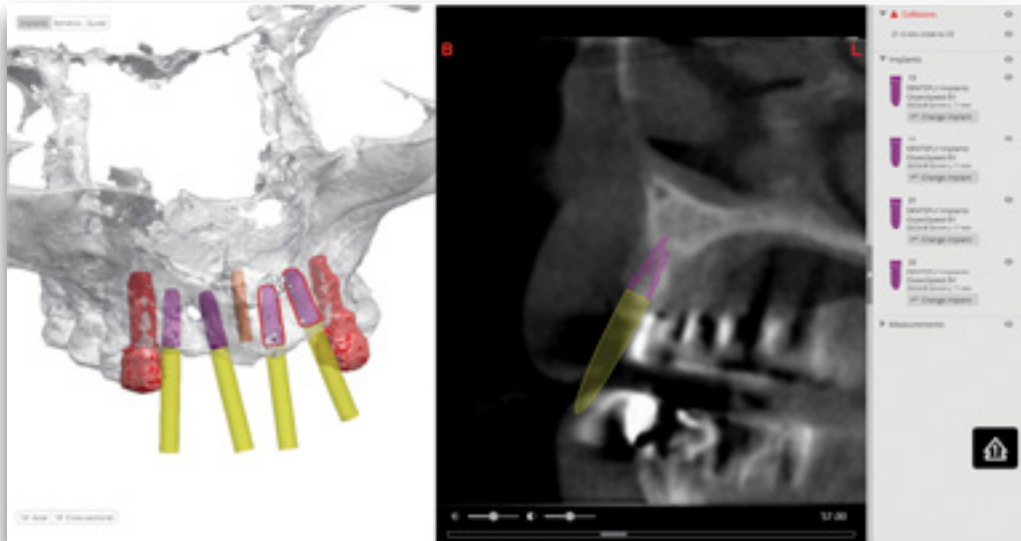
The default view after opening a case in SIMPLANT Editor is the 3D view on the left and the cross-sectional images on the right. The 3D view shows the transparent bone, the implants and fixation screws with the restorative space, the nerve, and the real teeth.

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.

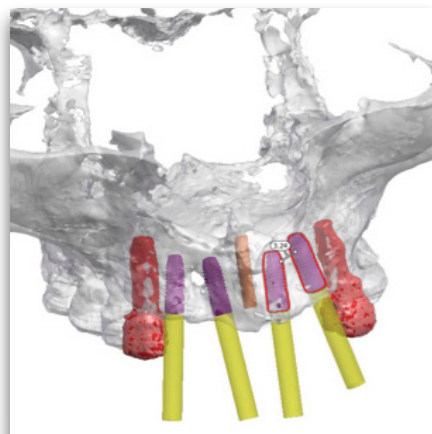
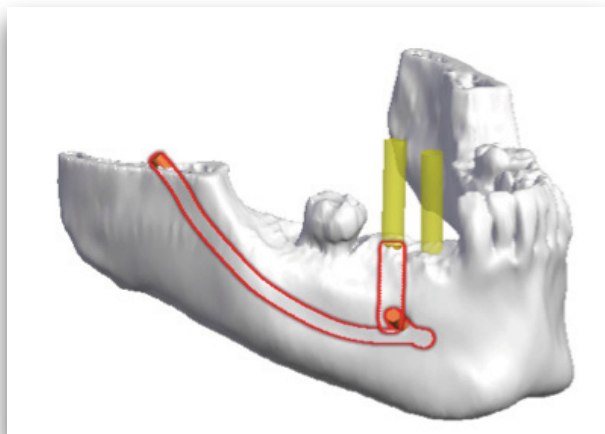


Collision detection between implant-implant and implant-nerve

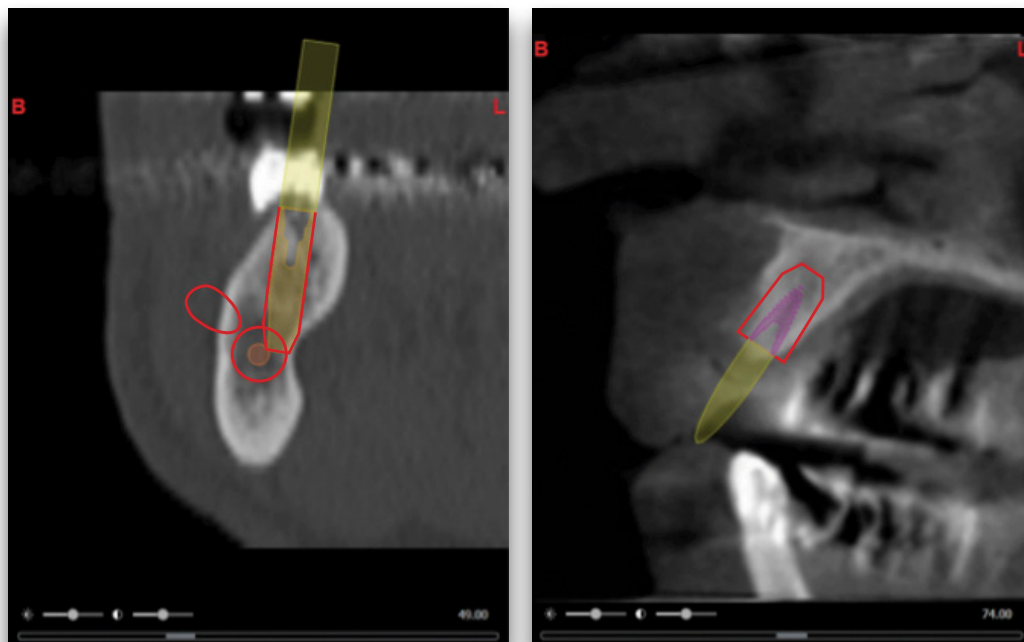
Safe implant placement even when close to nerve is one of the key benefits of 3D implant planning. SIMPLANT Editor automatically warns you when you place implants too close to nerves (2 mm) or to other implants (3 mm). Therefore it is very important to check the full list of collisions at the task bar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



The 3D view shows the red contours of colliding objects.



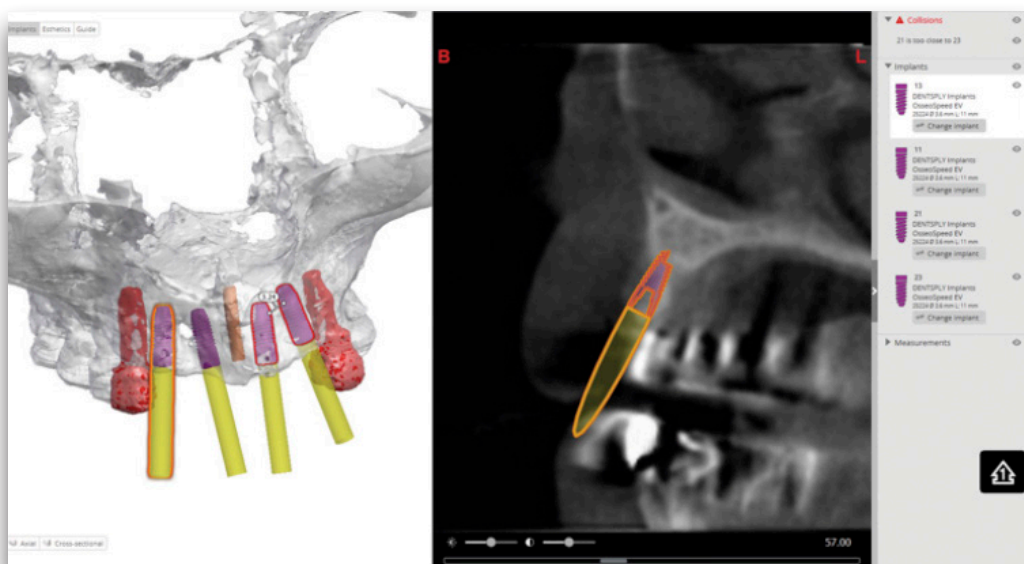
The 2D view shows the safety zones of the colliding objects.



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.

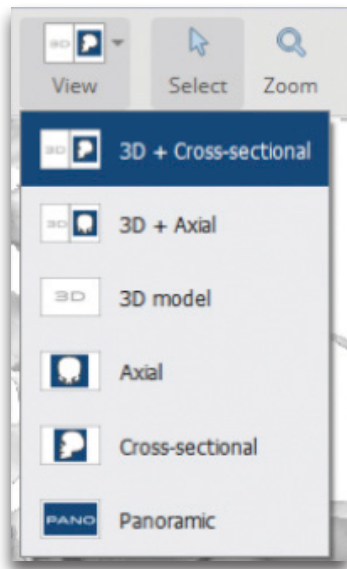
If you click on an implant in any of the views, the corresponding information gets highlighted in the Implants list. You can also select implants via the Implants list. Clicking an implant in the list will locate that implant in the 2D views and the X-ray view.



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 or product line.

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.



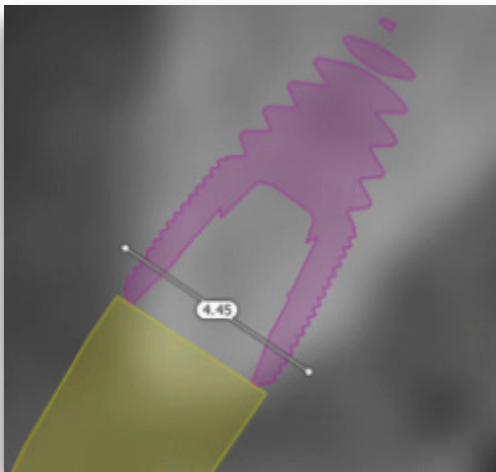
Using the View dropdown from the toolbar, you can choose to combine the 3D view with the cross-sectional or the axial images; or you can also visualize the cross-sectional, axial images or panoramic images in full screen.

The X-ray is flat reconstruction of panoramic 3D image data. To assess exact implant relations or collisions, the 3D and 2D 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.

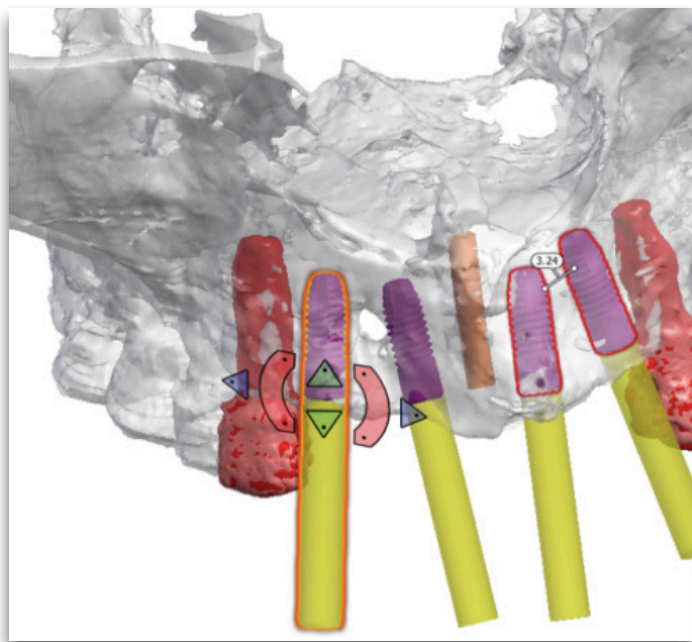
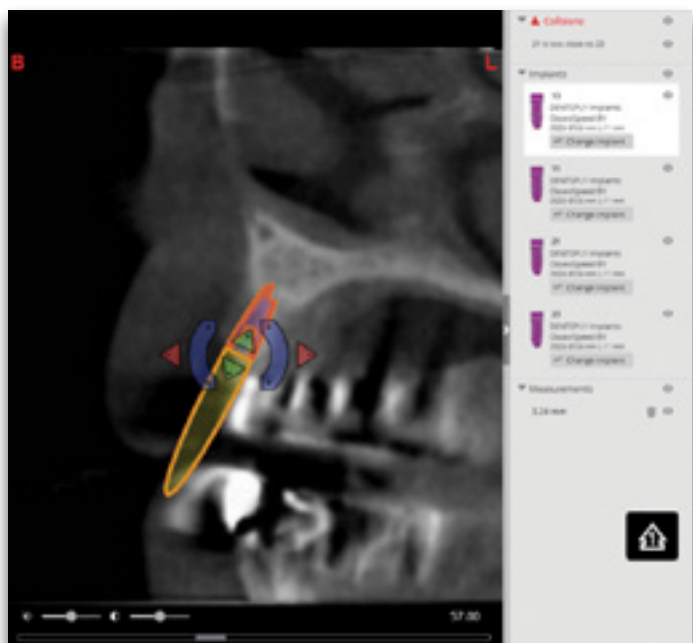


You can adjust the measurement by dragging either end to a new location. Measurements can be made on the 3D image and on the 2D cross-sectional and axial images. **It is advised to make measurements on the 2D views.**

Modify the proposed plan

Moving implants

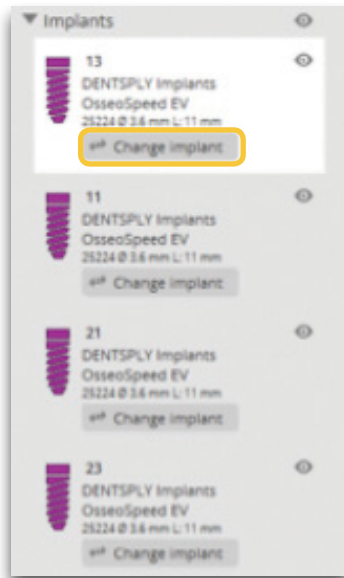
You can move the implant on any 3D or 2D view except the Panoramic X-Ray. It is advised to always check the implant position on the 2D cross-sectional and axial views. Select the implant which you want to move by selecting the implant on the view or in the task bar on the right. Then use the arrow and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



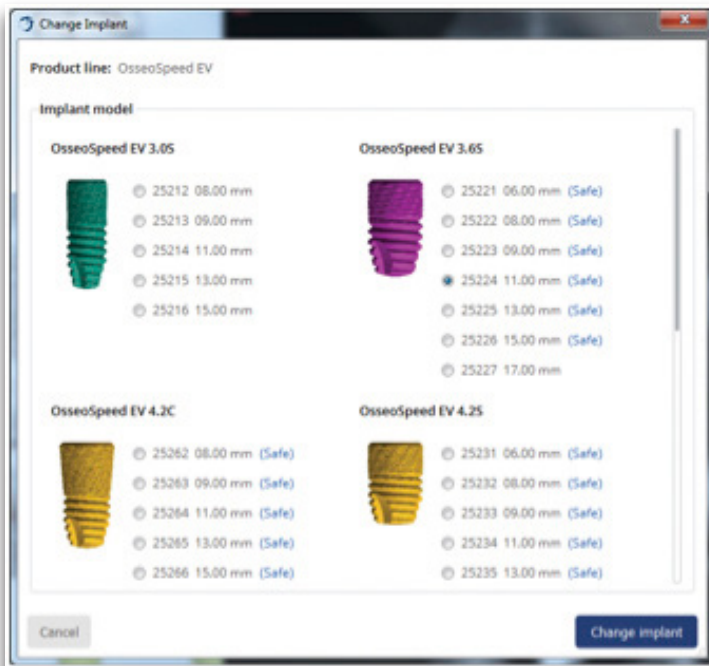
A plan for a fully edentulous patient will also contain fixation screws. Fixation screws can be moved in the same way as implants. As soon as you move an implant in the planning proposal, the SIMPLANT Guide object will be removed from your plan. When approving a modified implant plan, a new SIMPLANT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

Changing the implant diameter, length

To change an implant from the planning proposal click on the change icon next to the implant in 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 a modified implant plan, a new SIMPLANT Guide design 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.

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

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

About DENTSPLY Implants

DENTSPLY 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 CAD/CAM solutions and SIMPLANT® guided surgery, SYMBIOS® regenerative solutions, and professional development programs. DENTSPLY 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 International

DENTSPLY International Inc. is a leading manufacturer and distributor of dental and other healthcare products. For over 110 years, DENTSPLY's commitment to innovation and professional collaboration has enhanced its portfolio of branded consumables and small equipment. Headquartered in the United States, the Company has global operations with sales in more than 120 countries.