Blue Sky Plan®

USER MANUAL

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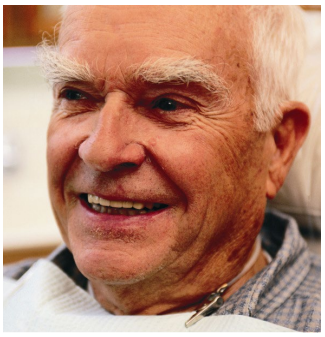
1. Introduction

Blue Sky Plan® is Windows and Mac-based computer software intended for 3D virtual surgical implant placement, giving clinicians a more accurate way to treat patients. Blue Sky Plan® is precise and can help the clinician determine the ideal position for implant placement for the best esthetic and functional results. Blue Sky Plan® can be used for diagnostic purposes and can aid in the fabrication of surgical guides for computer-guided surgery. Using Blue Sky Plan® is the way to give your patients the best care available.

Blue Sky Plan converts a Computer Tomography (CT) or Cone Beam Computer Tomography scan into a format that allows the dentist to assess the anatomic topography of the maxilla and mandible as well as the location of important structures. The patient's CT or CBCT images will be stored in DICOM format from an Imaging Center. The software converts these images and makes it possible to view the patient's anatomic structures. These data can be used for accurate pre-surgical treatment planning.



The dentist can use the program to:

- carry out pre-surgical planning
- help fabricate an accurate surgical guide
- decrease the risks of surgical complications
- create realistic simulations of the treatment plan
- assist in selecting the type and size of implants
- asses results of prior bone grafting procedures
- store the patient data
- allow visual communication with patients and the implant team
- demonstrate knowledge, credibility, and safety
- help provide advanced patient care

Blue Sky Plan® software can be downloaded from http://www.blueskybio.com. A user license must be obtained for each installation. During the installation process the software will prompt the user to request a license via the internet.

1.1. Indications For Use:

Blue Sky Plan is intended to be used as conversion software for Computed Tomography (CT) generated DICOM images into a format that allows a dentist to assess the anatomic topography of the maxilla and mandible as well as location of important structures. It allows the information to be used for pre-surgical treatment planning of dental implant procedures.

Blue Sky Bio Aligners are a series of clear, lightweight, plastic appliances indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e., all second molars). Utilizing a series of incremental tooth movements, it sequentially positions teeth by way of continuous gentle force.

Blue Sky Bio Computerized Bracket System is a software system intended for use as an aid in orthodontic treatment planning to correct Malocclusions in Orthodontic Patients. For use by dental professionals trained in orthodontic treatment, including radiographic analyses and treatment planning. Blue Sky Bio Computerized Orthodontic Bracket System is intended for use with commercially available brackets currently used in standard orthodontic treatment. The end product is an indirect bonding tray for use by the Dental professional to place multiple brackets at the same time.

The denture module is intended to be used to design a denture and export the entire denture or selected parts of the denture from the software for 3D printing

The crown and bridge functionality allows a dental professional to design one or more new teeth in the Blue Sky Plan that will attach to either a damaged tooth or a titanium based abutment

1.2. Warnings:

The software does not contain any functionality verifying if real-life implementation of the virtual treatment plan might result in damage to the patient. Any virtual treatment plan should be evaluated by a trained licensed professional confirming that the virtual treatment can be implemented in real life and will not cause harm to the patient.

If the segmentation function of the software is used, the segmentation has to be carefully evaluated to ensure that it matches the patient's anatomy and corrected if necessary.

It is important to verify that the imported and exported data sets are of adequate quality and match the patient's anatomical structures.

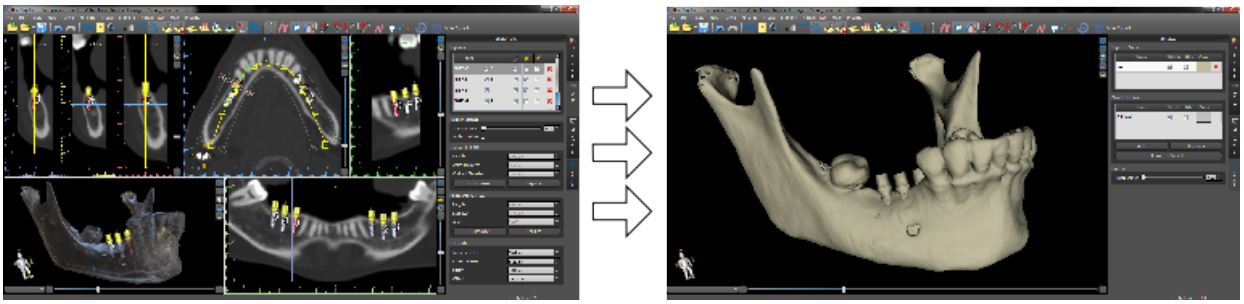
Appliances manufactured based on the virtual treatment plan should be made only from biocompatible materials that have suitable mechanical properties and are in compliance

with local regulatory bodies. Appliances should be marked with patient information to avoid errors when delivering the appliance.

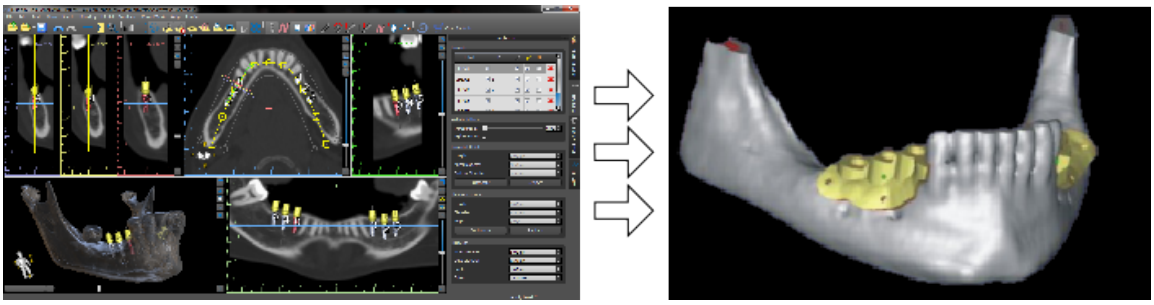
Poor quality radiographic or optical images, inadequate training of user or inadequate hardware can affect the image results.

The DICOM data can be used to do the following:

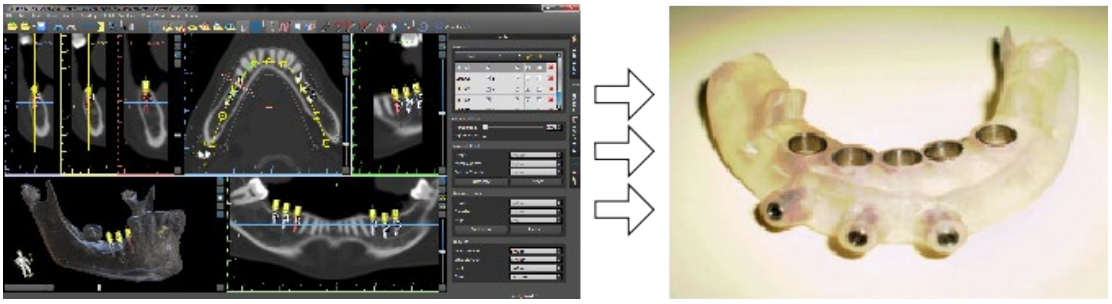
1) make a scale 3D model of the jaw with the planned implant according to the illustrations below:



2) fabricate a surgical guide supported on bone



3) fabricate a surgical guide supported on the gingiva



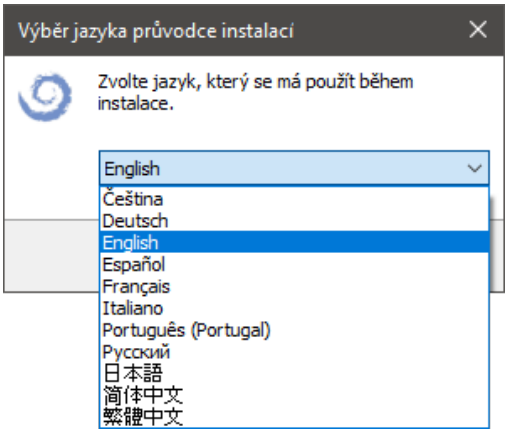
*The files with three-dimensional positioning of implants and the file of the three-dimensional guide can only be generated in Blue Sky Plan®.

2. Installing Blue Sky Plan

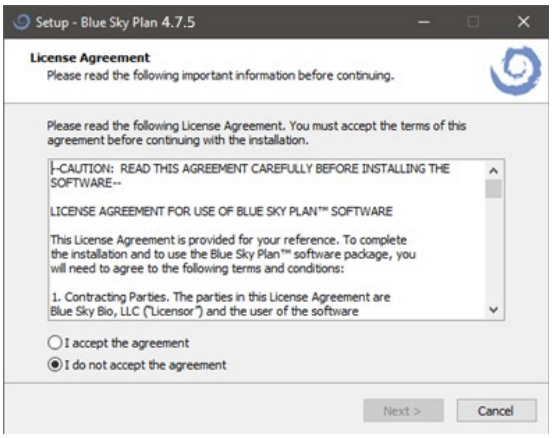
Blue Sky Plan® software supports both Windows and Mac OS X operating systems. Installation packages are available for the systems indicated.

2.1. Installation process (Windows)

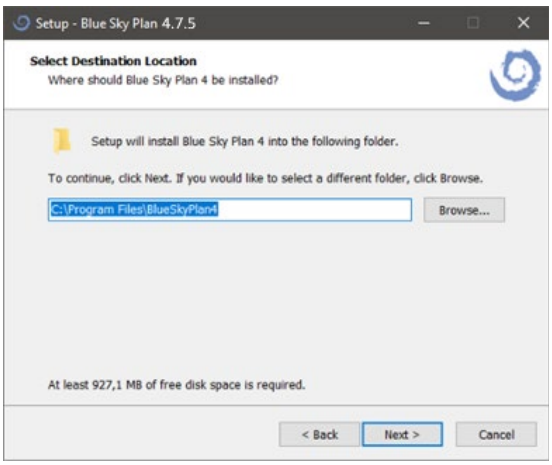
After downloading the Blue Sky Plan® software to your hard drive, simply execute the file and follow the steps to proceed:



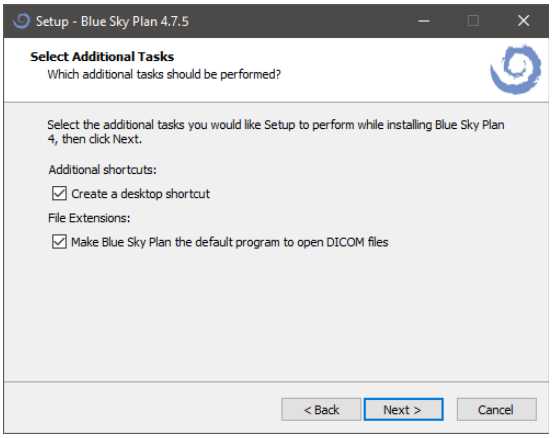
Choose the language and click *“OK”*.



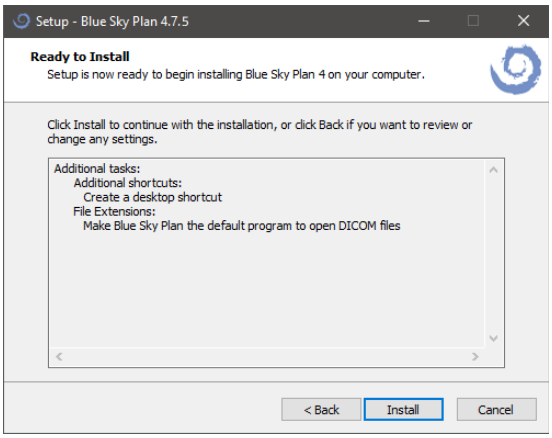
Carefully read the license agreement, select one of the options, and click *"Next"*.



Click *"Next"*.



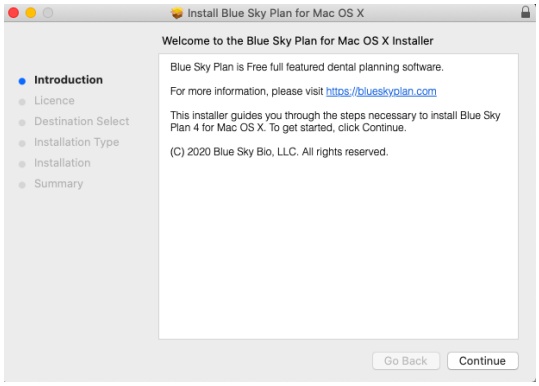
Click *"Next"*.



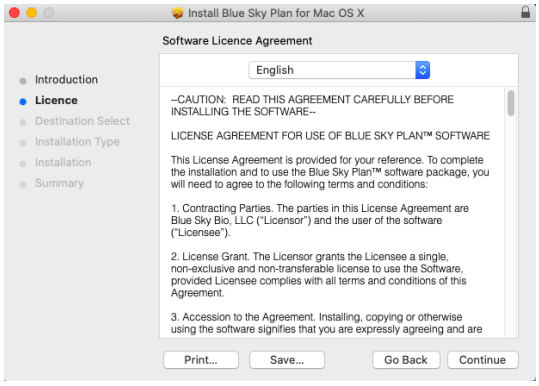
Click *"Install"*.

Click *"Finish"*.

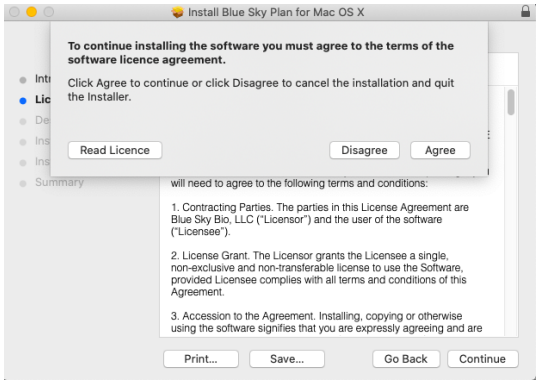
2.2. *Installation process (Mac OS X)*



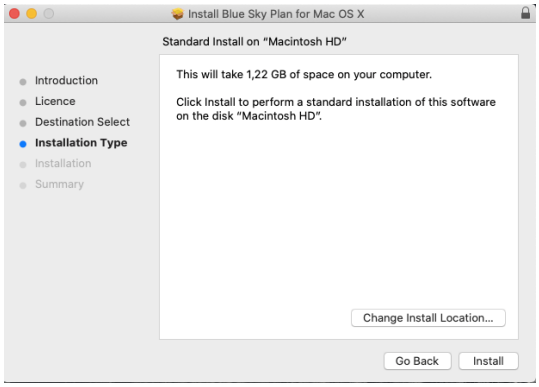
Click "*Continue*".



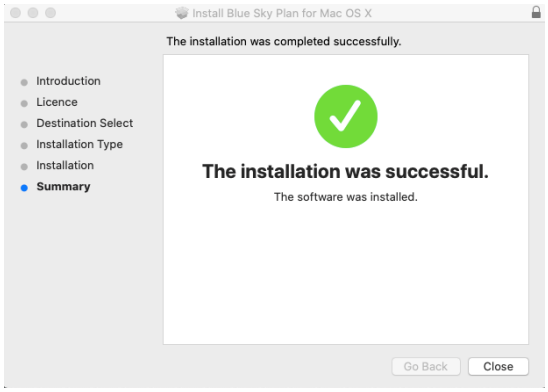
Carefully read the license agreement and click "*Continue*".



Choose one of the options and click the associated button.



Click "*Install*".



Click "*Close*".

2.3. Hardware requirements

Minimum requirements:

- Processor: Quad Core Intel i7 or comparable
- RAM: 16 GB
- Video card: NVidia, AMD or Intel, 2 GB of video RAM, OpenGL 3.3 supported (e.g. NVidia GeForce GTX 1050, GeForce 940MX, AMD Radeon RX 530, Radeon R5 M420, Radeon Pro 450 or comparable)
- Screen res.: at least 1440 X 900
- Hard Disk: 5 GB of free space

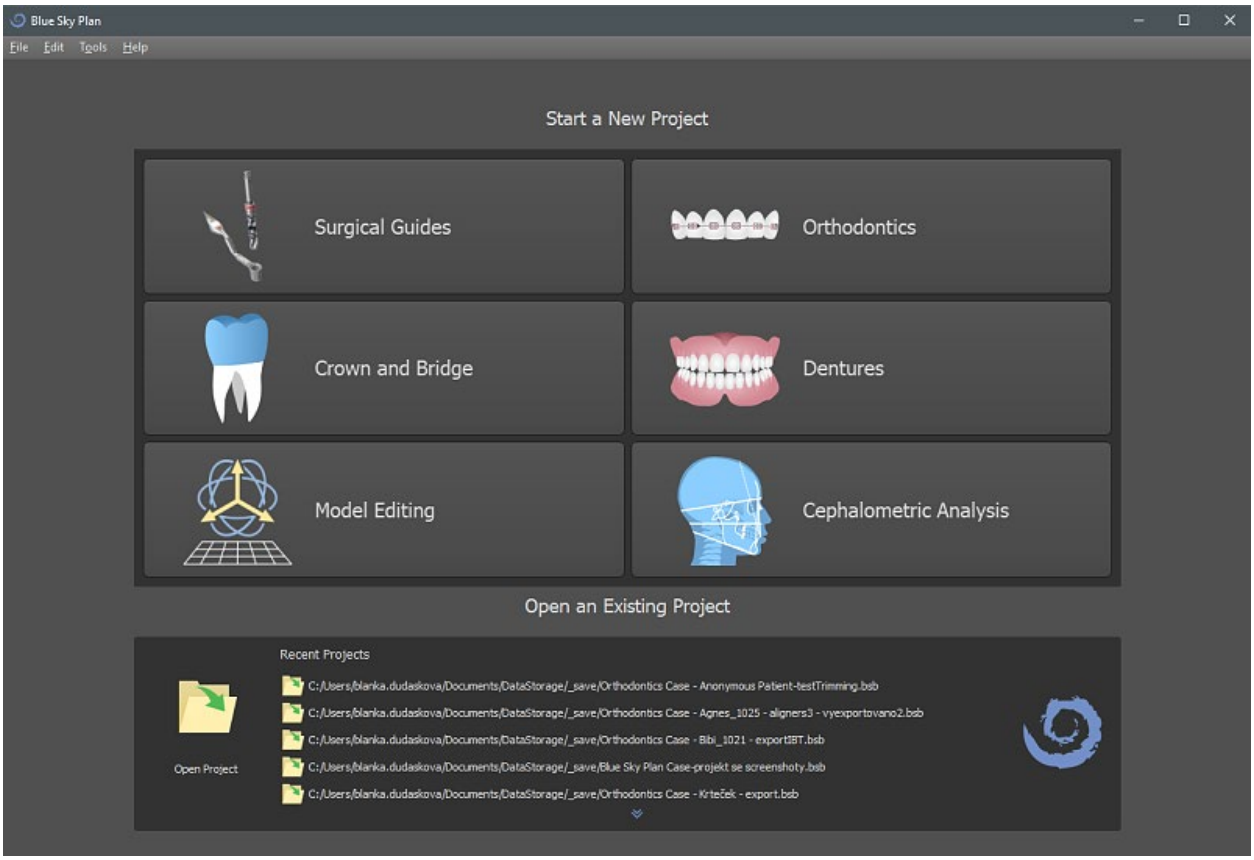
2.4. Operating system

Minimum requirements:

- Windows 10 Home/Professional 64 bit
- Mac OS X 10.13 (High Sierra) and newer

3. Intro screen and selection of planning type

Blue Sky Plan® allows many different types of planning. In addition to implant planning, it also allows the user to plan orthodontic treatments based on imported STL models of the jaw with teeth, create bridges and crowns, model and export dentures, and cephalometric analysis. Selecting a planning type and creating a new project is done using the intro screen, which appears after starting Blue Sky Plan as well as during the creation of a new project.



In most planning cases, the Model Editing module is the first one to be loaded. It's used for preparing STL models before the planning process itself. The Model Editing module allows the user to create models from CT surfaces, modify the orientation and positioning in the BSB coordinate system, but most importantly to modify the STL models – including cropping, polishing and surface modifications, closing and creating hollow models.

4. Loading the patient's CT or CBCT scan into Blue Sky Plan

Blue Sky Plan® can load uncompressed DICOM images (exported by all CT scanners) into the software. Blue Sky Plan is "self processing" allowing the user to directly import the DICOM images in a few easy steps.

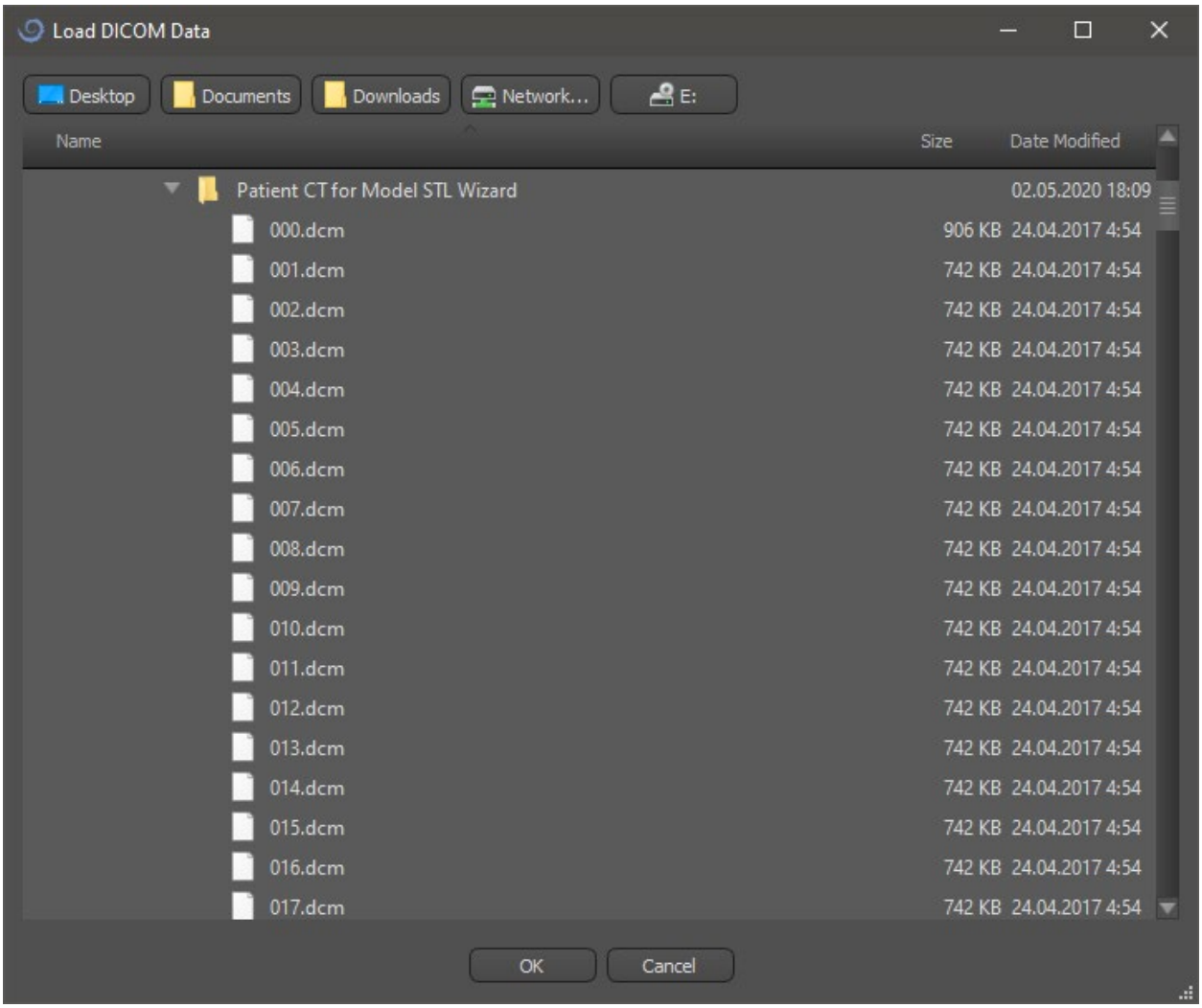
A complete scanning protocol is available via the Blue Sky Bio website and can be sent to the scan site.

4.1. Selecting the DICOM images location

To import the patient's CT or CBCT images, follow these steps:

1. Select planning type "Surgical guides" and then "Import Patient CT Scan".

2. A new window will appear.



Note that there are several shortcut buttons that appear on the top of the window. The leftmost button is a shortcut to your desktop, and the next button is a shortcut to *"My Documents"*. These buttons allow quick navigation to the folder containing the DICOM images.

Select the directory that contains the DICOM images and click *OK*. Images must be stored in DICOM format from your Imaging Center in order to load them into Blue Sky Plan®.

4.2. Selecting the series

A list of available series that can be loaded will appear (1). Ideally each series should be saved in a separate folder, and only one series will appear.

4.3. Enhancing performance

In the case that the computer does not have sufficient system or video memory, and possibly also if the video card is not sufficiently powerful, the program makes it possible to reduce (downsample) the input data; the user may set this manually for each axis or choose one of the available settings (2).

The software will automatically compensate for the “skipped” slices, and the quality of the treatment plan and Surgical Template will not be compromised.

4.4. Scan alignment and defining the range of slices

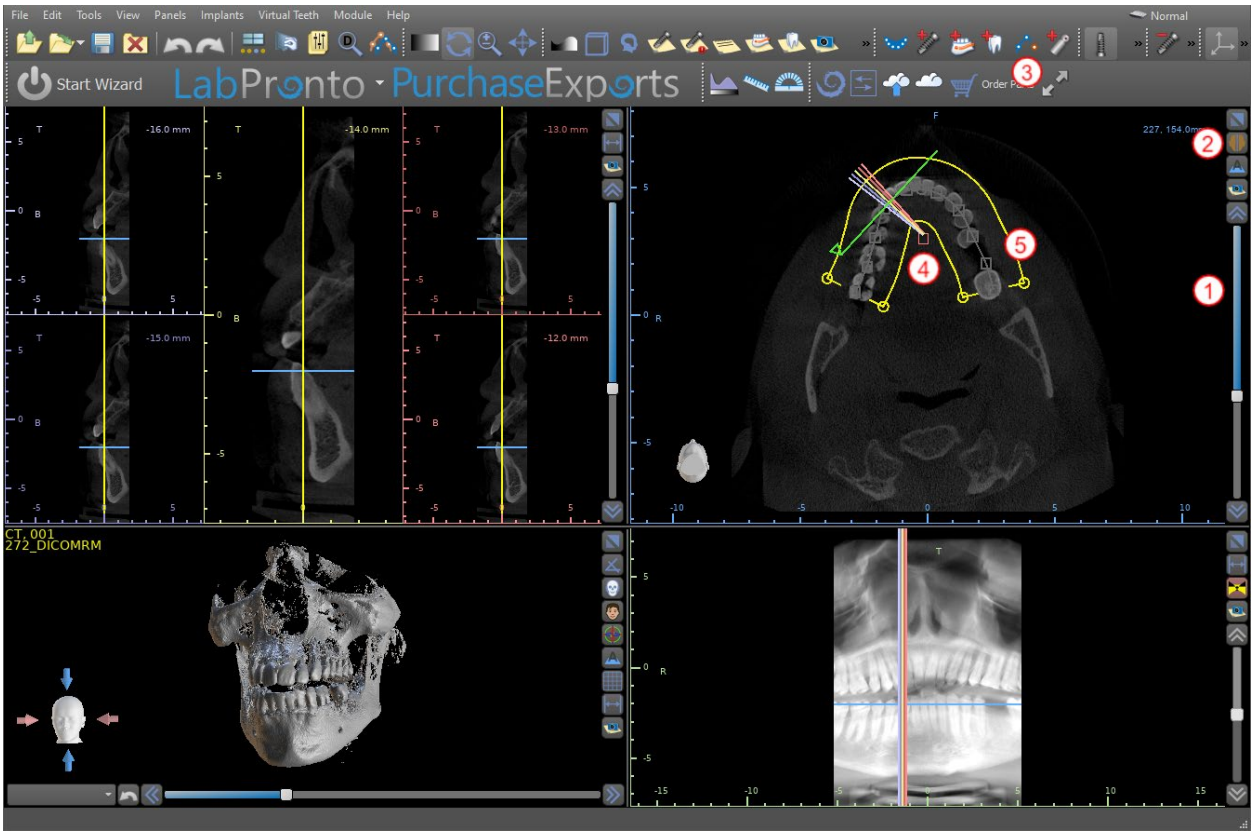
In this step you align volumetric data and delimit the area of interest in the data. It is possible to crop the data in all directions by dragging the yellow lines (1) or by directly setting the dimension of the slice for the individual axes (2). The data display mode can be changed by selecting *“Imaging Mode”* (3).

The data can be aligned using the blue circles (4); it is also possible to enter values for rotation around the individual coordinate axes manually (5). The transformation performed then applies correctly for importing and exporting data as well.

Given the significant memory and performance requirements for visualizing 3D medical data, it is advisable to crop the input data to the actual area of interest; this allows the program to run much more smoothly.

4.5. Positioning the panoramic curve

The panoramic curve (the middle of the three curves which appear in the axial view) should be positioned to pass through the middle of the patient's ridge.



This can be done by using the slider (1) to identify an axial slice which shows the complete arch/ridge of the patient's jaw. If necessary, it is possible to switch the display mode of the axial slice to an X-ray display by clicking button (2).

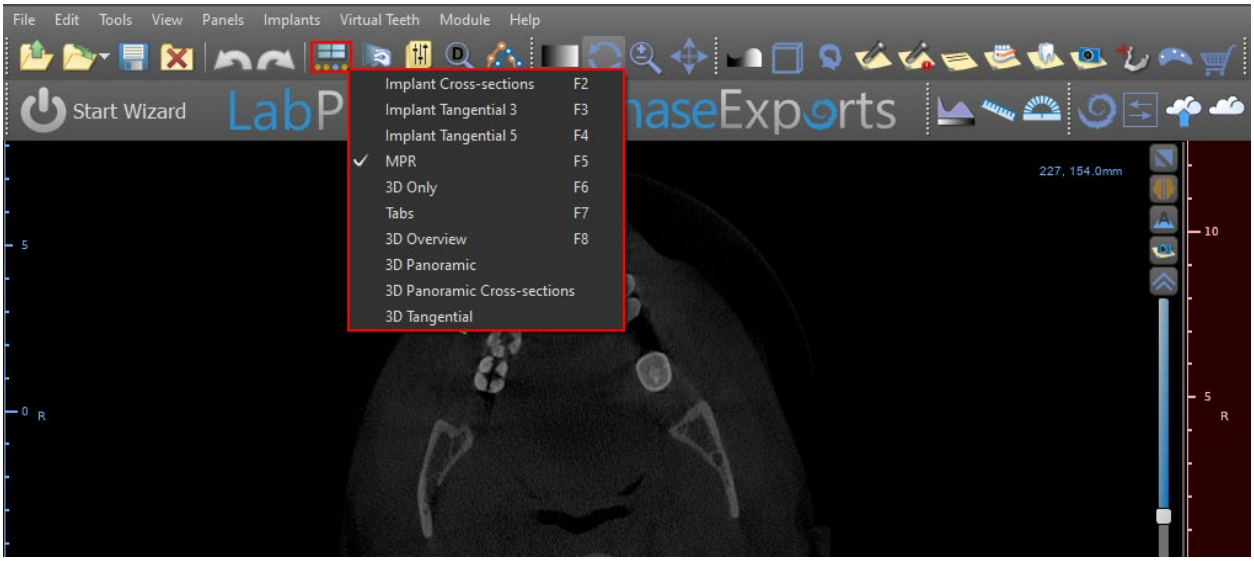
The curve as a whole can be shifted by dragging point (4), and the local form can be adjusted by dragging any yellow square (5). Dragging the yellow circle within the curve decreases/increases the curve.

Alternatively the entire curve can be redrawn by pressing the *"Edit Dental Curve"* button (3). The user can left-click periodically as the mouse moves around the arch (from left to right), placing dots. The software will connect the dots to draw the panoramic curve. Be sure not to double back over a section of the curve which is already drawn, as this will create inconsistencies in the curve. When the curve is complete just click on the *"Edit Dental Curve"* button (3) again, or press *"Esc"*.

5. Software interface

Blue Sky Plan® allows seamless interaction among the various windows displaying the axial, sagittal, coronal, cross-sectional, tangential, panoramic, and 3D images.

Depending on the intended use, it is possible to select the active windows for multi-planar functions (cross-sectional, sagittal, coronal, and 3D) or implant functions (cross-sectional, axial, panoramic, and 3D).



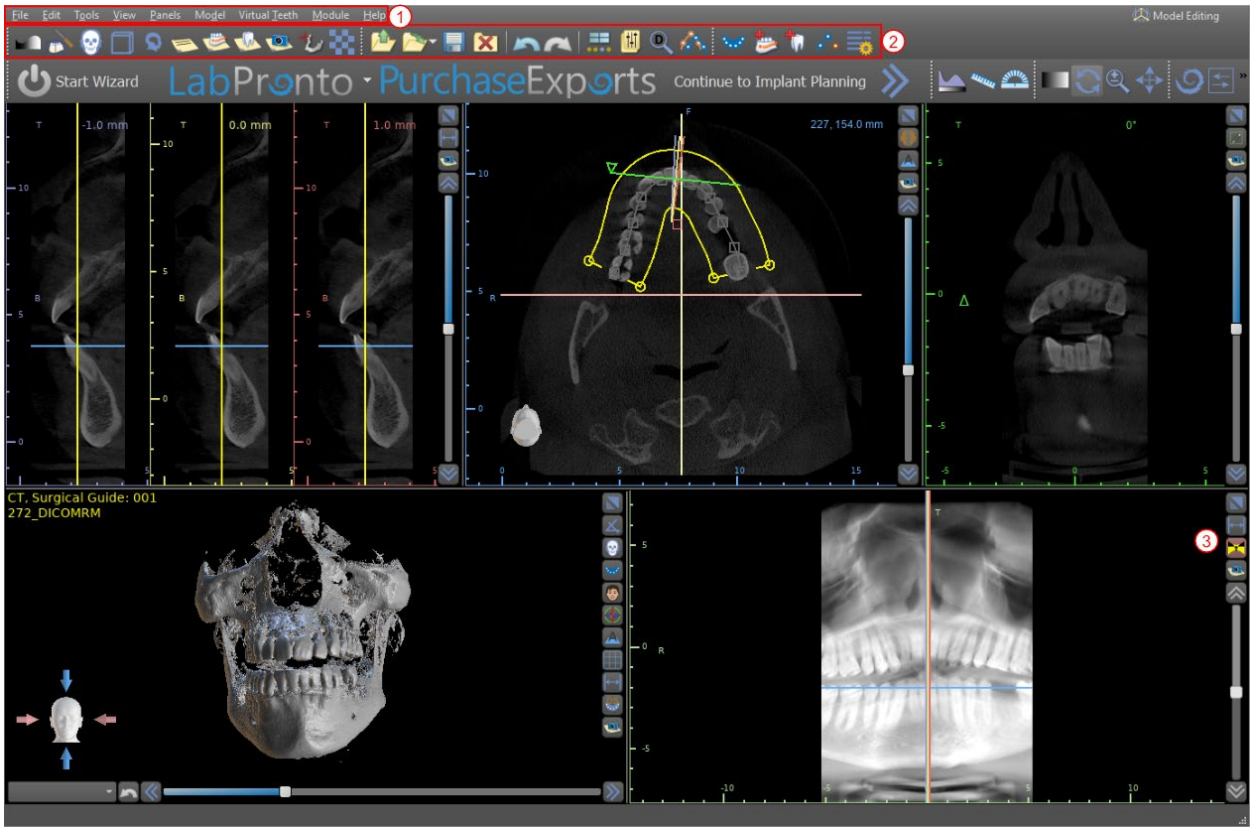
The following information and tools can be viewed in each active window:

- individual colors for each cross section of images,
- indicators showing the current position of the images,
- label of the image,
- rulers.

5.1. Screens and views

The implant screen allows visualization of the cross-sectional, tangential, axial, panoramic, and 3D images.

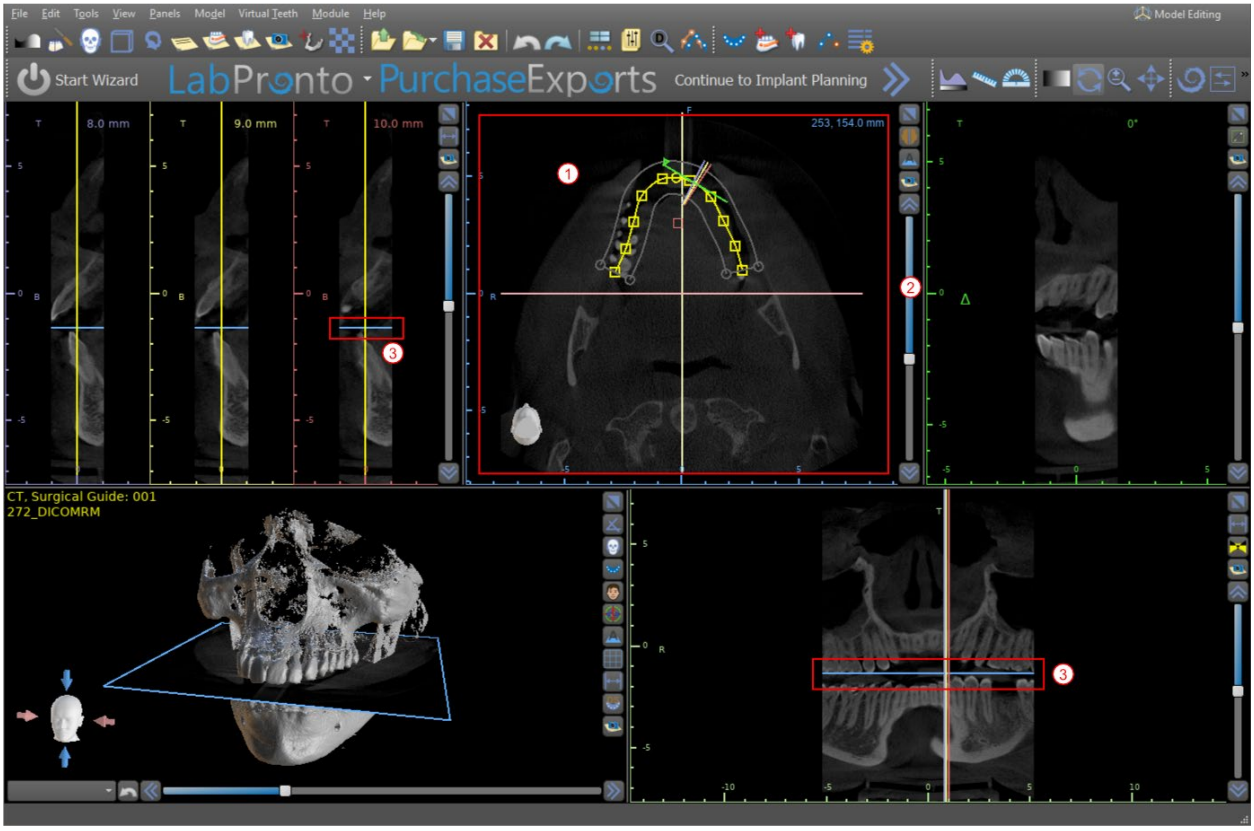
All implant planning tools can be accessed through the menu bar (1) below. The main toolbar and the toolbar of the panoramic image (2 and 3, respectively, in the following illustration) show the most-used tools.



5.1.1.Axial window

The axial images are horizontal slices of the volume and can be seen in the top right-hand view in the application (1). They are marked in blue. All the other images are generated from the sequence of axial images.

By moving the axial scrollbar (2), it is possible to view the whole sequence of axial images. The indicator line of the axial slice appears in the cross sectional (3), panoramic, and 3D images.

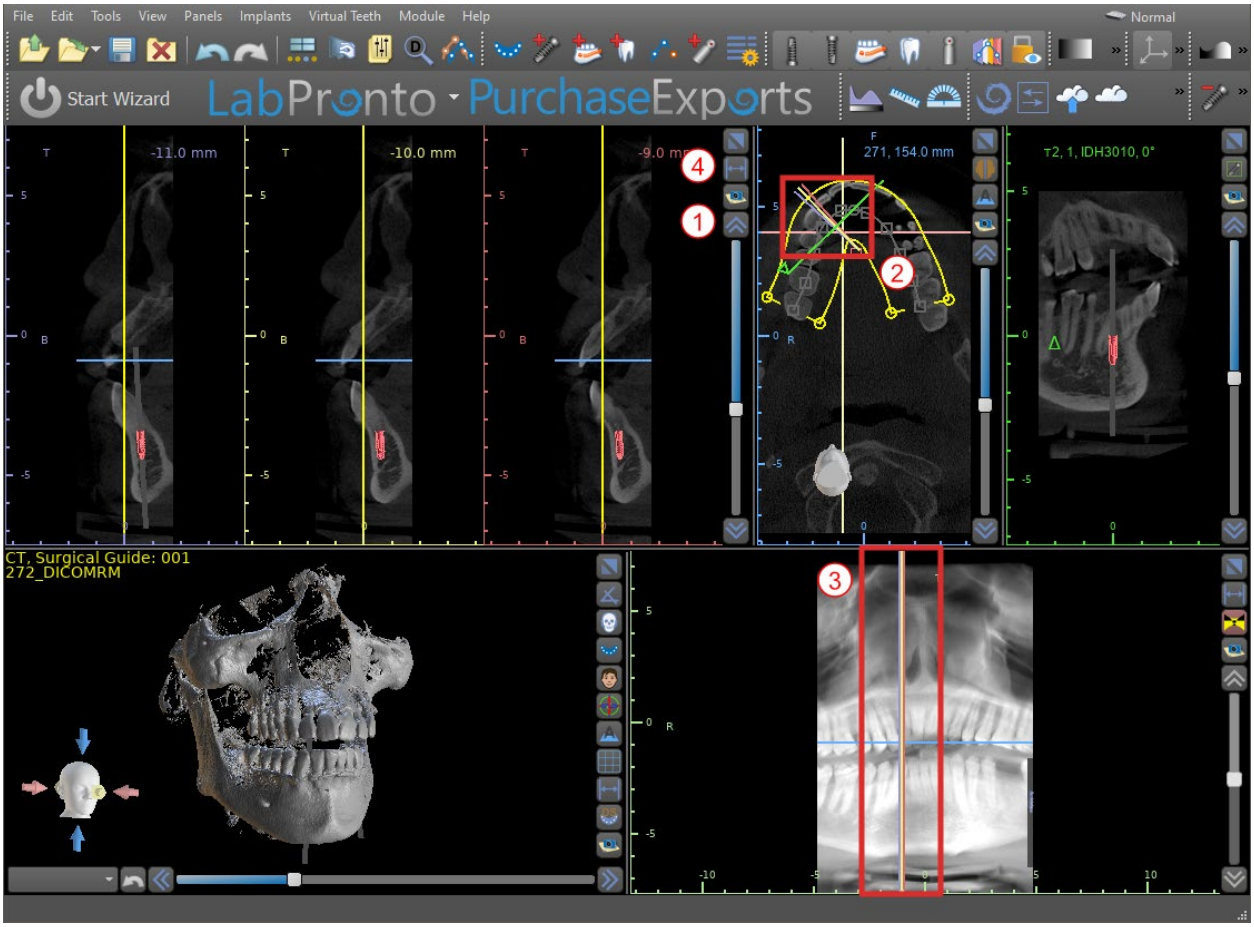


5.1.2.Cross-sectional window

The cross-sections view displays vertical slices going around the patient's ridge. As the user moves through the slices using the up and down arrows (1), the corresponding multi-color lines in the axial and panoramic views (2 and 3) will move accordingly, identifying the location of the five images being displayed in the cross sectional views.

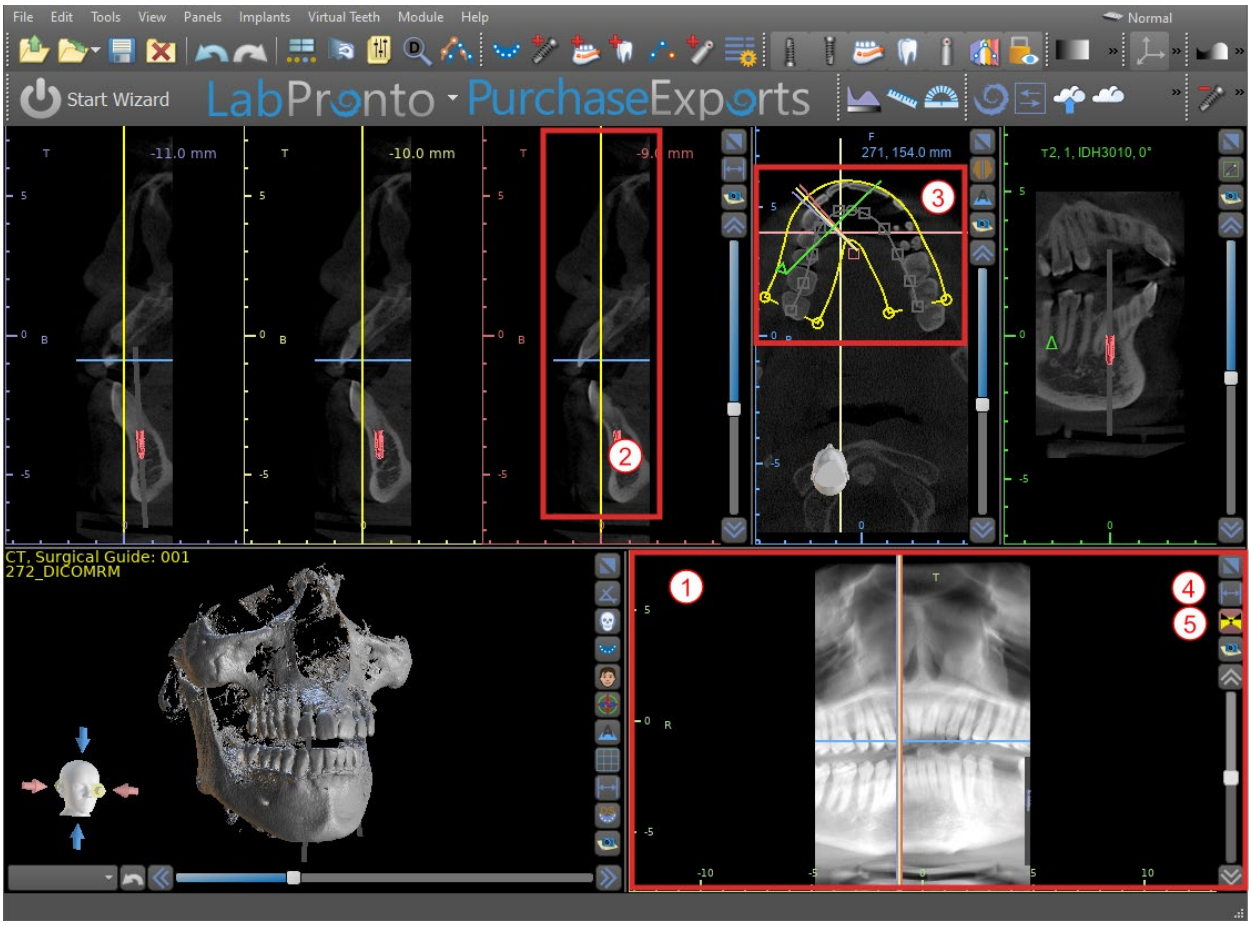
These images are used to evaluate the bone height and thickness in planning. When implants are placed, they are often placed into one of the images in the-cross sectional view.

The distance separating the images can be modified by clicking on the icon (4), and a new value can be selected from the drop-down menu. By default the distance between images is set to 1mm.



5.1.3.Panoramic window

The panoramic image is located in the bottom right-hand window of the application (1) and is marked with light green.



The indicator line of the panoramic slice appears in the cross sectional (2) and axial (3) views. As the user flips through the panoramic images, the panoramic curve will move along the horizontal axial plane to indicate the location of the specific slice represented by the location of the panoramic curve.

The range of the field of view reachable by the panoramic curve can be adjusted by clicking on the offset distance icon (4) and by choosing an appropriate step. The change in the range of slices reachable by the panoramic curve will be represented by a change in the distance between the inner and outer panoramic curves.

The view mode button (5) will change the panoramic view into a composite image representing an image similar to an X-ray. In such a situation the panoramic curve in the axial view will disappear, as no individual slices are being represented, and instead a composite image of all the slices within the relevant range is displayed. Selecting the view mode button again will return the panoramic view to the standard section view.

5.1.4.Tangential/implant window

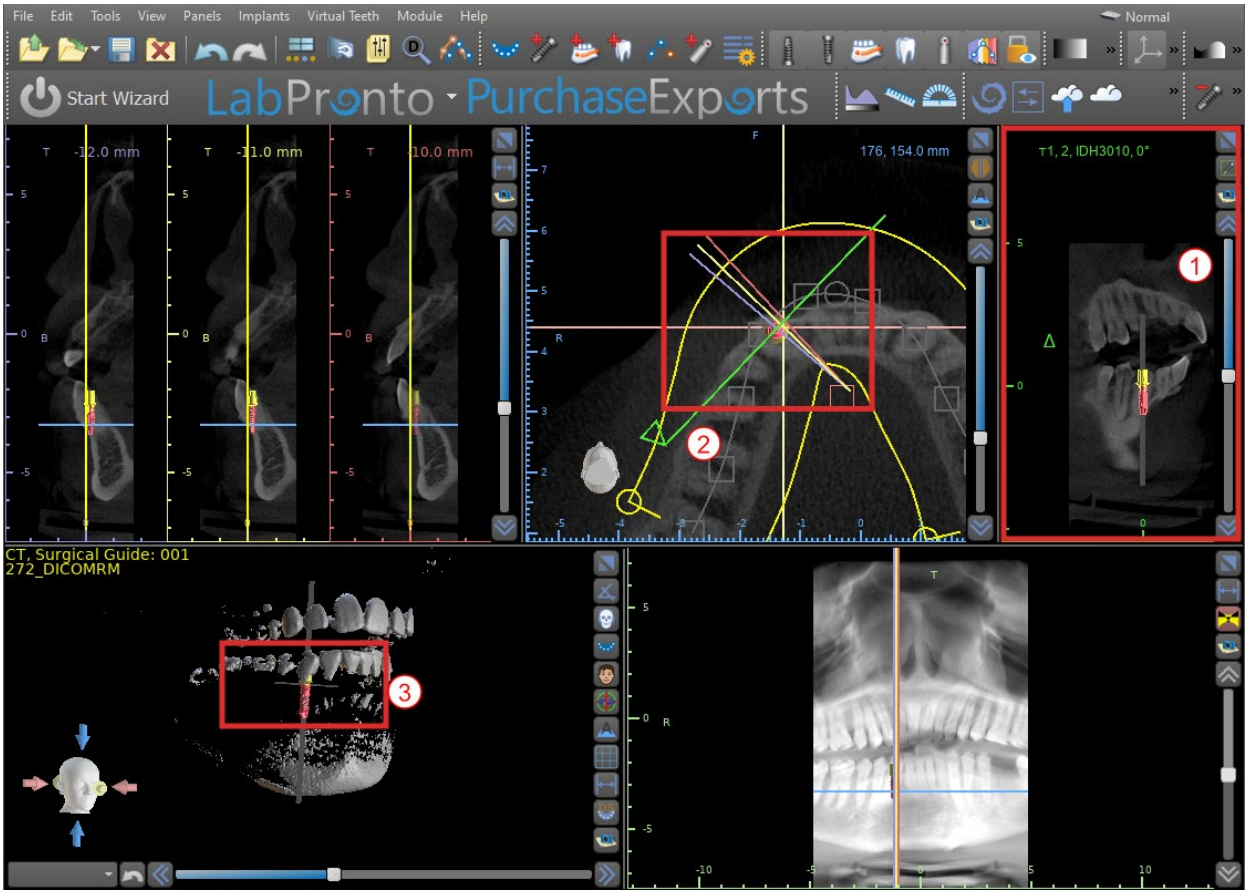
The tangential view is located in the upper right-hand part (1) of the window and is marked in green. It works in two modes. If no implant is active, it displays the view orthogonal to the cross-section view (tangential to the curve).

The plane displayed can be rotated with the scroll bar in the tangential view window (1) or by dragging the line displaying the intersection of the plane with the axial slice in the axial view window (2). The direction of view on the plane of the tangential slice is indicated in the axial view with a green triangle.

If an implant is active, the view orients itself in a tangential position to the curve when switching to the implant. Nonetheless it does not display the perpendicular plane but rather the plane passing through the implant. In this mode the orientation of the plane is indicated not only in the axial view but also on the associated implant in the 3D window (3).

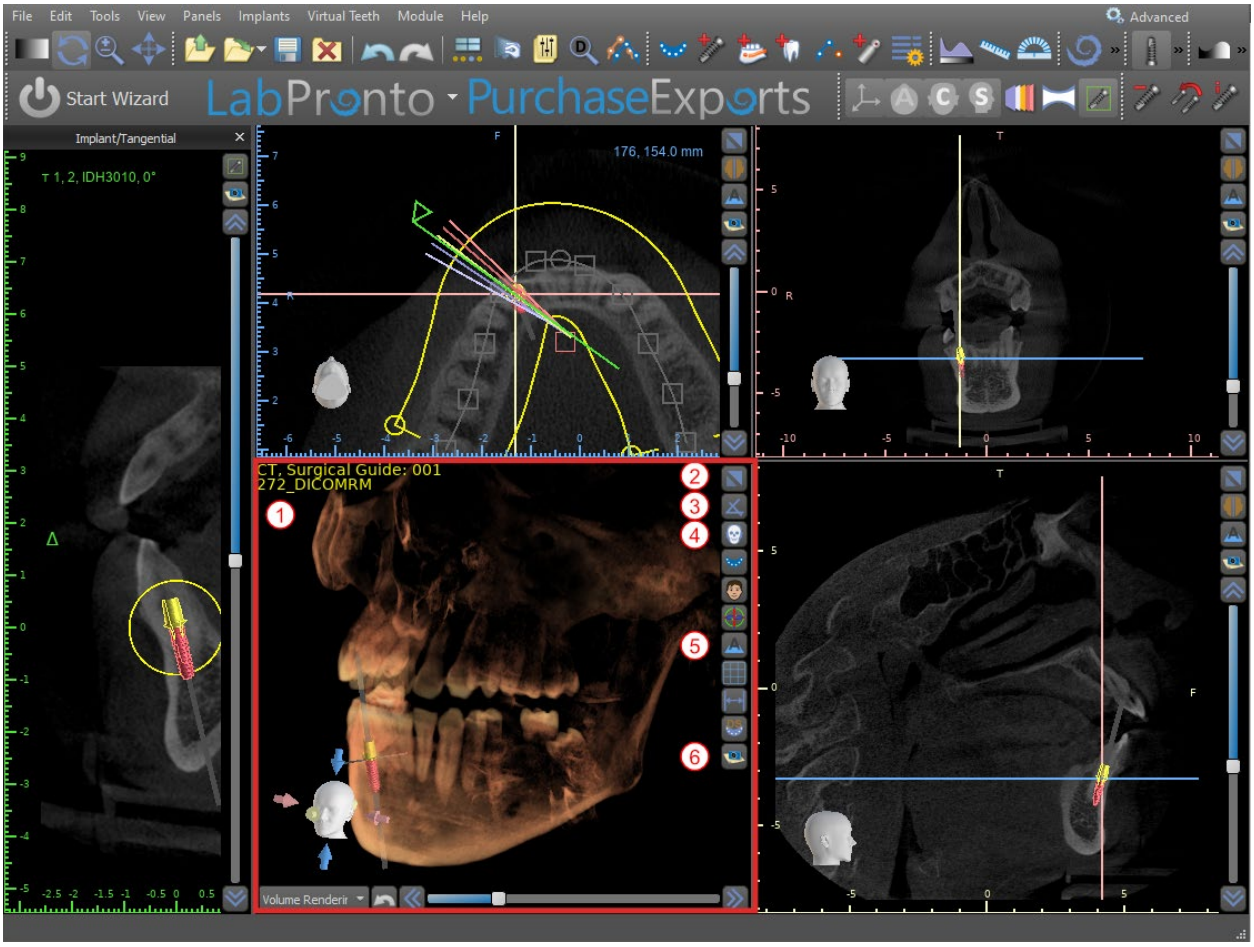
If the implant is rotated in a different view, the plane displayed in the window (1) automatically changes to the rotated plane of the implant.

Thanks to the option of rotating the plane passing through the implant, it is possible to easily check and correct the tilt of the implant's position when viewing from any angle.



5.1.5.3D View

The 3D image is located in the bottom left-hand view of the application (1). To rotate the 3D image, click the left mouse button in the model, and to zoom, click the right mouse button.



5.1.6.3D Shortcut buttons

The 3D view has several valuable shortcut buttons on the right side of the view.

The first button (2) maximizes the window.

The second button (3) allows the user to change the positioning of the view. The user can click on the button to open a fly out menu. The orientation of the patient's anatomy will adjust according to the option chosen.

The third button (4) allows the user to take advantage of different volume rendering options. It is possible to set the rendering type and quality using the contextual menu options or the Volume Rendering panel, which can be accessed from the Panels menu.

The *“Presets”* option opens a selection of different 3D volume rendering presets with different coloring schemes.

In “*Surfaces*” mode, differential surfaces (“density surfaces”) are depicted that are defined in the *“Surfaces”* panel, which can be accessed from the main menu under the *"Panels"* option or by double-clicking in the 3D window.

The user can assign a name to each density surface and set threshold values, the color, or the transparency.

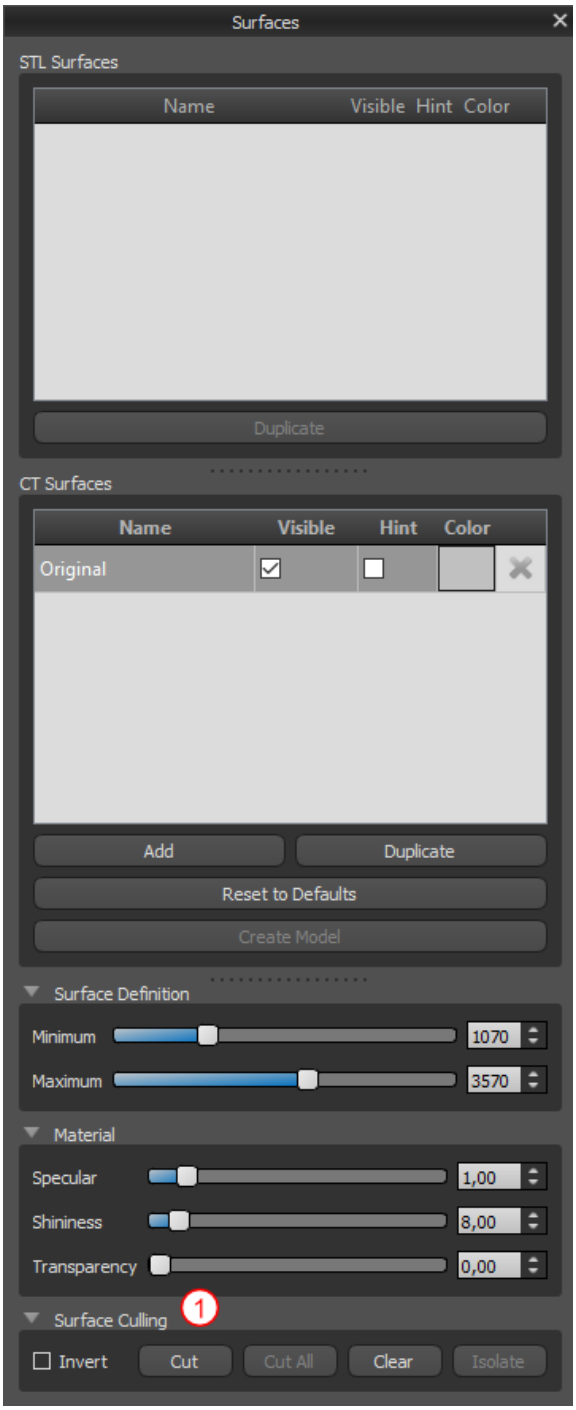
In the *“Imported Surfaces”* table located on the same panel, users can find created or imported models for which it is possible to set the color, visibility, and transparency.

The visibility of imported models, unlike that of density surfaces, is not limited by the chosen volume rendering mode.

The fourth button (5) turns on the visibility of the vertical slices in the 3D window.

The fifth button (6) inserts a current snapshot of the 3D window into the *"Screenshots"* panel.

5.1.7.Surface culling (3D cut)



A 3D visualization can be cropped with the *Surface Culling* function (1). In "*Surfaces*" mode, each density surface is cropped independently of the others. The first non-deletable surface shares its cropping area with the other visualization modes (*Shaded Bones*, *MIP, X-Ray*, etc.).

Cropping serves to:

- remove noise
- remove superfluous anatomy
- isolate anatomy

The cropping tools are in the lower part of the *"Surfaces"* panel (1). It is possible to crop data with the *"Cut"* button, to delete a previously performed crop with the *"Clear"* button, and to isolate the selected anatomic portion. It is also possible to invert the current cropping.

After the user clicks the *"Cut"* button, the application switches to drawing mode. At this point, by clicking on the left mouse button in the 3D window and dragging the cursor, it is possible to draw an area which is cut out of the selected surface after when the mouse button is released. Drawing can also be invoked at any point by pressing the *"Shift"* key and holding it down during the whole drawing period.

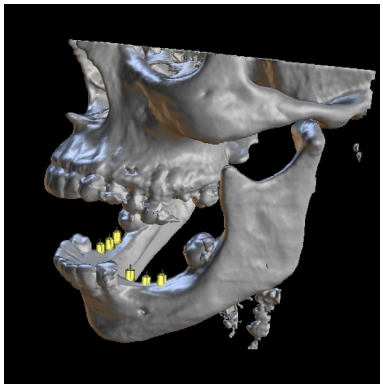
If we want to isolate a particular part of the anatomy, we must first ensure that it is not connected to any other parts. We can ensure this using the cropping function described above. We can isolate anatomy in this way with the "*Isolate"* button and by clicking on it in the 3D window. All parts of the anatomy are then removed except for the selected part.

As soon as we have a cropped part of the anatomy that we want to display, it is possible to invert the cropping with the Invert check box.

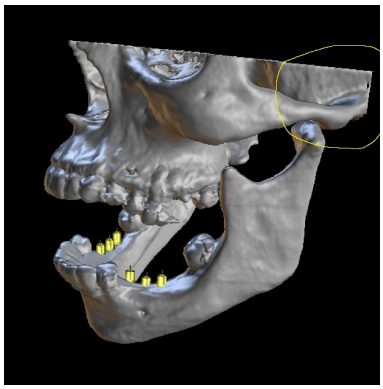
Any cropping actions can be reversed using the "*Undo"* function.

The following is an example of working with the *"Surface Culling"* function:

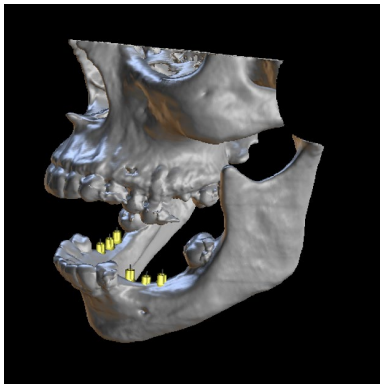
1) After the data has loaded, the 3D visualization contains a certain amount of unwanted information. We press the "*Isolate"* button and click on the lower jawbone.



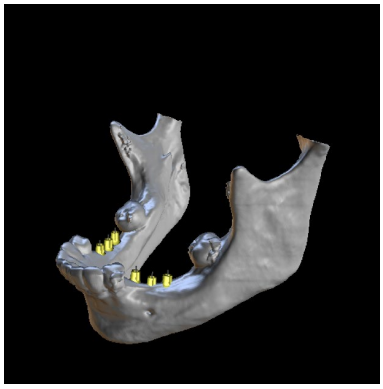
2) A portion of tissue continuous with the lower jawbone has now been isolated. The vertebrae and other small parts have been removed. However the upper jawbone remains in the visualization because it is connected to the lower jawbone in some location. We press the *Cut* button and cut away part of the tissue on both sides.



3) After cutting, we again press the "*Isolate"* button and click on the lower jawbone.



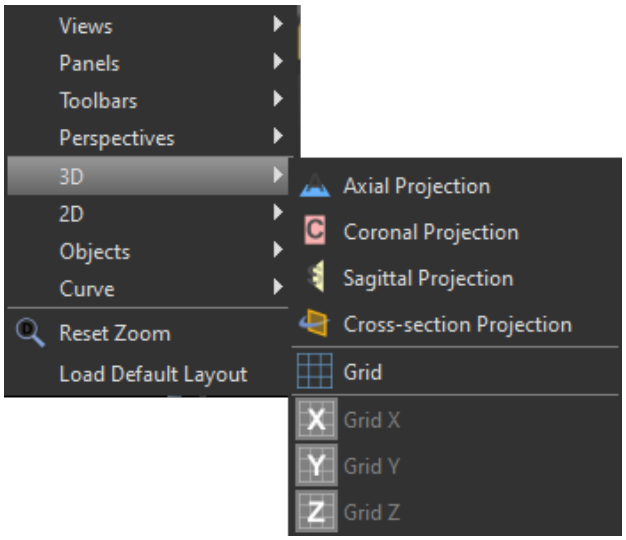
4) Only the lower jawbone now remains visible.



5.1.8.Indicators

The indicators are reference lines that indicate the positioning between the images shown on the screen.

Usually the indicators are already enabled in the windows of 2D images. To disable them, click *"View > 2D"* in the menu and choose the indicator to be disabled.

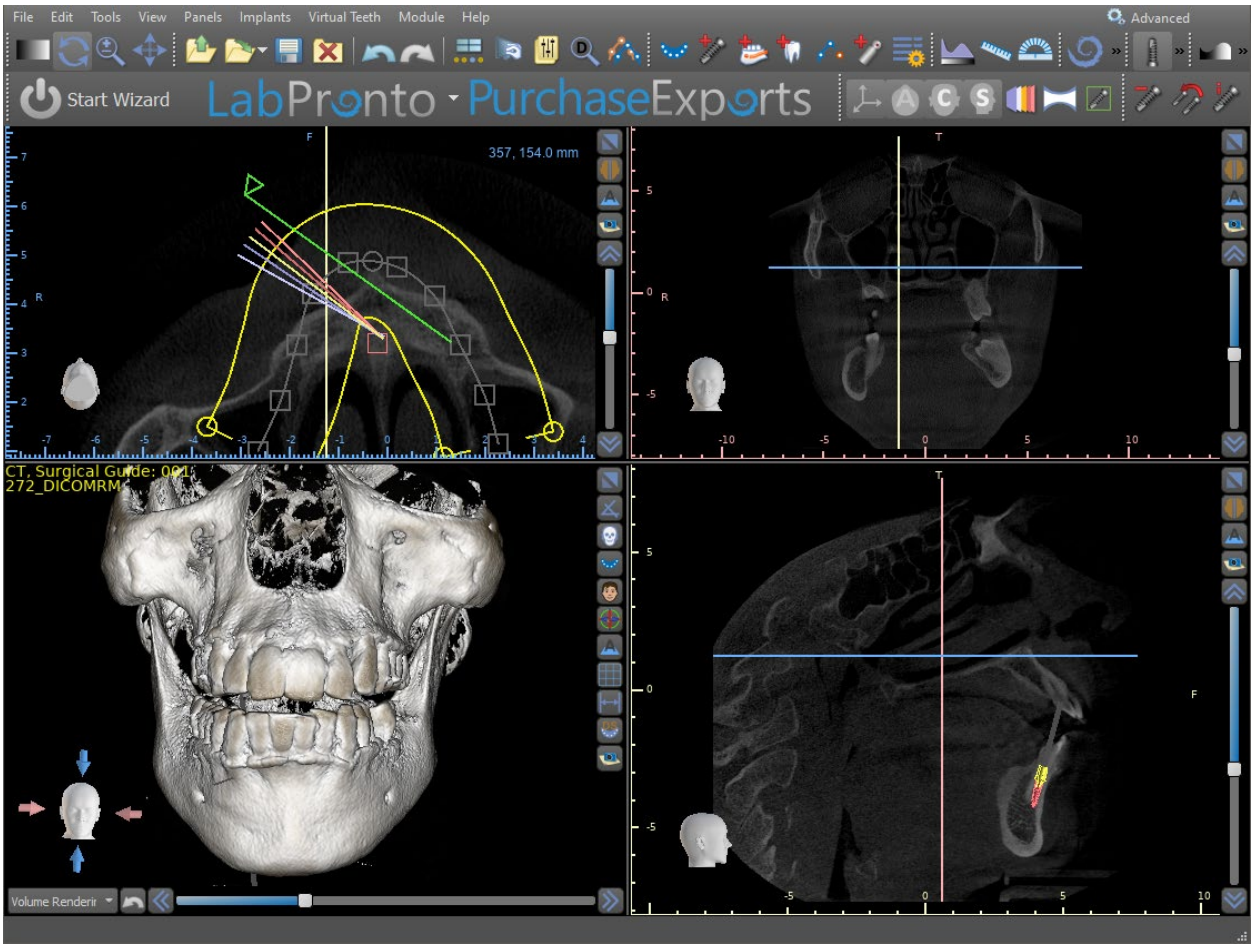


It is also possible to enable the indicators on the 3D images. Click *"View > 3D"* in the menu and choose the projection type to be enabled on the 3D image.

To change the visibility of objects such as implants or teeth, it is possible to use the associated panels, the buttons in the main menu bar, or the *"View > Objects"* option. After switching the visibility of the dental curve and slice indicators in the 2D views, it is now possible to use the "*All projections"* icon in the main menu bar.

5.2. Multi-planer screen

To access the multi-planar screen, click the *"View > Perspectives > MPR" menu option*. The multi-planar screen makes it possible to view coronal, axial, sagittal, and 3D images. This screen is generally used for applications such as oral and maxillofacial lesions and defects, removal of impacted teeth, and treatment of temporomandibular joint pathology.

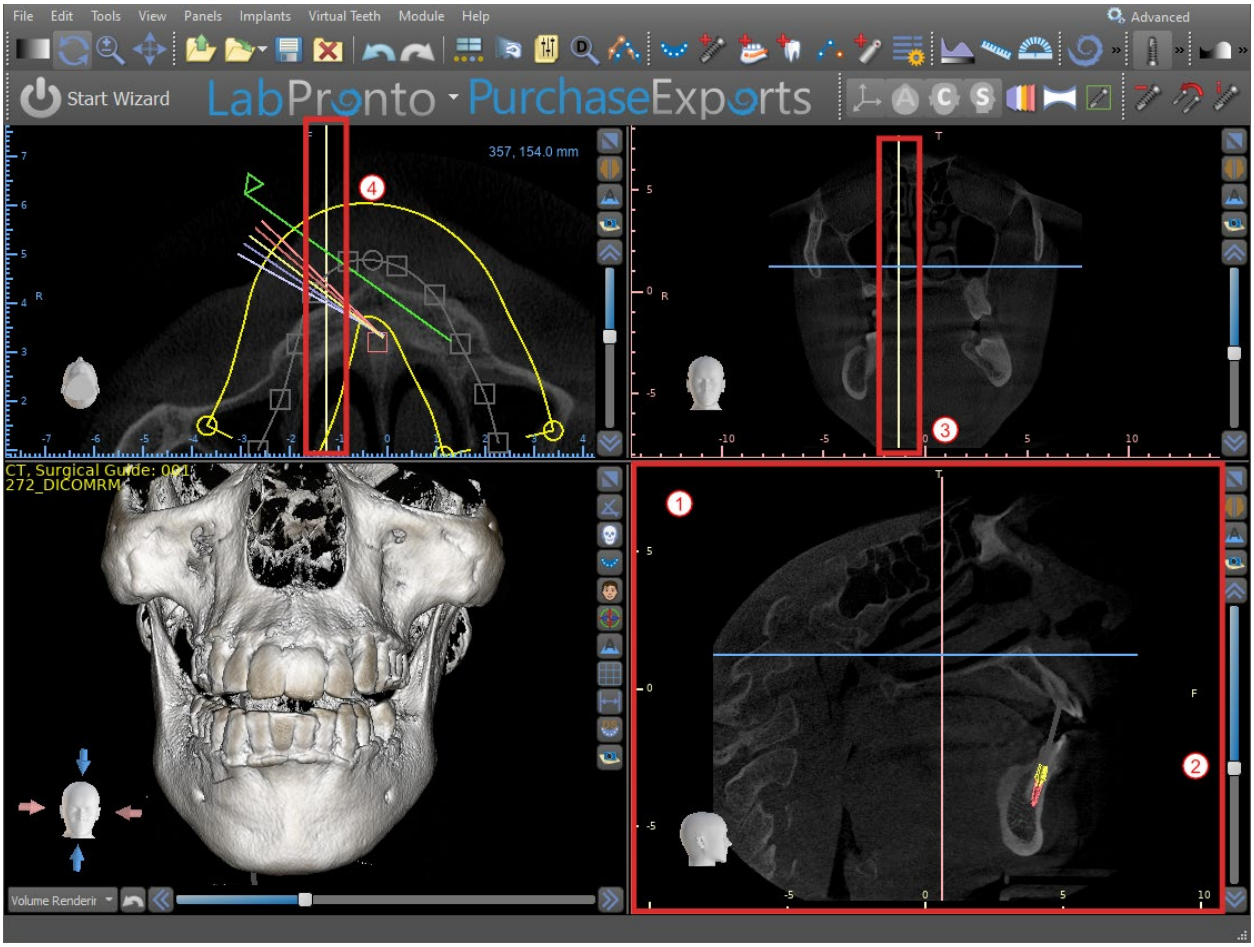


To locate the desired image, move the slide bar located next to the windows. Indicator lines show the exact image position of one window in relation to the images in the other windows.

5.2.1.Sagittal window

The sagittal image is a vertical plane that divides the skull into a right and left side. It is located in the bottom left window of the software (1) and is marked in yellow.

When the user moves the scrollbar of the sagittal window (2), the whole sequence of images in this group will be shown. The indicator line of the sagittal slice appears in the coronal (3), axial (4), and 3D images.



5.2.2. Coronal window

The coronal image is a vertical plane that divides the skull into a front and back part. This image is located in the top right-hand window of the application and is marked in pink.

When the user moves the scrollbar in the coronal window, the whole sequence of images in this group will be shown. The indicator line of the coronal slice appears in the axial, sagittal, and 3D images.

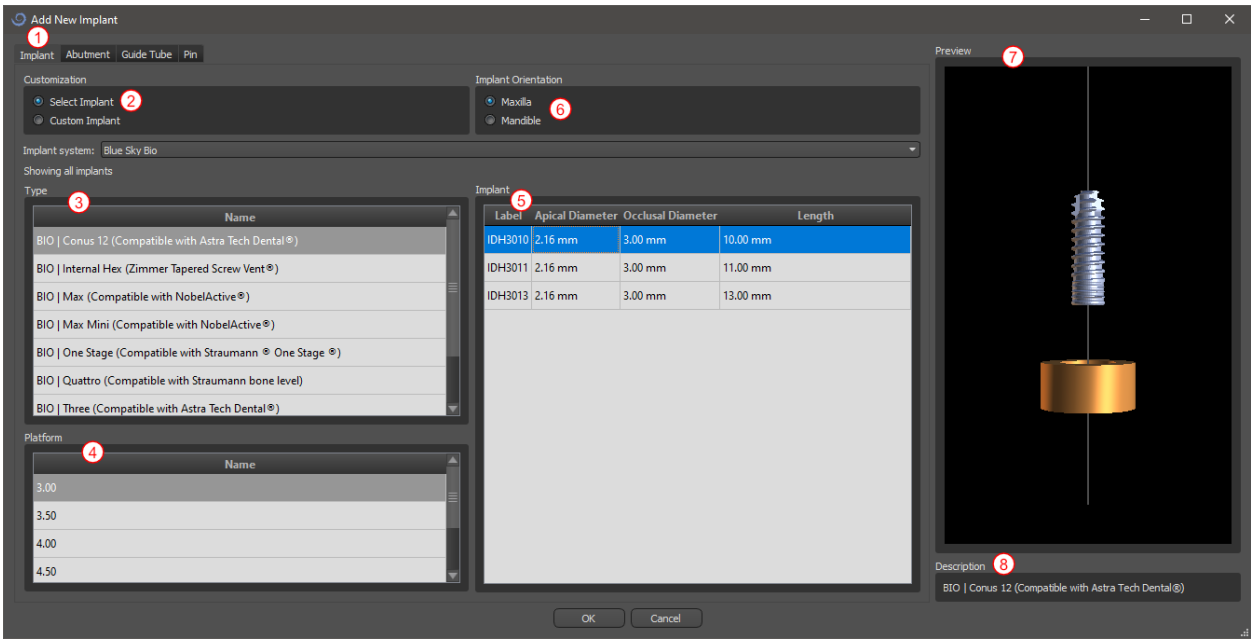
6. Placing implants and pins

Blue Sky Plan® allows virtual implant planning via the patient's CT or CBCT images. It is possible to add, exchange, move, and rotate the implant and abutment or pin in the different views.

6.1. Adding an implant or pin

6.1.1.Implant from the catalogue

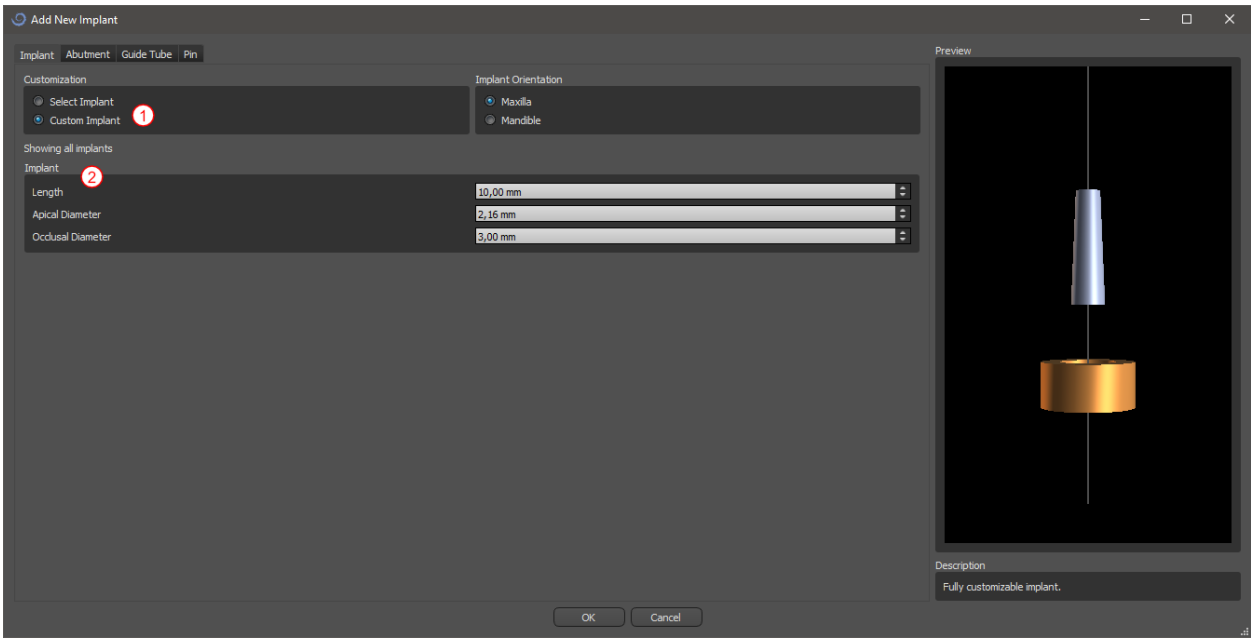
Before positioning the implant, it is recommended to first measure the dimensions of the bone. In this way it is possible to estimate what dimensions the implant should have. Clicking on the icon in the toolbar opens a dialog for adding an implant.



In this dialog it is possible to modify the implant parameters, abutment, and drill guide. The corresponding parts can be selected in the individual tabs (1). "*Select Implant*" (2) is selected by default, which makes it possible to select an implant from the catalogue on the basis of its type (3) and platform (4) and then according to parameters (5). It is also possible to specify the orientation of the implant (6). The currently selected implant can be viewed in the preview (7). A short description of the implant (8) is also located in the lower part of the dialog.

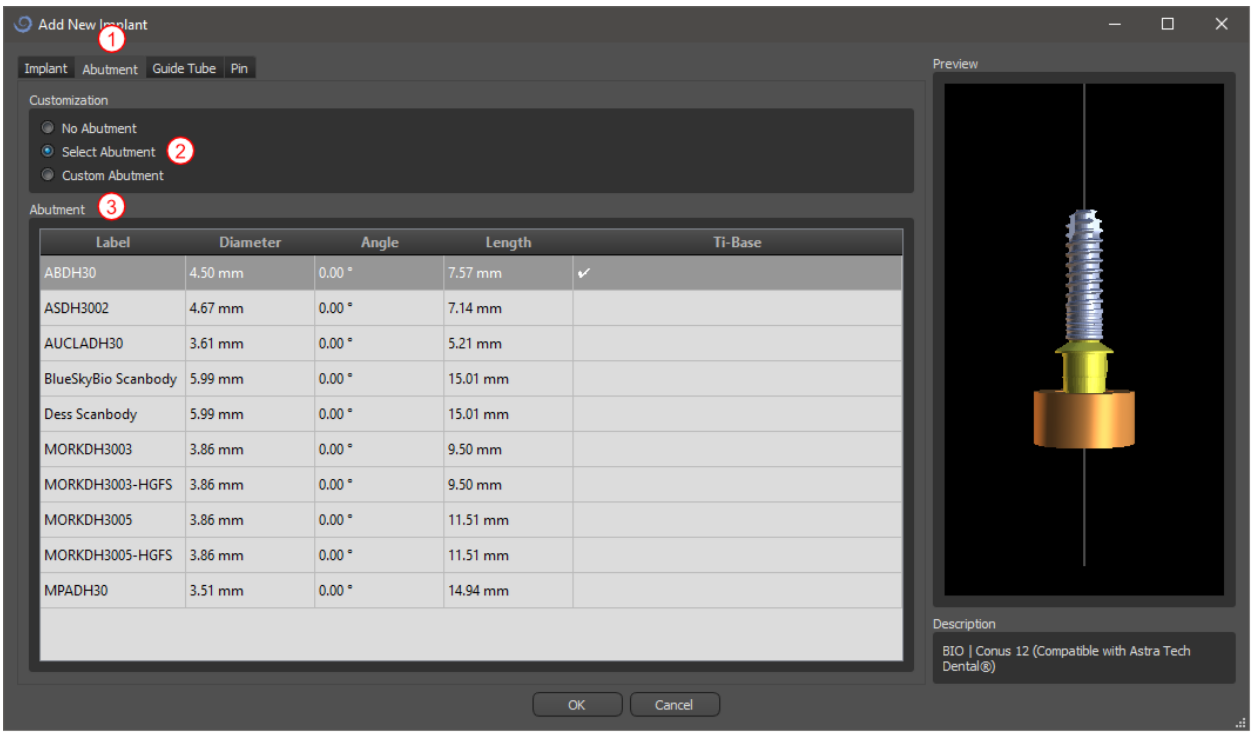
6.1.2.Custom implant

If none of the implants fulfills the particular requirements, it is possible to create a simplified but fully parameterized implant. This is achieved by clicking on the *"Custom Implant"* option (1). The individual parameters (2) can be modified with the corresponding fields. These changes appear immediately in the preview.



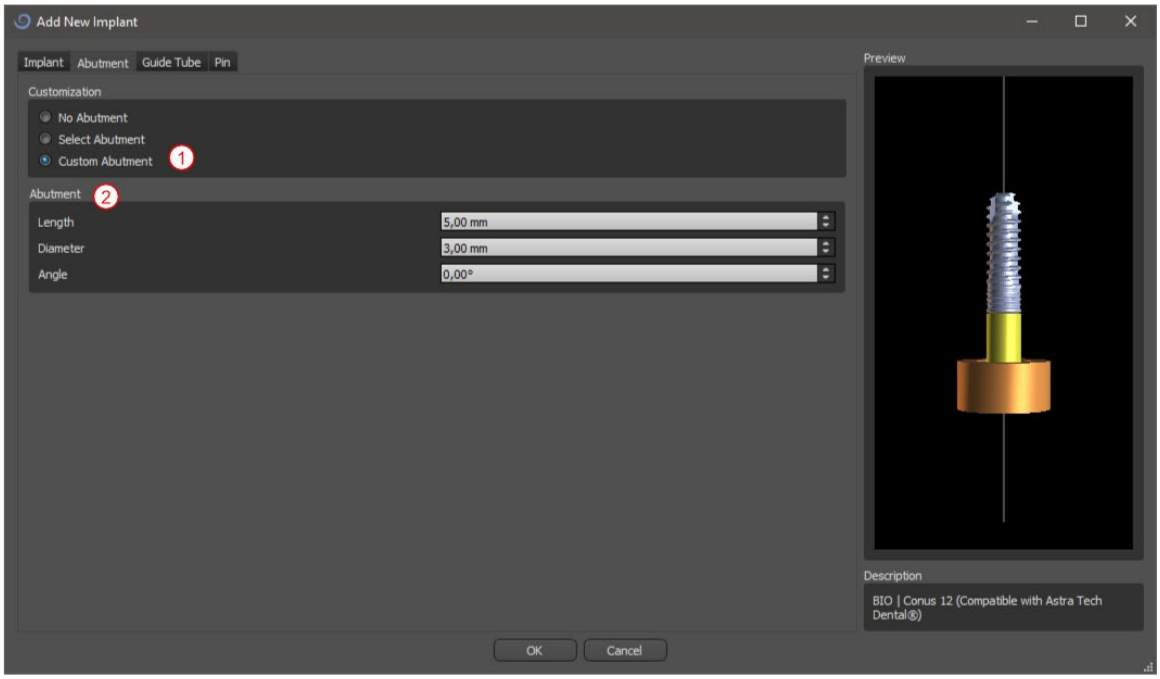
6.1.3.Abutment from the catalogue

By default, the implant is loaded without an abutment. If we want to add an abutment, it is necessary to first switch to the *"Abutment"* tab (1) and then select the *"Select Abutment"* option (2). A list of abutments that are compatible with the selected implant appears in the table (3). Once we have chosen a parameterized implant, a table for selecting the type and platform will be displayed here similarly as for the implant.



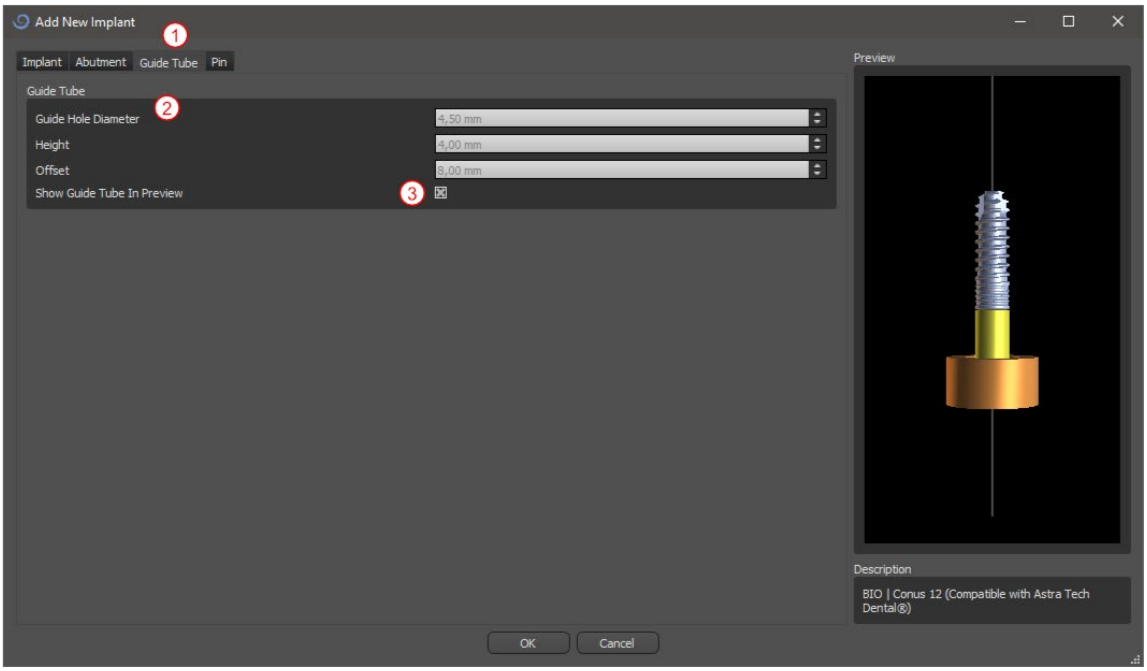
6.1.4.Custom abutment

The abutment can also be fully parameterized in the same way as the implant. We first select *“Custom Abutment”* (1); it is then possible to set the individual parameters (2).



6.1.5.Drill guide

The implant has an auxiliary drill guide added by default. If we want to modify it, it is necessary to switch to the *“Guide Tube”* (1) tab. Its parameters can be changed in the corresponding fields (2). If we want to display it or hide it in the preview, we can use the check box (3).



6.1.6.Pin from the catalogue

Instead of an implant, it is possible to add a pin. This is a special implant for positioning a template more firmly. In contrast to an implant, it cannot have an abutment but only a drill guide.

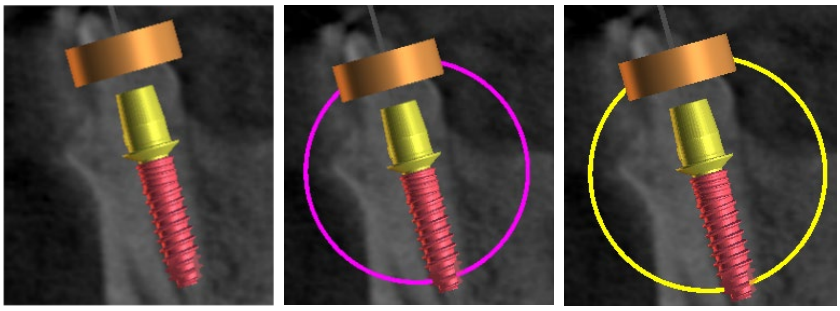
6.1.7.Your own pin

It is also possible to adjust your own pin similarly as for previous parts. Length 0 sets the length of the blue part of the pin; length 1 then sets the length of the green part.

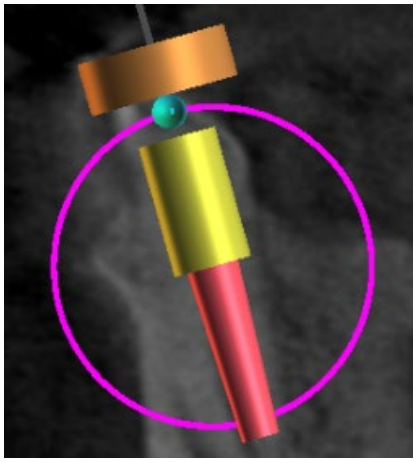
6.2. Positioning and manipulating the implant

We confirm the choice of implant in the dialog by pressing "*OK*". The mouse cursor then changes to . We can then position the implant by clicking on the slice and, if necessary, on the 3D visualization in any window. After being added, the implant is always positioned perpendicular to the selected orientation. It is up to the user to fine-tune the position and rotation.

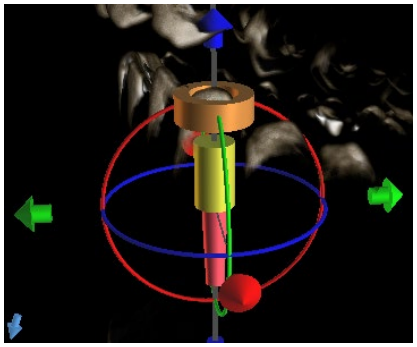
It is possible to move the implant in all of the windows. This is achieved by moving the cursor onto the implant, clicking the left mouse button, and dragging. The implant always moves in the plane of the view.



Besides moving it, it is also possible to rotate it using the so-called draggers. These are displayed when you position the cursor on the implant, its abutment, or the drill guide. If we move the mouse curser onto the dragger and click the left mouse button, the dragger changes color, and by dragging the mouse we can modify the rotation of the implant.



If the implant has a parameterized abutment, it is possible to change the angle of the abutment with the spherical blue-green dragger.



In the 3D window, the situation is a little more complicated because, unlike the other windows, the implant is manipulated in space. Three circles of different colors appear around the implant, which rotate it around the associated axes of the local coordinate system. Besides these, arrows appear both above and below the implant, by means of which it is possible to move the implant on its axis.

It should be added that clicking on the implant makes the implant active, and all the slices move onto it. It is possible to recognize it in the windows by its red coloring. The other implants are colored light blue.

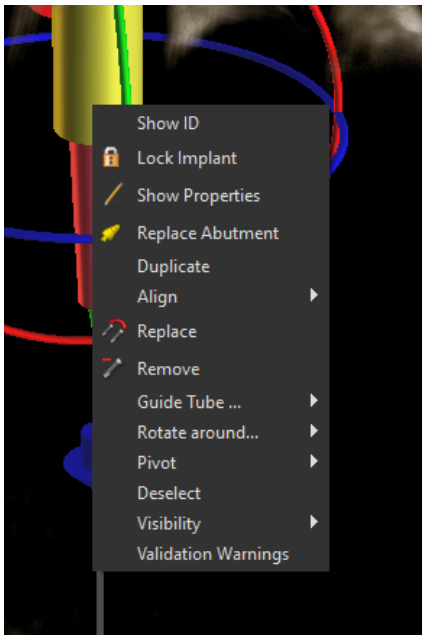
6.3. Further operations on the implant

6.3.1.Toolbar

In the upper menu bar it is possible to display a toolbar of further operations on the implant by selecting *"View > Toolbars > Implants Toolbar"*. Here there are icons for removing the implant (1), replacing the implant (2), and displaying information about the implant (3).

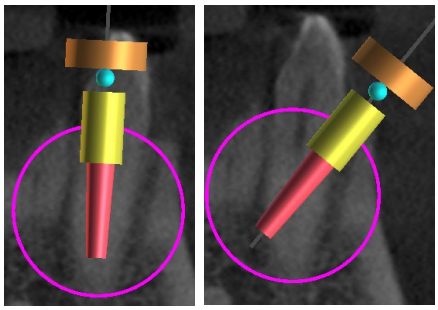
All of these operations are used in the same way: we click on the icon, move the cursor onto the implant, and click on it. For the option of replacing the implant, the same dialog appears as when adding the implant, in which we choose which implant we want to replace the selected implant with.

6.3.2.Context menu

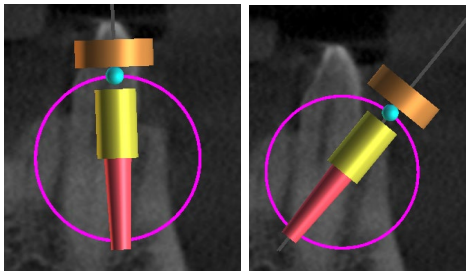


It is also possible to perform several operations on the implant via the context menu, which we can invoke by clicking the right mouse button on the implant.

It is possible to display the implant ID (a short editable description of the implant) or its properties. It is also possible to lock the implant against edits. The locked implant has a padlock icon displayed next to it. It is similarly possible to replace and, if necessary, add an abutment. The entire implant can be duplicated or aligned with another implant. That means that although the implant remains in its position, it turns in the space in such a way that its axis is parallel to the axis of another implant. A complex implant replacement can also be performed from the context menu. The implant can also be removed. Besides this it is possible to change the point around which the implant rotates during manipulation (the so-called Pivot). Finally, it is possible to cancel selection of the active implant via the context menu.



Pivot set to *Center*. The implant rotates around its center.

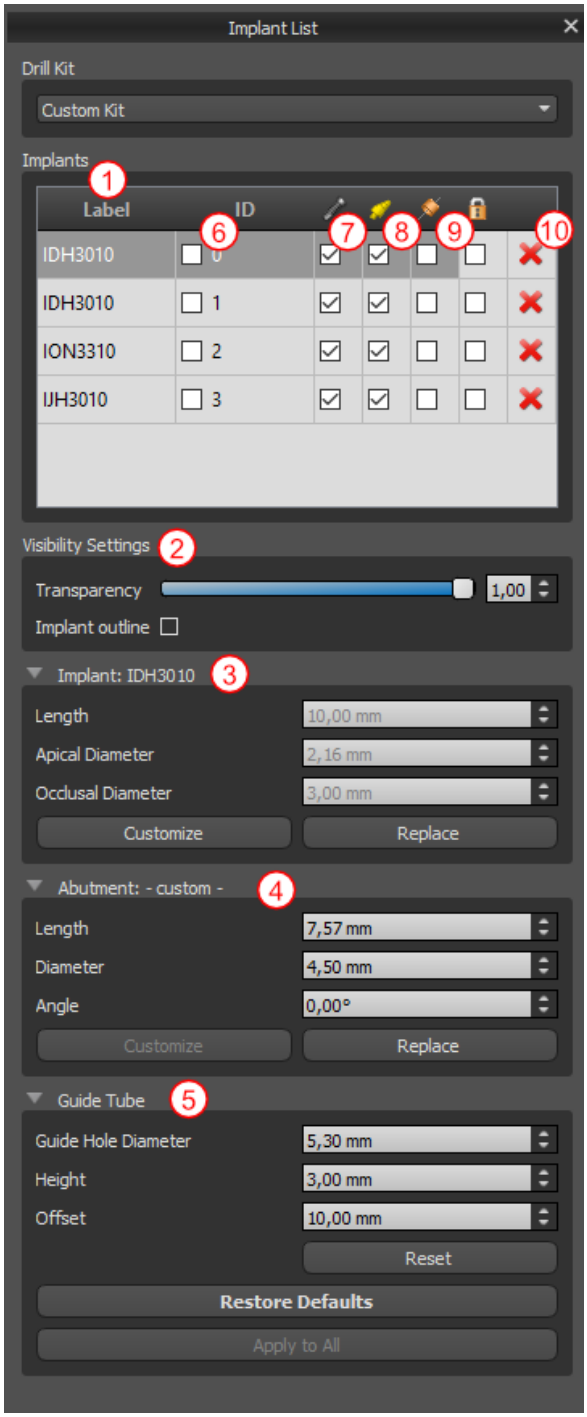


Pivot set to *Head*. The implant now rotates around its head.

Finally, the visibility of individual parts of the implant can be changed (*"Visibility > Implant/Abutment/Drill Guide"*).

6.4. Side panel

To make it easier to find our way among implants, the side panel can be displayed via *"Panels > Implant List"*.



It contains a list of all the implants (1), settings for the transparency and visibility of outlines (2), the parameters of the active implant (3), its abutment (4), and the drill guide (5). For a pin, the properties of the pin are displayed instead of the properties of the implant and abutment. For the implant and abutment sections, there are also *"Customize"* and *"Replace"* buttons. The *"Customize"* button replaces the implant with its fully parameterized variant. *"Replace"* opens the same dialog as for adding an implant and makes it possible to replace the implant with the selected variant.

Several properties of the implant can be changed quickly in the list of implants. One is the ID (6), which is a short description of the implant. It is possible to change the visibility of the ID by double-clicking on it and to toggle its visibility in the windows with the check box. The check box under the implant (7) changes the visibility of the implant, the check box under the abutment icon (8) toggles the visibility of the abutment, and the check box under the drill guide (9) changes the visibility of the drill guide.

All the visibility settings are independent of each other, and the following rules control whether the implant can be seen in the windows:

1) If the implant is active (red color), it is always visible. The abutment and drill guide are controlled by the check boxes.

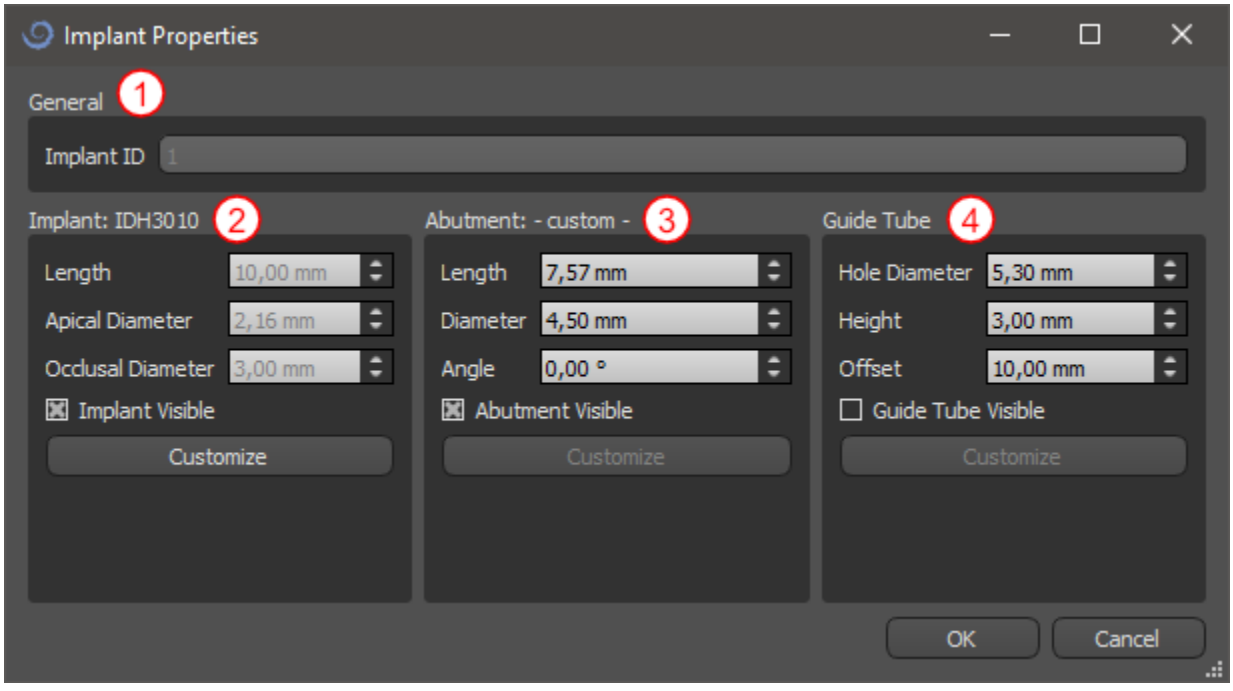
2) If the mouse cursor is positioned over the implant, its abutment, or the drill guide, the draggers and the implant are displayed. The abutment and drill guide are controlled by the check boxes.

3) In all other cases, the visibility of the individual parts is controlled by the check boxes.

Finally, for every implant there is an icon for removing it (10) and locking it (between drill guide and deletion).

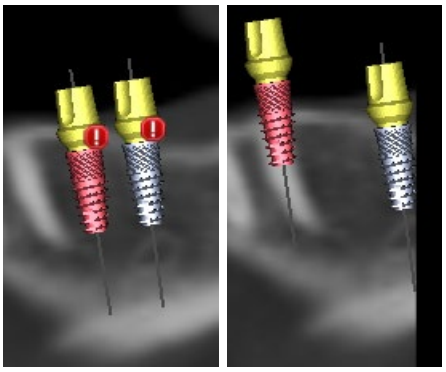
6.5. Dialog with the parameters of the selected implant

The parameters of the implant can be displayed from the context menu. If the side panel is displayed, then the associated implant is selected in this panel, and its parameters appear. If this panel is hidden, a special dialog appears when the user attempts to display the parameters. It again displays the implant ID (1), the parameters of the implant (2), the parameters of the abutment (3), and the parameters of the guide tube (4). For a pin, the parameters of the pin appear here instead of the parameters of the implant and abutment, similarly as in the side panel.

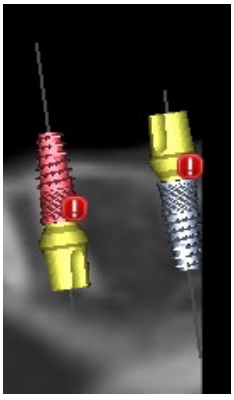


6.6. Validating implants

All implants are validated on the background. That means that their positions with respect to each other and to the nerves are checked. If an implant is evaluated as invalid, the icon appears next to it.



The first criterion considered is the distance between implants. If two implants are too close to each other, both are evaluated as invalid, which is represented by the appearance of icons over both implants.

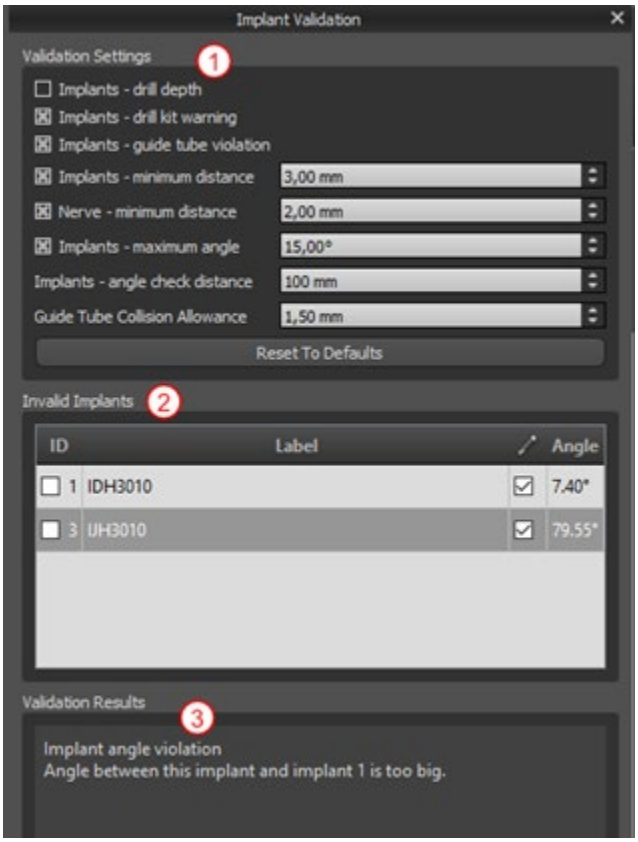


The second criterion is the angle between implants. If this angle is too large, the implants are again evaluated as invalid, despite the fact that they are relatively far apart. To fulfill the validation criteria, we must reduce the angle between the implants and, if necessary, to increase the distance between the implants again.

The third criterion is the distance from the nerve. The same considerations apply here as for the distance between implants.

If you are not certain why the validation had failed, you may open a panel with the validation results via “Panels > Implant Validation”. In this panel it is also possible to set the validation parameters (1). There is a list here of all invalid implants (2) and the reasons the validation of the selected implant failed (3).

Note: pins are not validated either against themselves (or implants) or against nerves.



6.7. Ordering implants

Implants can be ordered directly from the application by selecting Order Parts (1) in the toolbar.

The Blue Sky Bio website will load automatically, and the implants which were used in the treatment plan will be added automatically to the shopping cart. Additional implants and items can be added to the shopping cart by continuing to shop via the website.

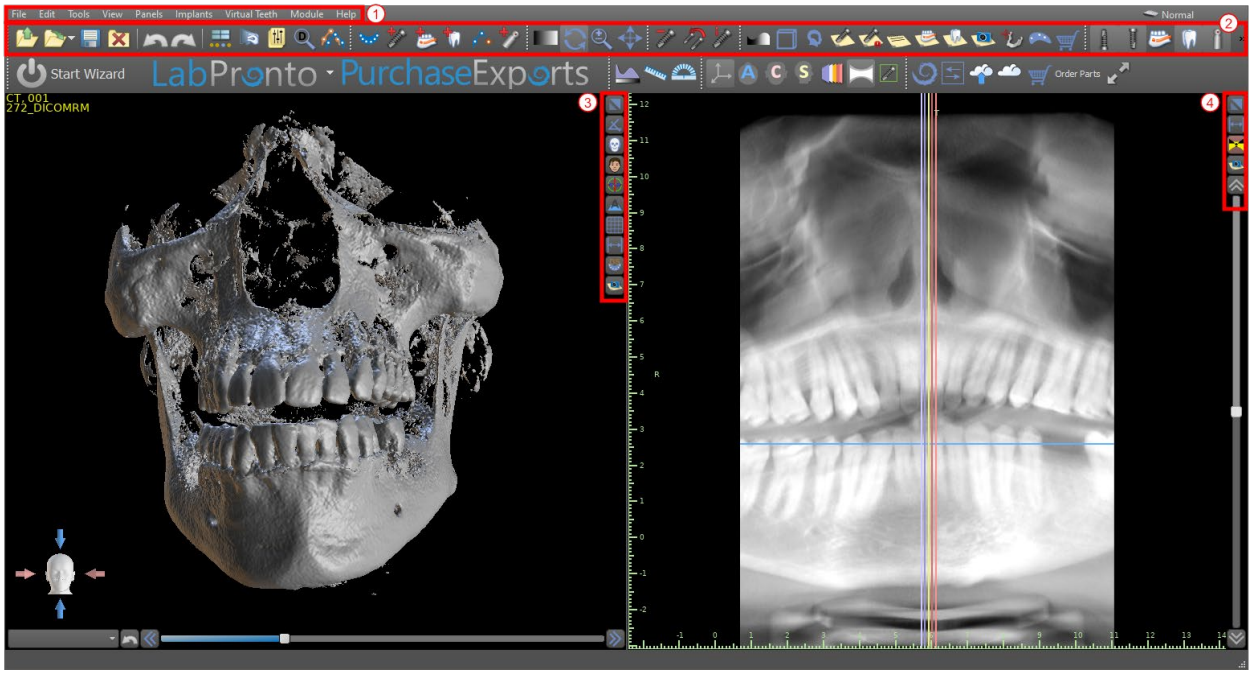
If custom implants were used (implants that were not selected from the Blue Sky Bio catalog) in the treatment plan, those implants will not be added automatically to the shopping cart.

7. Tools

This chapter explains the properties of each Blue Sky Plan® tool and the toolbar that contains the most-used tools in the application.

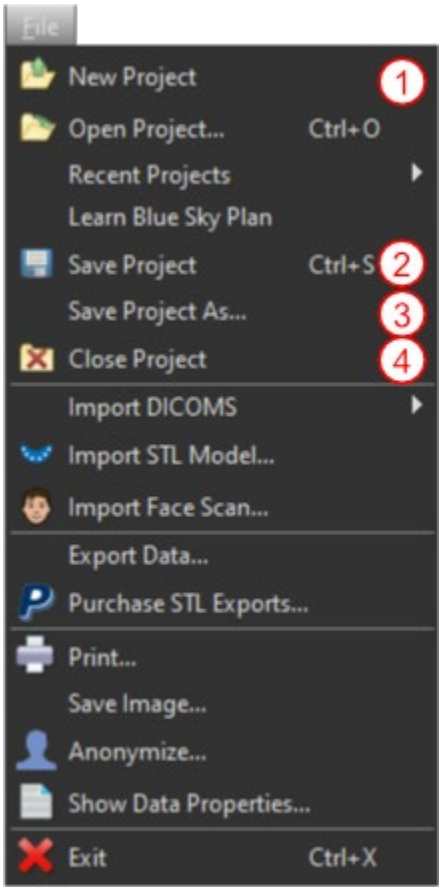
7.1. Toolbar

1 – Menu bar (access to all the software tools)
2 – Icon bar (fast access to the main tools)
3 – 3D view icons (view rotation, volume rendering settings, and visibility of slices)
4 – Panoramic icons (offset step, X-ray mode, etc.)



Further toolbars can be displayed by means of the context options in the main bar or via the option *"View > Toolbars"*.

7.2. Opening a project



After clicking the "File > Open Project" (1) menu option the application will return to the main menu. You can create new project by selection of planning type.

7.3. Saving a project

To save a modified project, click the *"File > Save Project"* (2) menu option. To save a project under a new name, click the *"File > Save Project As"* (3) menu option.

7.4. Closing a project

To close a project file, click the *"File > Close project"* (4) menu option.

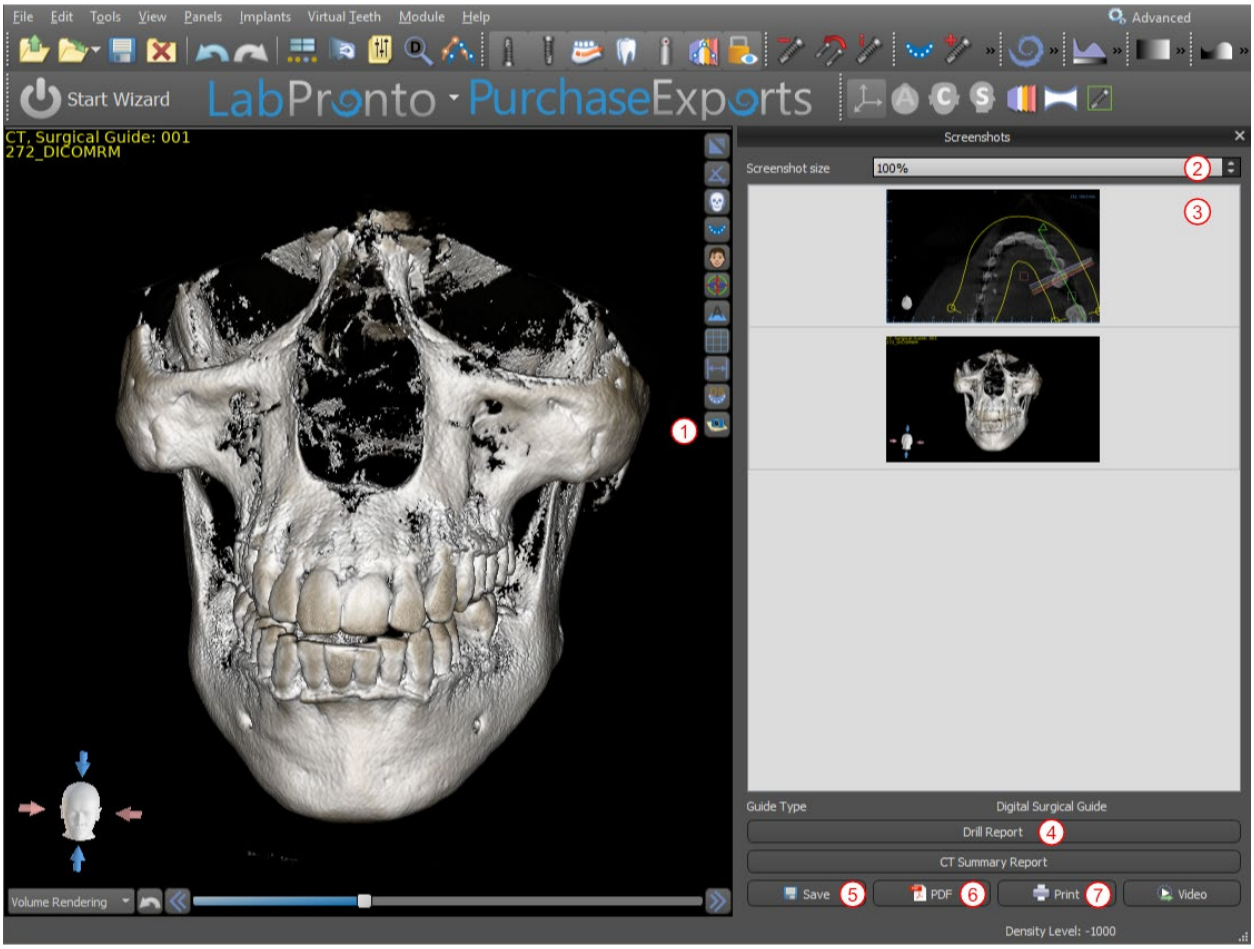
7.5. Saving images in JPG format

To save the currently visible screen images in .jpg format, click on the *"File > Save Image" menu option*, then choose the folder where you want to save the images or PDF file.

7.6. Saving screenshots and generating a Drill Report

Screenshots can also be captured individually using the *"Screenshot"* button (1) located on the right side of each view. Captured screenshots are inserted into the list in the *"Screenshots"* panel (3), which can be accessed from the *"Panels"* menu.

For most slices this makes it possible to extract not only the current view, but also all further possible slice positions with the current settings. Snapshots are captured in the size corresponding to the current window size and the setting (2) in the *"Screenshots"* panel.



Using the context menu options in the list of screenshots (3), it is possible to copy the selected screenshot to the clipboard, save it to disk, or remove it from the list. The screenshot can be displayed in its original size by double-clicking on the preview.

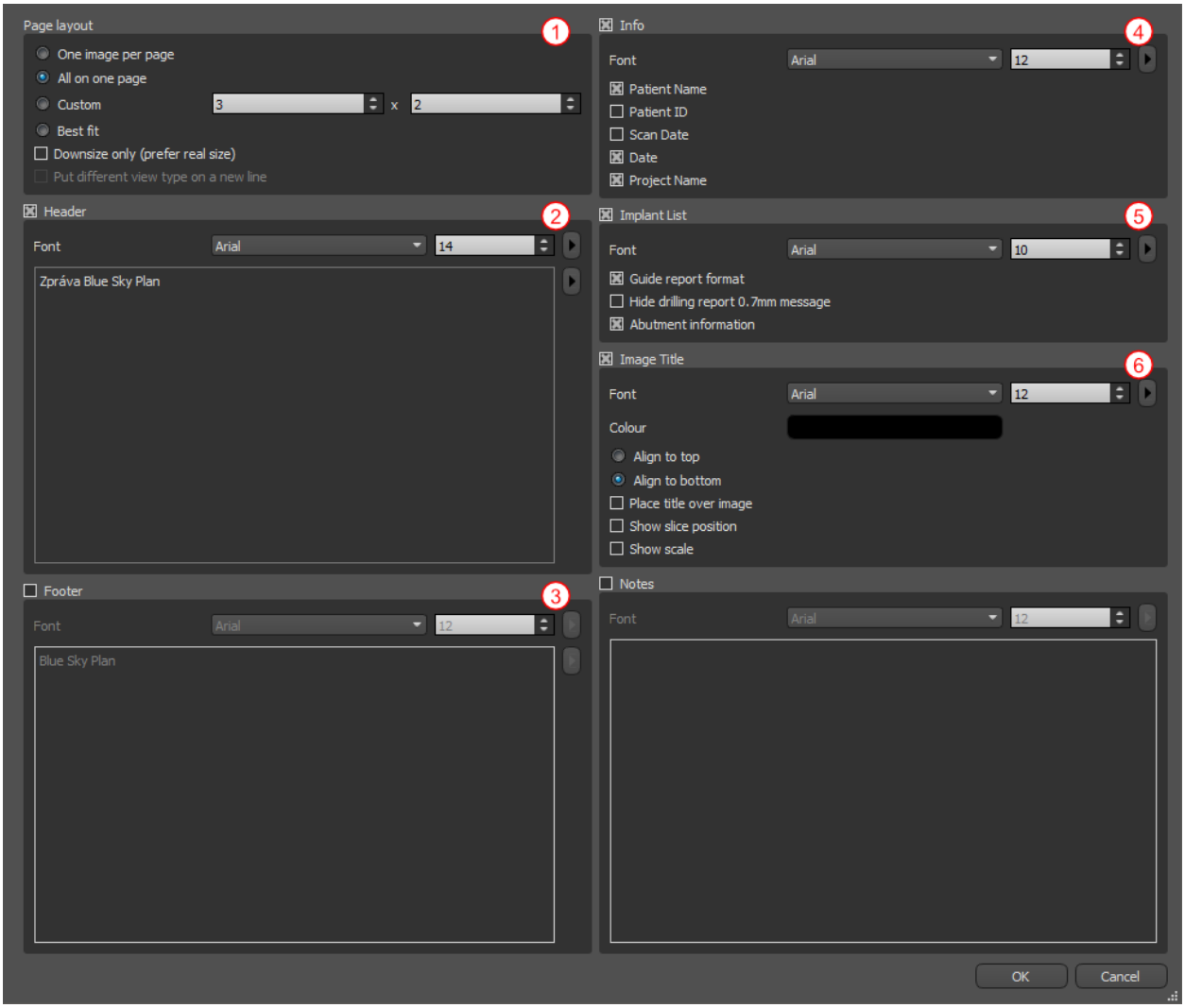
Snapshots can be saved individually in the selected bitmap format (5), a PDF document of all the windows can be created (6), and the document can be printed out directly (7).

7.6.1.Drill report

A set of screenshots can also be created with the *"Drill Report"* button (4) which creates a set of snapshots containing the 3D view, the panoramic view, and a pair of the normal and tangential view for each planned implant.

7.6.2.PDF export and print settings

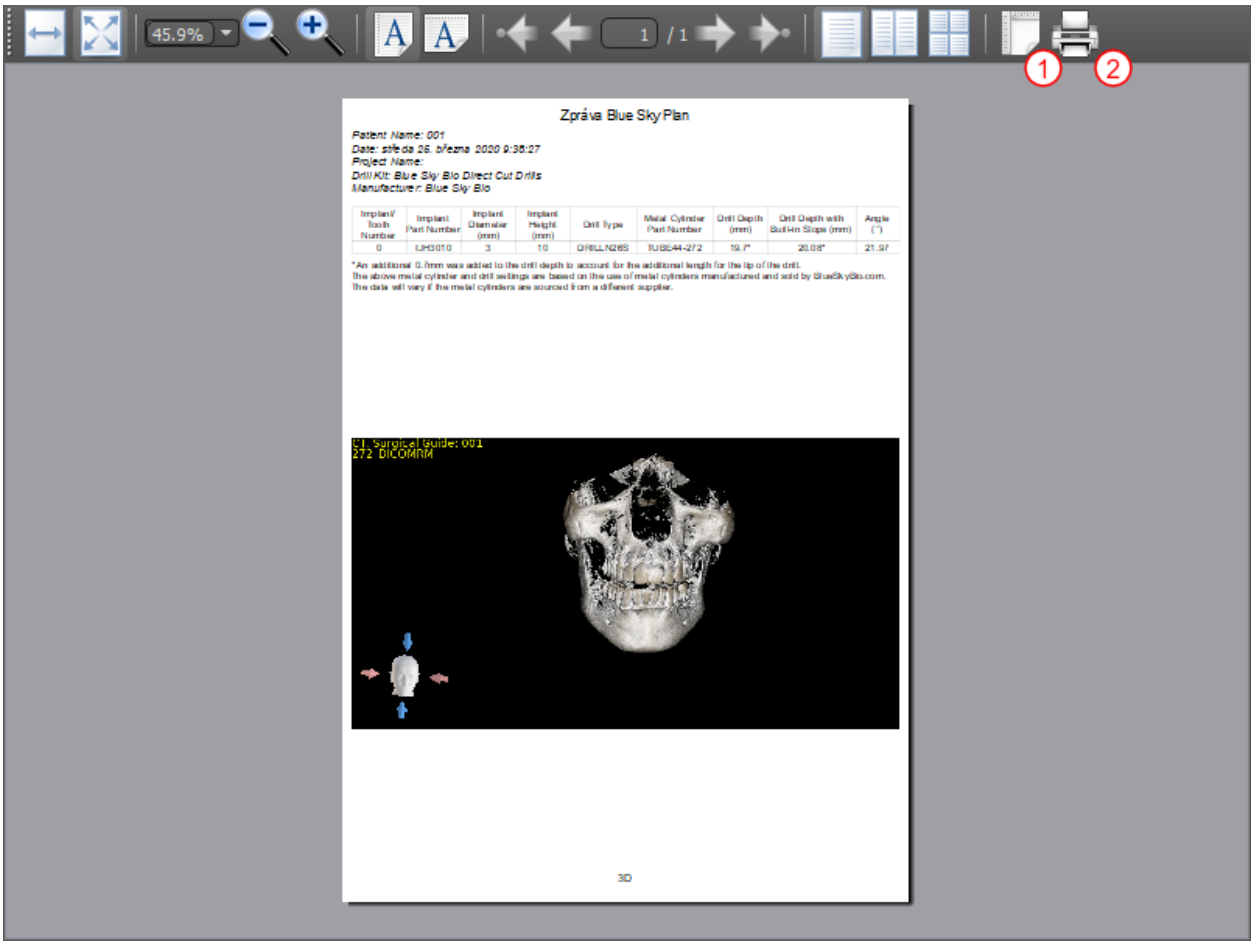
When exporting to a PDF file and printing, the layout of the images on the page can be selected in the *"Page layout"* section (1). In *"Downsize only"* mode the program will not enlarge the images and will attempt to maintain their actual size.



The document created can be supplemented with a user header (2) and footer (3), basic information about the patient and project (4), a table of implants (5), and a description of each image inserted in the image (6).

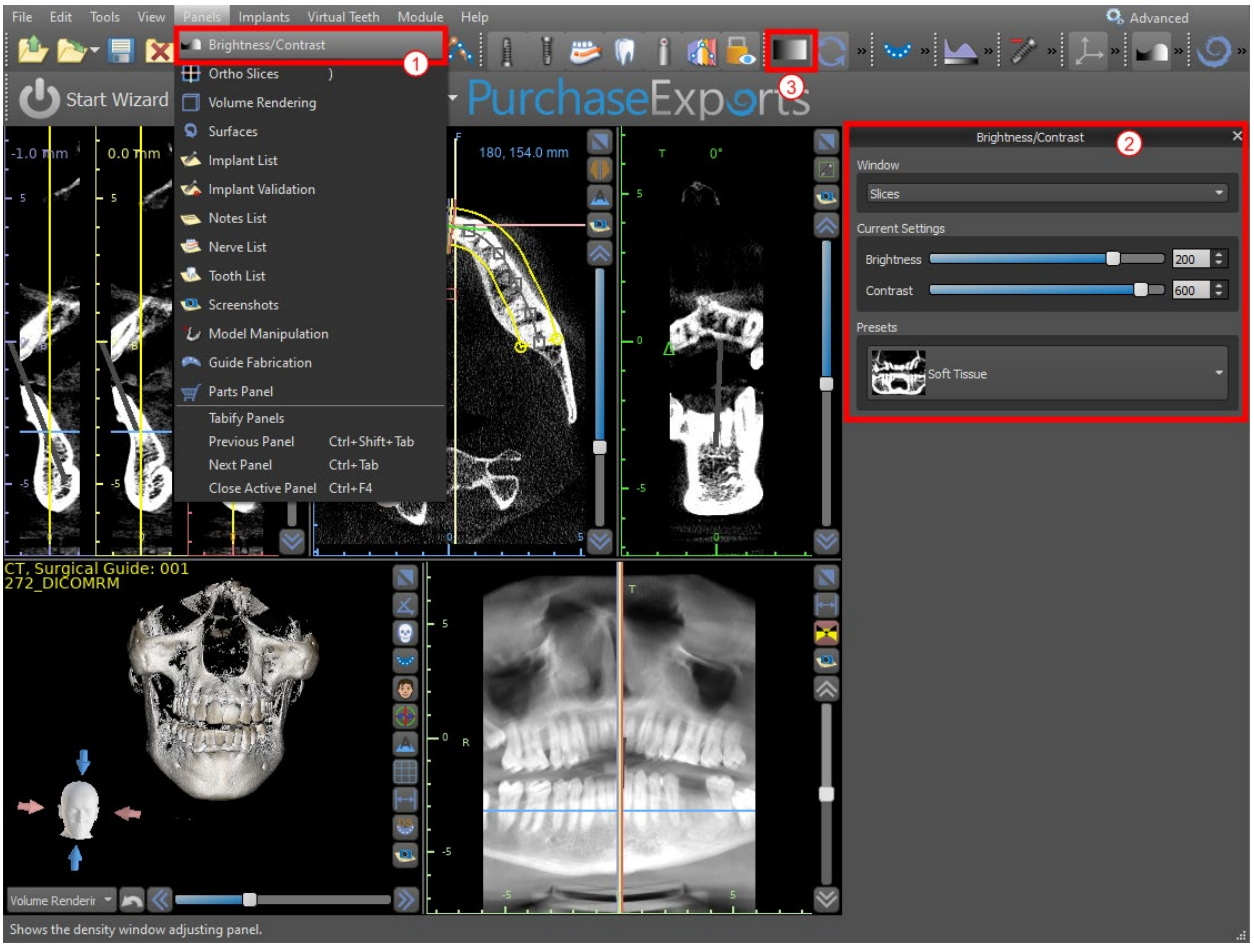
7.6.3.PDF export and printing

Once the settings are confirmed, the document created appears in the preview window. The *"Page setup"* button (1) can be used to set the page format for printing. Clicking the *"Print"* button (2) then prints it or saves it to a PDF file.



7.7. Modifying window and level

The display brightness and contrast of density data can be changed in the *"Brightness/Contrast"* panel (2), which can be accessed from the *"Panels"* menu (1). The brightness and contrast can also be changed with a special mouse mode (2) in which movement along the horizontal axis while pressing the left mouse button changes the brightness, and movement along the vertical axis changes the contrast.



7.8. Zooming

To zoom in, press and hold down the right mouse button and drag the mouse up or down.

A second option is to select the zoom icon (as shown below) and hold down the left mouse button while moving the mouse forward or backward.

7.9. Moving the image

Click on the *Move Image icon* and drag the image as desired. An image can also be moved by holding down the mouse wheel (pressing it, not scrolling it) and dragging the image.

7.10. Moving objects

In the default mouse mode, left-clicking changes the position of the slice. If the mouse cursor is positioned over an object that can be manipulated, the mouse cursor changes, and the object can be moved, and if necessary its angle of rotation or size can be changed using the displayed dragger.

7.11. Measurements and overlays

Users can perform any measurement of density (1), length (2), or angle (3) in 2D images. They can also insert arrows (4), text descriptions, or rulers (5).

7.12. Linear measurement

Click the *"Tools > Distance Measure"* **menu option** (6) in order to perform any 2D measurements (2).

Click the left mouse button with the pointer on the image to mark the start point of the distance to be measured and click again on the image to mark the end point of the measured distance. To correct the measurement you can grab one of the end points and move them.

7.13. Angular measurement

Click *"Tools > Angular Measure"* **menu option** (6). Click the left mouse button with the pointer on the image and repeat the process twice to get an angle (3). To correct the measurement you can grab the points specifying the angle.

7.14. Density measurement

Click the *"Tools > Density Measure"* menu option (6). The value of the density measurement is obtained from the information contained in the patient's image and can vary for each CT or CBCT scan. The measurements are given in Hounsfield units.

7.15. Measurement correction and number position

The user can correct the measurement and all the overlays in the default mouse mode. It is possible to correct a measurement by clicking at the edge of the measurement with the left mouse button and dragging. It is also possible to position the numerical value of the measurement outside of the image.

7.16. Deleting a measurement

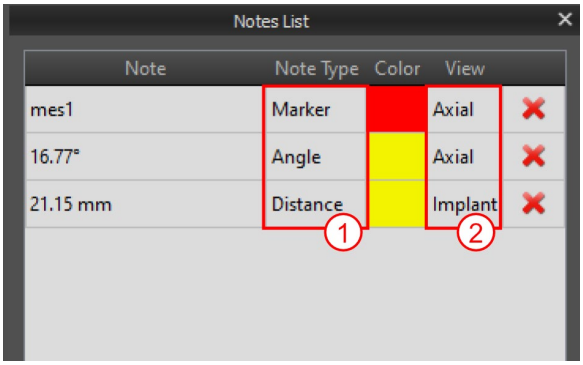
It is possible to erase a measurement in two ways:

a) Click the measurement edge or click on the number with the right mouse button. A menu will appear with the deletion option.

b) Click the *"Panels > Notes List" menu option.* A panel will appear (7) with a list of all measurements, their types, values, and colors. To erase a measurement, click the X beside the measurement.

7.17. Overlays

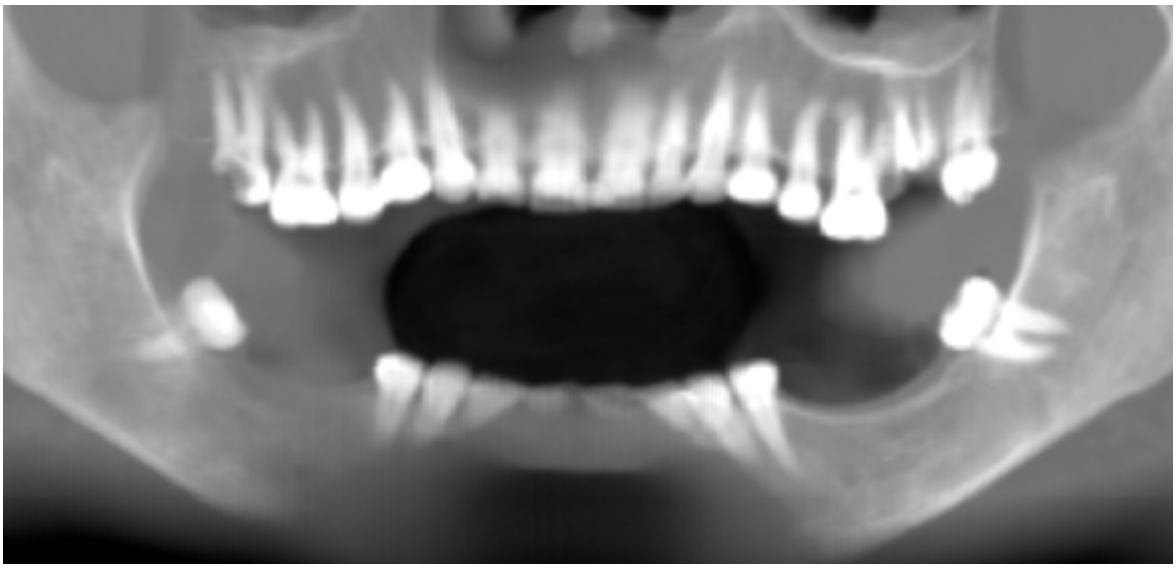
To add text or other types of overlays, select the corresponding action from the "*Tools*" menu. Specify the position of the item in the selected window by clicking on it. The inserted overlay is bound to a specific position in the slice; it will not be visible for other positions. Orthogonal slices and the normal slice can be positioned in the location of an overlay by double-clicking on the *"Note Type"* field (1) or *"View"* field (2) of the associated item.



The text of an overlay can be changed by clicking on the *"Note"* field in the *"Notes List"* panel (7) or via the context menu on the item in the associated slice. The color of several types of items can also be changed in the *"Notes List"* panel by clicking on the *"Color"* field.

7.18. Panoramic

A panoramic image is a panoramic slice of the mouth and teeth. It is a perpendicular plane of the axial image.



7.18.1.Creating a panoramic line

Refer to Section 3.3.

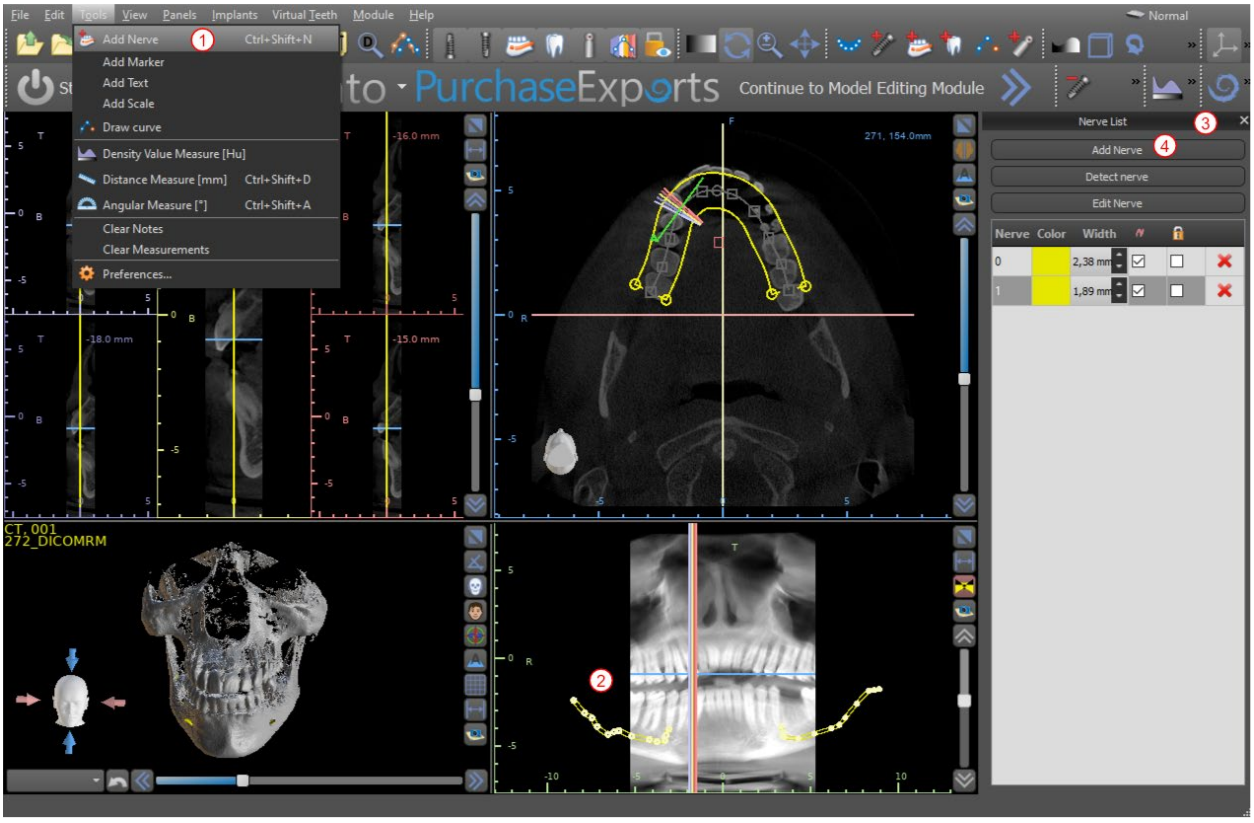
7.18.2.Mandibular canal

The mandibular canal can be added in the panoramic image and viewed in all of the images.

7.18.3.Adding a mandibular canal

Adjust the panoramic curve to fit the patient's arch as described in section 3.2.1. Click on the *"Tools > Add Nerve"* menu item (1). The *Nerves panel* (3) will appear to show default properties for the nerve (2). Click on portions of the nerve in the panoramic window and follow the canal to the mental foramen.

When entering nerve points, the position of the slice can be changed with the scroll bar on the right side of the window, and the last-added point can be removed with the *"Edit > Undo"* action.



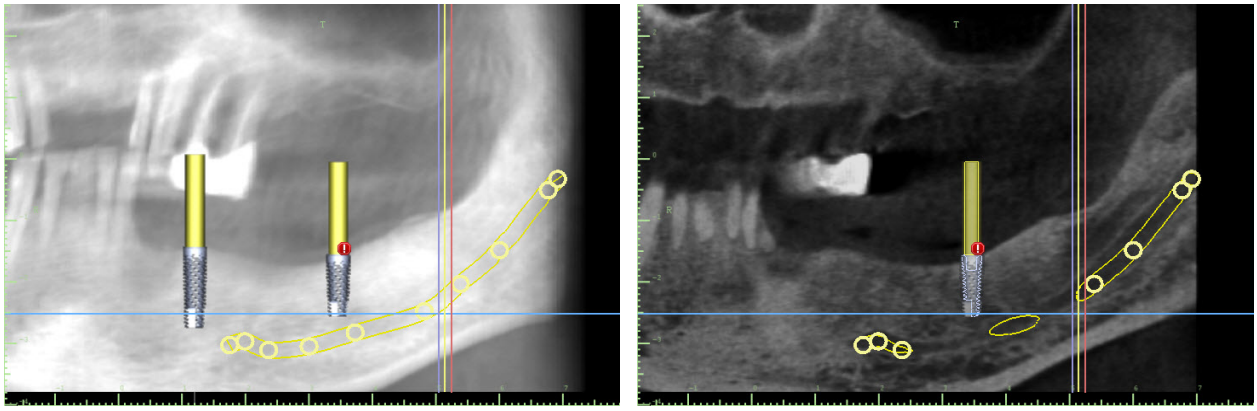
You can fine tune the buccal/lingual aspect by adjusting the nerve point in the cross sectional view later. Add another nerve by clicking the "*Add Nerve"* button (4) on the Nerves panel, and repeat on the other side. All images should show the nerve with a default diameter in yellow.

7.18.4.Changing mandibular canal parameters

Clicking on the color of the nerve in the list (3) opens color selection window. After choosing, confirm your selection by pressing *"OK"*. The width of the nerve is displayed in the adjacent column. This can be changed either by clicking on the window and entering new values or by repeatedly clicking on the arrows beside it to change the value in increments of 0.1 mm.

7.18.5.Deleting the mandibular canal

Select the *"Panels > Nerve List"* menu option and click on the letter X beside the nerve to be deleted.



7.18.6.Canal display in different panoramic view modes

As described in Section 6.18, within panoramic view it is possible to switch between composite mode and slice display mode. In composite mode, the entire mandibular canal is displayed in the form of an outline, including all control points (see image). In slice mode, only the control points near the panoramic plane are visible. The mandibular canal itself is only displayed in the form of slices of the same plane.

8. Importing the Scan Appliance

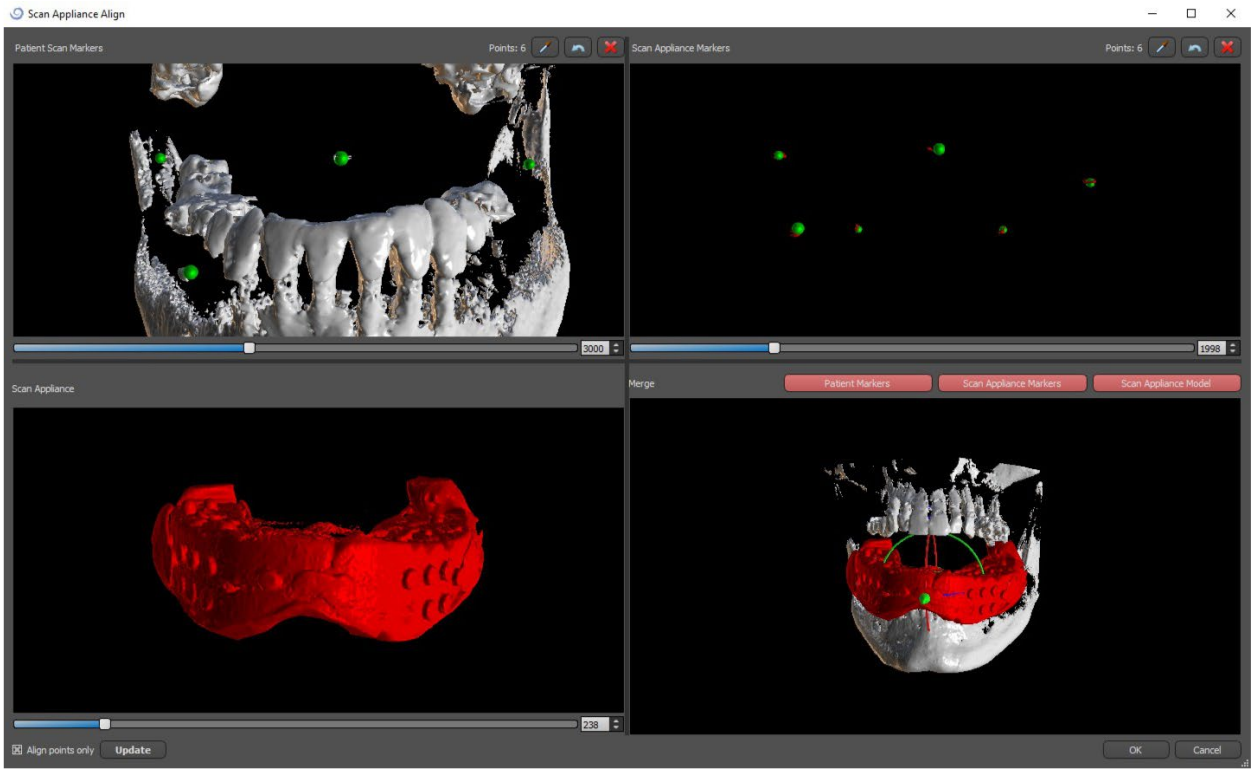
The Blue Sky Plan® Scanning Protocol calls for two CT scans. The first scan should be of the patient wearing a Scan Appliance, and the second scan should be of just the Scan Appliance. Since the Scan Appliance is made of mostly radiolucent material, the Scan Appliance does not appear in the patient's scan. It does however appear when scanned alone, since the relevant density of the Scan Appliance is greater than the density of air, causing it to appear in the scan.

The software allows the two scans to be merged in order to have the Scan Appliance appear in the scan of the patient. Merging the Scan Appliance assists with proper treatment planning as it shows the position of the future teeth and removes any artifacts which may have previously appeared in the area of the teeth.

Follow the steps below to import the Scan Appliance:

1) Load the DICOM set of the patient into the Blue Sky Plan application.

2) Choose *"File > Import Scan Appliance"*. Follow the prompts to identify the location of the Scan Appliance DICOMs and select the relevant region of interest, selecting only the range containing the Scan Appliance.

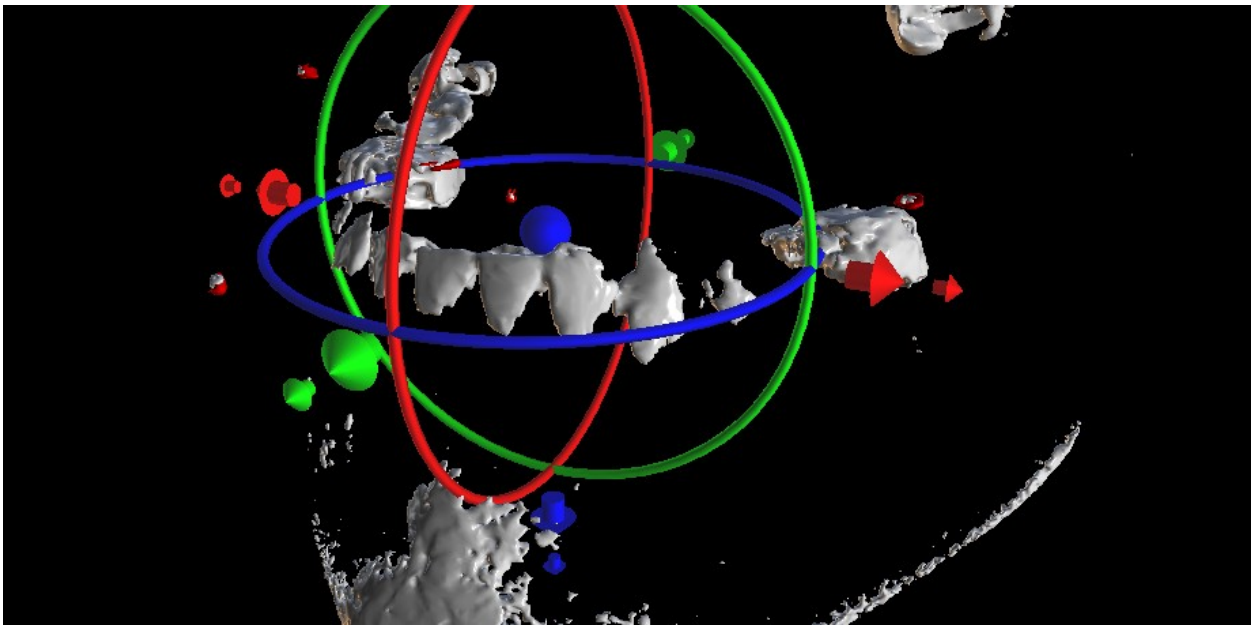


3) In the process of alignment, you can use the buttons to toggle simultaneous display of the patient data gutta markers (white) and Scan Appliance (red). You can display or hide the Scan Appliance model with button.

The top left-hand box contains the gutta markers from the patient's scan. The top right-hand box contains the gutta markers of the Scan Appliance. The bottom left-hand box contains an image of the Scan Appliance. The bottom right-hand box displays both sets of gutta markers if they coincide.

8.1. Gutta percha markers coincide

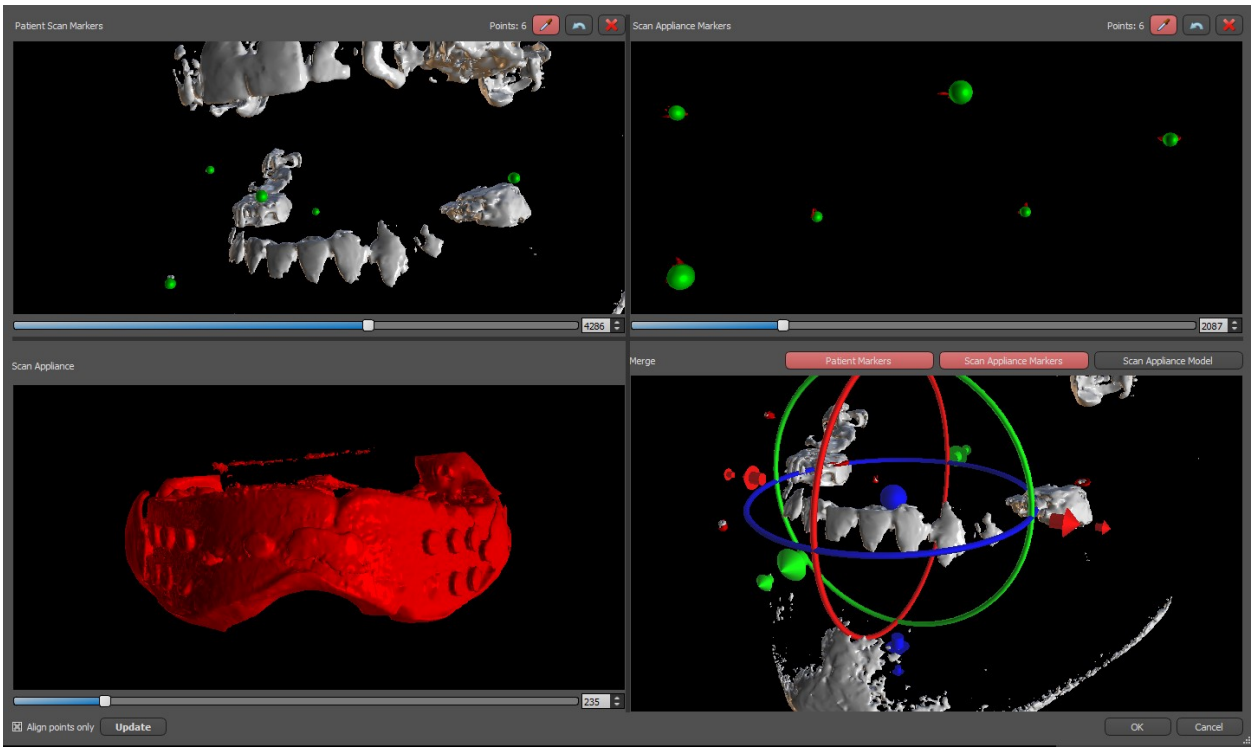
If the two sets of markers do coincide, we continue as follows. If they do not coincide, proceed to section 8.2.



4) Confirm the data alignment by pressing *"OK".*

5) The Scan Appliance will appear in the 3D image of the patient's jaw. The properties of the Scan Appliance can be changed in the *"Surfaces"* panel in the *"Imported Surfaces" table.*

8.2. *Gutta percha markers do not coincide*



4) In the top right-hand box use the zoom tool (right mouse button), the 3D density slider, and the rotation tool (left mouse button) to clearly view at least four gutta markers. Identify the gutta markers by clicking the button or pressing the *"Shift"* key followed by left mouse clicks on the gutta markers. An erroneous identification of one marker can be reversed with button. If necessary, all identifications can be canceled with button.

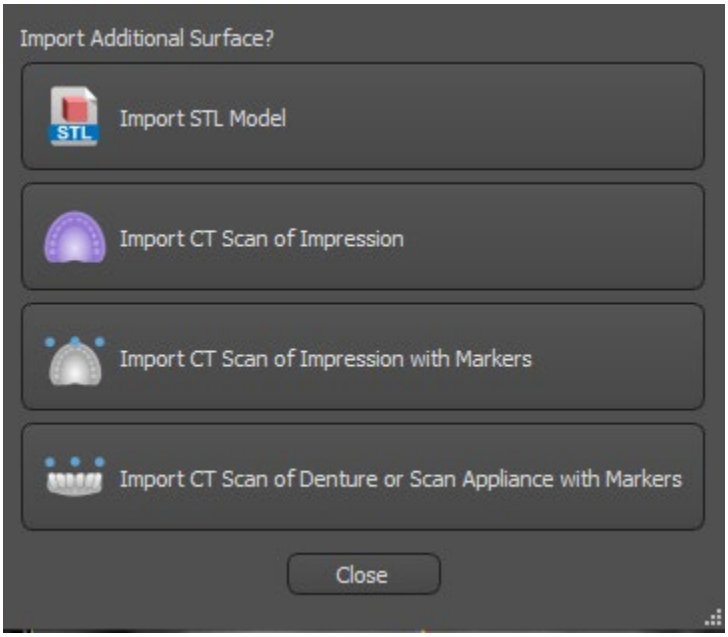
5) Repeat the previous step for the top left box to identify the patient's markers.

6) Perform the alignment on the basis of the gutta markers identified by pressing the *"Update"* button. If the result noes not roughly correspond to what is desired, identify more points for alignment or, for data with gutta markers that are hard to discern, check *"Align points only"*. Under this setting the program aligns the points identified without reference to dimensional data. The alignment can also be corrected manually using the dragger in the lower right-hand window.

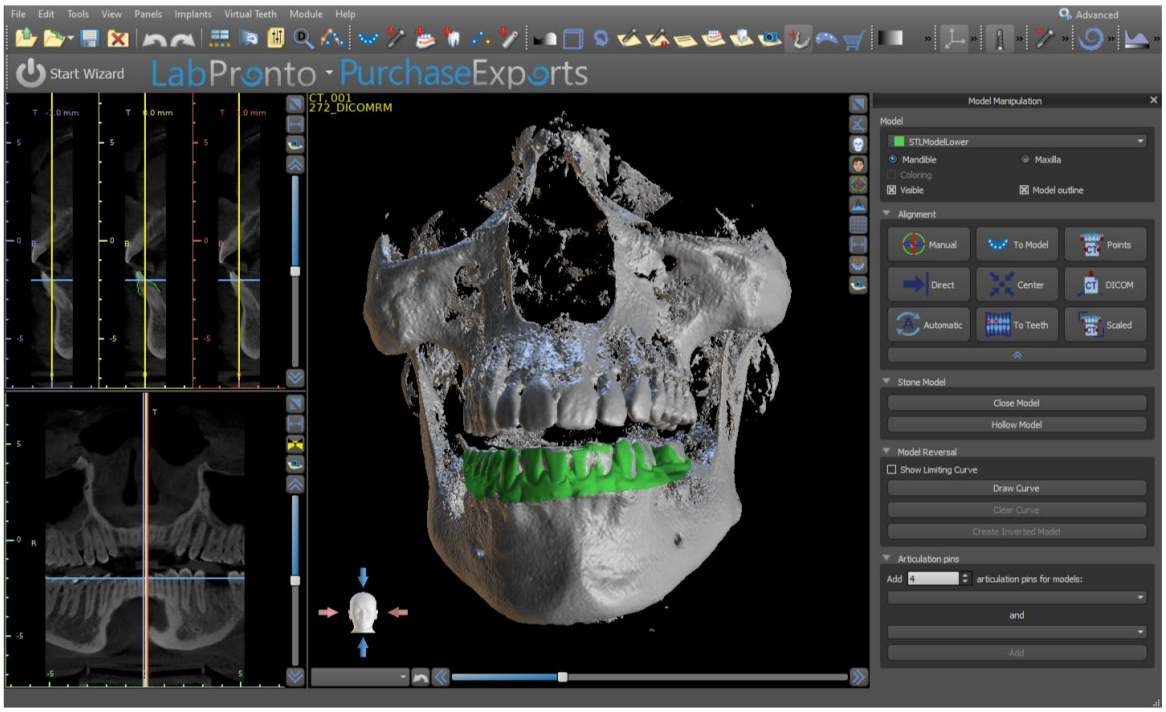
7) The Scan Appliance will appear in the 3D image of the patient's jaw. The properties of the Scan Appliance can be changed in the *"Surfaces"* panel in the *"Imported Surfaces" table.*

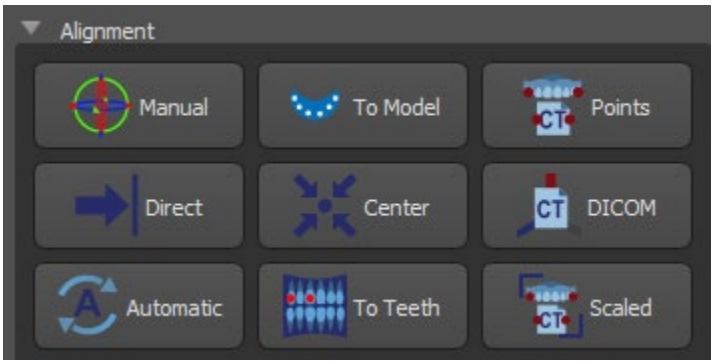
9. STL model import (planning with CT scan)

Existing STL models are imported into Blue Sky Plan® by selecting "*Import STL Model*" option from automatic pop-up menu after Patient CT Scan Importing. Another possibility is selecting "File > Import STL Model".



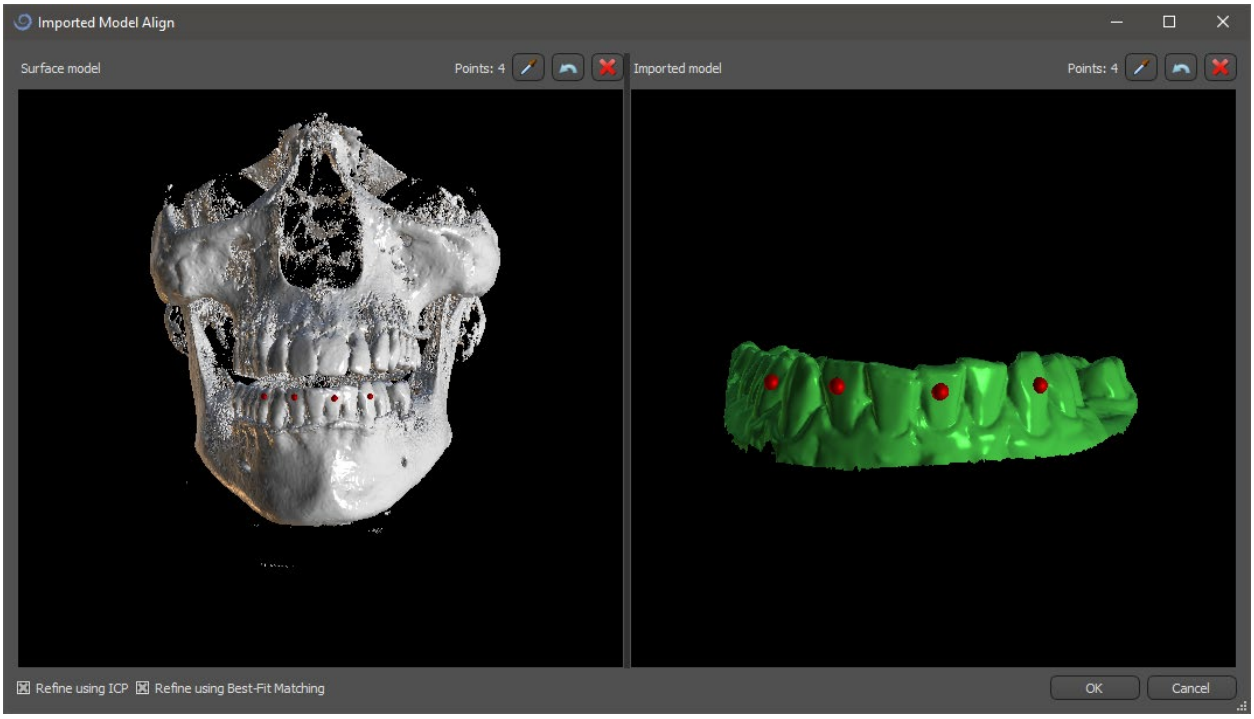
After the model has loaded, the Blue Sky Plan Automatic Alignment asks for model orientation and attempts to align the model automatically. You can use the "Model Manipulation" panel to position the model to desired location as well.





If the model is already aligned with respect to the data, the *"Direct"* should correspond to the correct position of the model. For STL models created with different software than Blue Sky Plan®, use the *"DICOM"* alignment. "*Center*" places model into middle of the scene without performing any rotation.

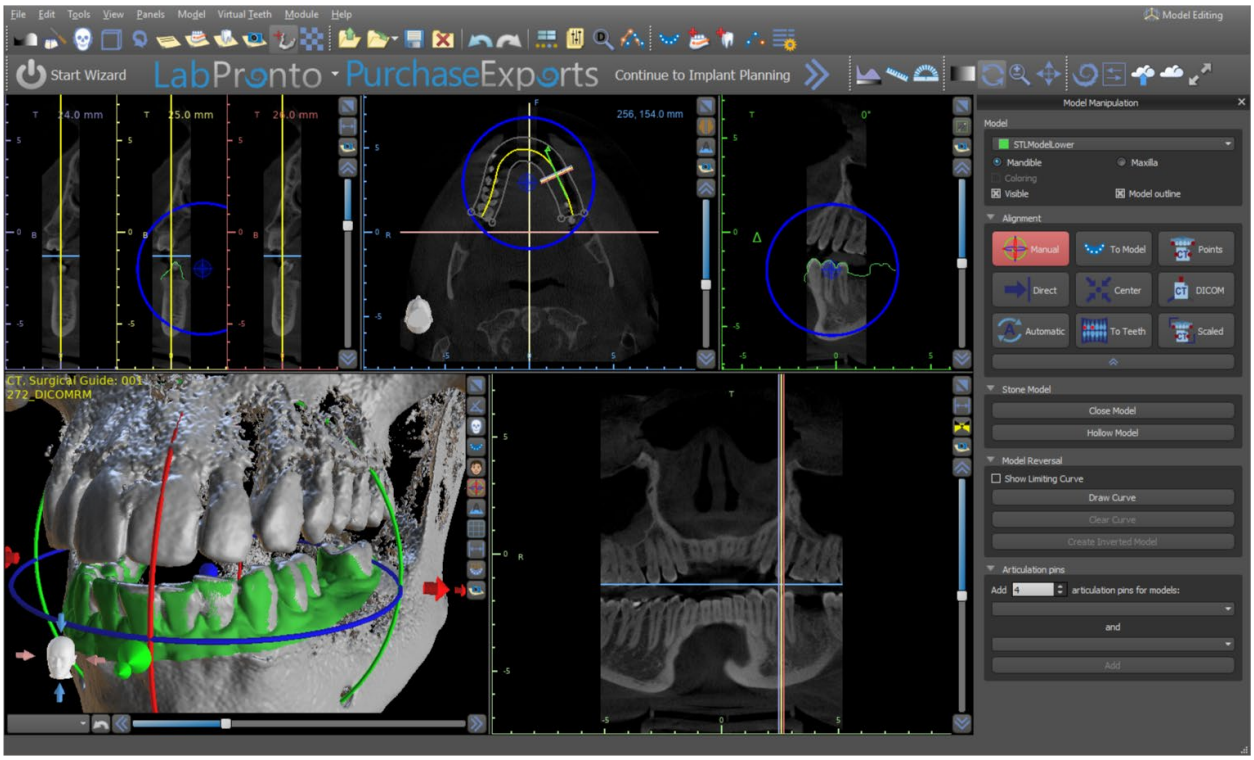
Because automatic alignment is usually not precise enough, Blue Sky Plan® also makes it possible to perform the alignment by entering a pair of points corresponding to each other. If you select *"Points"*, a dialog appears for entering points manually. The surface model displayed in the left-hand window of the dialog is created on the basis of the settings of the currently selected density surface. You can also significantly influence the time it takes to create the model and the visibility of appropriate reference points by setting the thresholds of the density surface appropriately.



Points can be added by clicking on the button with the eyedropper or by pressing the Shift key. If *"Refine using ICP"* is activated, the program attempts to perform an additional automatic alignment after the alignment based on the points entered.

A similar point based way of alignment is “Scaled” (works extra with scale) and “*To Teeth*” (works with the panoramic image instead of the surface model).

It is also possible to align the model manually in the 3D window using the dragger that appears when you press the *“Manual”* button. Clicking this same button closes the manual alignment mode, and the dragger disappears.

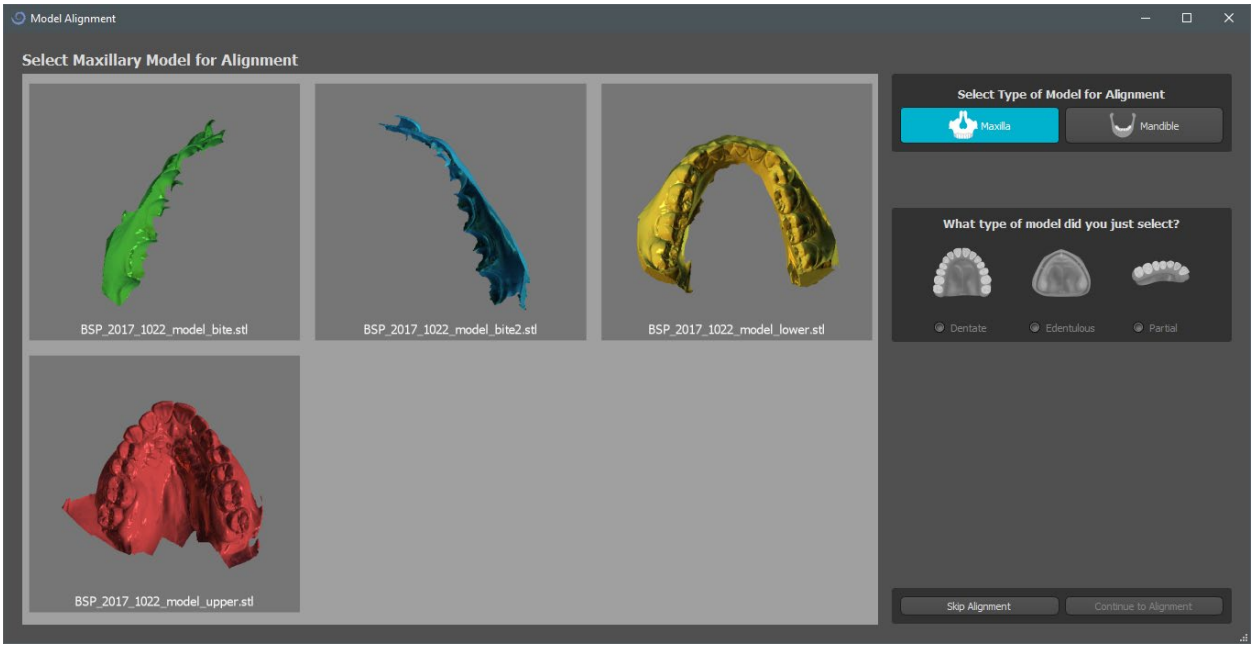


When aligning manually, it is possible to define a fixed point (a so-called pivot) around which the model rotates. In 2D views, the pivot is represented by a cross. By dragging the cross, it is possible to move the model in the plane of view. The model can be rotated using the blue circle. Hold SHIFT and click the mouse button to position the pivot at a different position in 2D views. In the 3D window, the pivot can be repositioned using the small dragger arrows.

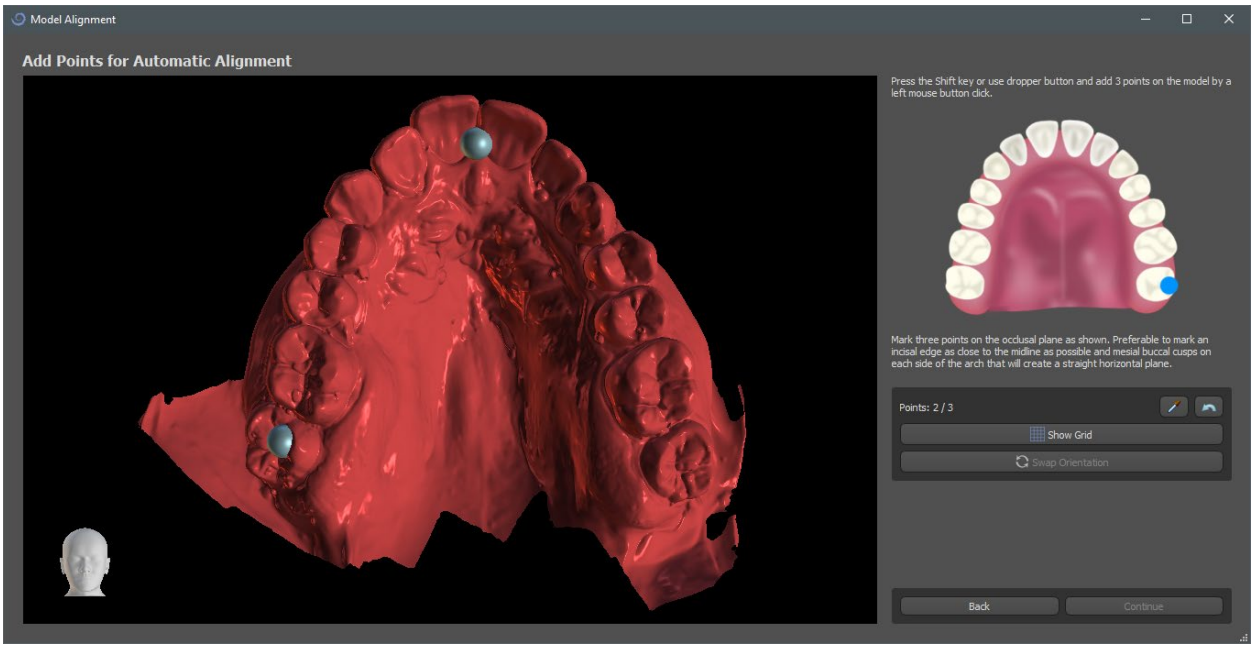
10. Planning without CT scan

Blue Sky Plan® software also allows planning for cases without a CT scan – STL models only.

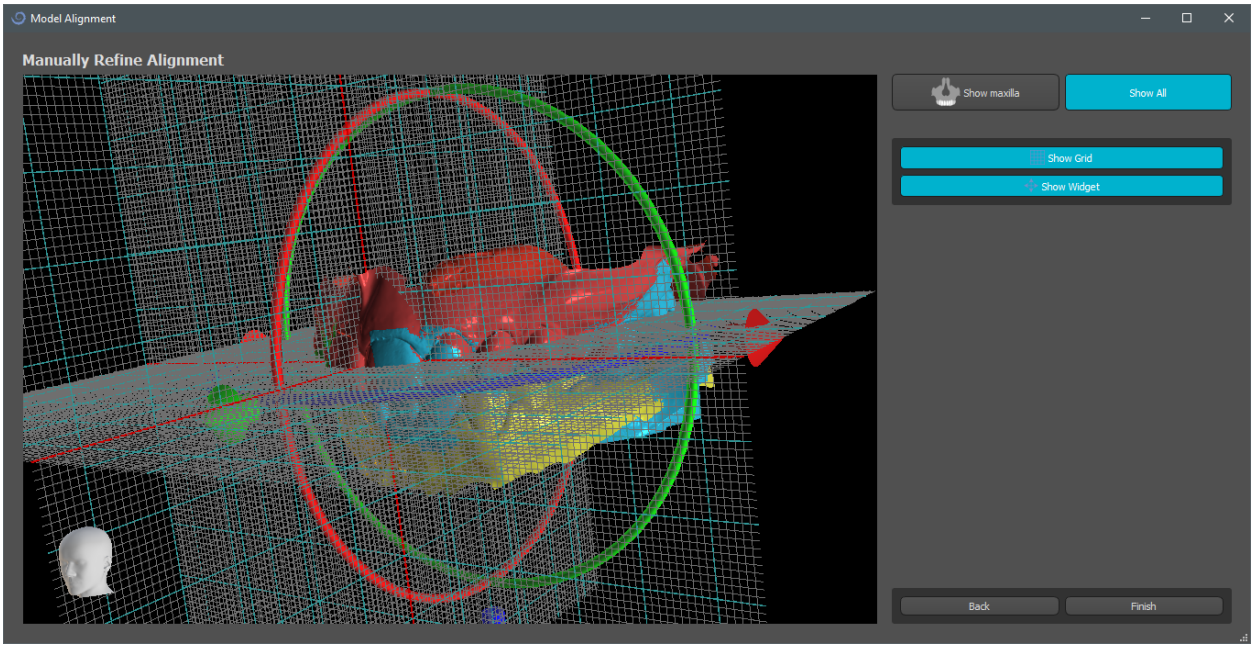
If a user plans a case without a CT scan, the imported models might not be oriented properly (the orientation does not match the head in the bottom left of the 3D view). This makes planning very difficult. For these cases, Blue Sky Plan has a model alignment dialog, which opens when selecting the planning type of the “Import models”. You can import one or several models. For alignment, it is necessary to select the primary model (ideally Maxilla) through which the alignment is done. The user also needs to specify if the model is a Dentated Arch or Edentulous Arch.



In the next step, the user marks three dots on the model to help the software align the models properly (to match the orientation of the BSP coordinate system). The rest of the models will be aligned relative to the alignment of the primary model.

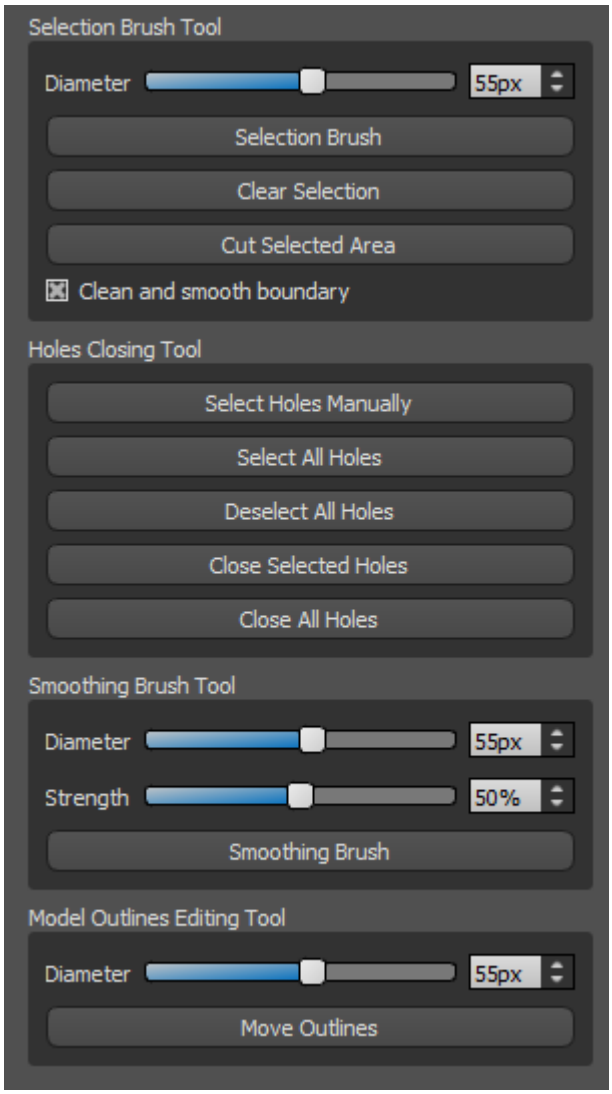


In the last step, the user can manually fine-tune the primary model using the grid. If several models were imported, they will move together as a group.



11. STL model adjustment

Blue Sky Plan software allows the user to select and remove part of the surface (model) and close any holes which can be created during the process.



All the necessary tools are available in the Model Edit panel. Using the "*Selection Brush*" the user can select a part of the surface and remove it by pressing the "Cut Selected Area" button. This way the user can clean the surface from scuttered parts or "extract" a tooth, for example.

Removing parts of the model, however, will create a hole (or several). The "*Holes Closing Tool*" can be used to close them. The user can select and close one specific hole using "Select Holes Manually". It is also possible to close all of them at once.

Note: *This tool is made for closing smaller and simpler holes. More complicated* cases *may take a long time. The complete closure and repair of the model can be done using the "Close Model" tool, which also creates a stone model with a base in the process.*

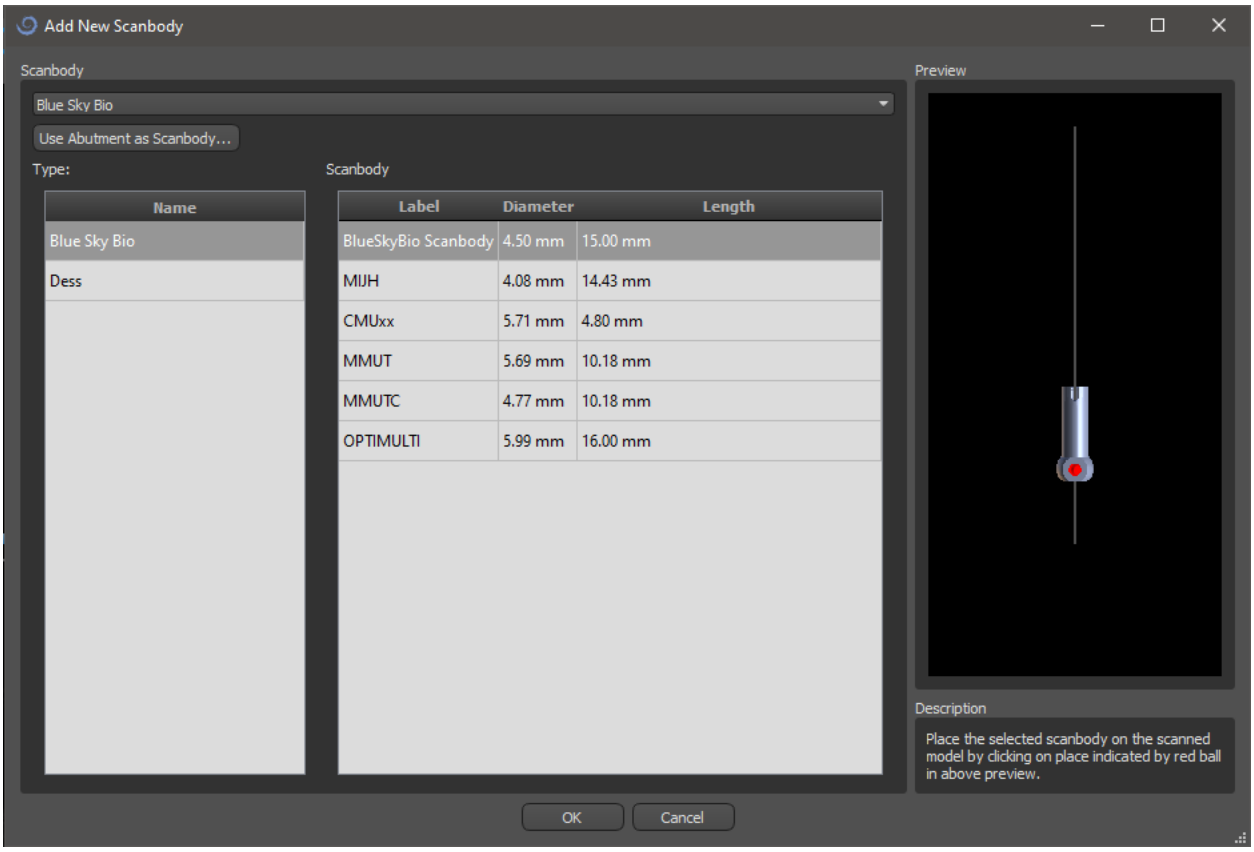
Surface irregularities can be fixed using the "*Model* Outlines *Editing Tool*" which can only be used in the orthogonal view (it doesn't work in the 3D view). For final modifications and polishing the surface of the closed hole, the "*Smoothing Brush Tool*" can be used.

12. Scan Body Registration

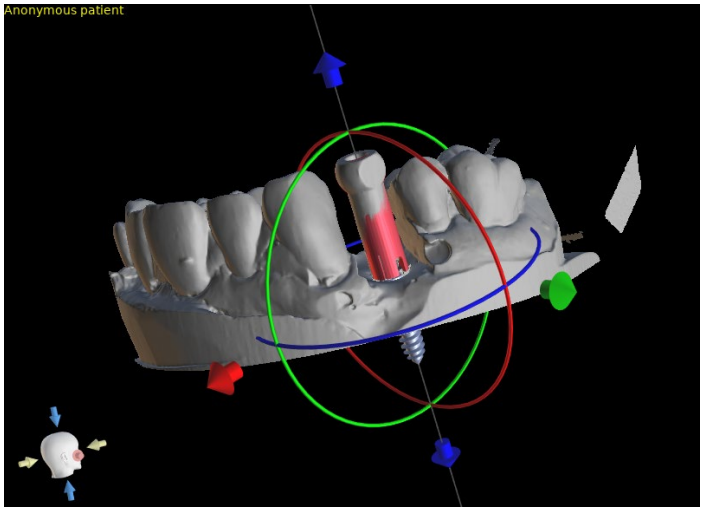
Blue Sky Plan® has useful functionality that allows the user to register the STL files of the scan bodies present in the BSP parts catalog to the scan bodies visible in a scanned model.

Blue Sky Plan® has the ability to convert the scan body (type of abutment that serves as a "post" at the time of the scan) to an actual abutment with an implant attached.

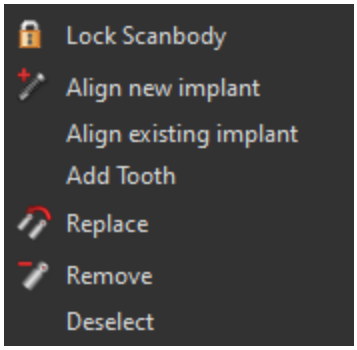
Once the STL model with visible scan bodies is imported, clicking on the icon in the toolbar opens a dialog for fitting the catalog scan body to the scanned model.



After choosing a scan body from the catalog, it can be placed by clicking on the head of the scanned abutment in the model – for the best fit position, it is good to click on the place illustrated by the red marker as shown in the catalog scan body preview.



Later on, the scan body position can also be refined manually using the common manipulation widget in the 3D view.



Once the scan body position is precisely defined, either an existing or a new implant can be aligned with the scan body. The functionality is available in the menu shown by right clicking on the scan body.

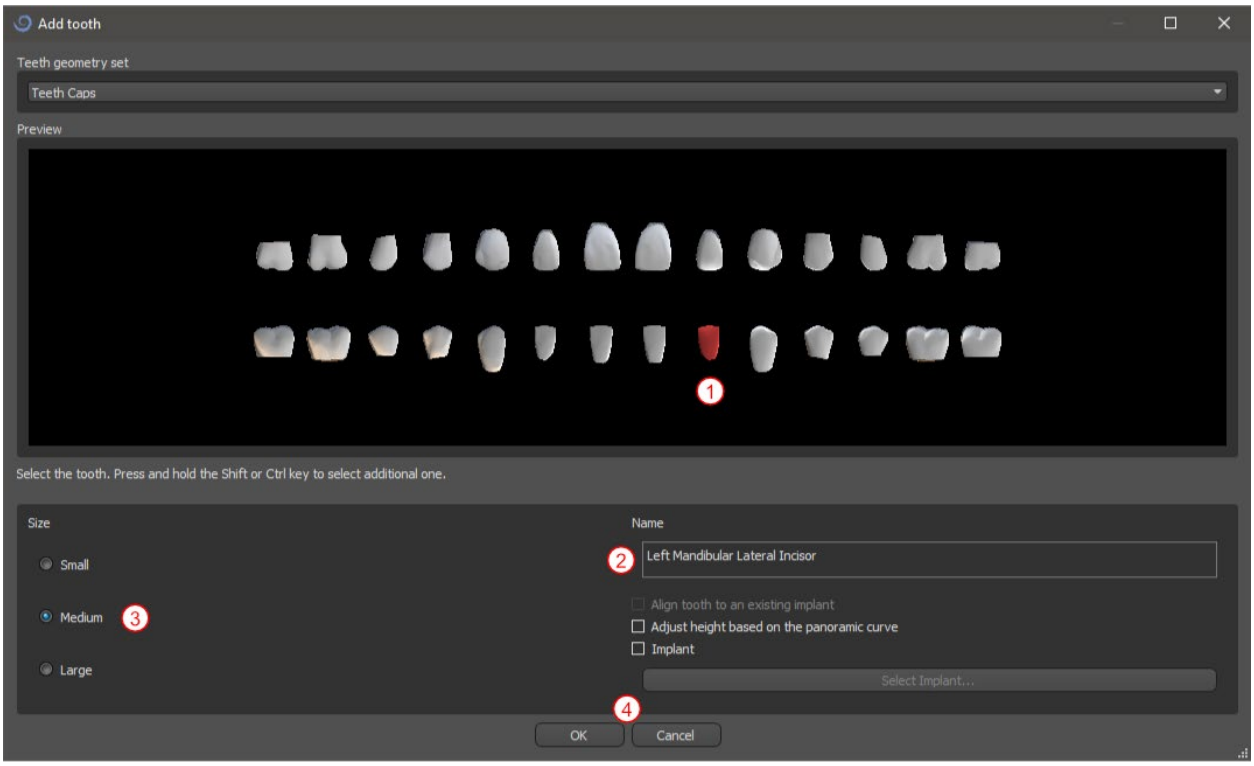
13. Virtual teeth

Blue Sky Plan® makes it possible to insert "virtual" teeth into the project. Using pre-prepared models of crowns inserted into the data, we can show the patient the possible result after all planned procedures have been performed. Virtual teeth also make it possible to align either a new or an existing implant and thus easily visually inspect the respective position of the resulting crown with respect to the position of the implant and to plan any abutment.

13.1. Inserting crowns

It is a good idea to first have a correctly specified dental curve, since the inserted crown will be rotated automatically with respect to it. We insert the individual crowns either by clicking on the icon in the toolbar or by using the button in the side panel (indicated below), if necessary choosing the *"Virtual Teeth > Add Tooth" menu item.*

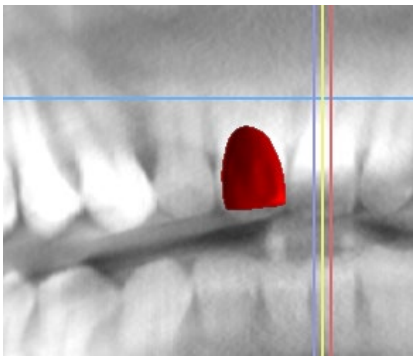
A dialog for selecting crown then opens. Clicking on the associated tooth (1) selects it, and a text description of the crown appears in (2). It is also possible to select from three sizes (3). The dimensions of the tooth can subsequently be modified directly in the sequence. We confirm the selection by clicking the *"OK"* button (4); the *"Cancel"* button closes the dialog without making a selection.

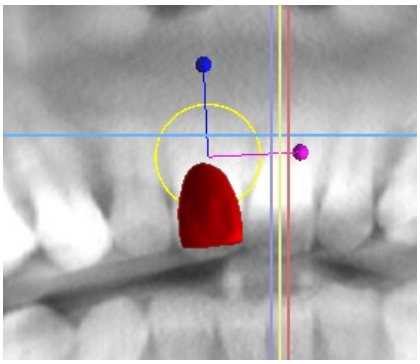


13.2. Positioning the crown and manipulating it

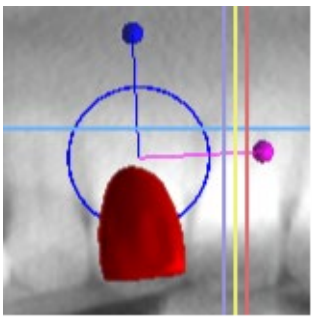
The mouse cursor changes to a cross when the dialog closes. We can then position the crown by clicking on the slice, and if necessary on the 3D visualization in any window. The crown is positioned in a vertical position according to the type of the simulated tooth and rotates with respect to the dental curve. It is up to the user to fine-tune its position.

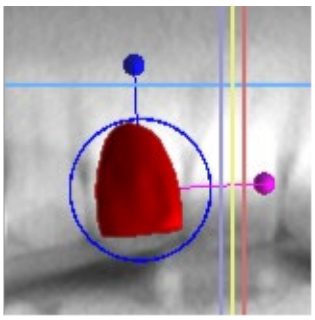
The tooth can be moved in all the windows. This is achieved by positioning the mouse on the tooth geometry, clicking the left mouse button, and dragging. The tooth always moves in the plane of the view. The tooth can also be rotated using the so-called draggers. These appear again when the mouse cursor is positioned on the tooth. We can subsequently grab the dragger by clicking the left mouse button; the dragger changes color, and we modify the rotation of the tooth by dragging.

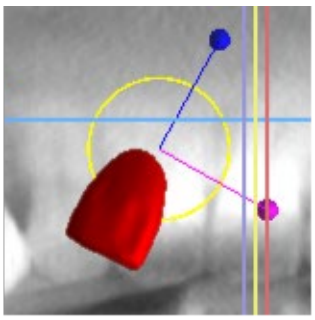


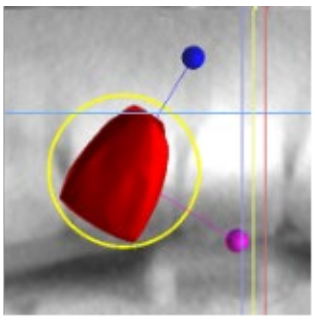


The rotation point (the so-called Pivot) can either be in the center of the tooth geometry or at the beginning of the local coordinate system. This is located in the same place as the head of the aligned implant.



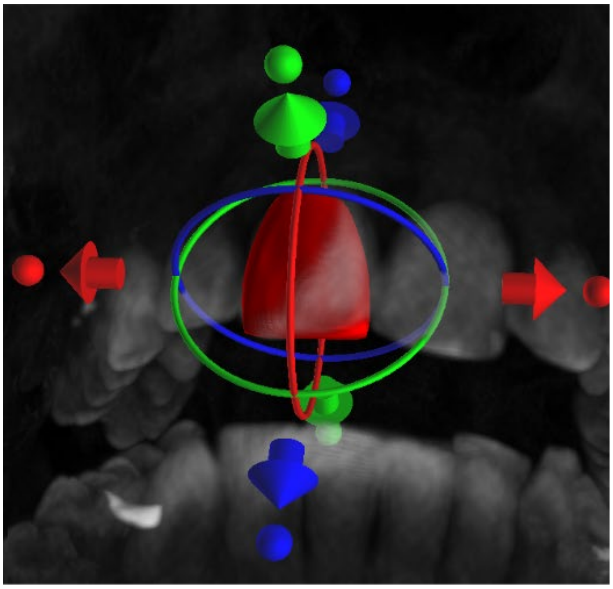


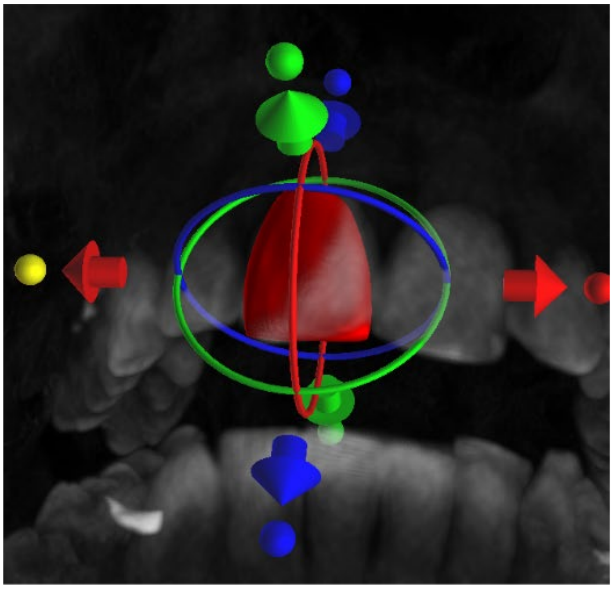




In the 3D view, the tooth can be dragged not only in the plane of the view but also along the axis of the tooth. As in the other views, it is necessary to move the cursor onto the tooth and display the draggers. The blue arrows above and below the tooth serve to shift it along the axis. We change the position of the tooth by moving the cursor to the arrow, clicking the left mouse button, and dragging. As for implants, three differently colored circles appear in the 3D view for rotating the tooth around the corresponding axes of the local coordinate system.

In addition to the position and rotation, the size of the crown can also be modified in the 3D view. Spheres displayed along the axis of the tooth serve to change the size. We change the size of the tooth by moving the cursor to it, clicking the left mouse button, and dragging.



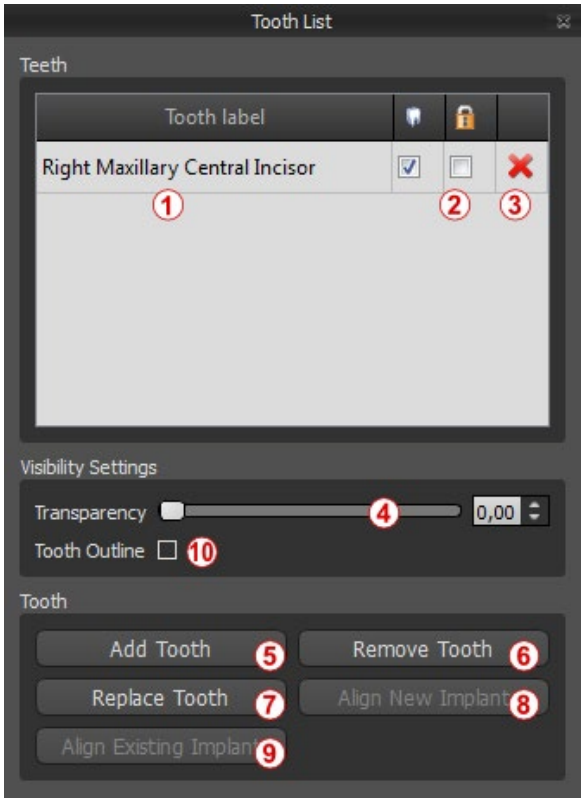


13.3. Aligning an implant and further operations

The side panel, which can be opened with the *“Panels > Tooth List”* menu option, provides further operations on the tooth. A list containing a description of the tooth (1), a check box (2) for turning the visibility of the individual tooth on and off, and a button to remove the given tooth (3) appear in this panel. The currently selected tooth is displayed in red in the sequence, and the associated row is highlighted in the list.

As for implants, it is also possible to set the transparency (4) or outline display (10) for teeth.

There is also an *"Add Tooth"* button here for adding a tooth (5), which functions the same way as the toolbar button described above, optionally via a menu item.



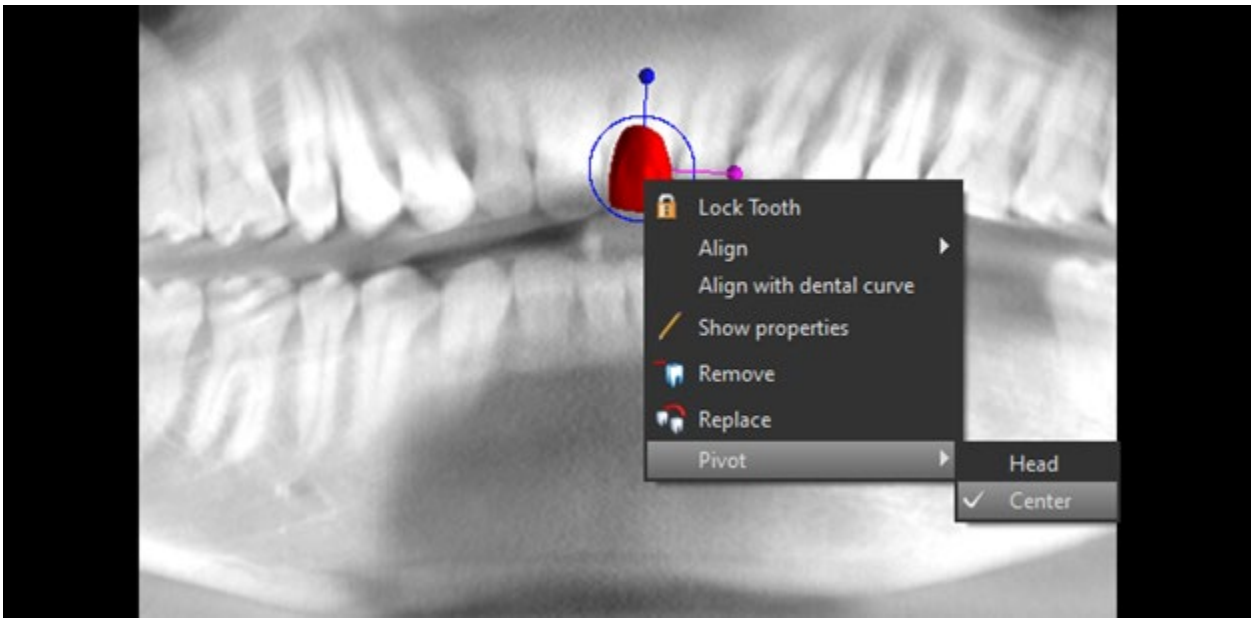
The result of clicking the *"Remove Tooth"* button (6) depends on whether a tooth is designated as selected. If so (if one of the teeth is designated), the action is performed directly on the designated tooth. If not, the selected tooth is removed from the sequence by clicking the mouse. The button for changing the geometry of the tooth is *"Replace Tooth"* (7). The dialog for selecting the new geometry works analogously: if one of the teeth is selected, the new geometry is set to it; if none is selected, the mouse cursor changes to a selection cross, and the geometry changes to that of the tooth selected by clicking on it.

The *"Align New Implant"* button (8) first opens a dialog for selecting the implant (see chapter 5), and after the selection is confirmed with the *"OK"* button, the new implant is added to the project with the position setting corresponding to that of the selected tooth.

The button for aligning an existing implant (9) works analogously. When it is pressed, the mouse cursor changes to a selection cross, and when one of the existing implants is clicked on, its position with respect to the tooth is modified.

13.4. Context menu

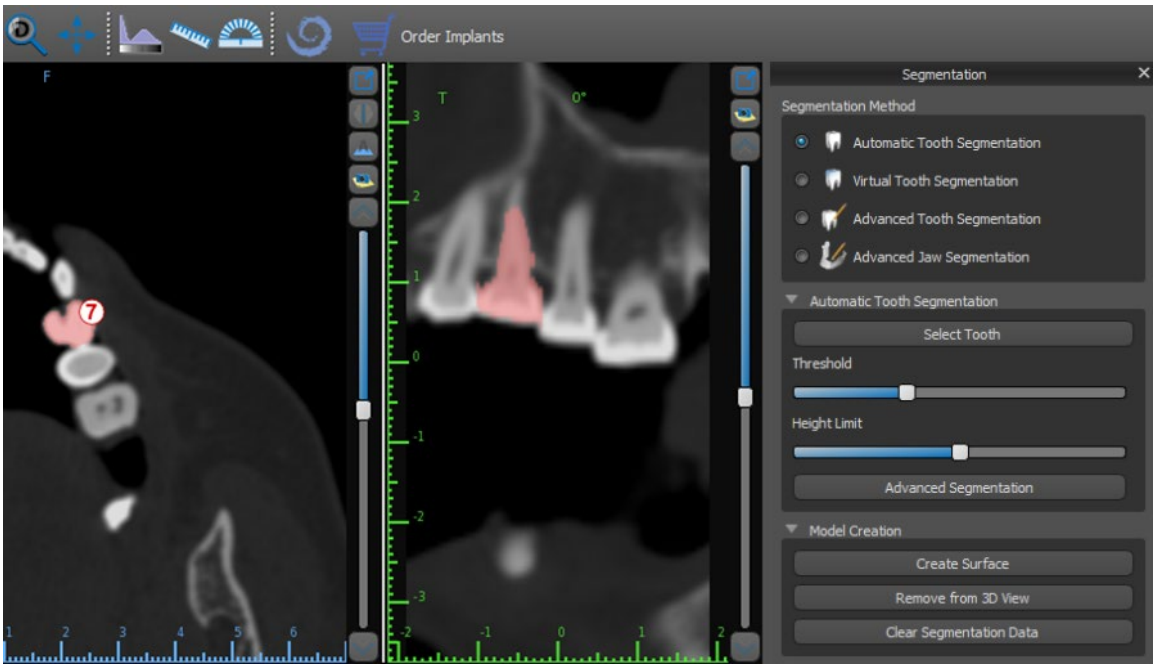
Some operations can also be performed via the context menu. We invoke this by clicking the right mouse button on the tooth geometry. Besides the operations described previously, such as aligning the implant, removing the tooth, or replacing it with another type, it is also possible here to choose the point of rotation of the draggers (the *Pivot*) as described in chapter 5.2.

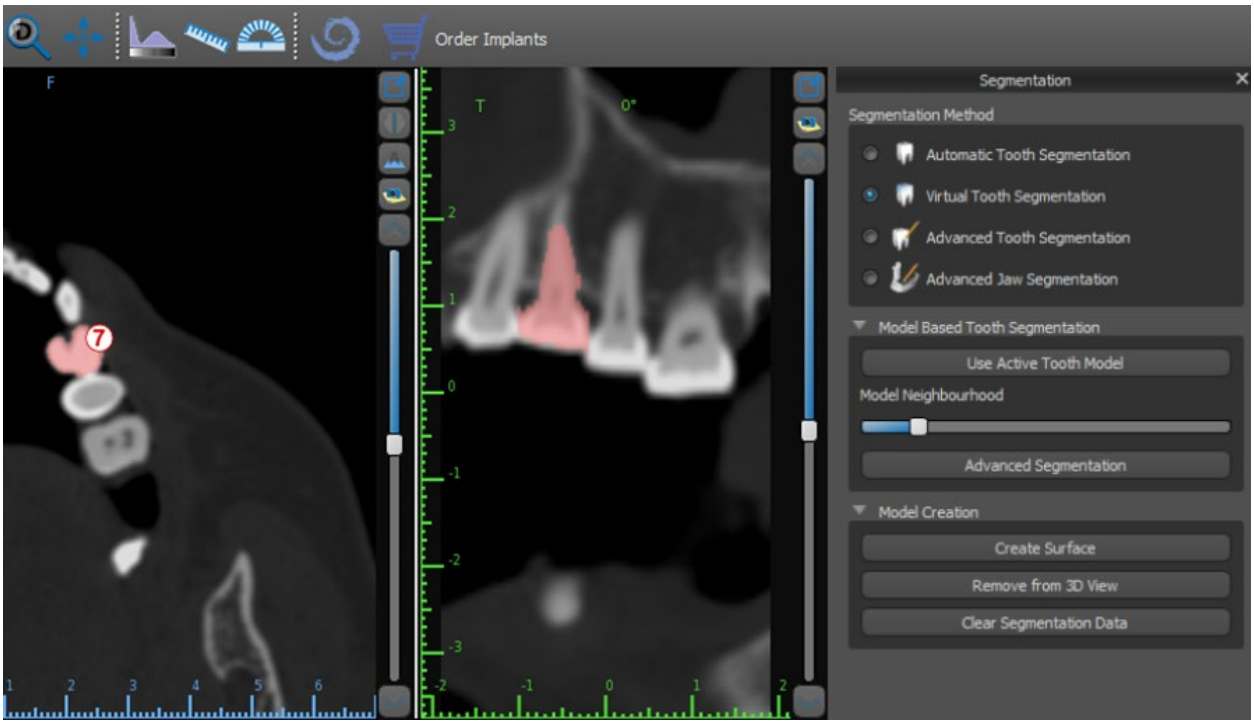


14. Tooth segmentation

Blue Sky Plan® makes it possible to segment and remove individual teeth from the data. The following two segmentation methods are supported.

With a correctly set dental curve it is possible to select a tooth by clicking on the data in one of the orthogonal slices. The result of the selection will be colored in all the slices. The result of the automatic segmentation can be corrected with the *"Height Limit"* parameter which determines the distance from the slice up to which the program should attempt to detect the tooth. By reducing this, it is possible to compensate for erroneous detection in an area where the tooth is difficult to differentiate from the bone automatically.





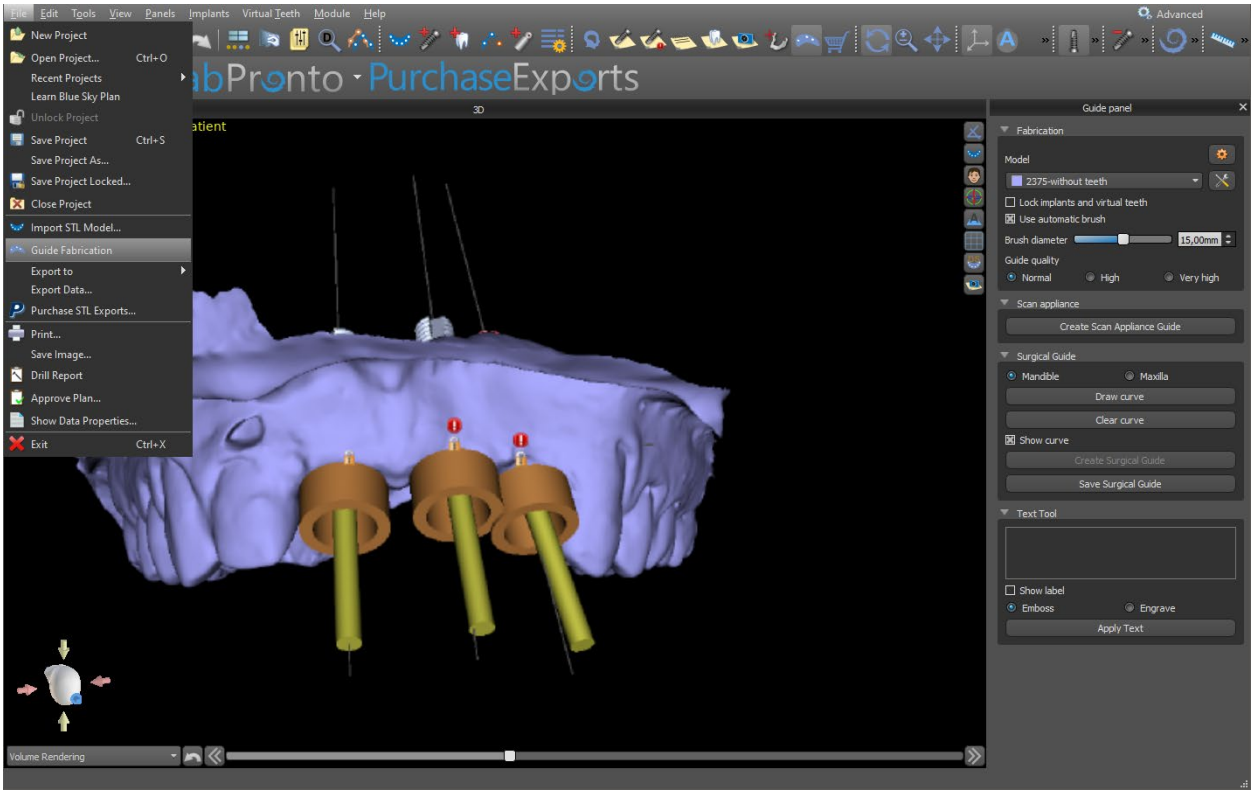
If automatic delimitation of the tooth fails, it can be selected in the data using the virtual tooth manually positioned in the data via the *“Virtual Teeth > Add Tooth“ option from the main menu.* After positioning the model, perform the *“Use Active Tooth Model”* action for the designated data on the basis of the tooth model entered. Using the *"Model Neighbourhood Parameter"* you can perform a slight correction of the area around the positioned model which is selected.

It is possible to transfer the area of the tooth marked in the data into the model by clicking *“Create Surface”*. The model created in this way appears in the *“Surfaces”* panel in the *“Imported Surfaces”* table.

The tooth can be removed from the data by clicking *“Remove Tooth”*. If you are not satisfied with the result, the action performed can be reversed with the *"Undo"* button, and the tooth selection parameters can be modified.

15. Surgical guides

It is possible to fabricate surgical guides in the program on the basis of imported STL models or a so-called scan appliance. It is also possible to edit the surgical guide fabricated. Text labels can be created on the surface with the *"Label Tool"*. Surgical guides are fabricated using the functions located on the *"Guide"* panel, which you can open by clinking on the *"File > Guide Fabrication"* menu item. The tools are divided into groups according to their purpose.



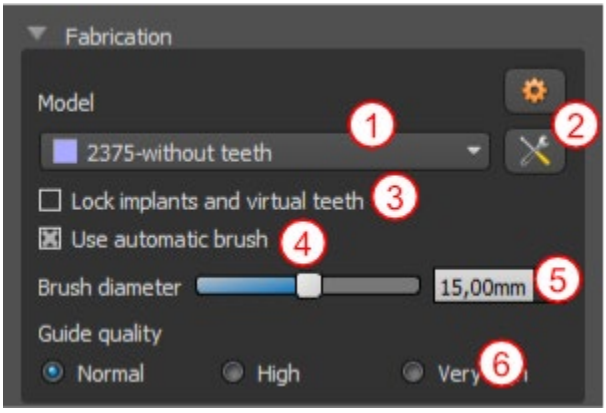
The first group combines elements used together for both model types. The second contains a button for fabricating surgical guides on the basis of a scan appliance model. The third contains all elements for fabricating an offset surgical guide from a surface model of the oral cavity. These are followed by panels for creating labels.

The method of fabrication differs according to the type of model being processed.

15.1. Guide fabrication based on scan appliance

It is first necessary to import a scan appliance model and correctly align it with CT data.

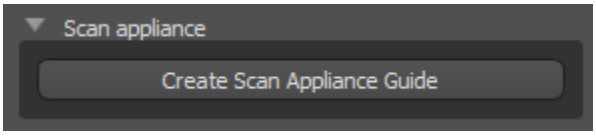
Then open the *"Guide Fabrication"* panel. The first section (*"Fabrication"*) contains all common settings for fabricating a surgical guide. The combo box (1) is used to select the input model.



Some input models may be damaged – they are composed of several parts, and their internal structure may not be correct. Fabrication of the surgical guide may fail in these cases. If the input model is damaged, it is possible to try to correct the input geometry using the correction tool (2) and run model fabrication again. When manipulating the model, it is a good idea for the option of working with implants to be turned off so that they are not moved unintentionally, for example. The *"Lock Implants"* checkbox (3) locks them. Implants are also locked automatically when using certain tools for fabricating surgical guides.

In order to be able to work conveniently with the resulting surgical guide and so that protruding parts do not prevent you from working with the tools, it is possible to select automatic alignment of the areas above and around the guide tubes. Select *"Use automatic brush"* (4) for this purpose and then use setting (5) to set the diameter of the free area. If these selections are not checked, only an area of the same diameter as the given guide tube is enabled above the guide tubes.

The detail of the resulting model is adjustable (6). The general rule is that the more detailed the model is, the longer it will take to generate it, and the slower manual edits with tools such as the *Brush Tool* will take. A model with the *"Normal"* setting should be sufficiently detailed for most input data.



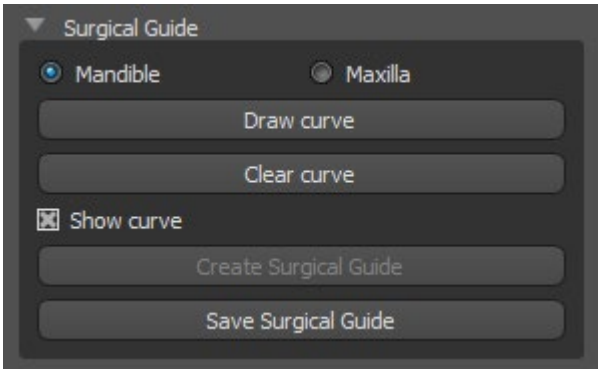
After entering and checking all settings in the *"Fabrication"* panel, it is possible to proceed to automatic fabrication of the surgical guide. Clicking the *"Create Scan Appliance Guide"* button in the *"Scan Appliance"* section runs this. A progress bar is then displayed, and once this runs out, the resulting surgical guide is displayed automatically.

15.2. Guide fabrication based on scanned surface models

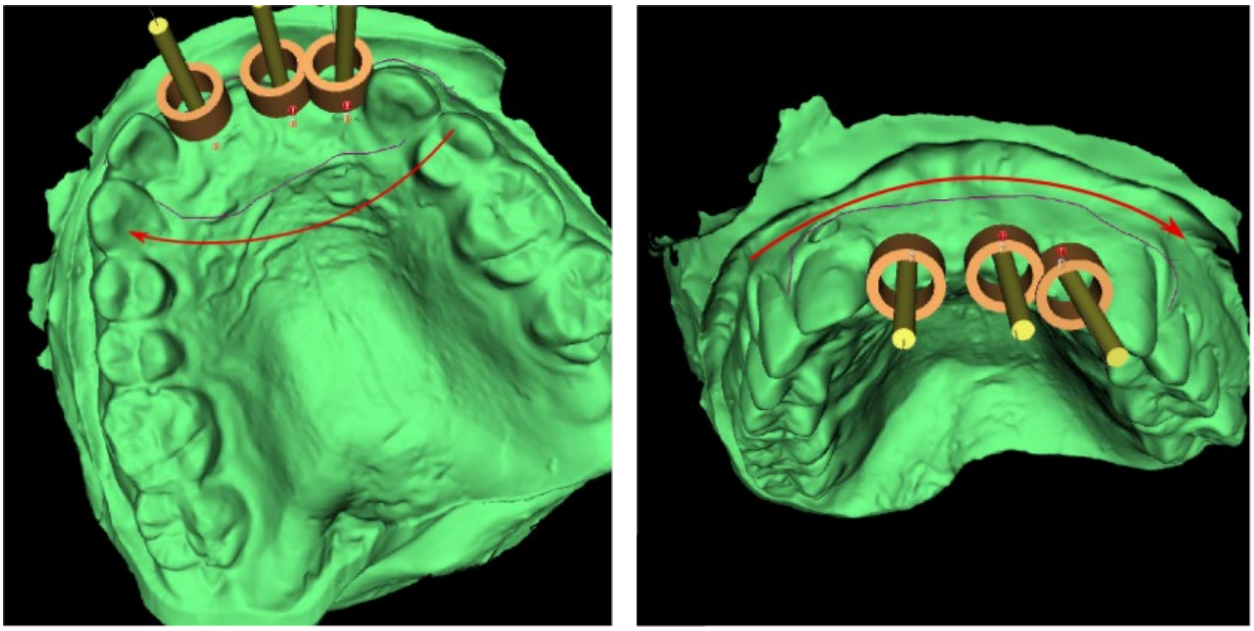
It is necessary to have an input STL model open in this case as well.

First check whether all the settings in the *"Fabrication"* panel are correct, i.e. whether the correct input model is selected, whether or not automatic model alignment is used above the guide tubes, and what level of detail is selected for the resulting surgical guide. Further settings specific to fabricating a surgical guide from a surface model are found in the *"Model settings"* section.

When opening a project, the program tries to guess whether it contains maxillary or mandibular data and automatically makes the selection (1). The same test is then also conducted when initiating generation of a surgical guide. If the program's guess does not agree with the actual situation, it is possible to change selection (1) manually. When generating the model, the application then asks whether you really want to fabricate this type of surgical guide.

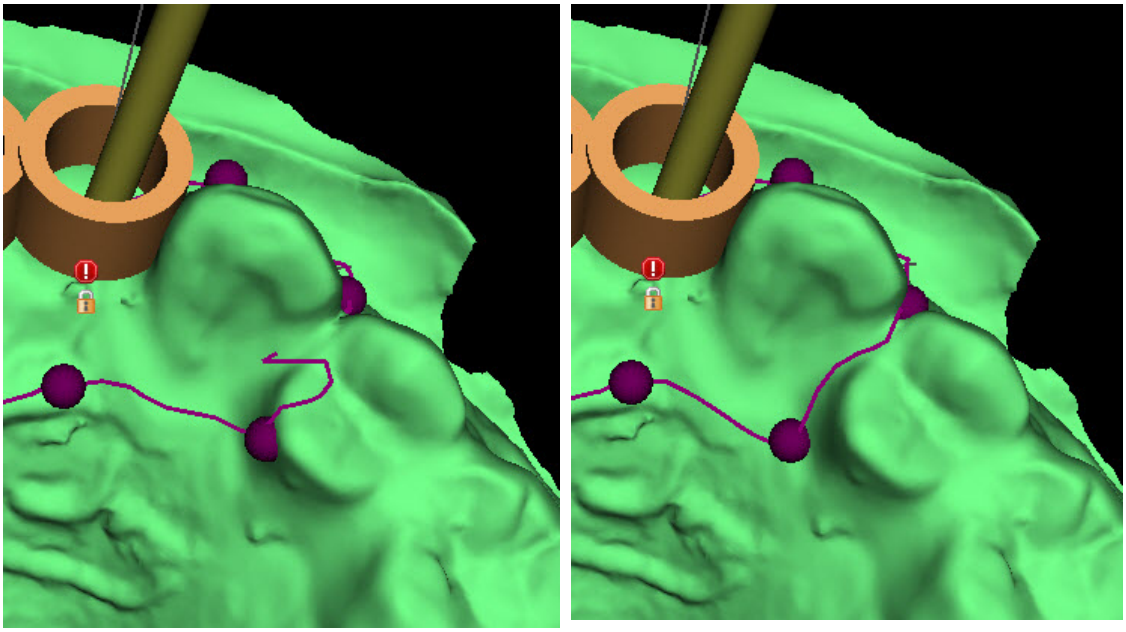


Before actually fabricating the surgical guide, it is necessary to specify the area that should be covered. This is done by drawing and then editing border curves directly on the surface of the input model using the three buttons (4–6). Clicking the first button (4) activates drawing mode. The state of the button is indicated by a change in color. If we are in curve drawing mode, it is possible to manipulate the model without pressing any keys, and for the actual drawing it is necessary to press and hold down the *"Shift"* key. The mouse cursor changes shape from an arrow to a cross, and a stroke can be drawn by pressing the left mouse button and dragging the mouse along the surface of the model. The individual lines do not need to be connected, but the relationship of the orientation of the individual sections must be maintained (see the pair of images).



After sketching the basic shape of the surgical guide, switch to border curve editing mode by pressing (6). The shape of the curve can be edited using individual control points on it. Before actually generating a surgical guide, it is a good idea to check its shape in this mode.

As a consequence of fragmentation, errors in some input models, and, in some cases, local unevenness in the surface, it can happen that the curve does not correspond to the intended shape exactly. In this case, it is necessary to move the nearest points of the erroneous section so that the resulting outline aligns; see the following images.



After you finish editing, you can run generation of the surgical guide with button (8). The now unnecessary cropped curve is hidden automatically at this point. This is indicated by the *"Show curve"* checkbox (7), which can be used to redisplay the curve.

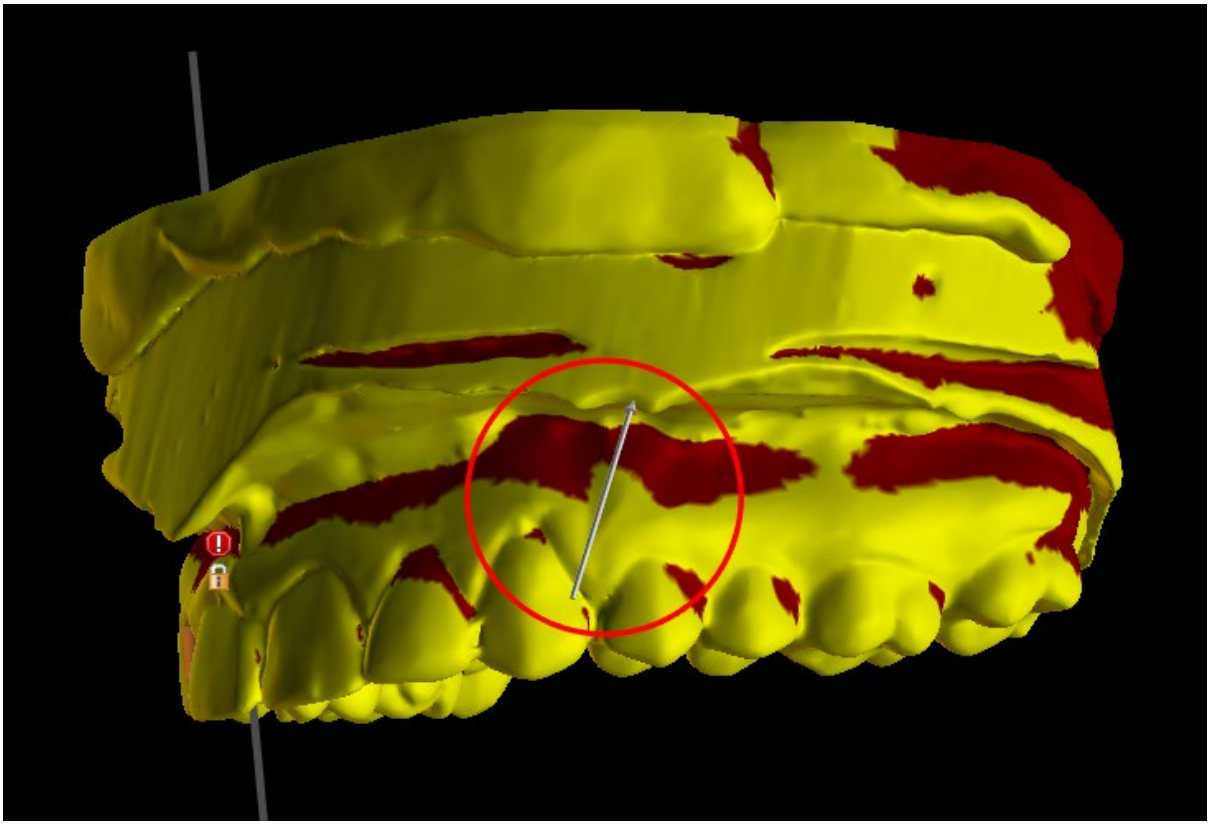
If the curve entered and thus the resulting surgical guide do not contain all the planned implants, the user is notified and has the option of halting generation.

Once it is completed, the model surgical guide fabricated is displayed and also added to the list on the *"Surfaces"* panel, where its parameters can be changed in the standard way.

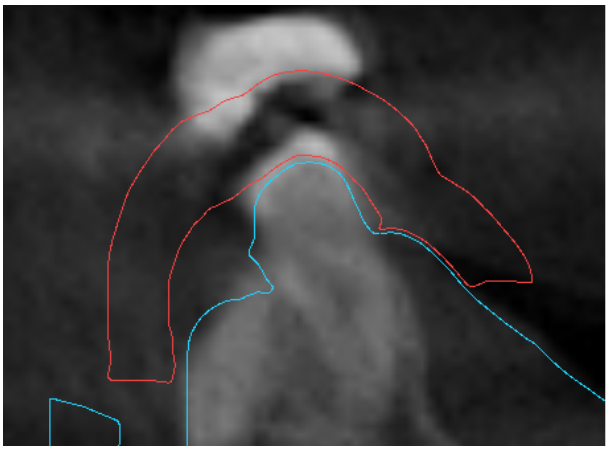
The surgical guide can be regenerated with edited parameters and the same curve; the curve is merely hidden and can be displayed with selection (7), edited again, and used to create a modified model.

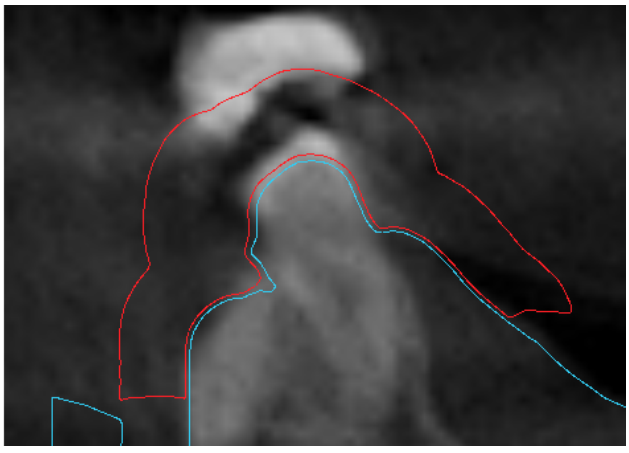
15.1. Removing undercuts

The “Surgical Guide Insertion Path” function is used to define the direction from which the surgical guide will be inserted. Using this function, you can visualise the areas that run “under” the surgical guide (undercuts) and may cause problems when inserting the surgical guide on teeth, especially in the case of using stiff materials for fabrication. These areas can be removed automatically when generating the Undercut Model. The surgical guide fabricated on this model will be easy to mount.

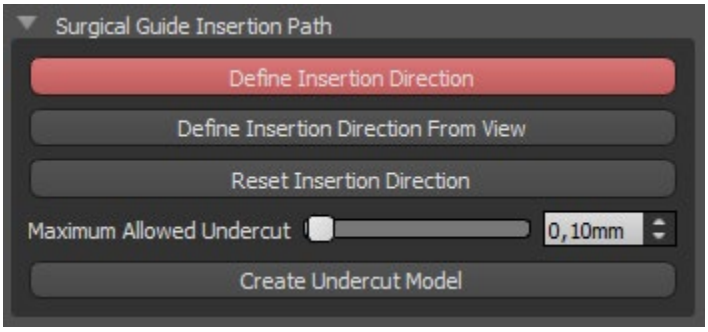


The differences between individual outputs can be compared in the following pair of images. On the left is a guide on the model with undercuts removed; on the right, all details are preserved.

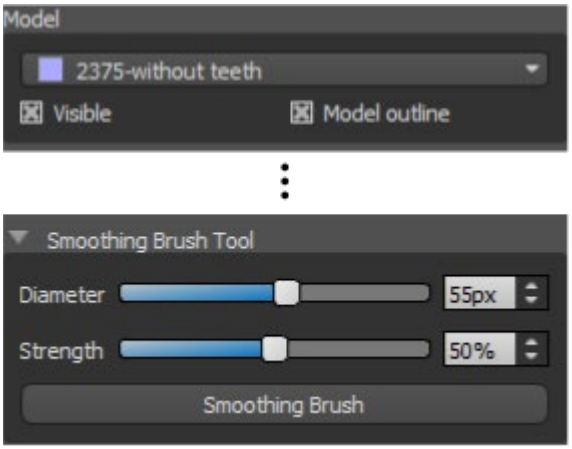




The default Insertion Path Direction angle and default Maximum Allowed Undercut are defined in Preferences, Surgical Guide tab. In addition, the Define Insertion Direction From View functionality is available from the Guide Panel. Creating an Undercut Model generates a new model that can be worked with independently.



15.2. Brush tool

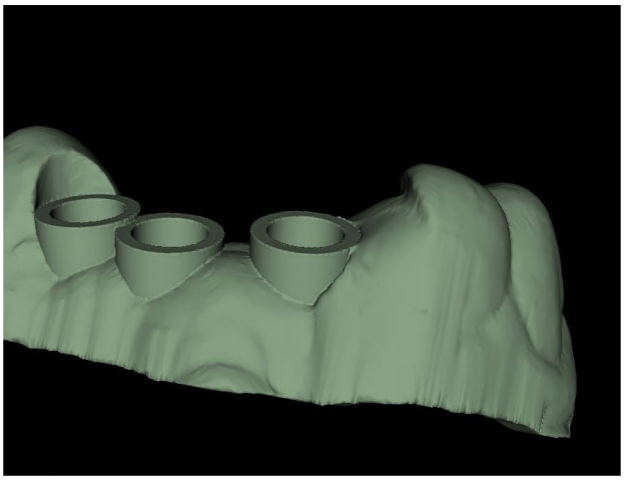


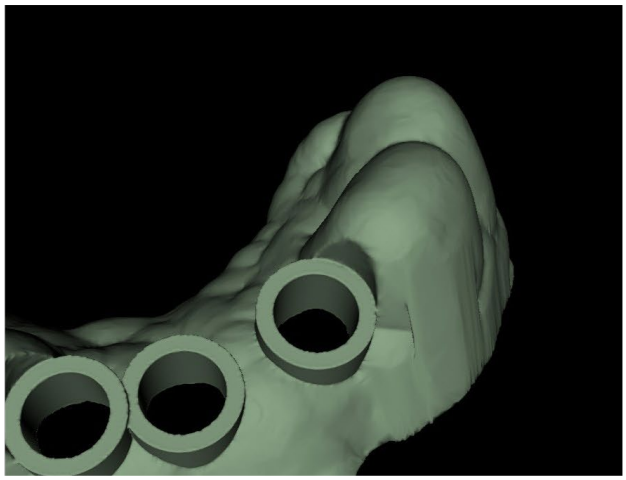
The application provides a basic tool for manually smoothing the resulting surgical guide: the *"Brush Tool"*. This tool smooths the surface, i.e. it lowers bulging parts and evens out depressions. Before using it, ensure that model you really want to edit is selected in (1). If the model is not visible at that given point in time, the program notifies you when you turn on editing mode.

The diameter of the circular area that the brush tool will edit can be adjusted in the associated section (2) of the panel. Correctly adjusting the size significantly alters the behavior of the tool – it is necessary to set the diameter somewhat larger than the area we want to even out. The selection for *"Strength"* (3) adjusts the strength of the resulting smoothing effect.

For significant unevenness, it is a good idea to first work with a lower tool strength and smaller diameter until surface smoothing occurs and only then use a greater strength and larger diameter and press down the entire area with it.

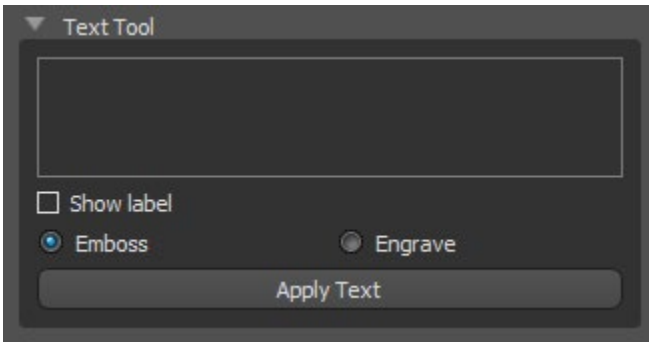
The *"Smoothing Brush Button"* button starts editing mode and changes color to indicate its status. In this mode the model can be manipulated in the usual way. Surface smoothing mode is activated when the *"Shift"* key is pressed. The effect is then applied by pressing the left mouse button while simultaneously dragging the mouse cursor over the model surface.





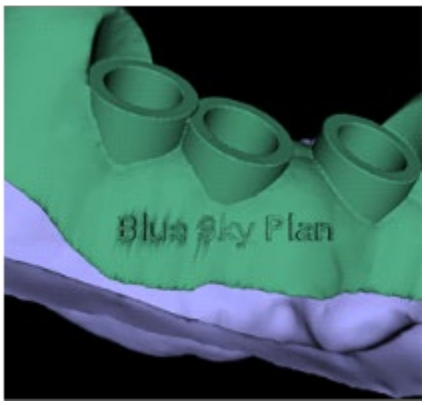
15.3. Text tool

The surgical guides fabricated can be supplemented with one or more labels with a 3D profile. This is done with the *"Text tool"*.



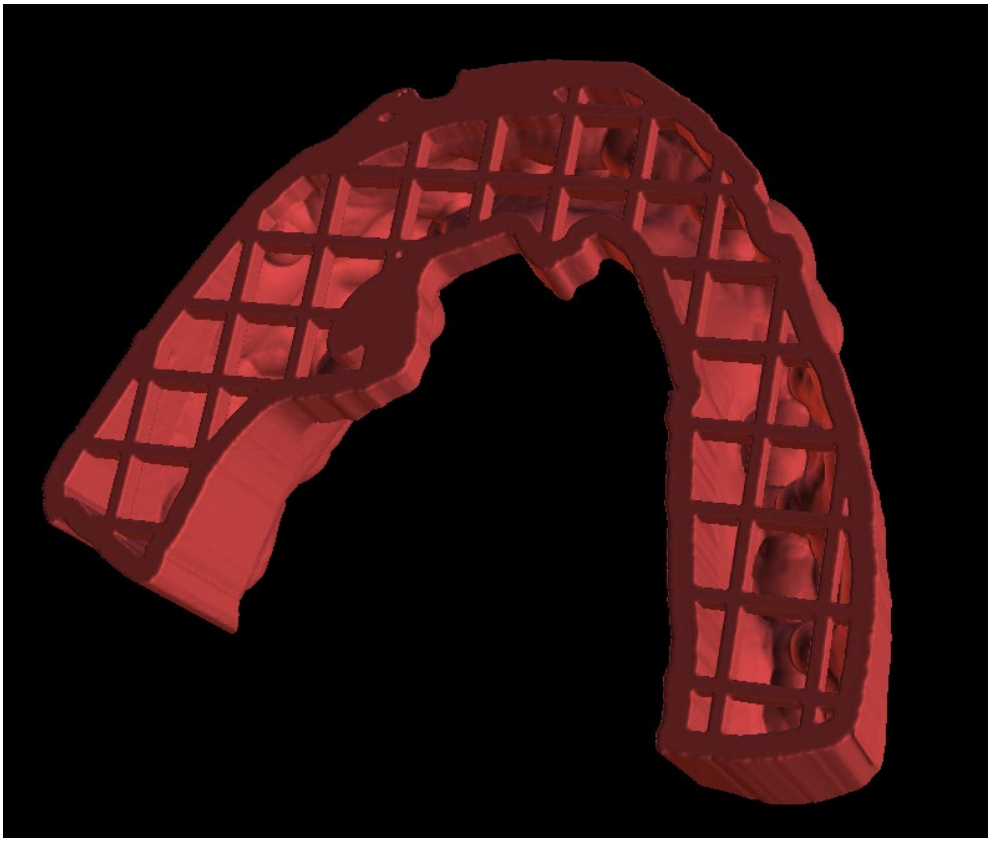
It is first necessary to check whether the correct model is selected. If the model is set as invisible at this point in time, the user is notified of this when he or she tries to insert a label on it. The text is inserted into the editing field. At this point, an auxiliary display of the text entered is also shown in the 3D display window. The text will be located on the model at the location at which it is displayed in this window. Therefore, it is necessary to position the model in the 3D window in such a way that the text will be at the right position on its surface.

Then press the *"Apply Text"* button. The auxiliary display of the text in the 3D window is hidden, and the text is pressed into the surface of the surgical guide. The auxiliary display in the 3D window can be reactivated with the *"Show label"* checkbo.



15.4. Hollow models

Using the *"Hollow model"* function in the *"Model manipulation*" panel allows the user to make an optimized printable hollow model from a common STL model with a cross pattern at the bottom.

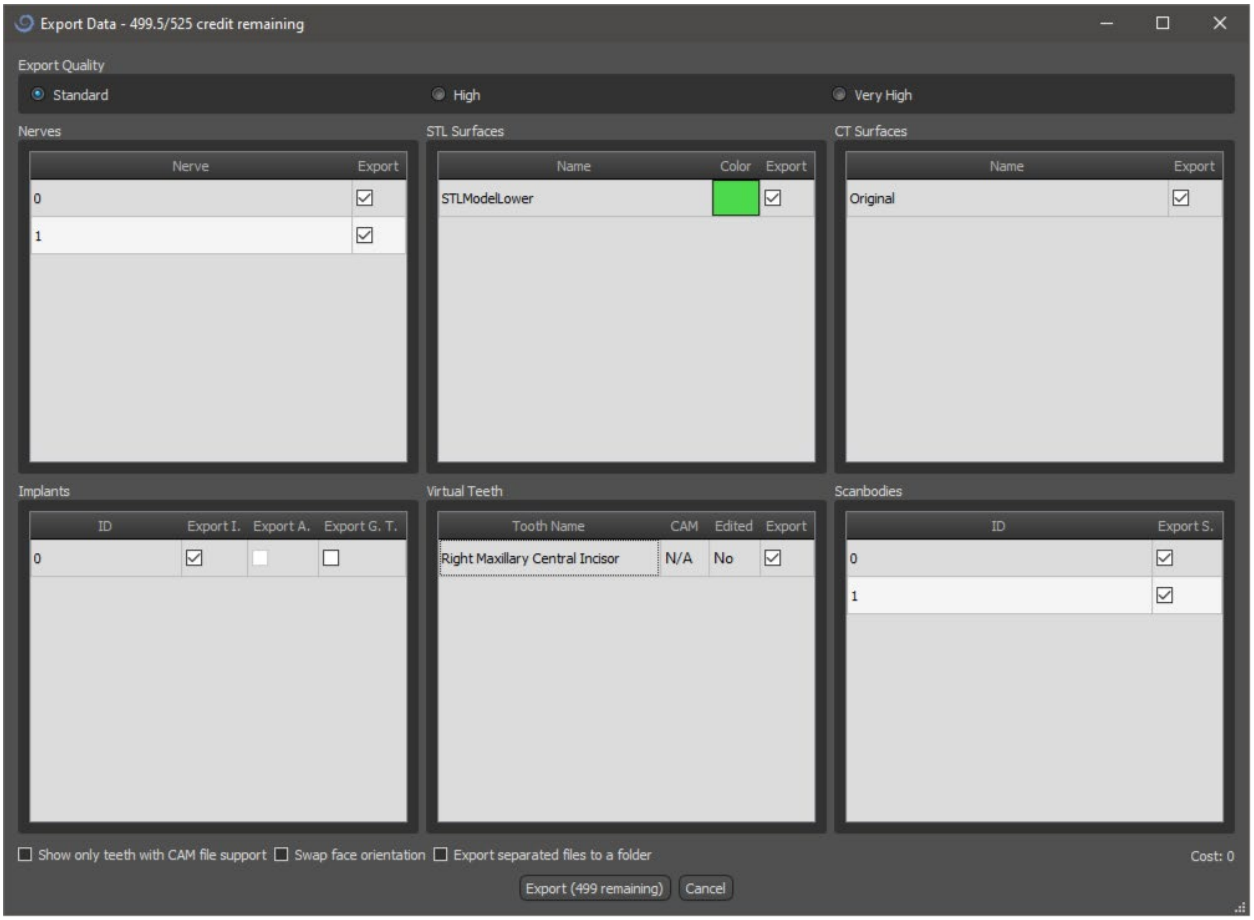


16. Data export

Most of the project data can be exported from the application in the form of an STL model. The menu selection “File > Export Data” is used to export data.

The quality of the export can be set in the dialog, which influences the quality of the resulting model but also the time necessary to generate the export. With the check boxes, it is possible to select what should be exported from the project. Selection is limited to data that are currently visible in the 3D view of the application. Nerves , imported models, implants, density surfaces, virtual teeth and scanbodies can be selected. It is possible to export either to a file or directly to the installed VRMesh application

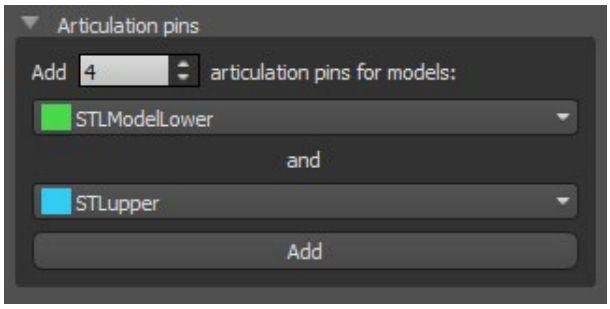
For a license with a limited number of exports, the number of remaining exports is indicated on button and in the title of the window; within the project currently open, the number of exports is only reduced once.



17. Articulation pins

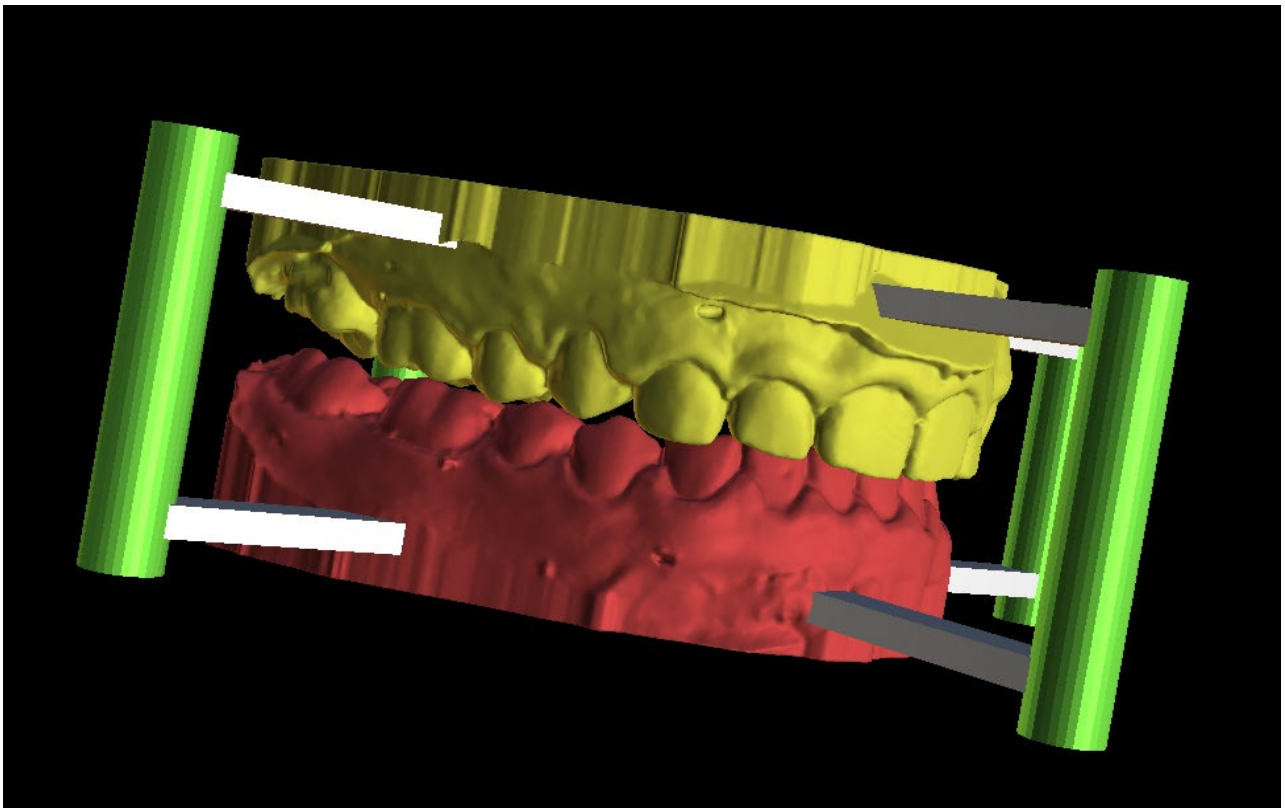
For cases when the user needs to 3D print models of the upper and lower jaw in an exact position, the Articulation pins function should be used. Articulation pins can be attached to two arbitrary STL models (two opposing jaws), and the models with the pins can be exported.

Once the upper and lower jaws are printed (models, denture bases, etc.), the user can insert the male and female pins into each other to recreate the exact articulation. Articulation pins can be placed in the Model Manipulation Panel in the Surgical Guide Module.



The user needs to select the upper and lower jaw models and click the “Add” button. The number of pins can be changed as well.

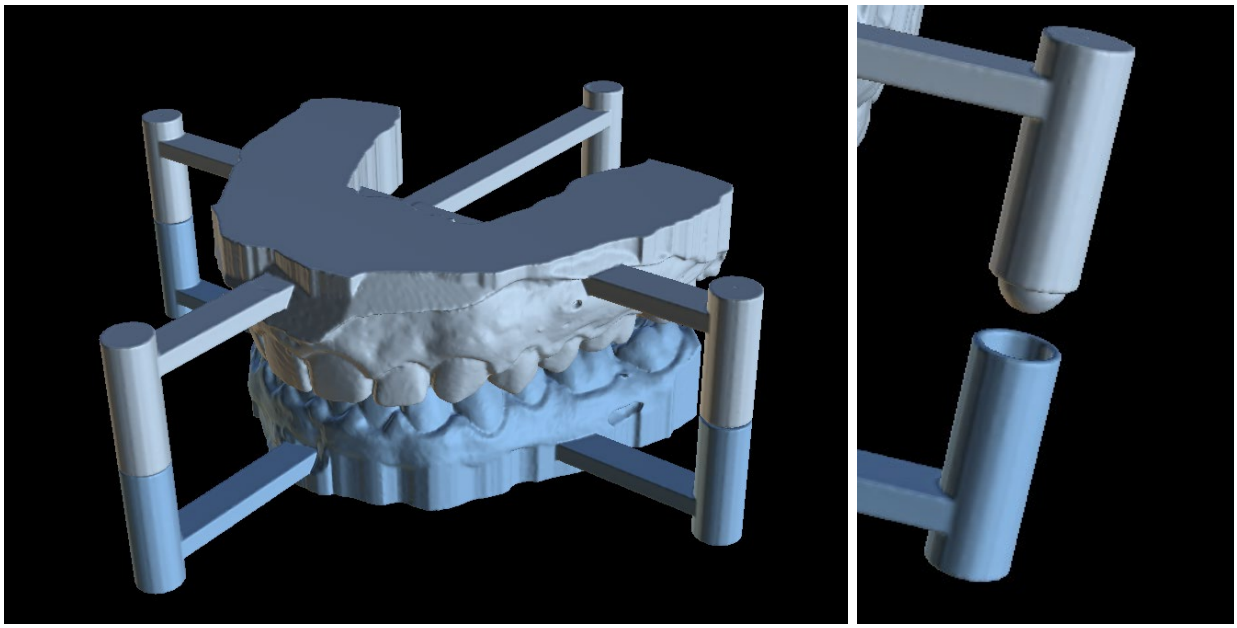
Both of the models do not need to be closed before adding the articulation pins. Open models are closed during this process automatically. Both of the models should be aligned before adding pins.



Pins and manipulation widgets will show up. The dimensions of the connecting arms as well as of the pins can be changed by dragging the manipulation widgets which appear when the user hovers over that object. The arrows enable the moving of pins to the sides and the scale widgets change the thickness of the pins. It is not possible to drag the pin arms outside of the pins.

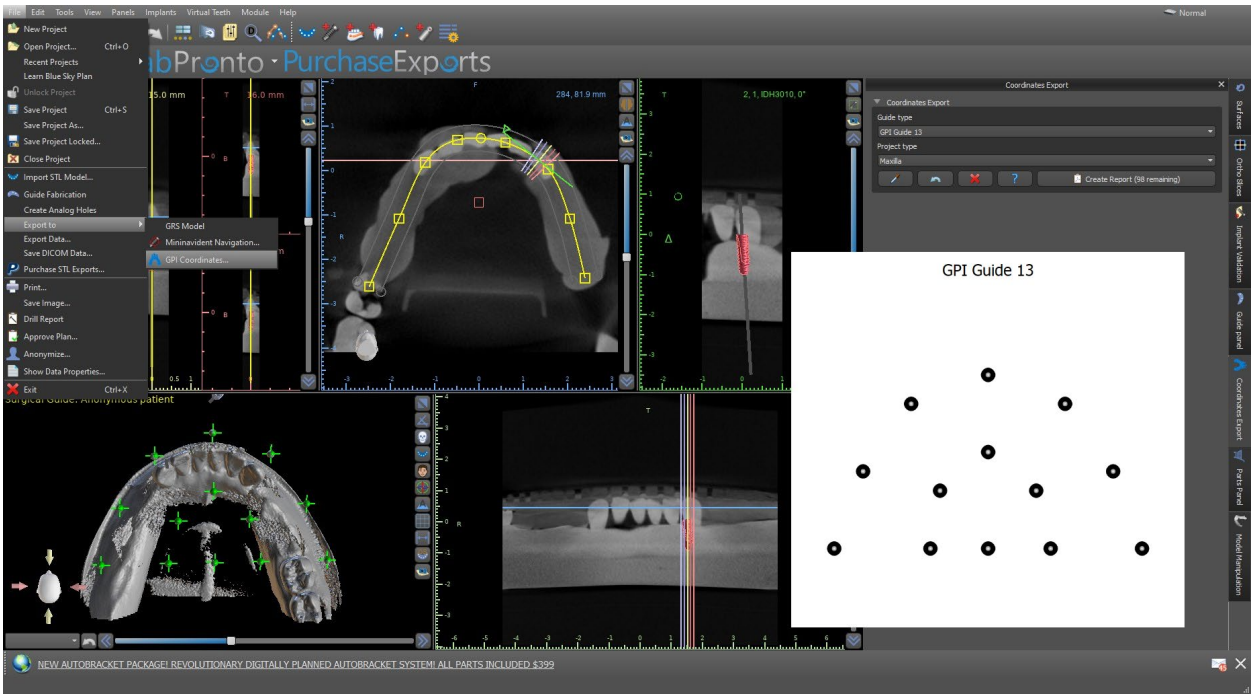
The default dimensions can be set in Preferences, in the Surgical Guide tab, as Default Articulation Pin Arm Width and Default Articulation Pin Arm Height.

Once the position and size of all pins and arms are tuned, by clicking on the "Create Articulation Pins" the final jaw models with the articulation pins are created. The upper and lower jaw models are separated for export and prepared with male and female articulation pins so they can be connected in the original position.



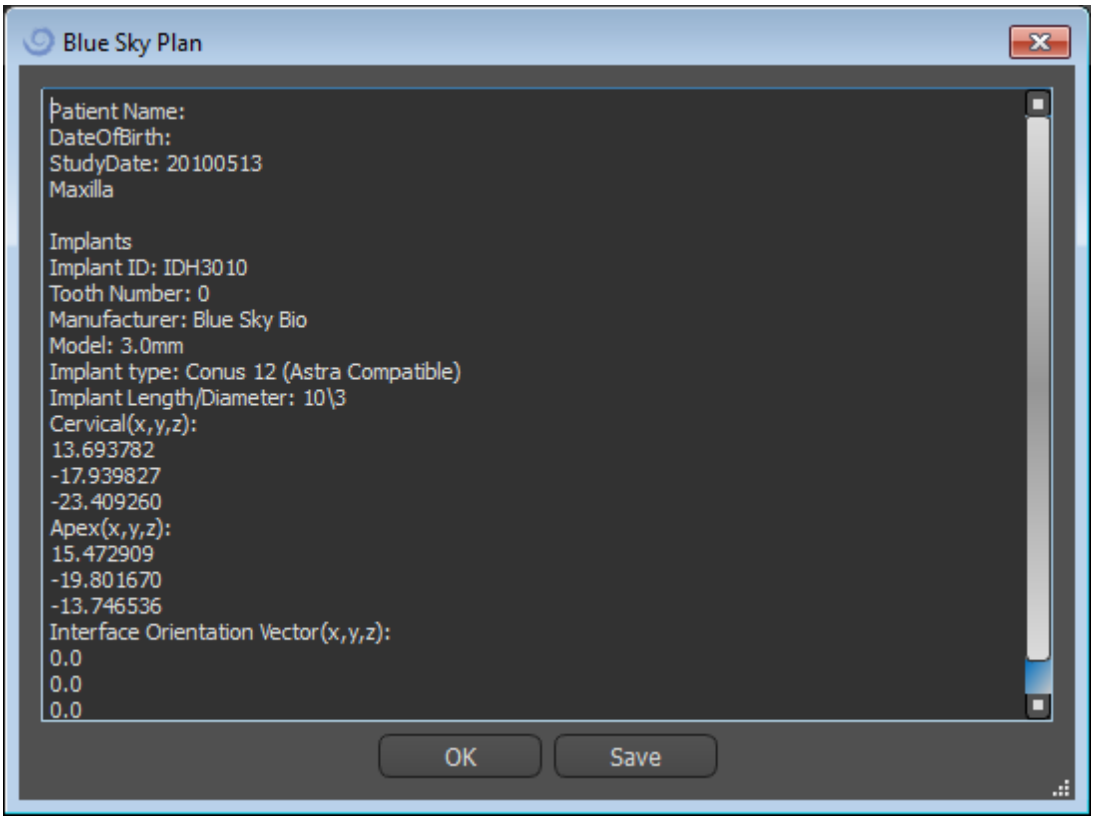
18. Coordinates export

For the purpose of producing a surgical guide, the program has a function for exporting the coordinates of implants on the basis of markers that are part of the scan appliance. It is necessary to first designate markers which are visible in the data. From the menu option "*File > Export Coordinates…*" (1), open the panel with the coordinates export functions (2).



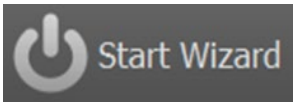
In the coordinates export settings panel, select the corresponding type of scan appliance. A schematic preview of the template currently selected can by displayed by clicking on the help button. In the 3D window, view the model from above and adjust the display with the slider so the markers are clearly visible. Click button to activate marker display mode, and designate markers by clicking on them. The order in which the markers are designated must correspond to the order marked on the schematic template. If no order is prescribed then markers can be selected in any order. The markers can be designated in all available views and their position is automatically adjusted for the best fit.

If you make a mistake when entering a marker, the most recently entered point or all points can be removed by clicking the corresponding buttons or with a right click on a marker when the marker selection mode is active. The coordinates are actually exported when you click the "*Create Report"* button. For a license with a limited number of exports, the number of remaining exports is indicated on button; the number of exports is only reduced once each time the project is opened.


Blue Sky Plan
Patient Name:
DateOfBirth:
StudyDate: 20100513
Maxilla
Implants
Implant ID: IDH3010
Tooth Number: 0
Manufacturer: Blue Sky Bio
Model: 3.0mm
Implant type: Conus 12 (Astra Compatible)
Implant Length/Diameter: 10\3
Cervical(x,y,z):
13.693782
-17.939827
-23.409260
Apex(x,y,z):
15.472909
-19.801670
-13.746536
Interface Orientation Vector(x,y,z):
0.0
0.0
0.0
OK
Save

19. Blue Sky Plan Wizard

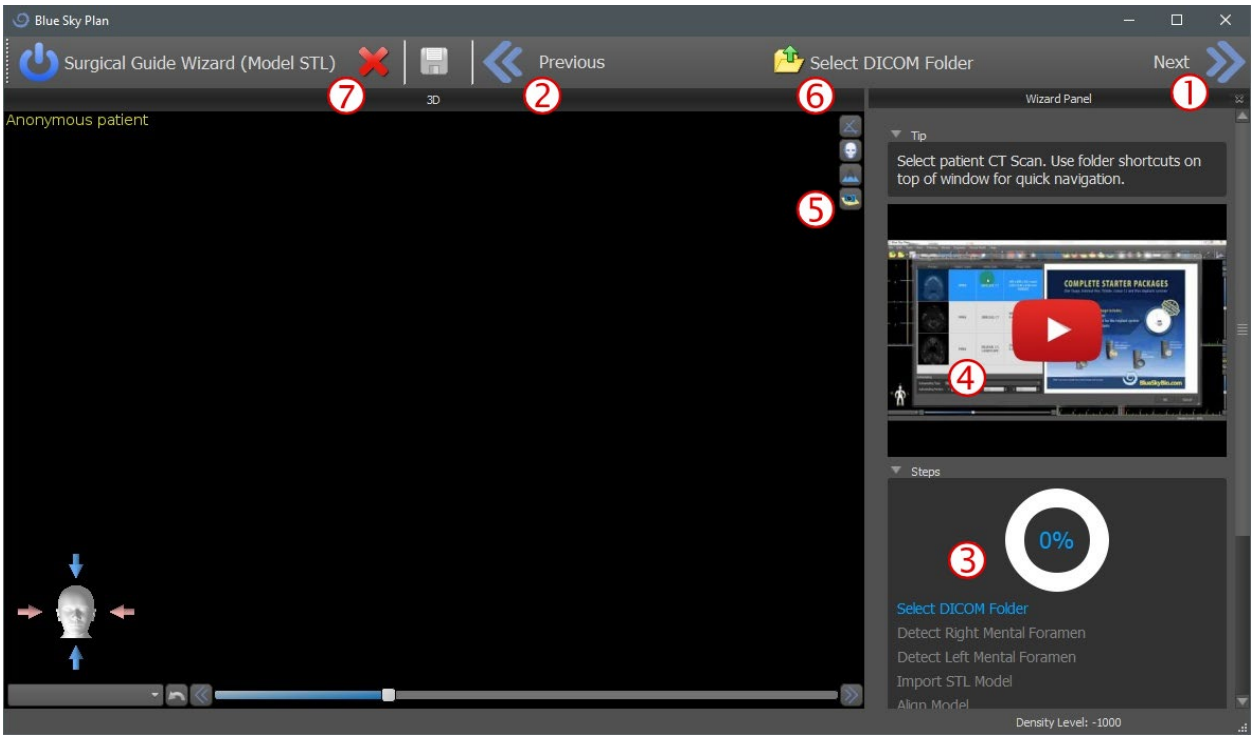
For easier cases of implant planning in the Normal Mode there is the Blue Sky Plan Wizard tool. The tool allows case processing in the form of partly automated sequential steps with help. To start the Wizard, first switch to the Normal Mode and press the “Start Wizard” button in the Wizard Toolbar in the top left corner.



You can move between individual Wizard steps using the “Next” (1) and “Previous” (2) buttons. Every step clearly shows the Wizard stage you are in (3). There are thematic learning videos available for some of the activities (4). Whilst running the Wizard you can use the “Save Screenshot” (5) button and continue working with the screenshots via the *“Screenshot Panel”*. The button in the top bar is used for reactivating or restarting the currently used tool (6).

If you find that the case requires more complex processing you can switch the Wizard off at any time and continue work in the Normal Mode (7). Any nerves that have been detected, implants inserted or guides created will be saved.

The Blue Skype Plan Wizard may also be used as a tutorial. The menu selection “File > Learn Blue Skype Plan” opens a special dialog allowing source data to be uploaded to the model case. The model case is further analyzed in the learning videos available for every program step.

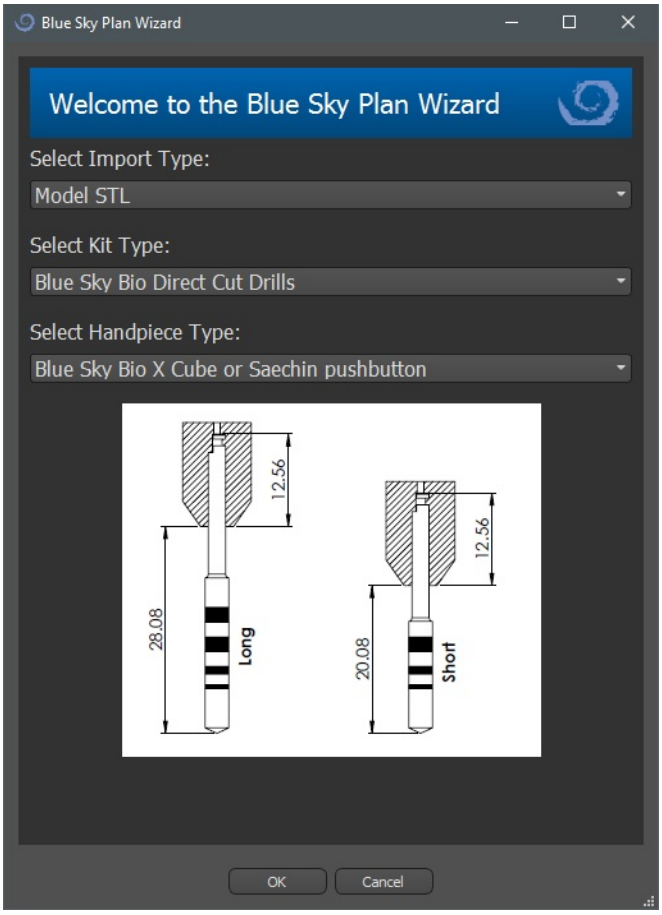


The Wizard allows planning on the basis of various types of input data (Import Type):

- DICOM + STL Model (Model STL)
- DICOM + Model Scan (Model CT)
- DICOM + Impression Scan (Impression CT)
- DICOM + Impression Scan with Markers (Impression CT With Markers)

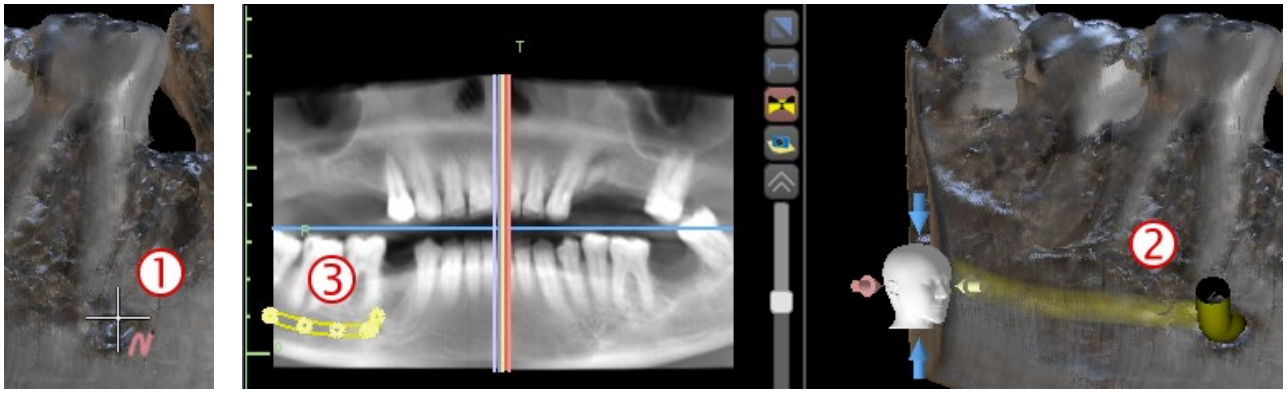
19.1. Load DICOM data

After starting the Wizard a dialog will open where you can select the import type, kit type and, after selecting Blue Sky Bio Direct Cut Drills, the handpiece you want to use. The following windows serve for DICOM data upload, potential dataset selection and to select volume of interest. If you have already uploaded some DICOM data when you started the Wizard, you will work with these data. The window “Load DICOM Data” will not open and the Wizard will move directly to the next step.



19.2. Adding a mandibular canal

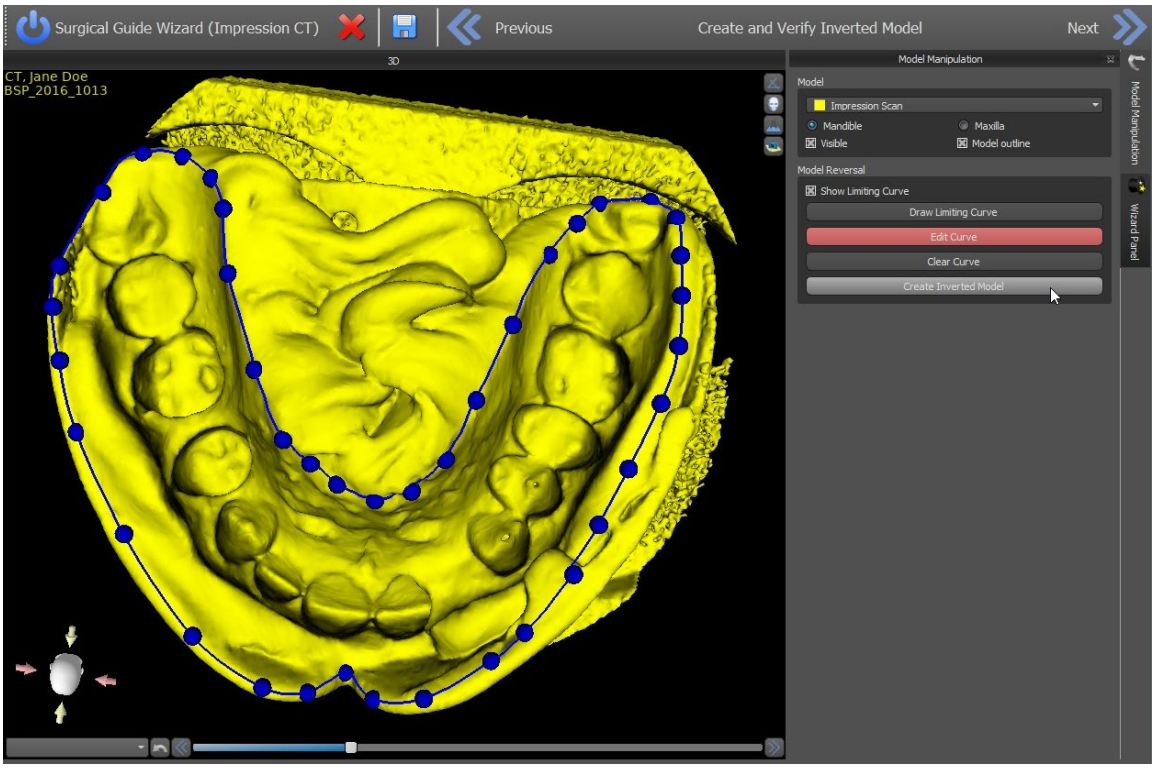
The subject of this step is automatic nerve detection. In the 3D view click the cross-shaped cursor first on the right and then on the left mental foramen (1). The mandibular canal is automatically detected (2) and its progress may be edited manually in any view except for 3D (3). If you do not need to detect the mandibular nerve you can skip this step using the *“Next”* button. If you are working with the maxilla, click directly on the “*Maxilla*” button in the top bar.



19.3. Model upload and preparation

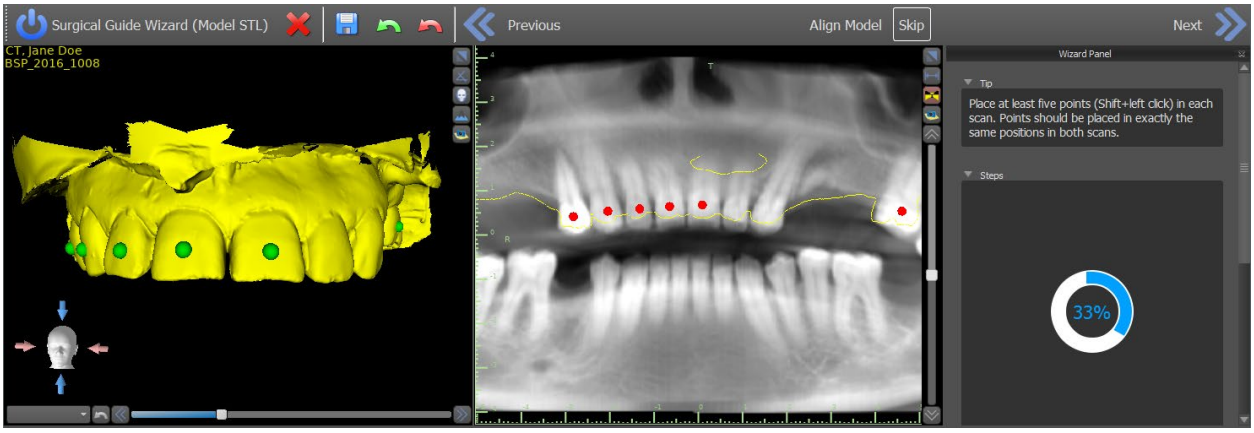
In the next step the model will be uploaded and prepared. Depending on the surface scan import type, several preparatory steps may be run before you get a model prepared for aligning with the DICOM data.

- Model STL - simply upload.
- Model CT - it is necessary to set the surface threshold and create a surface model.
- Impression CT - it is necessary to first set the surface threshold and create an impression model. Then you must plot and edit a curve in the impression model delimiting the appropriate model part (see figure below) and create an inverted model.
- Impression CT with Markers – you need to align the scan appliance with the gutta percha markers (refer to section 7) and then, as in the case of the Impression CT, create an inverted model.



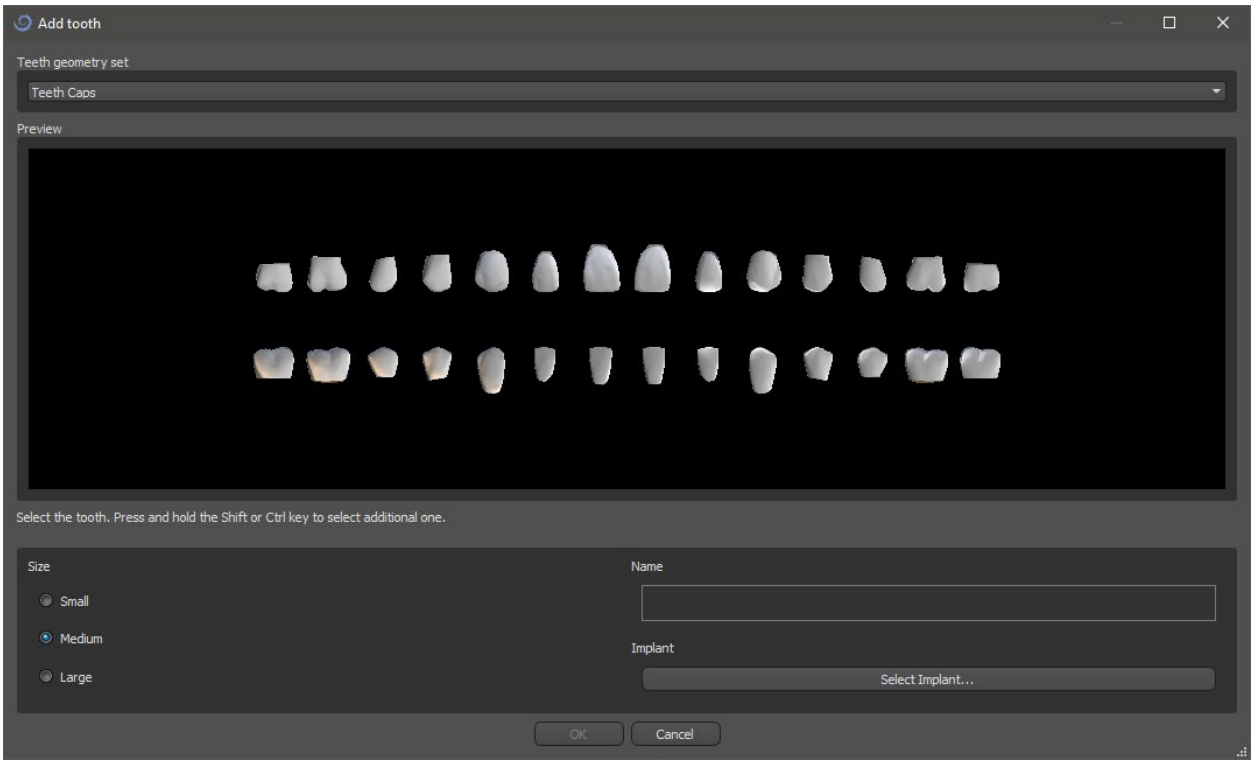
19.4. Model aligning

Aligning and further progress with all imported types and the prepared model is performed identically. The Wizard uses Matching Teeth Alignment. At least five identical teeth must be marked in the model and in the panoramic image. Points should be placed in exactly the same position in both scans. In the next step you must confirm the alignment or return to the previous step to improve the point setting.

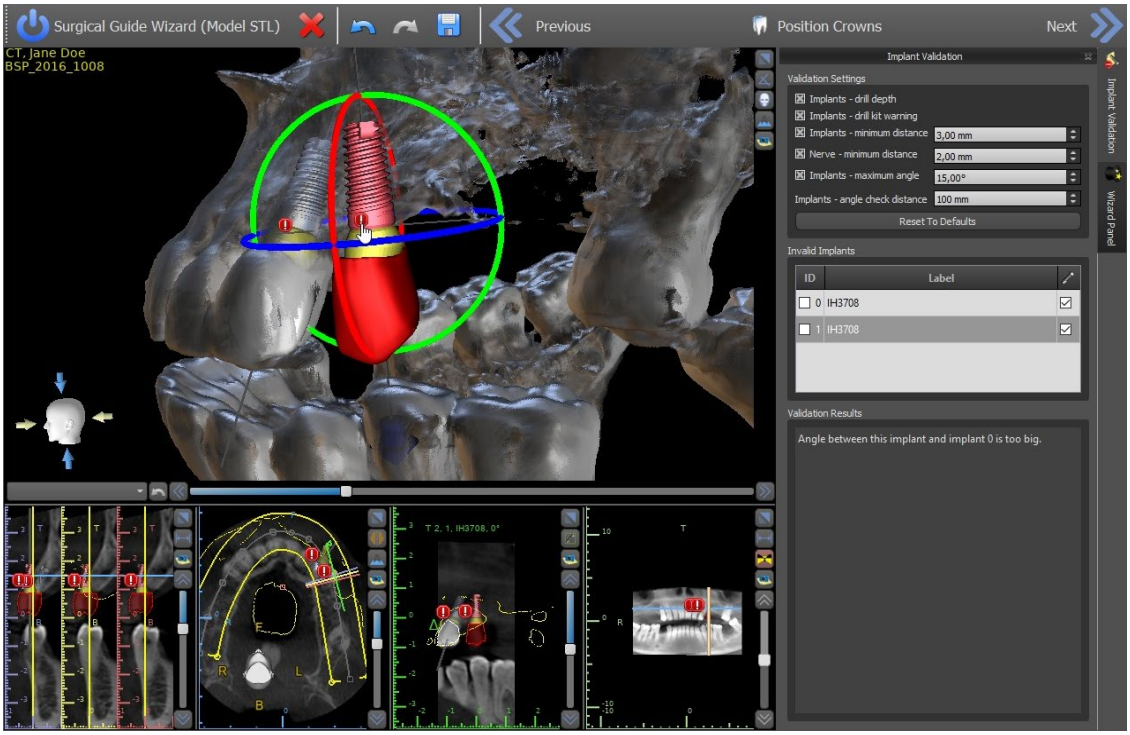


19.5. Crowns and implants

Now you can add crowns and implants. You can choose from three teeth geometry sets and implants compatible with the kit type selected at the start of the Wizard. The crowns are added together with the selected implants and in this step, you can only move them jointly.

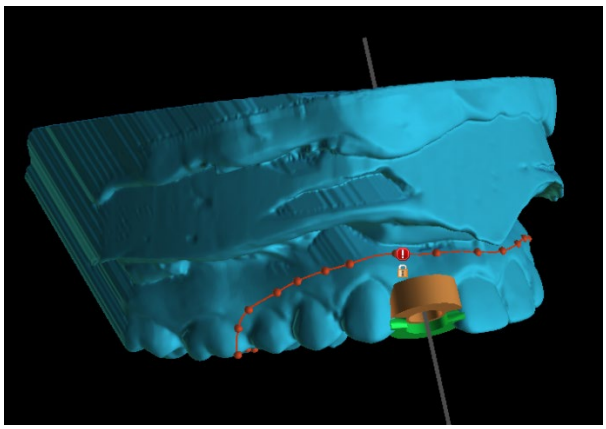


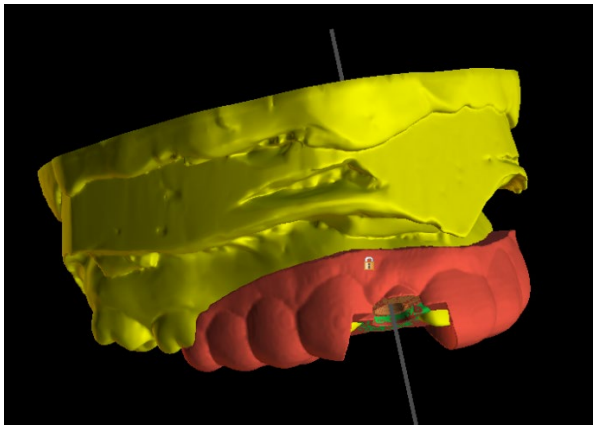
In the next step you can adjust the implant and the crown positions separately. Both steps also display validation information about the status of the individual implants. The icon appears if an implant is evaluated as invalid. After double clicking on this icon the Implant Validation Panel will open with further information.



19.6. Surgical Guide

Prior to fabrication of the surgical guide you must specify the part of the mandible to be covered. In the “Draw Guide Curve” step, first draw a curve around the area of interest (Shift + left click). The curve is drawn on the model without undercuts (newly-generated model with undercuts removed). You can edit the curve by moving its individual points and when moving on to the next step, the surgical guide will be fabricated. In the “Create Surgical Guide” step, you can see the surgical guide still on the model without undercuts. Windows can be added by right clicking on the model, and a surgical guide can be recreated with windows. In the next step, “Verify Surgical Guide”, the surgical guide is displayed again on the original model for better control.





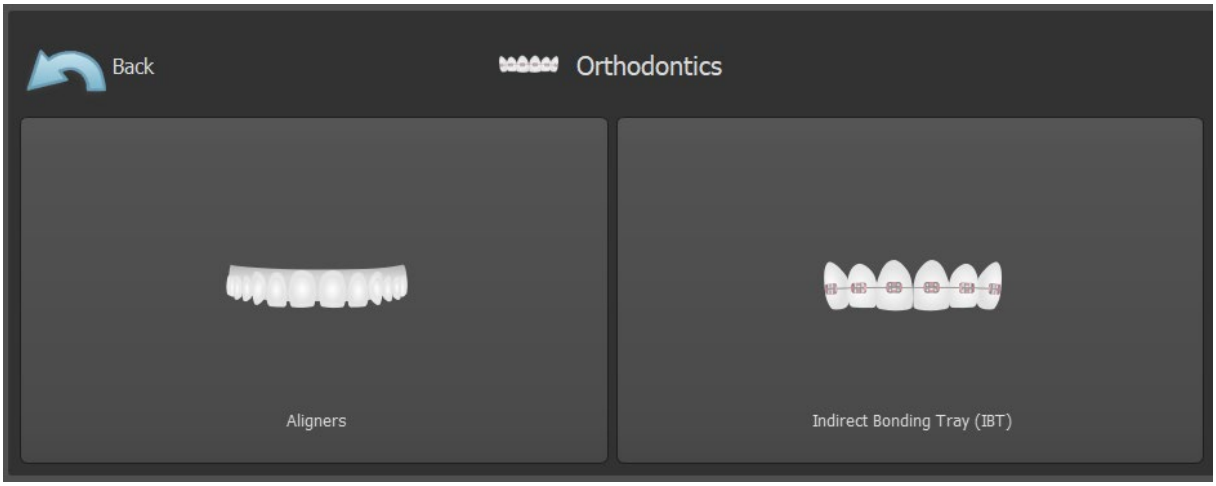
19.7. Saving and ordering

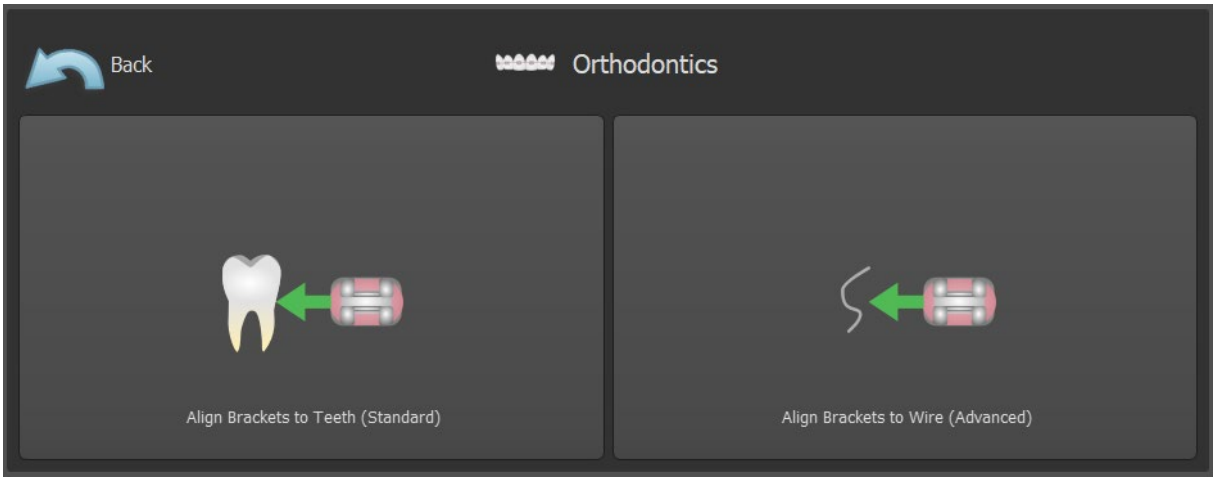
In the remaining Wizard steps, you first save the prepared project. The template created is exported and can be submitted via BioBigBox.com. Then the PDF report with basic information and screenshots is saved. The necessary parts can be ordered directly at http://www.blueskybio.com. Then you can continue with a new case or close the Wizard.

20. Orthodontics module

Blue Sky Plan makes it possible to plan orthodontic treatments based on imported STL models of the jaw with teeth. All of the controls are available in the *"Orthodontics"* panel.

The planning begins with an intro screen titled "*Orthodontics*", where the user selects the type of planning – "*Aligners*" or "*Indirect Bonding Tray*", which splits further into *"Align Brackets to Teeth"* and *"Align Brackets to Wire"*.





The specific type of planning can't be changed in an upcoming process. You can view the selected type of planning for your project in the top left corner of the 3D window where the patient data is shown.

The functions for model preparation are identical in all types of planning. Specifically, this includes the steps for Loading the Input Model, Jaw Alignment, Teeth Segmentation and Model Trimming.

The individual types of planning include:

- **Aligners:** Teeth Moving – Edit Steps – Add Buttons (optional) – Design Aligners or Aligner Trim Curve (optional) – Export
- **IBT (Align Brackets to Teeth):** Add Brackets – Prepare IBT – Export
- **IBT (Align Brackets to Wire):** Teeth Moving – Edit Steps – Add Brackets – Prepare IBT – Export

20.1. Loading the Input STL Model

The planning starts by loading the STL jaw model using the menu selection *"Import Models"* and choosing the correct orientation. It is also possible to use the option *"Import Patient CT Scan",* with the stepwise uploading of CT data and jaw models. The alignment of the STL model and the CT scan is done via *"Matching Teeth"*, and the STL model can then be further worked with.

If the other jaw (the opposing arch) is available, it can be imported in this step. After its uploading, the function *"Show Opposing Arch"* is activated, permitting the user to show/hide this other model together with the *"Collisions"* function, switching on the colour visualization of collisions as the teeth approach each other or collide.

Both jaws may already be aligned, or it is possible to activate the model alignment widget to allow the user to move the jaw manually in the 3D view. Another available function for this purpose is "buccal bite registration" (see chapter 14.2).

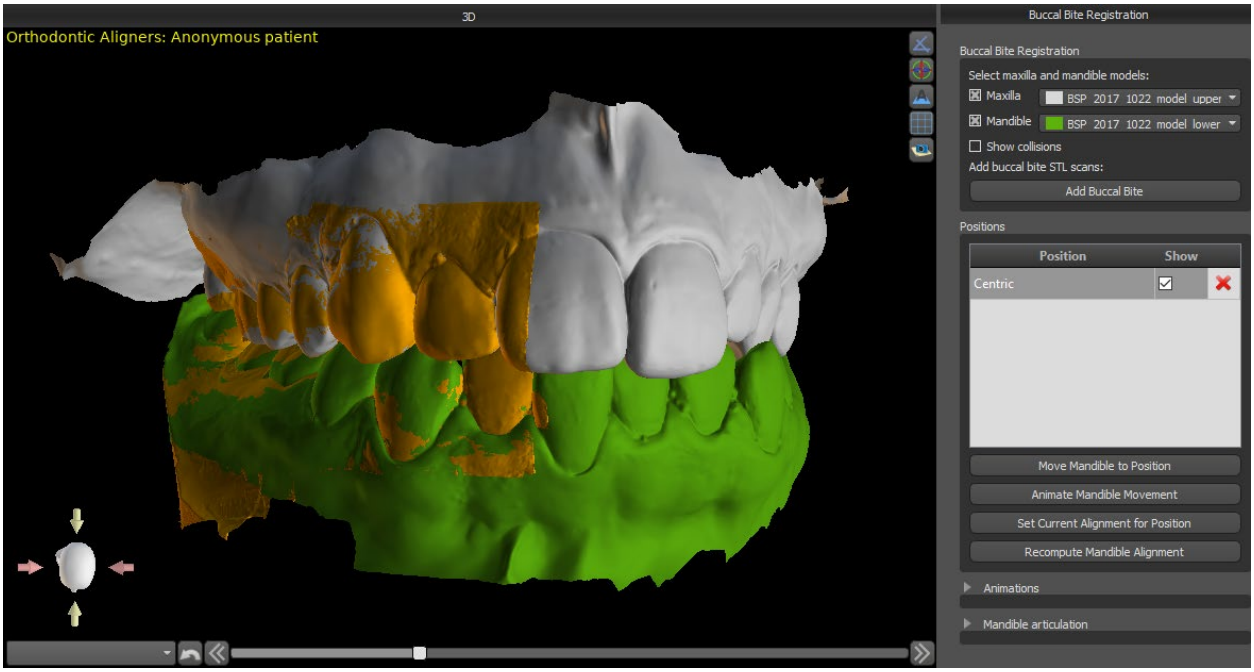
Blue Sky Plan also permits the processing and planning of both jaws in a single case. This requires uploading and aligning both models in the import stage.

This step further includes the entry of the patient's name, and for the next step you can proceed by clicking the "Continue to Jaw Alignment" button.

20.2. Buccal Bite Registration

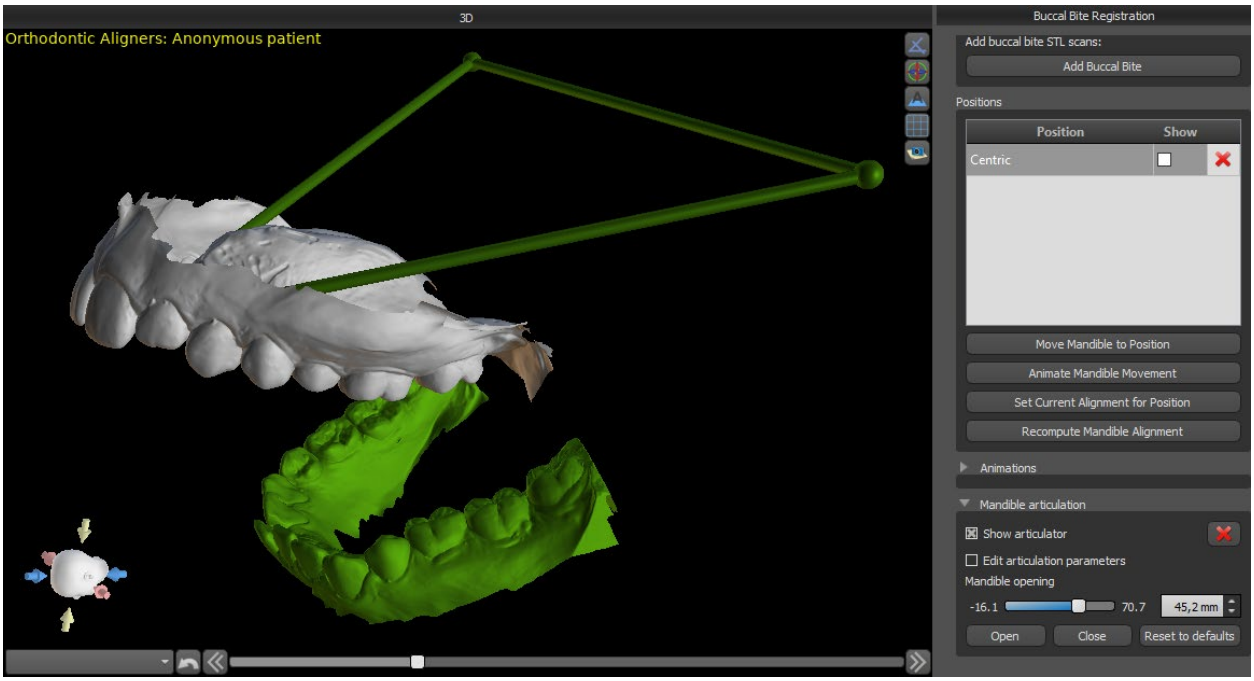
Blue Sky Plan allows for upper-lower jaw alignment using a "buccal bite" surface scan. This process requires both jaw models to be imported. Then, the *"Buccal Bite Registration"* button can be used for transferring to the special *"Buccal Bite Registration"* panel. The maxilla and the mandible are already automatically uploaded to the panel

and it is only required to add one or more buccal bite scans. The software then automatically aligns the maxilla and the mandible. Additional buccal bite alignments can be created (according to the number of the buccal bite scans) and visualization is possible for the mandible moving from the normal to each of the additional buccal bite alignments.



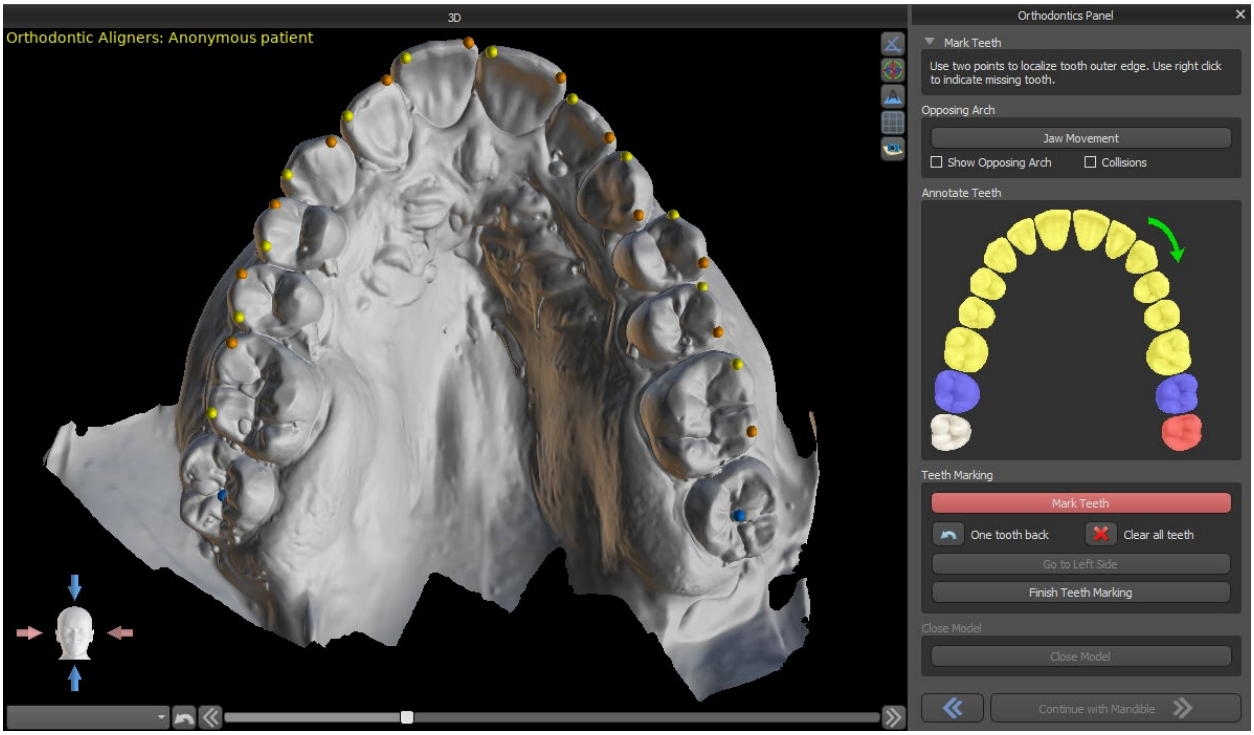
20.3. Mandible articulation

The lower jaw articulation can be visualised by adding jaw articulator. This functionality is not dependent on import of the buccal bite and is available in all types of planning and all their steps on Buccal Bite Registration panel. Collisions between the upper and the lower jaw can be shown in all positions.



20.4. Annotating Teeth and Jaw Alignment

Once the jaw model is imported, it is necessary to mark all teeth, including those teeth that will not be moved or teeth that are missing. The teeth annotation is only possible when the *"Mark Teeth"* button is active.



The tooth from which the teeth marking starts is highlighted in red in the schematic jaw figure in the panel. First, the teeth on the patient's right-hand side are annotated starting from the incisor and finishing with the molars. To mark a present tooth that will be moved, hold the *"Shift"* key and left click on the tooth. Orange and yellow dots illustrate the annotated teeth on the 3D model. A tooth that will not be moved, or is missing, should be marked by right clicking on the mouse (blue dots appears on the model).

Once all the teeth on the first side are annotated, you can proceed with the other side by clicking *"Go to Left Side"* starting from the incisor highlighted in red again.

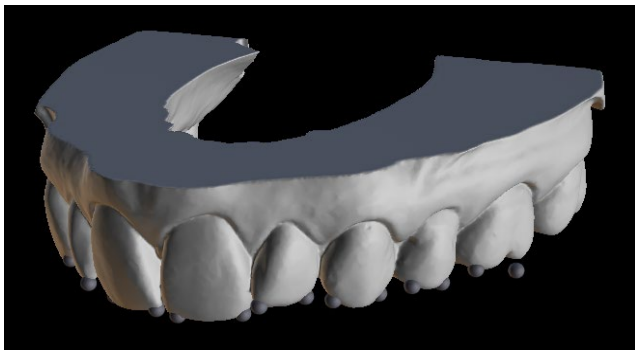
It is not necessary to annotate all the teeth on each side. If the last molar, or so, is not present, you can skip marking the remaining teeth on the side by clicking either *"Go to Left Side"* or *"Finish Teeth Marking"*.

While marking the teeth, it is possible to return one step back (the *"One Tooth Back"* button) and repeat the marking of the previous tooth, or to start from the beginning again by pressing *"Clear All Teeth"*.

To complete the step, click the *"Finish Marking Teeth"* button.

Note: *The proper marking of the teeth is crucial for the subsequent automatic teeth segmentation step. It heavily impacts the precision of the segmentation. Incisors and canines should be marked by clicking/placing two dots on the occlusal edge of each tooth. Molars and premolars should be marked by placing the dots on the buccal side of the tooth surface as indicated in the image above.*

If the input STL model was obtained by 3D scanning, it can be closed and repaired by clicking the *"Close Model"* button. The thickness of the final stone model, i.e. the minimal allowed height in millimetres, is at least 20 mm and can be increased in Preferences.



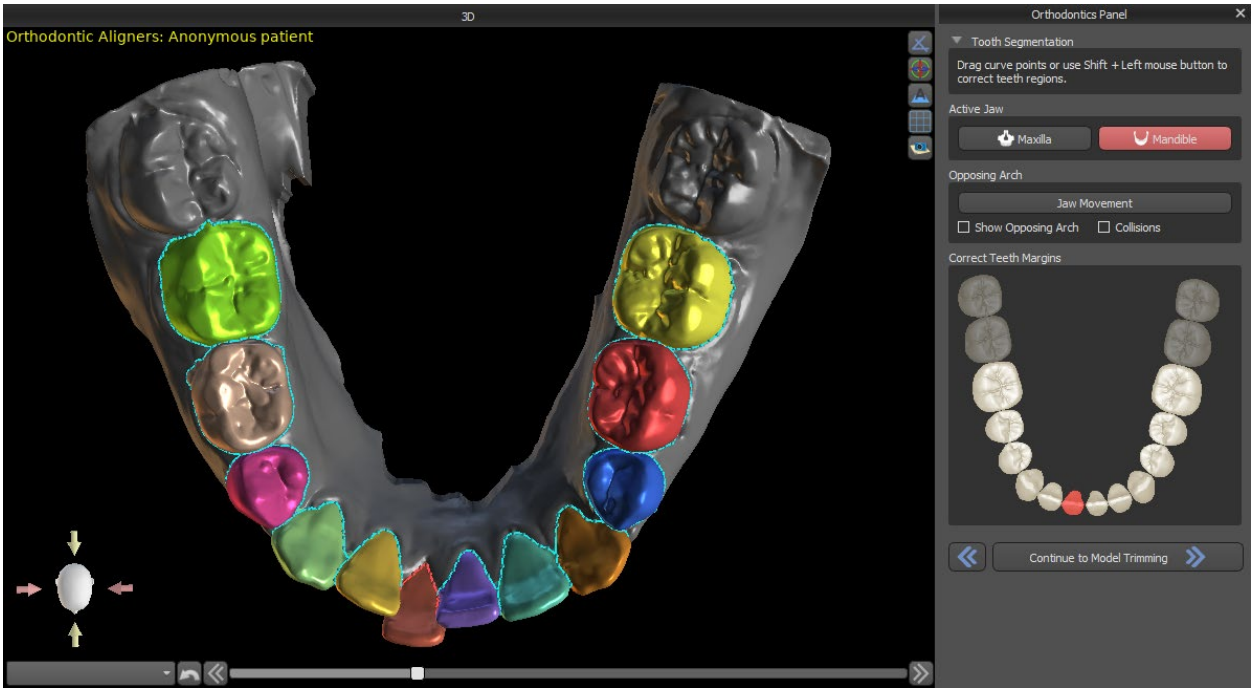
20.5. Two Jaw Functionality

Once the teeth of the first jaw (maxilla) are annotated and the model is closed, the transfer to the mode of planning both jaws is activated. By default, the workflow is set so that after clicking *"Continue with Mandible"* a direct transfer is performed to the second jaw

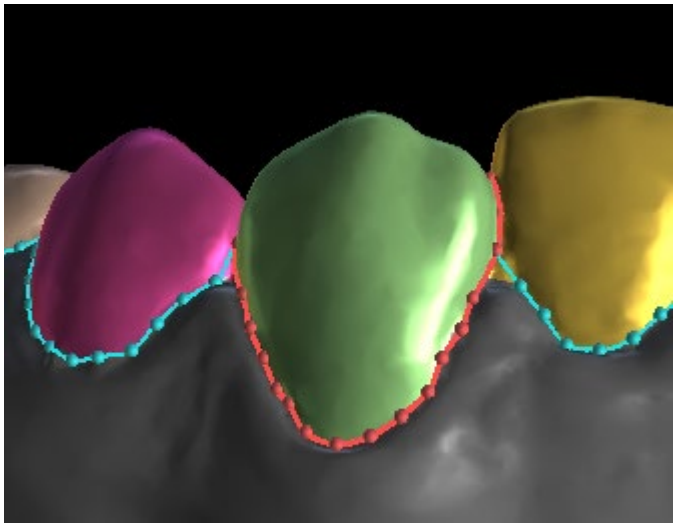
annotation. To plan both jaws, both models must be annotated and aligned. In the following steps there is the option to actively work with one or the other jaw. If the dentist uses the other model (the opposing arch) for visual control in the course of the planning step and for the depiction of possible inter-mandibular collisions only, the *"Skip this Jaw"* button can be used for direct transfer to a single jaw segmentation.

20.6. Teeth Segmentation

The transfer to the step of the automatic segmentation of individual teeth may take a while as the program tries to identify the gingival margin automatically.



After the automatic segmentation, you can adjust the detected gingival margin of the active/selected tooth by dragging the control points of the curve, or by manually drawing a part of the curve on the model while holding down the *"Shift"* key and left mouse button simultaneously.



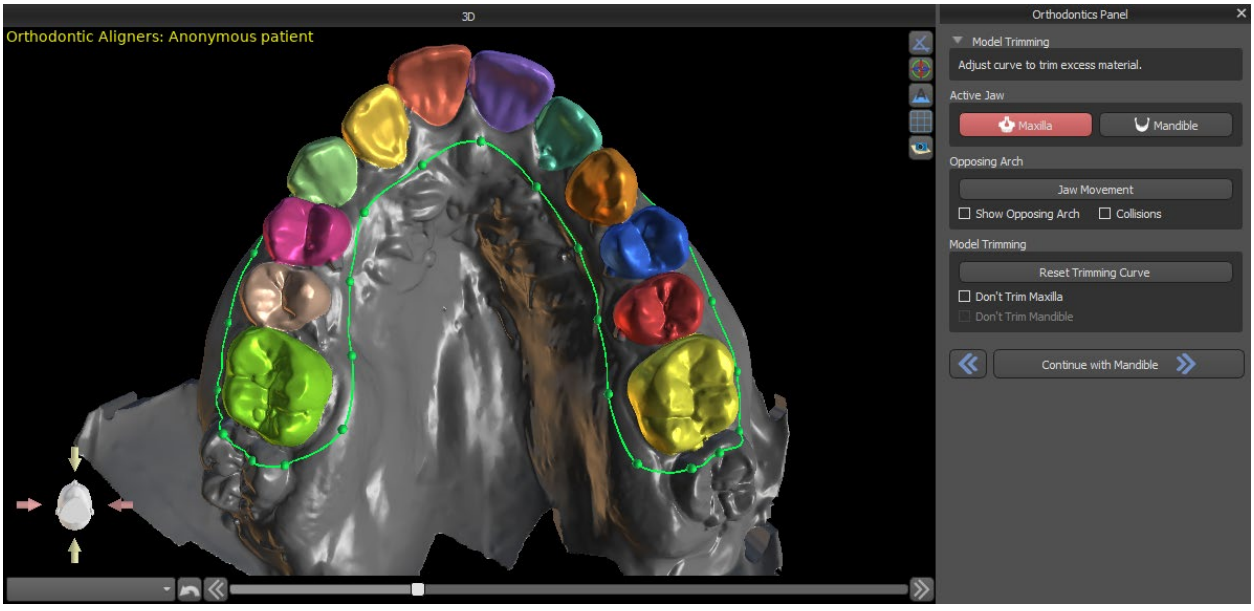
The gingival margin can be edited for the active tooth only. The active tooth can be changed throughout the schematic jaw image in the panel, or by clicking the segmented tooth directly in the 3D view.

Once the boundaries need no further refinement, you can finish the segmentation by clicking the *"Continue to Model Trimming"* button. This applies the changes made and separates the teeth from the 3D scan being able to move them.

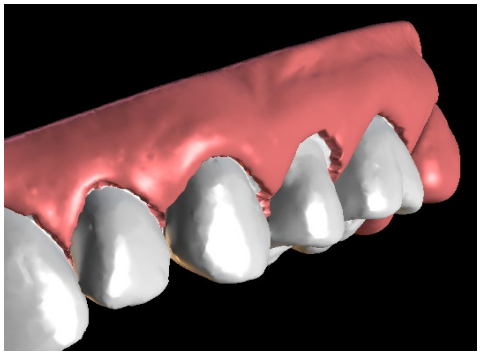
20.7. Model Trimming

The STL model imported to BSP may contain excess material and printing it would mean an unnecessary waste of printing material. For these situations, BSP offers the trimming function by means of a curve. The trimming curve is created automatically at a distance from the teeth based on the "*Gingiva Trim Margin*" parameter (which can be modified in Preferences). The curve is further manually adjustable by dragging the control points.

Part of this step is also the closure and trimming of the model at a specific height based on the distance of the segmented teeth. The parameters *"Model Height Below Mandible Teeth After Trimming"* for the lower jaw and *"Model Height Above Maxillary Teeth After Trimming*" for the upper jaw can be modified in Preferences. The Model Trimming step can be skipped by using the options *"Don't Trim Maxilla"* or *"Don't Trim Mandible".*



In this step, Model Trimming is only defined. It will only start after clicking on Continue to Teeth Moving, so this operation may take a while.



After the separation of the teeth, the gingiva may be augmented (i.e. inflated) to prevent interference with the aligner and to help prevent tissue impingement.

Note: Due to the optimisation in the processes, the .0mm value is recommended for versions 4.7.50 and higher. The .2mm is recommended for versions 4.7.20 and older. This is the "Gingiva Augmentation Amount" parameter in Preferences.

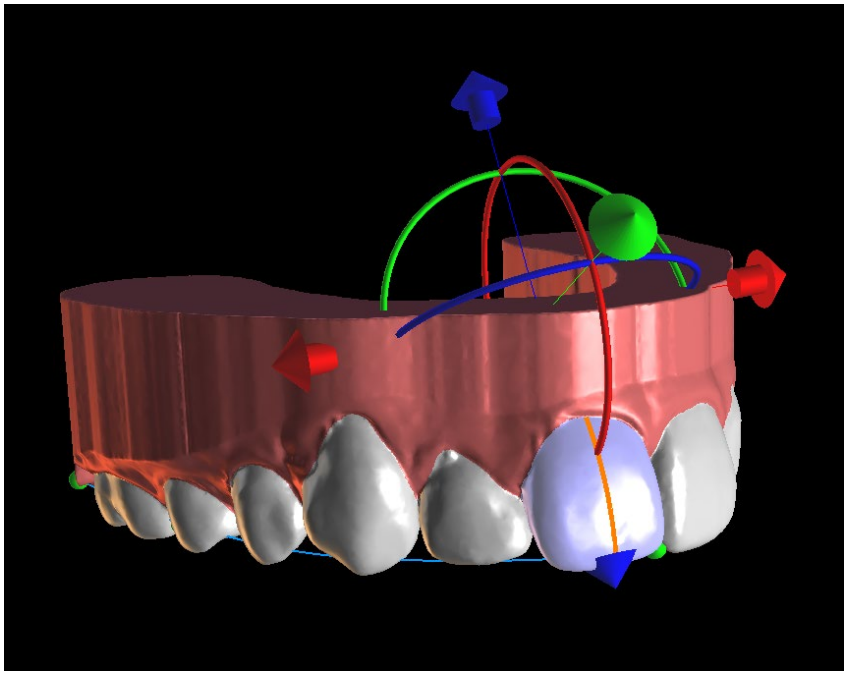
Also, the colours of the 3D model and the teeth change to a more natural pink and white, respectively. Now the software allows you to reposition the teeth and plan their final positions.

20.8. Teeth Moving

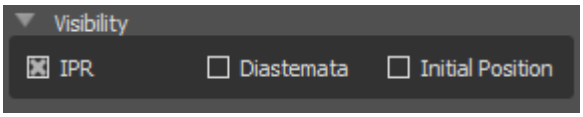
In this step, the target positions of individual teeth can be planned. You should start by selecting the active tooth – either by left clicking on a tooth in the schematic jaw image in the panel, or by clicking the tooth in the 3D view.

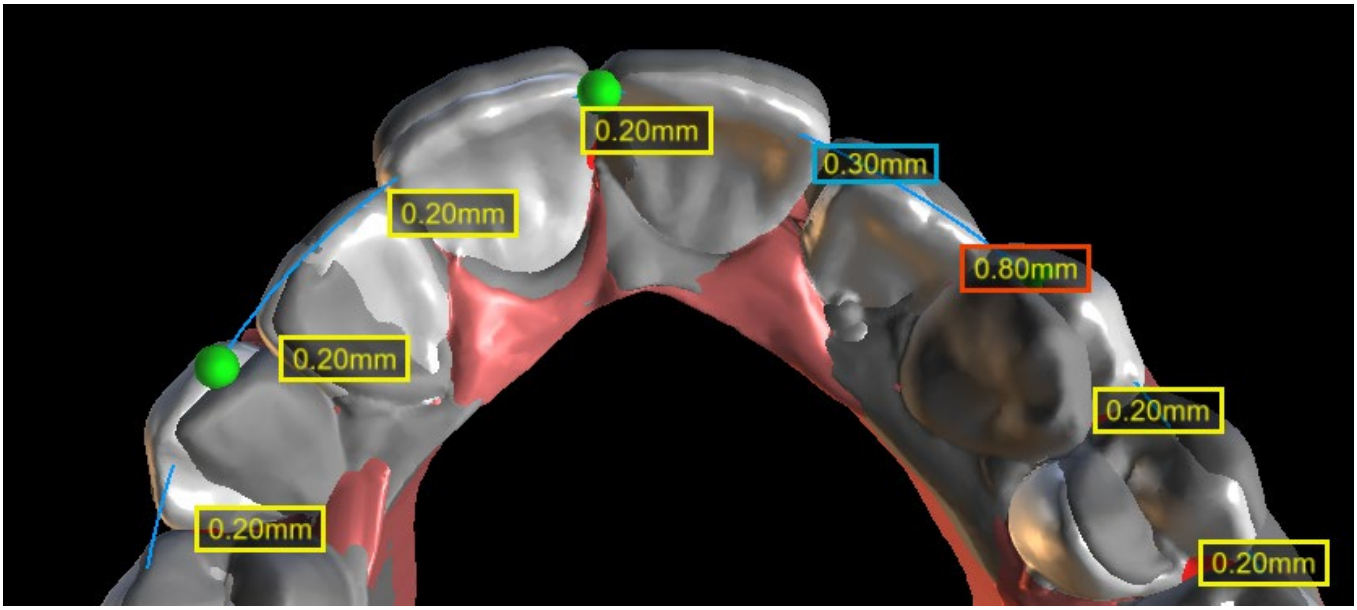
The active tooth has a visible tooth midline and a 3D manipulation widget shown around it. Using the widget, you can move and rotate the tooth in the following types of movements:

- Mesial / Distal tipping
- Buccal / Lingual tipping
- Rotation along longitudinal tooth axis
- Intrusion / Extrusion
- Left / Right
- Forward / Backward

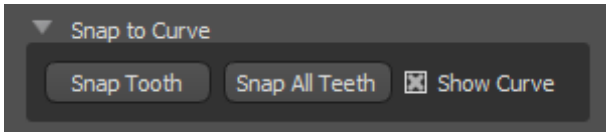


A couple of interesting functions can be activated in the orthodontic panel after this step. The “IPR” option will show a 3D view of the sizes of the over-limit Interproximal reductions, and the limits of the maximum allowed IPR can be set in Preferences. The red areas informatively visualise inter-teeth collisions. “Diastemata” shows the measurement of the space between the teeth. “Initial position” shows the original model before the teeth positioning.

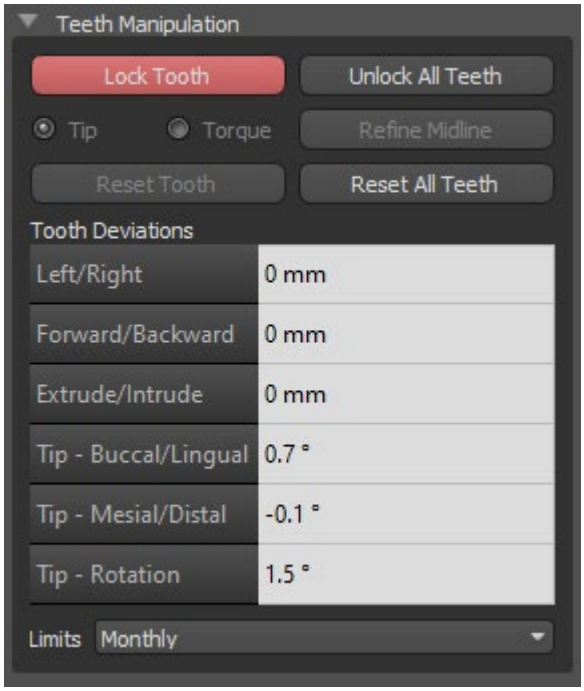




The *“Snap to Curve”* functionality allows the user to adjust a curve representing an ideal teeth arch and snap one or all teeth to this curve.



Every tooth can be locked in position by right clicking on the tooth or the button *“Lock Tooth”.* Unlocking proceeds similarly or the user can unlock all teeth at once.



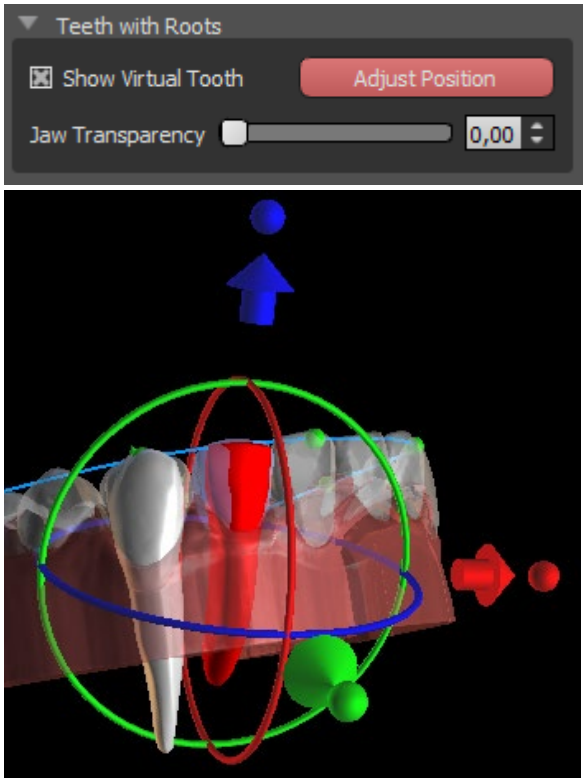
It is possible to change the point of rotation of 3D manipulation widget, i.e. to switch between the tipping and torque. The tipping and torque angles are tracked and reported separately. Pivot offsets can be set in Preferences. The user can also adjust the midline when the *“Refine Midline”* button is active.

The *“Reset Tooth”* button cancels all the adjustments made and returns the active tooth to its original position. The *“Reset All Teeth”* button returns all the teeth to their original positions.

As the active tooth is being moved, the *“Orthodontics”* panel shows information about the total movements in the form of distances [mm] and angles [°] from the initial position. Movement limits can be set as monthly, bi-weekly or weekly.

When positioning a tooth, it is sometimes useful to see the movement of the whole tooth, including its roots.

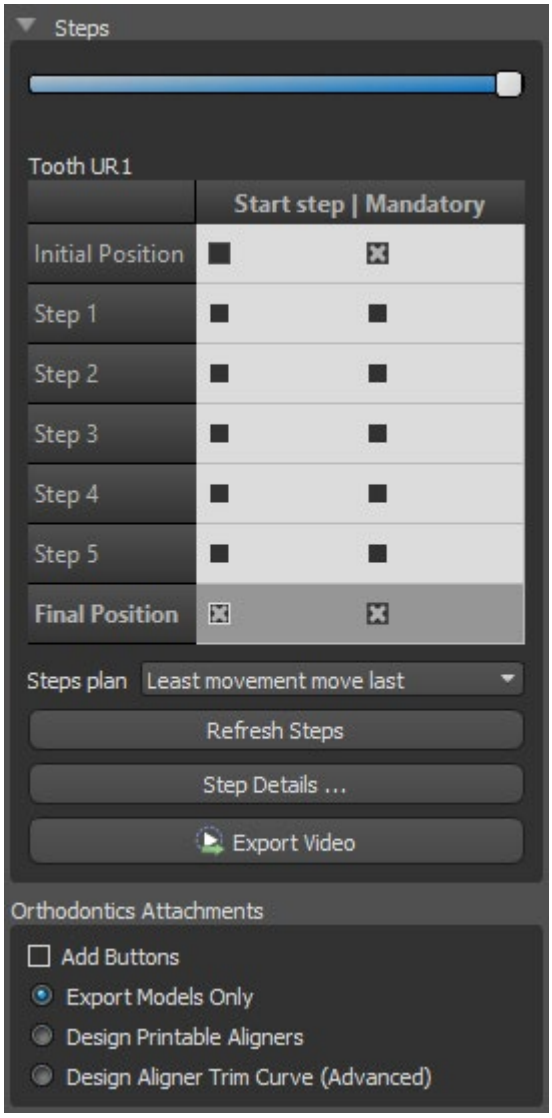
Therefore, Blue Sky Plan allows you to add a virtual tooth with roots by enabling the checkbox *"Show Virtual Tooth"*. To refine the shape and position of the newly added virtual tooth to closely match the underlying tooth separated from the 3D scan, click the tooth (it turns red) and enable the *"Adjust Virtual Tooth Position"* button. Now, you may adjust the position and size of the virtual tooth using the in-scene widget. For better clarity of the roots, you can increase the transparency of the jaw by moving the slider in the panel.



20.9. Generating Intermediate Positions

Once you are satisfied with the target positions of the teeth, use the *"Continue to Edit Steps"* button to generate intermediate positions and move to the next planning step.

The table in the *"Orthodontics"* panel lists the number of necessary intermediate steps to reach the planned target position of the active tooth. The number of steps is always the same for all the teeth, but it is possible to start the movement of teeth in later steps. The first and last row in the table represent the initial and target position of the active tooth, so these positions are locked and cannot be changed at this planning stage. The number of steps is estimated automatically based on the pre-defined settings of maximum movement limitations. The default movement limitations are stored in the application Preferences and can be adjusted manually.



The slider at the top of the *"Orthodontics"* panel allows you to move teeth over time and in intermediate steps. If the slider is moved to the left, the teeth are visualised at the initial positions. The very right position of the slider represents the planned target positions. By dragging the slider, you can animate the movement of the teeth through intermediate steps over time. Further, you can move the slider to one of the interim steps and, if needed, adjust the position of the active tooth in this concrete step to prevent collisions with its neighbouring teeth.

In the table, there are two columns of checkboxes. It may be important to start the movement of the active tooth later in a step. The starting step can be changed by checking the checkbox in the left column. After any change, it is necessary to regenerate the entire table by clicking the button *"Refresh Steps"*. The checkboxes in the right column can be used to lock the intermediate positions of the tooth – the tooth always moves through the locked intermediate positions.

Two optional plans are available – "*Least movement move last*" and "*Least movement move first*" for organising teeth movement.

In the Aligners planning type, it is necessary, at the end of this step, to select which method of creating aligners will be used further on. For the generation and export of model intermediate positions only, the default selection "*Export Models Only*" is sufficient.

By selecting the "*Design Printable Aligners*" option, the aligners will be drawn and generated directly as models in BSP, which can later be exported. Selecting "*Design Aligner Trim Curve*" means that the trimline, applicable to the mining machine, will be drawn on the models and exported. It's very helpful for automatic aligner trimming.

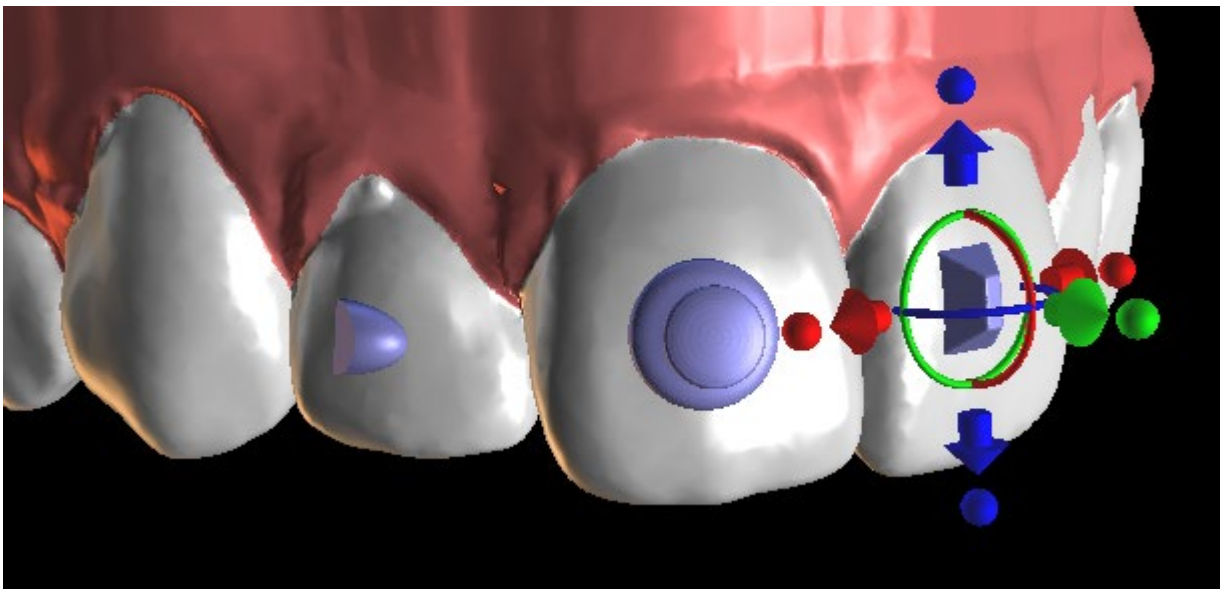
If buttons are meant to be added on model intermediate positions, it is necessary to check the "Add Buttons" as well. Doing that will add this step to the rest of the process.

20.10. Orthodontic Aligners

The method of creating aligners can be selected at the end of the step “Generating the intermediate positions” (described in the previous chapter). The upcoming steps will be based on this selection.

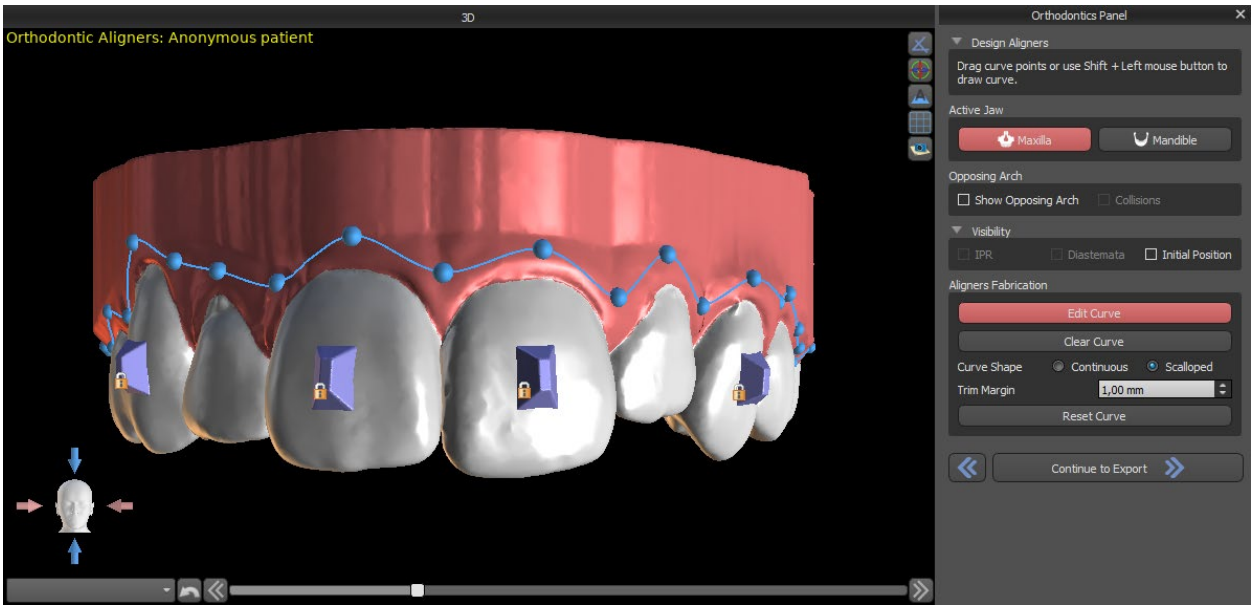
20.10.1. Add Buttons

Buttons are added after right clicking on the tooth in the 3D view and selecting among several sets, shapes, and sizes. The button position can be fine-tuned manually.



20.10.2. Design Printable Aligners

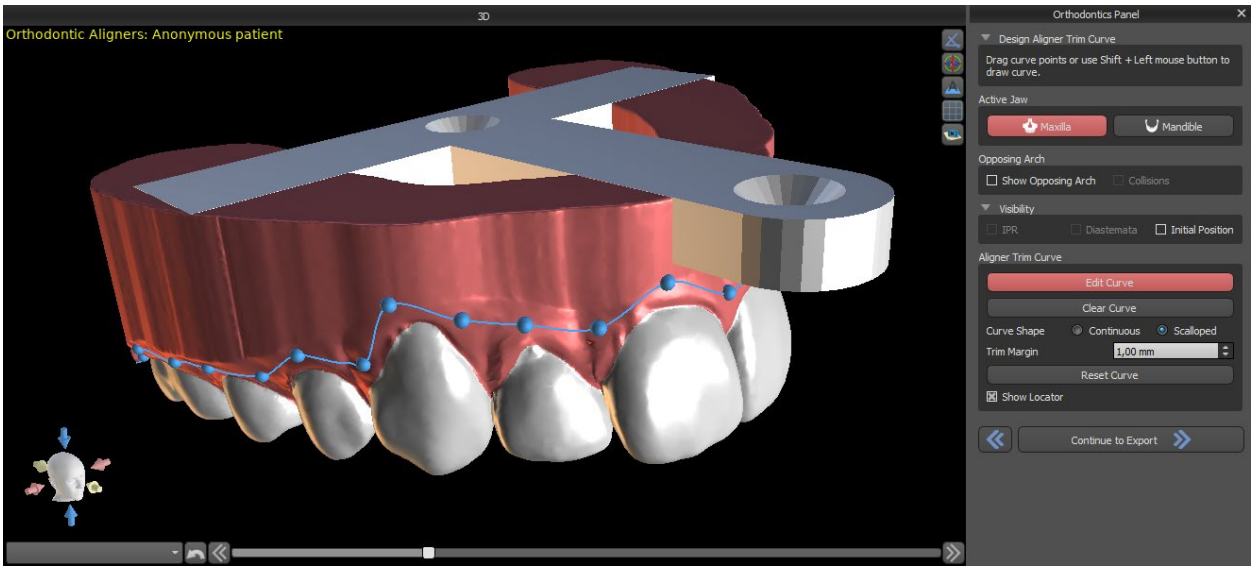
This step is intended to be used for drawing and editing the curve for the aligner fabrication. The aligner curve will be generated automatically based on the settings of the “Curve Shape” and “Trim Margin” parameters in Preferences. Both parameters can be adjusted as well and regenerate directly on the Orthodontics panel. These changes are saved in the project. If the parameters are changed in this process, it is necessary to regenerate the curve by clicking the “Reset Curve” button. The generation of aligners is a part of the transition to the STL model export step.



The production of aligners may be ordered at Blue Sky Bio. You must send the STL files containing the models with the 3D profile on them to identify the patient and stage number to Blue Sky Bio. Blue Sky Bio will make the aligners and ship them to you. If at any stage the patient no longer matches your model for that stage (making the aligner not fit) then edit the models and re-order the aligners. More detailed instructions for use are available in Footnotes 21.1

20.10.3. Design Aligners Trim Curve

The Aligner Trim Curve will be (just like the Aligner Curve) generated automatically based on the settings of the parameters “*Curve Shape*” and “*Trim Margin*” in Preferences. Both parameters can be adjusted as well and regenerate directly on the Orthodontics panel. These changes are saved in the project. If the parameters are changed in this process, it is necessary to regenerate the curve by clicking the “Reset Aligner Trim Curve” button. To use the trimline information for the automatic trimming of the aligners in the milling machines information in the future, it is possible to turn on “Show locator” and modify the trim curve appropriately. The export of the curve will be available in the last step.



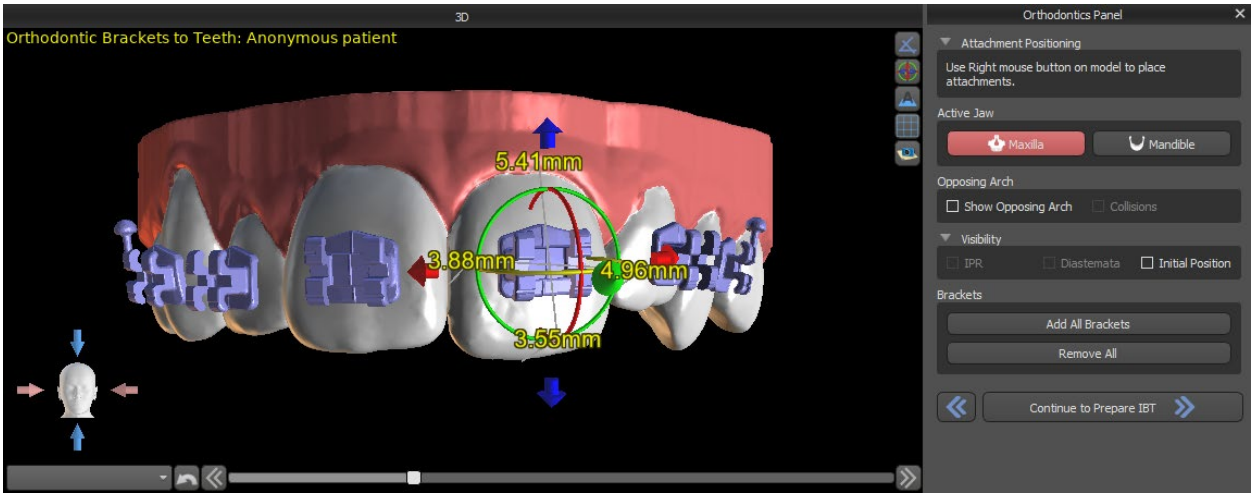
20.11. Indirect Bonding Tray – Align Brackets to Teeth

Blue Sky Plan also allows for controlled virtual bracket placement in the software and the fabrication of an indirect bonding tray to allow the physical brackets to be placed.

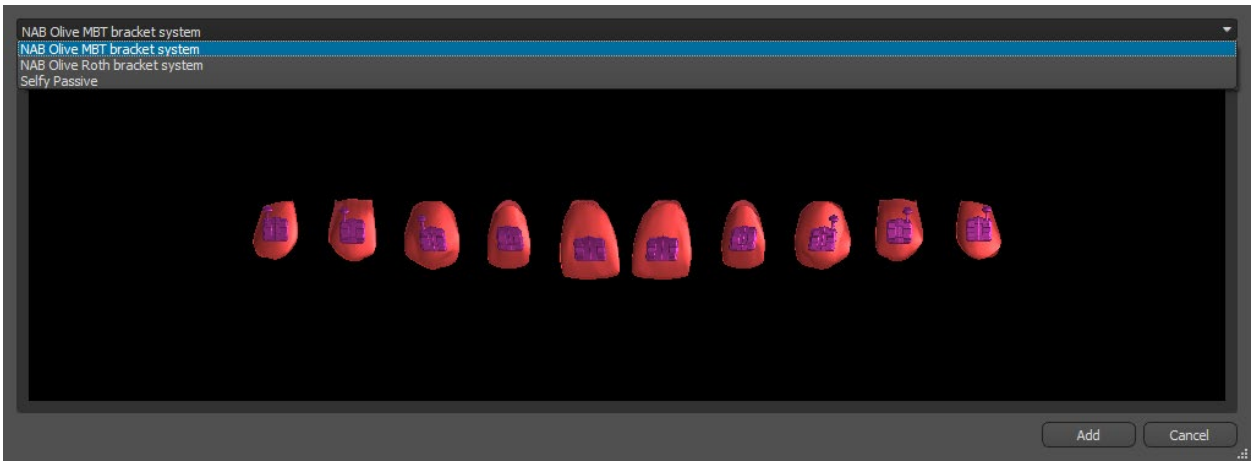
This planning type is used to add brackets to the initial position of the teeth. That is the reason why it doesn't include the Teeth Moving step and after Model Trimming goes straight to Add Brackets.

20.11.1. Add Brackets

Brackets are added directly on the teeth based on the predefined "*Brackets Placement Offsets*" in Preferences. The position of already added brackets can be modified by the 3D manipulation widget and the function "*Snap to Tooth*" by right clicking with the mouse.

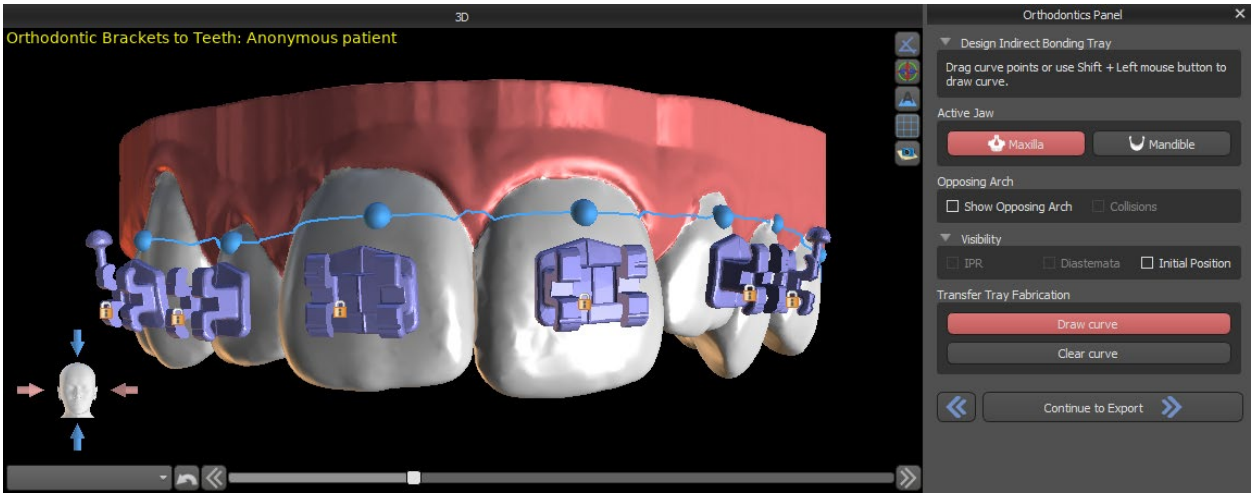


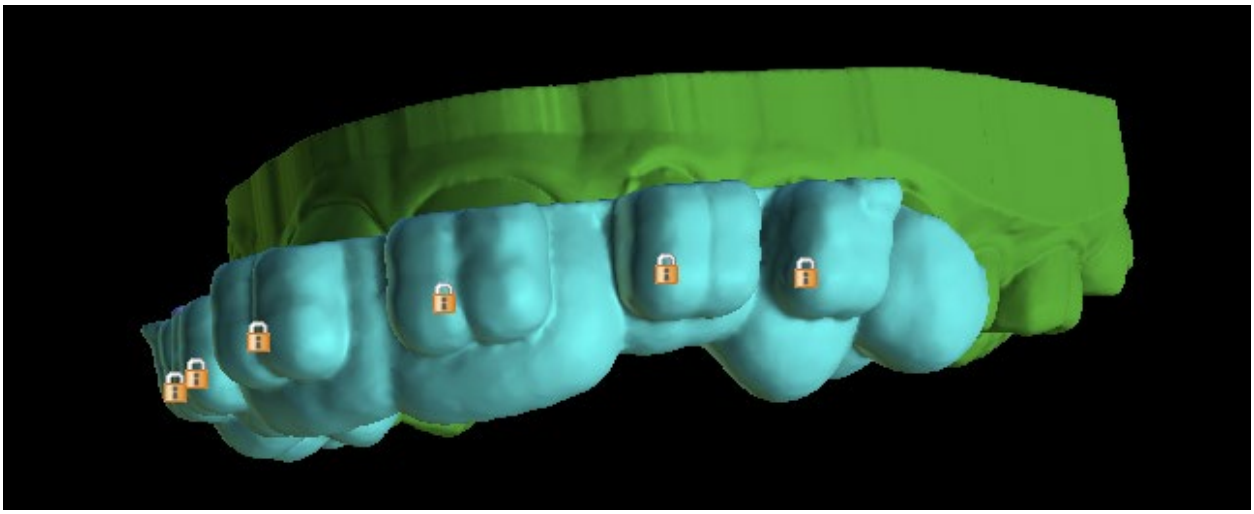
Brackets from several systems are available.



20.11.2. Prepare IBT

Once the brackets are placed, the next step will include drawing and editing the curve for indirect bonding tray fabrication. Its use allows the physical brackets to be placed accurately in real life.

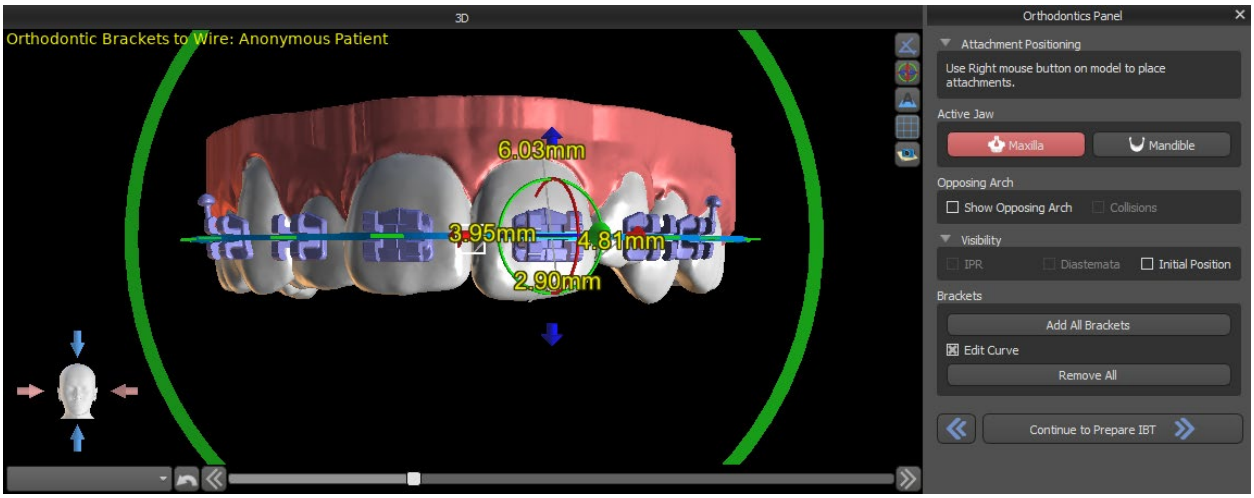




20.12. Indirect Bonding Tray – Align Brackets to Wire

20.12.1. Add Brackets

The "*Align Brackets to Wire*" planning type is used to add brackets to the final position of the teeth. Blue Sky Plan automatically places the brackets along the wire. The brackets fully respect the rectangular wire and do not adjust their position according to the teeth surface. Just as in the previous method, it is possible to choose from several bracket systems and the added bracket can be modified using the 3D manipulation widget and function Snap to Wire by right clicking with the mouse.

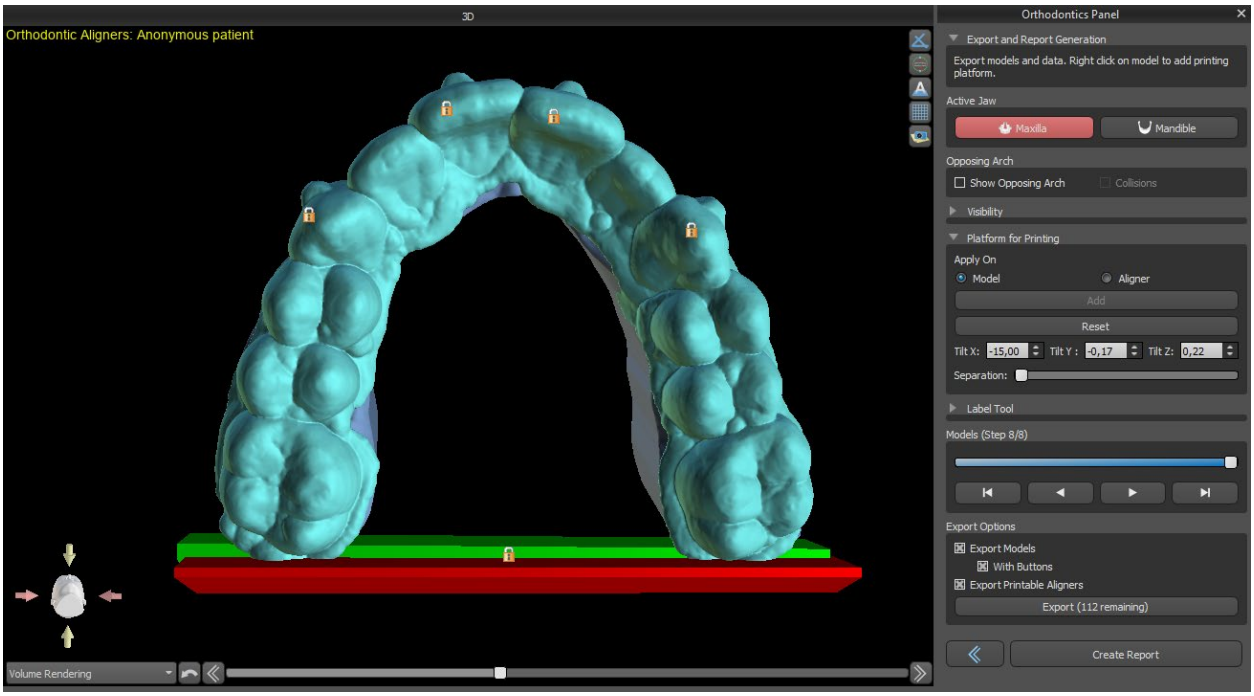


20.12.2. Prepare IBT

This steps includes drawing and editing the curve for indirect bonding tray fabrication similarly to the previous type of planning. The curve is drawn on the final position of teeth. The indirect bonding tray is generated for the first position model only. The default setting for IBT fabrication can be changed in Preferences.

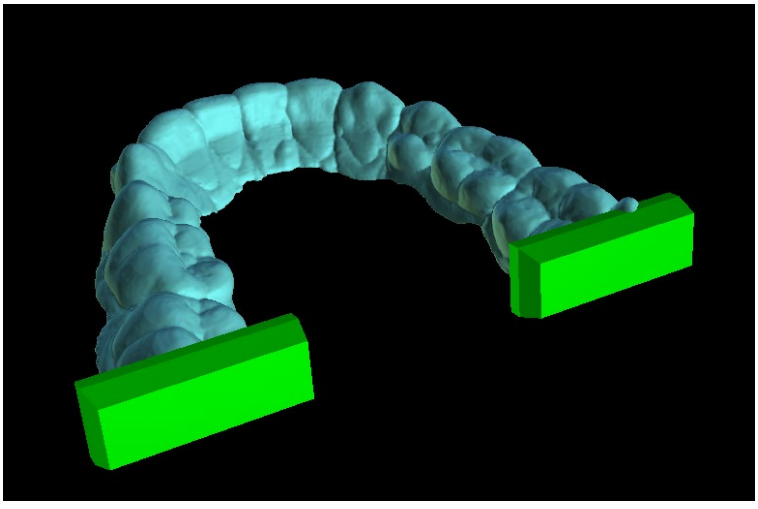
20.13. Generating and Exporting STL Models

The final step, Export, is again common for all types of planning. The only difference is in what can be exported in this final step (OBJ or STL models or the parameters of the curve).



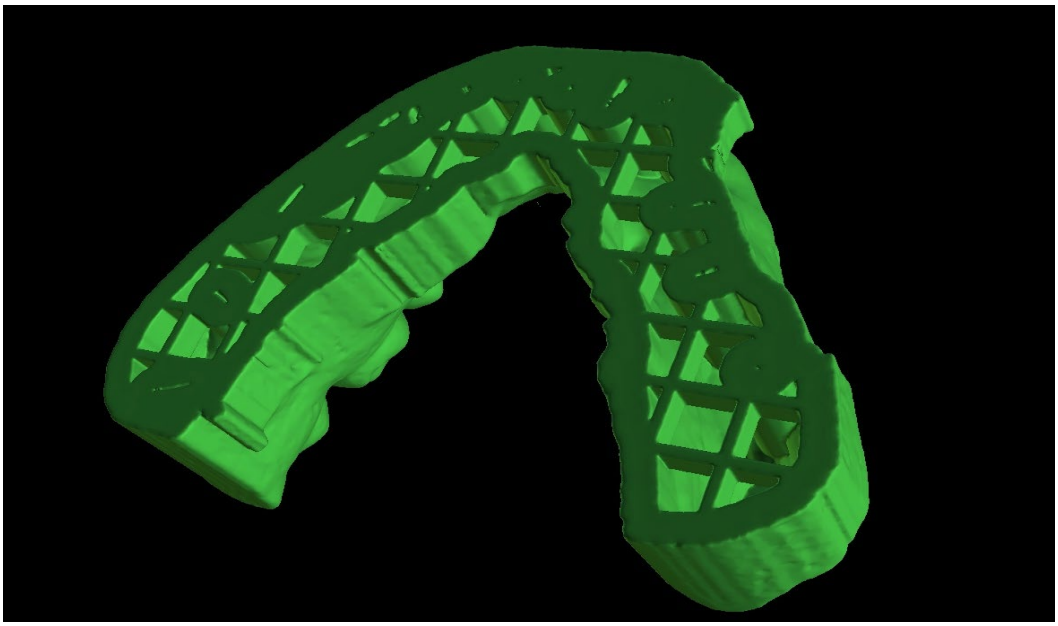
Before the export itself, it is necessary to check all of the intermediate positions of the generated models.

Platforms are automatically added to the generated models, allowing for the horizontal 3D printing of a larger number of models. They are added separately for models and for aligners, and for additional work with them, it is necessary to have the correct option checked on the Orthodontics Panel. The default settings for platforms (size and rotation) are found in Preferences, Orthodontics tab. These parameters can be further manually adjusted for a specific case. Using the “Separate” slider, it is possible to create two smaller parts at the end of the jaw, which are sufficient for printing. You can add the platform to a model just in one step – it will be generated in the remaining steps.



The Orthodontics panel also allows you to supplement the generated intermediate models and aligners or IBTs with text with a 3D profile emboss or engrave (typically the patient's name and the step number). This is done with the "*Label Tool*" which works like the one used to emboss text on surgical guides. The text needs to be attached to the first model only and it is automatically propagated onto the other intermediate models. It is necessary to choose either the emboss or engrave method in the "*Label tool"* and if it will be applied on the generated models or aligners (IBT). It is also possible to choose if the label text and number of the model will be generated on the same row.

If the generated STL model should be optimised for print, hollow with (or without) a cross pattern, the user must check the *"Generate Steps as Hollow Models"* and *"Generate Cross Pattern"* in Preferences, in the Orthodontics tab, before exporting.



Besides the models, the parameters of the Aligner Trim Curve can be exported as well for the Aligners planning type. The generated curves for intermediate models can be modified individually with the visualised locator to be optimally prepared for use on the milling machines. The parameters "*Curve File Delimiter*" and "*Curve File Extension*" can be modified in Preferences.

The generated models can be exported from the software in the form of STL models by pressing the "*Export*" button.

Note: To export the STL files, you must have a valid STL export license!

For immediate and automatic STL license activation, purchase exports directly in the Blue Sky Plan Software (File > Purchase STL Exports). You may also purchase STL case exports from https://blueskybio.com/store/stl-case-export.

Finally, it is also possible to generate the so-called *Tooth Movement Report* with the angles and displacements of the teeth moved from the original position to the final position. In addition, the report shows the movements from each intermediate position to the next stage.

20.14. Quick Instructions for Using the Computerised Orthodontic Bracket System

More detailed instructions for use are available in Footnotes 21.2

The user during the export step should select the check boxes for “Export models” and “With Brackets” and generate a model, including the bracket location indicators, in the form of an STL model.

20.14.1.Printing the Model

The user should use a relevant 3D printer that prints at a resolution of at least 150 microns on the x/y axis and 100microns on the z axis, to print the exported model in grey or tan model material. The printer control software, printer and model material should be labelled for use together.

Select the exported STL model file in the printer control software for printing.

20.14.2.Adding Brackets

Use cement to firmly secure the desired brackets to the bracket location markers on the 3D printed model.

20.14.3.Creating the Indirect Bonding Tray by Pressure Forming

The user creates the Indirect Bonding Tray by pressure thermoforming over the 3D printed model with brackets attached to an outer carrying shell from a legally marketed orthodontic resin such as Essix Ace. The user should then trim the shell to the middle of the brackets for easy release.

The brackets should then be placed into wells created in the shell. Skip to section 1.9 using the indirect bonding tray to place the brackets.

20.14.4.Creating the Indirect Bonding Tray by Printing (this method should only utilised in an FDA registered establishment)

The user should click “Create the indirect bonding tray”.

The user should check the print screen image of the tray for accuracy, and when it is correct export/print the indirect bonding tray by choosing File>Export Data and selecting the indirect bonding tray to be exported as an STL.

The user should use a relevant 3D printer that prints at a resolution of at least 150 microns on the x/y axis and 100microns on the z axis, to print the exported model in grey or tan model material. The printer control software, printer and model material should be labelled for use together. The material should be a light cured resin which is not recycled or recyclable.

Select the indirect bonding tray STL file in the printer control software to be printed in the legally marketed impression tray resin material called NextDent Ortho IBT.

Brackets should then be placed into wells created in the shell of the printed indirect bonding tray.

20.14.5.Using the Indirect Bonding Tray to Place the Brackets

The user should place the brackets onto the teeth by placing conventional cement onto the bracket pads following the manufacturer’s instructions and seat the tray with the brackets into the patient’s mouth. Excess cement should be removed, and a light cure should be used through the Indirect Bonding Tray.

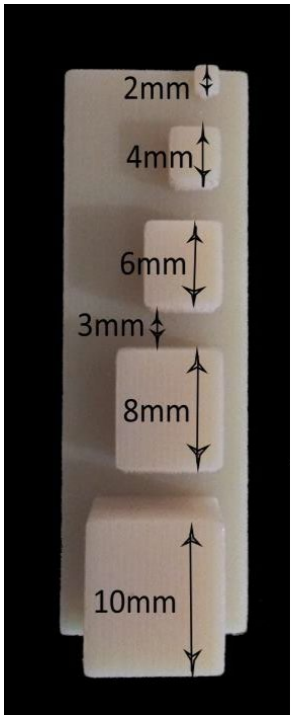
The outer carrying tray should be removed and the inner liner tray should be peeled off. Excess cured cement should be removed.

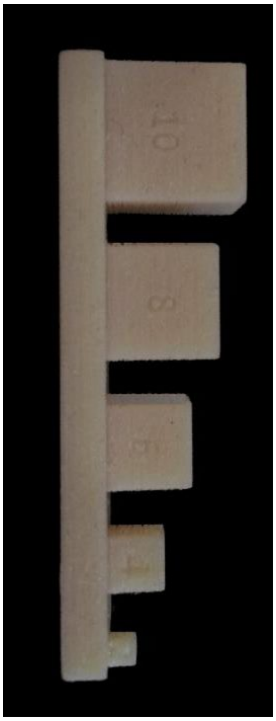
20.14.6.Use of the Blue Sky Plan Calibration Verification STL file

The calibration of the printer should be done according to the printer manufacturer’s instructions and in accordance with the quality system of the FDA registered establishment printing the trays. The frequency of calibration should be determined by the printer manufacturer’s printer instructions and the establishment’s quality system. Blue Sky Bio provides a calibration verification file to confirm adequate calibration. Calibration verification should be done whenever the printer is calibrated and any time the printing material is changed.

- Download the calibration verification STL file from the Blue Sky Bio website
- Import the STL calibration verification file into the printer control software
- Print the STL file

- Measure each cube in all 3 dimensions and the distances between adjacent cubes with calliper. The size of each cube is printed on the cube. The distance between cubes is 3mm. The measurements of the cubes and open spaces should be within the certified accuracy of the printer. If the measurements fall outside that range, recalibrate the printer according to the printer manufacturer's instructions.





Precautions: *Do not touch the bonding surfaces with your bare fingers as skin oils may diminish the adhesion. Do not allow adhesive to get under the bracket in the guide slot. The position of each bracket should be verified by the clinician and if necessary malpositioned brackets should be removed and repositioned. Ceramic brackets may abrade the opposing arch. Wait to apply the ceramic brackets until the bite has opened. If necessary, use metal brackets before the placement of ceramic brackets. Provide the patient with instructions on how to conduct thorough oral hygiene, as tartar or food debris may impair the function of the bracket. Do not apply excessive force when opening the bracket as the bracket may bend or detach from the tooth. To prevent splintering when removing the brackets, use the appropriate instrument. If patient experiences an allergic reaction, immediately remove the bracket and advise patient to seek medical care.*

21. Denture module

Blue Sky Plan permits the user to model and export dentures. The functions are available in the “Denture” panel once the user switches to the “Denture” module.

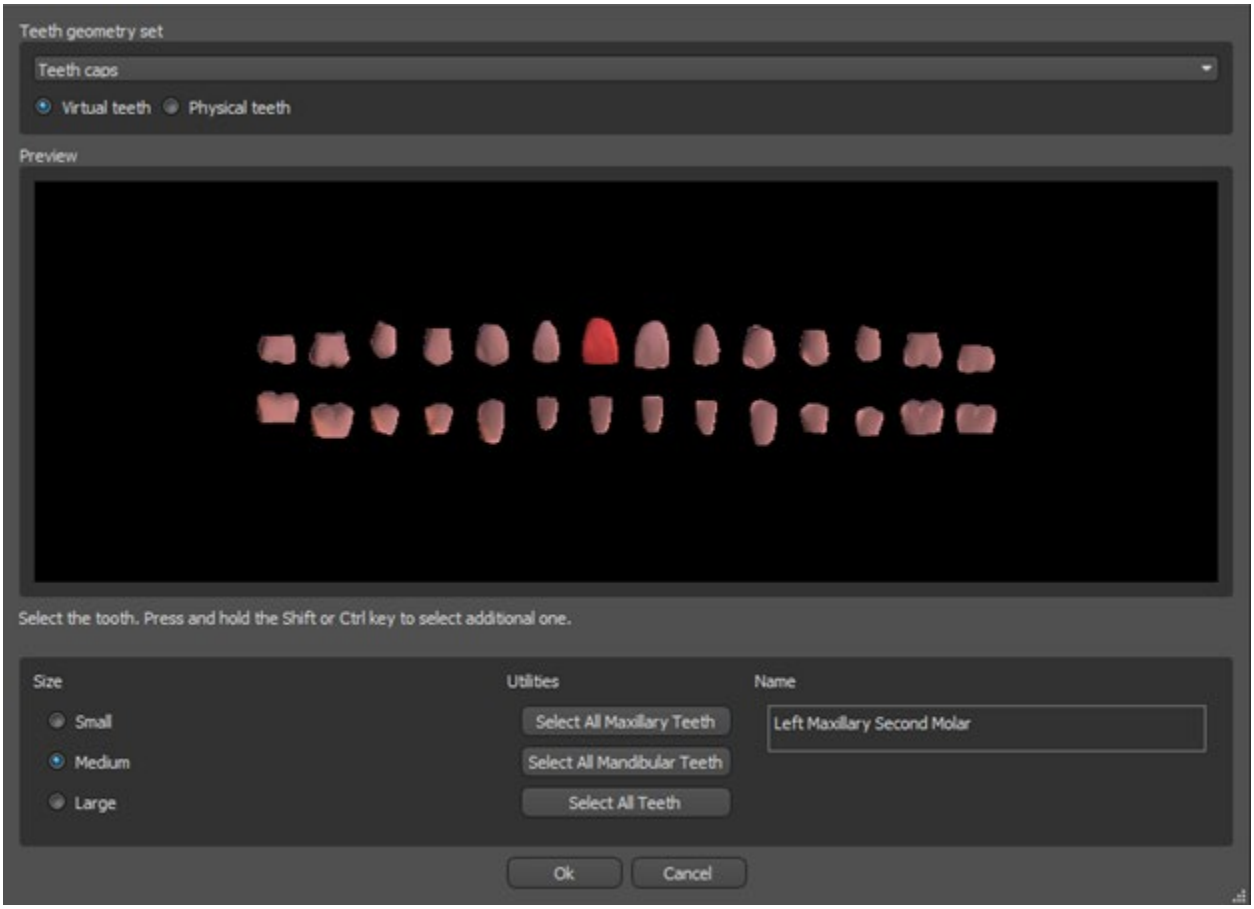
21.1. Loading the patient’s STL model

New planning starts by loading the STL jaw impression model using the main module selection *“Dentures > Import Models”*. To start planning the denture, the user needs to switch to the “Denture” module from “Model Manipulation”.

21.2. Adding virtual teeth

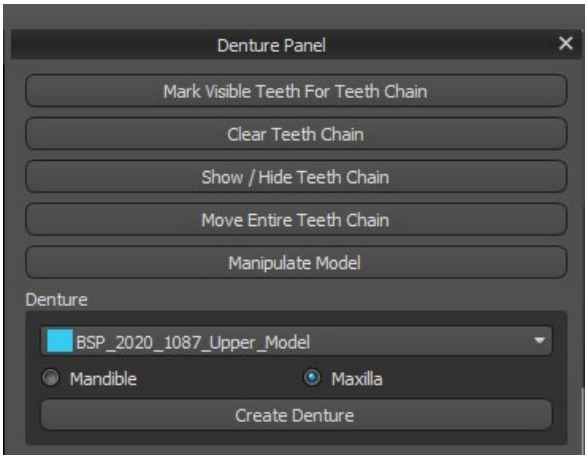
Virtual teeth can be added by clicking on the icon in the toolbar. A dialog for selecting crown(s) then opens. Clicking on a tooth selects it, and a text description of the crown appears below the preview. Multiple teeth can be selected by holding down the Shift or Ctrl key. Another possibility is clicking on Select All Maxillary Teeth/Select All Mandibular Teeth or Select All Teeth. It is also possible to select from three sizes. Teeth are added as teeth chain.

We confirm the selection by clicking the *“OK”* button; the *"Cancel"* button closes the dialog without making a selection.



Virtual teeth are regular teeth sets, available in Surgical Guide, Denture, and Crown and bridge, modifiable and exportable. Physical teeth are for Denture creation, cannot be modified and exported. Can be bought from the future parts panel.

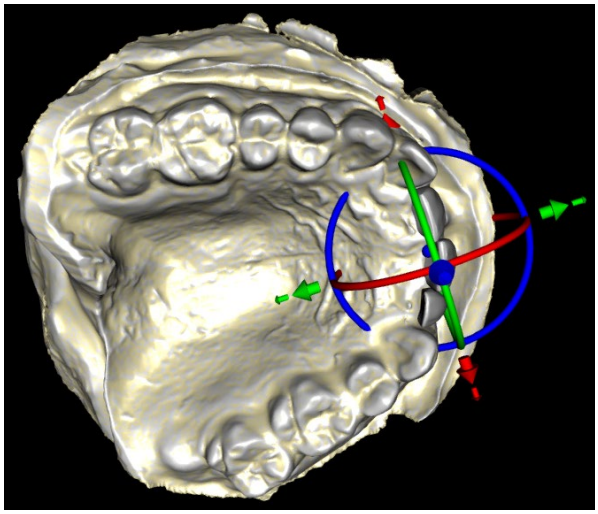
The Denture Panel is used for denture modelling. After clicking on the “Denture Panel” tab, the below menu will appear with buttons for working with the teeth chain.



21.3. Mark visible teeth for teeth chain

Clicking on “Mark Visible Teeth for Teeth Chain” and using the control allows for the manipulation of the teeth chain.

The teeth can also be moved individually with the arrows to different sides. Rotation is done by using the circles surrounding the teeth chain. Each axis is represented by one colour.

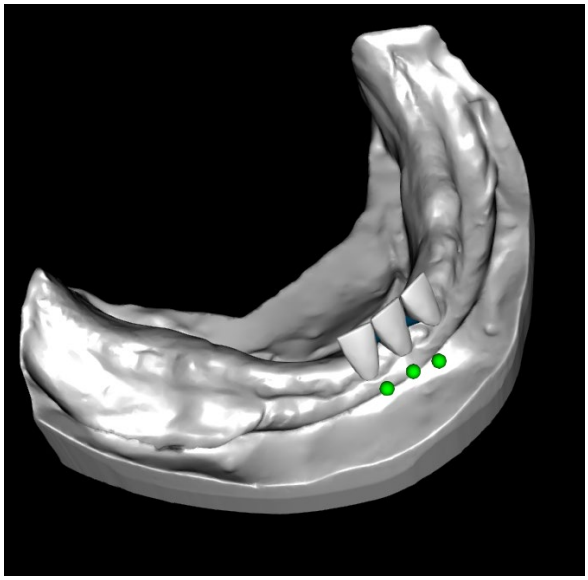


21.4. Clear Teeth Chain

Clears selected teeth chain.

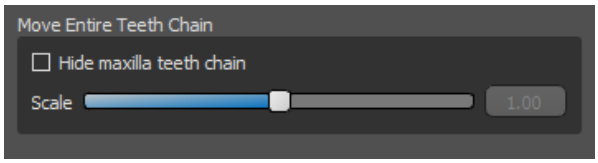
21.5. Show / Hide teeth chain

The button “Show / Hide Teeth Chain” is used for showing and hiding the green dot indicators in the teeth chain. There is one indicator per tooth.



21.6. Move Entire Teeth Chain

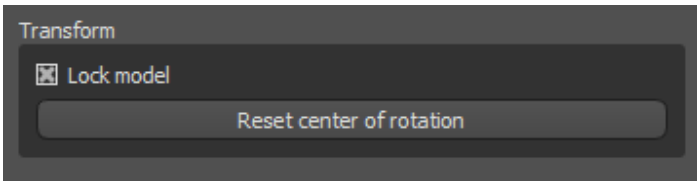
“Move Entire Teeth Chain” permits the user to hide teeth chains in the maxilla or the mandible by selecting the appropriate option.



The scale is used to enlarge or diminish the teeth.

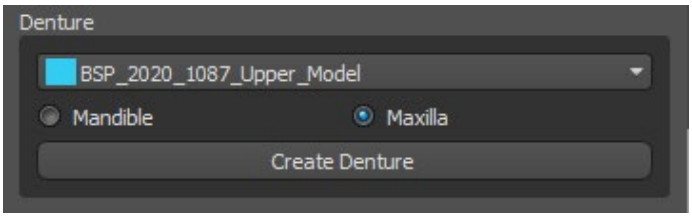
21.7. Manipulate model

The model can be unlocked by clicking the checkbox and the centre of rotation can be changed.



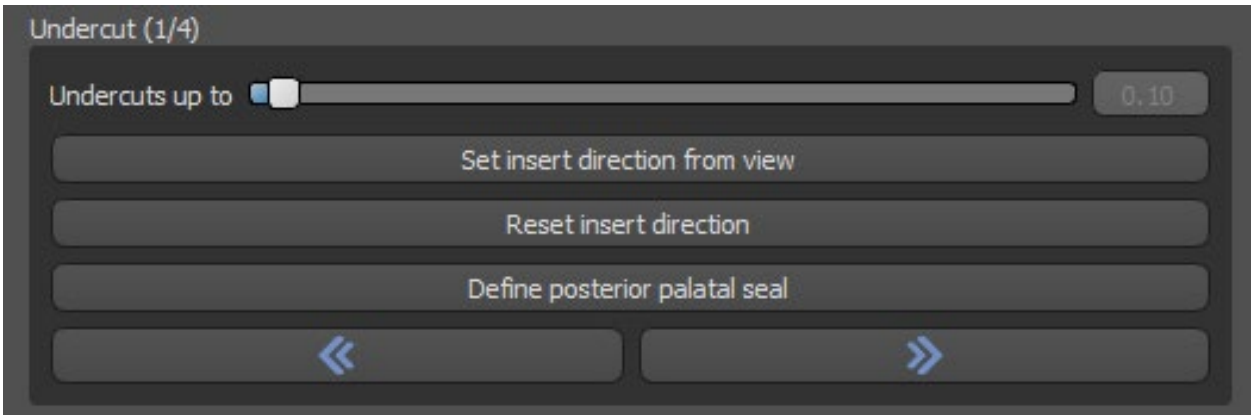
21.8. Create denture

A Denture can be created in the menu in the right panel. This requires selecting a file, the correct jaw orientation, and confirming by clicking “Create Denture”.



21.9. Step 1 – Undercuts and insert direction

Step 1 is used to define the initial parameters for the denture.



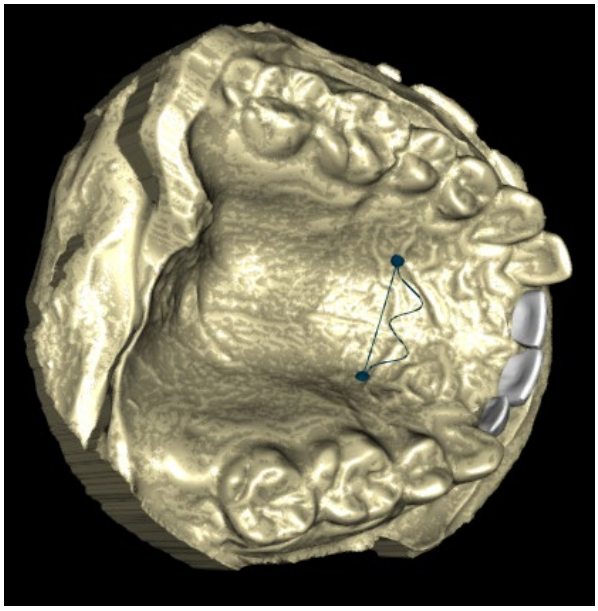
The sliders can be used for setting the values for offset and undercut removal.

The insert direction should be adjusted using the rotation ring so that the undercuts are minimised.

“Set insert direction from view” is used to set the insert direction according to the current viewing angle setting.

“Reset insert direction” will restore the original status of the arrow and the model.

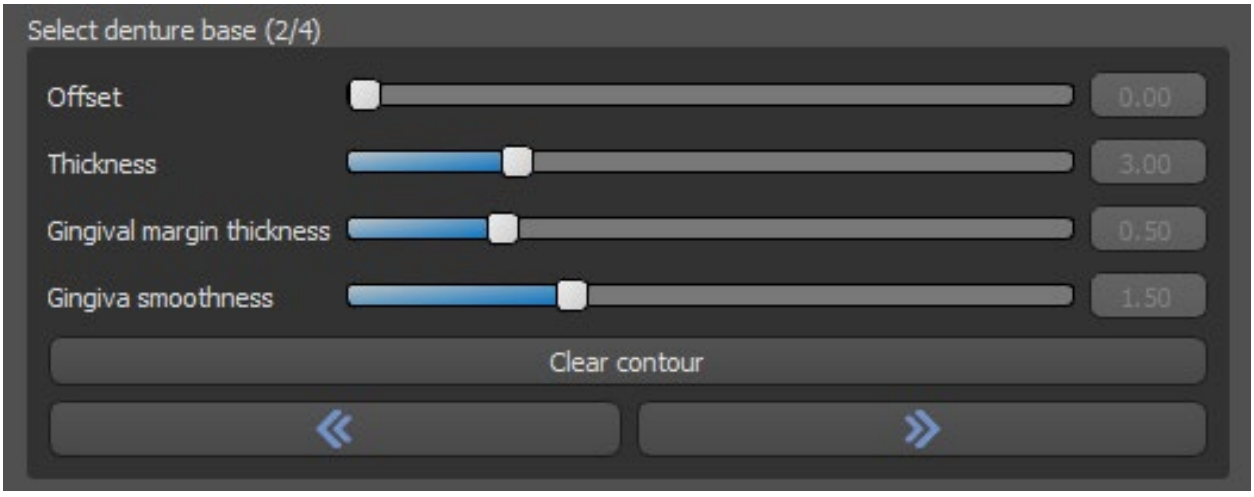
"Define posterior palatal seal" permits the modelling of this structure. The Palatal Seal is created by left clicking with the mouse on the two required points with Shift key pressed. Adjustments can be done by drawing with the mouse.



The "Back" and "Next" buttons are used for moving one step back or forwards.

21.10. Step 2 – Select denture base

Step 2 defines a contour around the teeth chain to define the borders of the denture. If a contour is not defined, user is not able to get to another step.

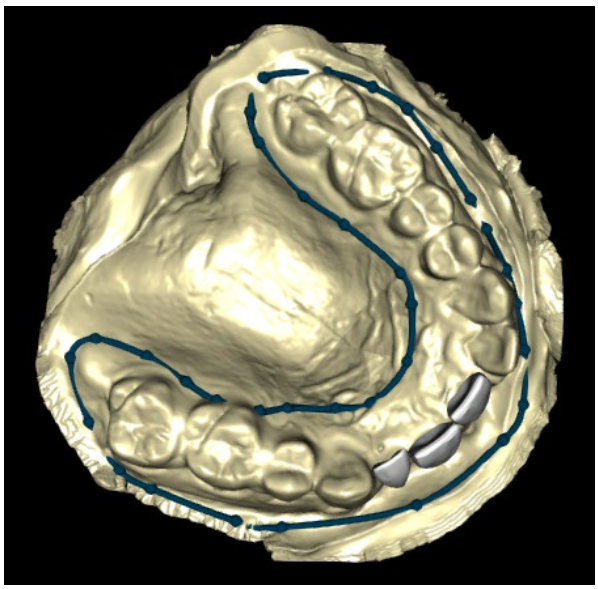


The offset from the gingiva and thickness of the denture can be set by the sliders.

Gingiva extension allows the user to extend the gingiva with the slider. The thickness and smoothness from the gingiva can be set with the sliders.

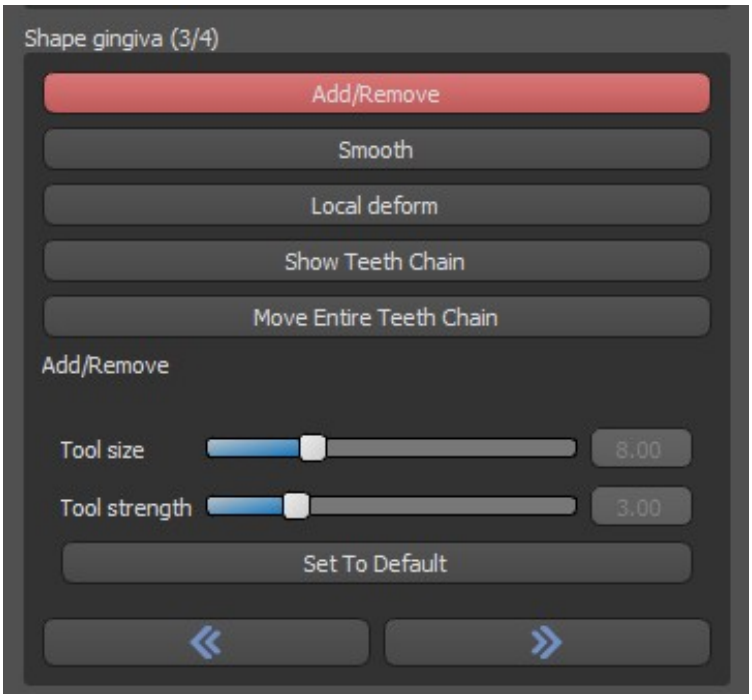
Pressing the Shift key and double clicking on the model around the teeth will add new points and create a blue contour around the area representing the denture base:

The contour can be deleted by selecting “Clear contour”.



21.11. Step 3 – Shape gingiva

Step 3 is used for adjusting the created gingiva.



The following adjustments can be made within this step

Add/remove – addition/removal of gingiva material

Smooth – gingiva surface smoothing

Local deform – creation of ups and downs

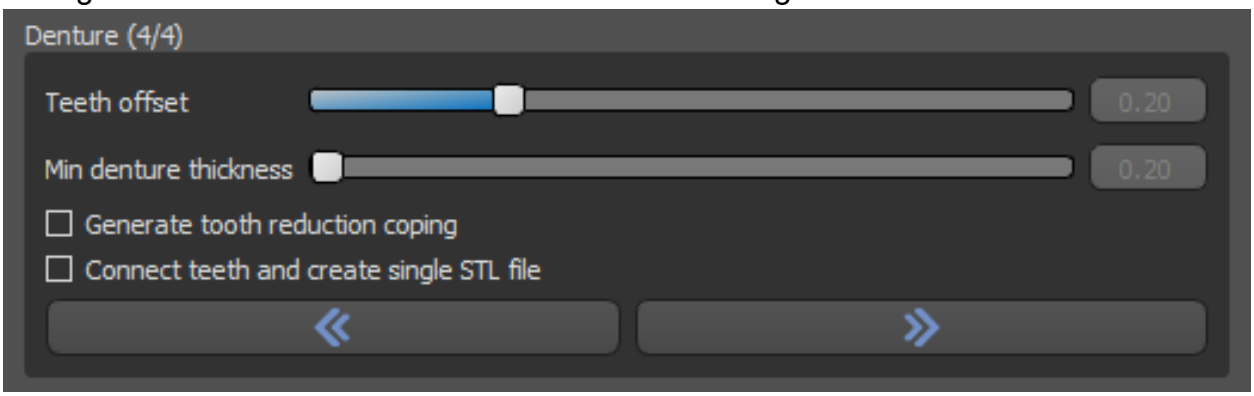
Show Teeth Chain – display of the green dot indicators

Move Entire Teeth Chain – manipulation with the teeth chain

The “Tool size” slider is used for tool size selection, and “Tool strength” defines the strength of the tool. The original values can be restored by selecting the “Set to Default” button.

21.12. Step 4 – Denture

Step 4 is used for finalising the denture creation. During this step, virtual teeth penetrating through the denture base are reduced while maintaining the minimum denture thickness.

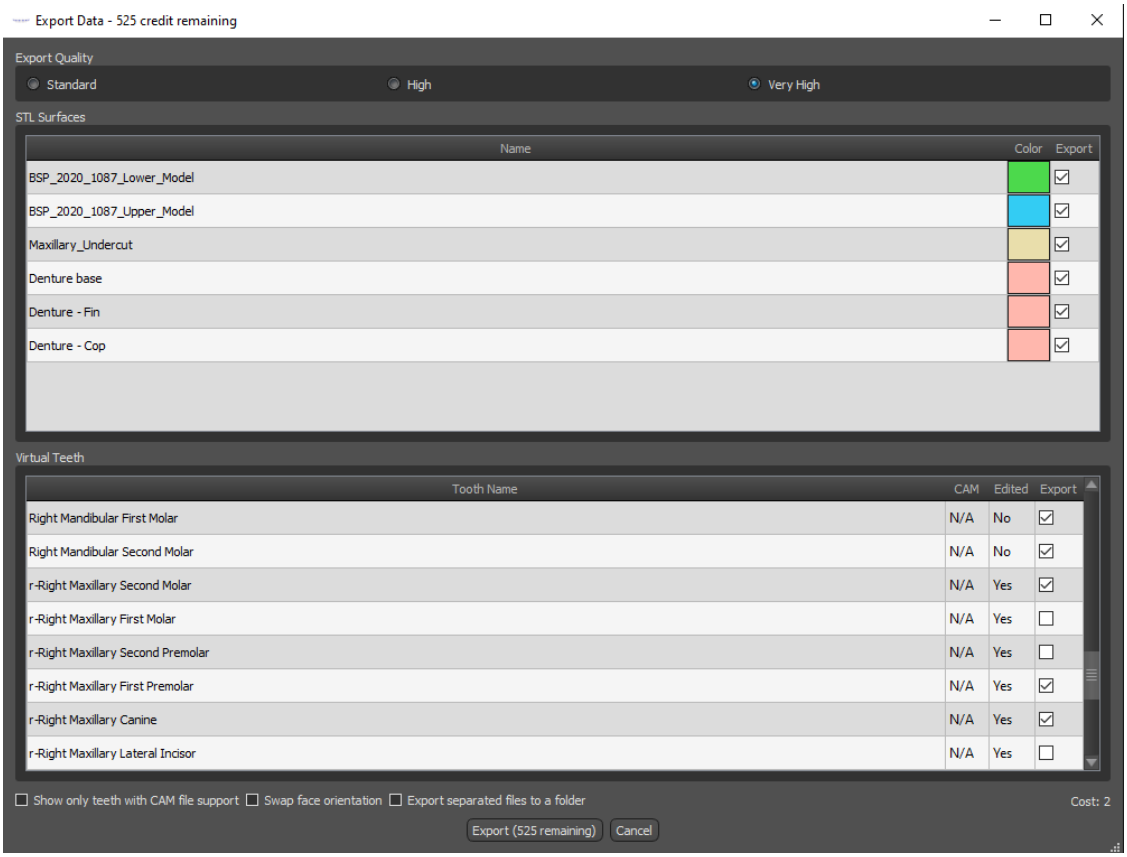


Sliders are used for selecting Teeth offset and Min denture thickness.
Tooth reduction coping generates denture cop primarily for physical teeth followed by cutting in the laboratory.
Connect Teeth as single STL file makes the work easier for the export.

The model design is completed by selecting the “Finalise” button.

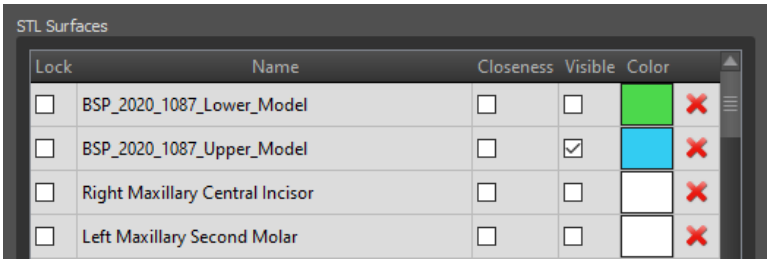
21.13. Export

The user can export created denture in this step. Quality of the export can be set as well as swap face orientation. Export separated files exports selected objects to a separated file or one single file created by the user.



21.14. Teeth Surfaces panel

Teeth Surfaces lists the imported patient's STL models, placed virtual teeth and their reduced versions, and the newly generated denture base:



The table includes the following attributes:

“Lock” – surface locking controlled by a checkbox

“Name” – surface name

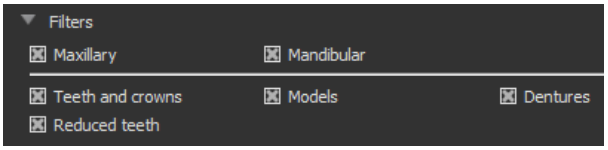
“Closeness” – surface closeness controlled by a checkbox

“Visible” – surface visibility or hiding by a checkbox

“Colour” – surface colour

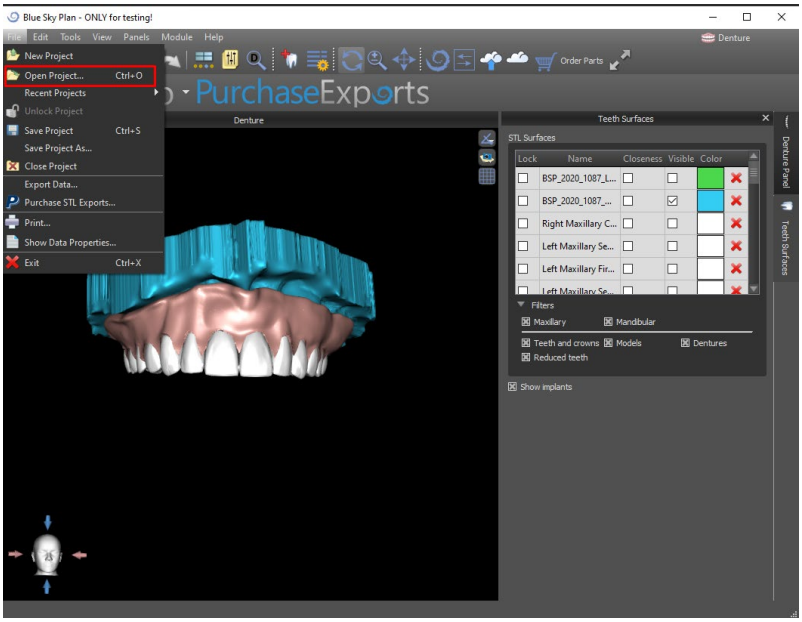
- surface removal

Filters can be used to display either the maxilla or the mandible only or selected object types:

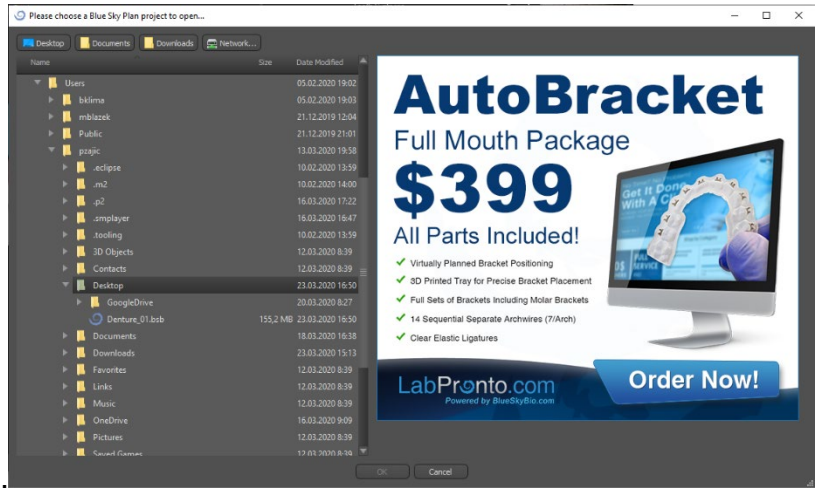


21.15. Opening saved project

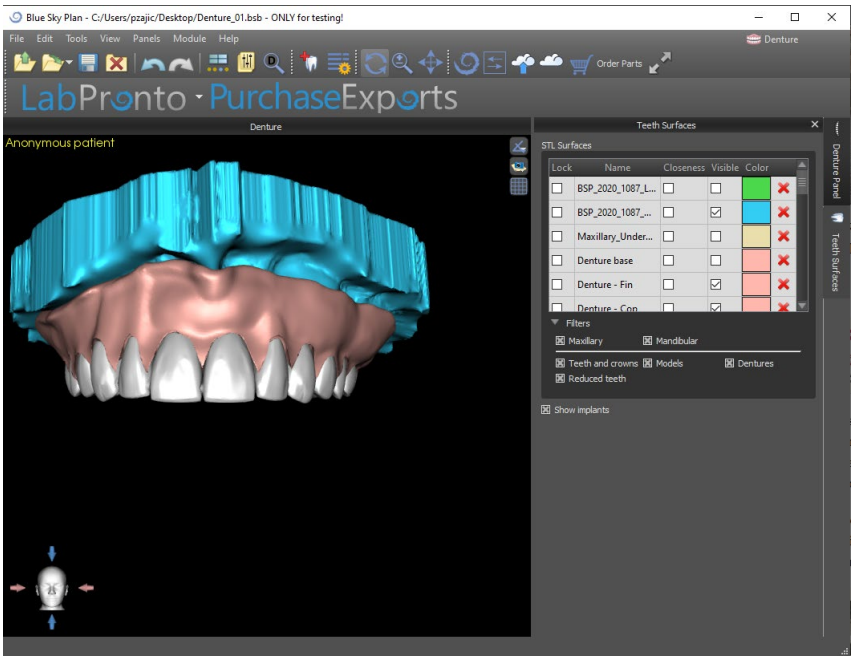
A saved case is opened with “File > Open Project…” in the top left corner.



After clicking, the file to open is selected and the selection is confirmed with “OK”.



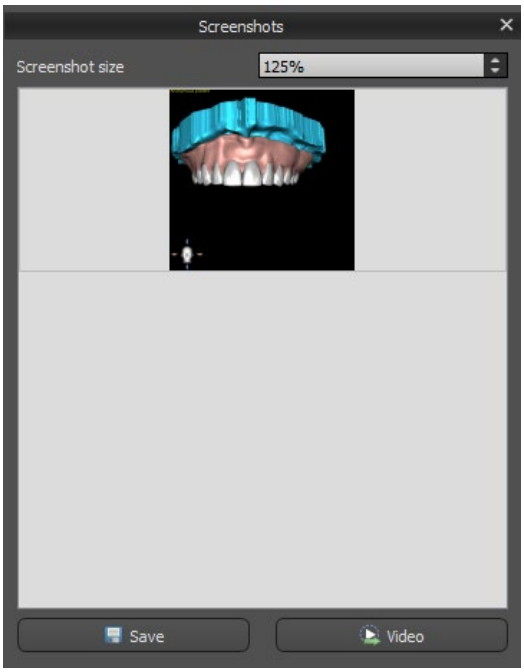
The selected project opens.



21.16. Screenshots

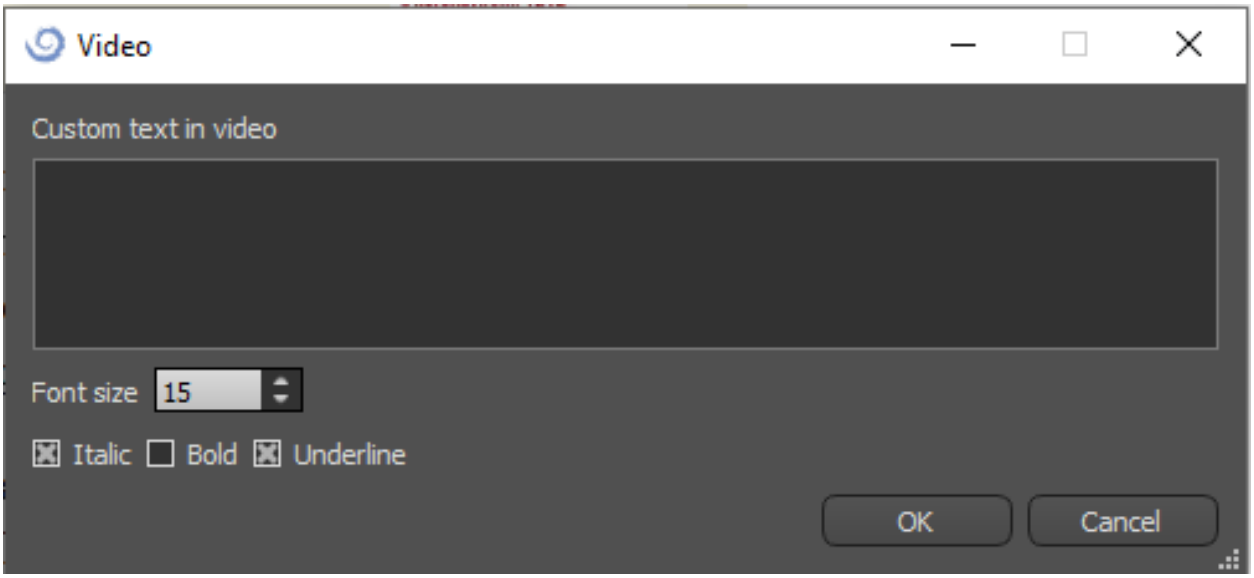
The Screenshot panel can be used for taking a screenshot with the button located in the top right corner of the workspace.

After clicking the button, the “Save screenshot” message appears, and the screenshot is included in the column in the right panel.



The arrows on the right are used for changing the screenshot size.

Video allows the exporting of the screenshots as AVI video or animated gif with custom text and selected font size and type.



22. Crown and Bridge module

Blue Sky Plan allows the user to create a bridge and crowns and change the geometry of the virtual teeth. These functions are available in the "*Crown and Bridge*" panel once the user switches to the Crown and Bridge module.

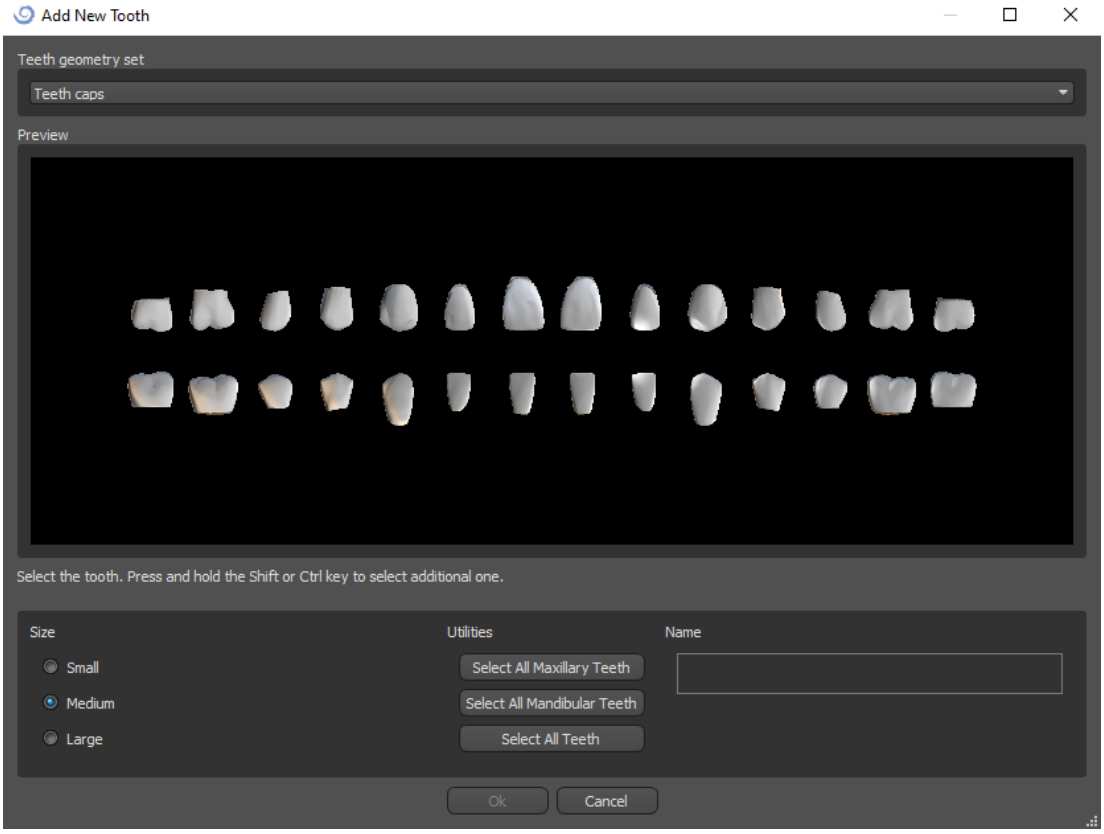
22.1. Loading the patient's STL model

The new planning starts by loading the STL jaw impression model using the main module selection *"Crown and Bridge > Conventional Crown | Crown for Titanium Base | Bridge"*. To start planning the crown and bridge, the user needs to switch to the "Crown and Bridge" module from "Model Editing".

22.2. Adding virtual teeth

Virtual teeth can be added by clicking on the icon in the panel list "Virtual Teeth > Add Tooth". A dialog for selecting the crown(s) then opens. Clicking on a tooth selects it, and a text description of the crown appears below the preview. Multiple teeth can be selected by holding down the Shift or Ctrl key. Another possibility is clicking on Select All Maxillary Teeth/Select All Mandibular Teeth or Select All Teeth. It is also possible to select from three sizes. Teeth are added as a teeth chain.

By clicking the "*OK*" button, the selection is confirmed; the "*Cancel*" button closes the dialog without making a selection.

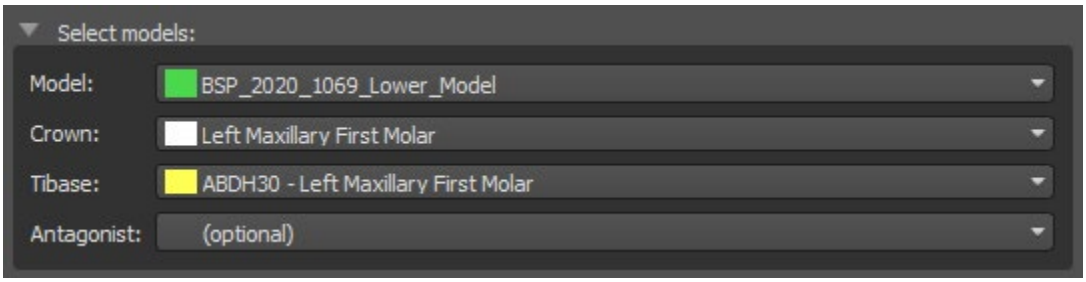


Virtual teeth are regular teeth sets, available in the Surgical Guide, Crown and Bridge and Denture module, are modifiable and exportable.

22.3. Restoration Design panel

The Restoration Design panel allows the user to choose the restoration type – crown on a tibase and conventional crown. It is also possible to select the jaw type and antagonist model as well as to create a bridge.

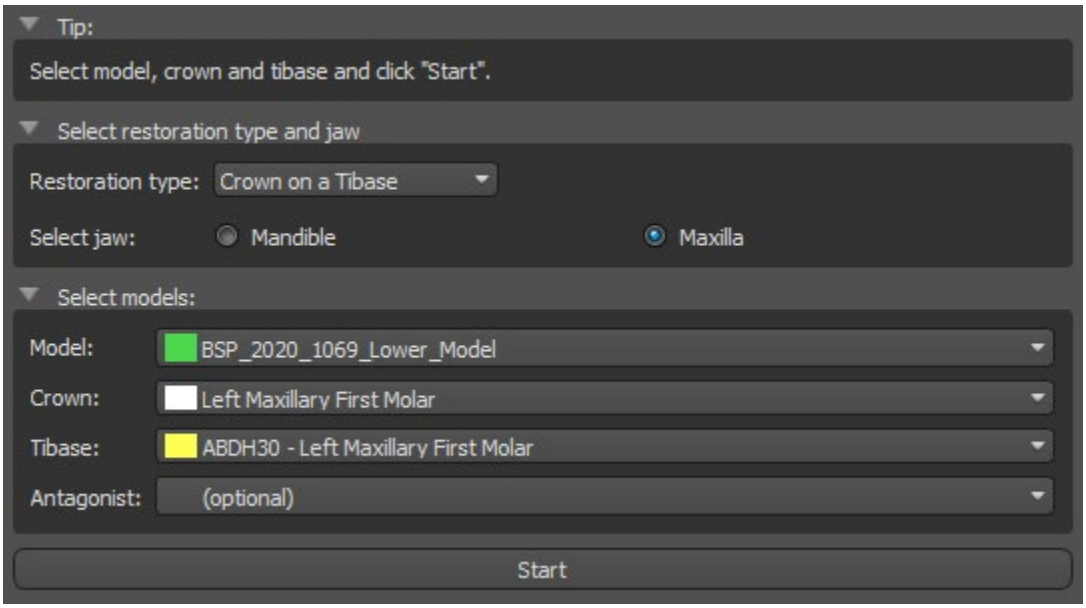
The antagonist model resolves and detects a teeth collision.
If there is only one jaw available, the “no antagonist” selection resolves this situation.



The tibase can be chosen by clicking on the tooth or by clicking on the tibase dropdown. If a tibase is not selected, the user cannot go further.

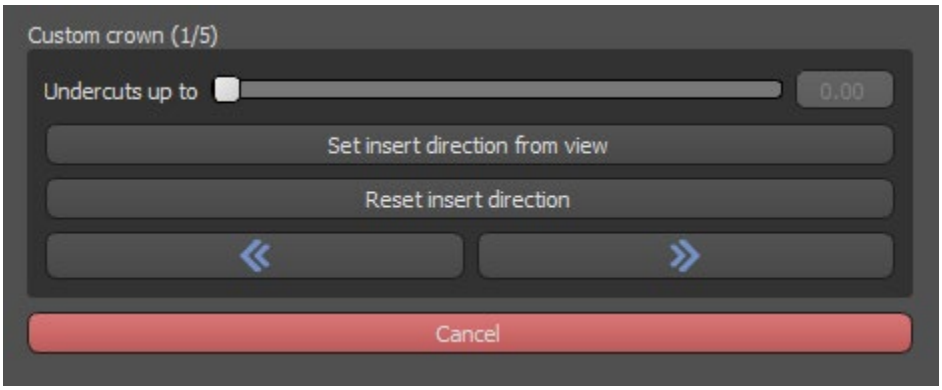
22.4. Restoration type selection – Crown on a Tibase

The Crown on a Tibase selection can be chosen in the menu in the right panel. This requires the selection of a restoration type, jaw, model, crown, tibase, and antagonist model (optional) (if a user uses maxilla and mandible) and confirming by clicking *“Start”.*



Step 1 – Undercuts

Step 1 is used to define the initial parameters for the crown.



The slider can be used for setting the values for the undercut.

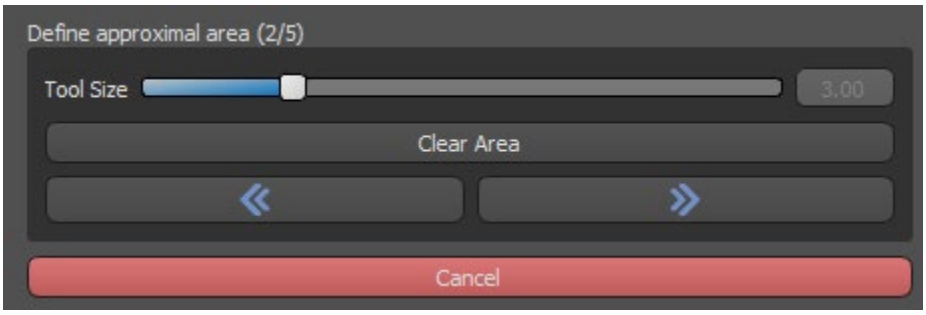
"*Set insert direction from view*" is used to set the insert direction according to the current viewing angle in the 3D view.

"*Reset insert direction*" restores the original setting of the insert direction.

The "*Back*" and "*Next*" buttons are used for moving one step back or forwards in the design flow.

Step 2 – Define approximal area

Step 2 is used to select/colour the existing adjacent teeth so the crown can be resized by the software to fit.



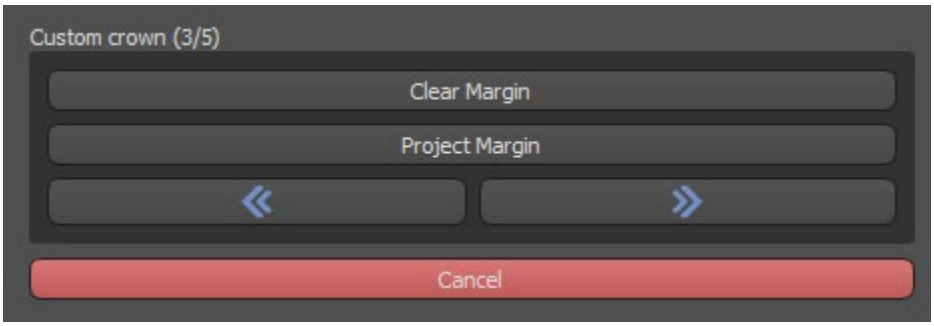
The approximal area can be deleted by selecting "*Clear Area*". Pressing the Shift key and holding the left mouse button will define the approximal area and create a brown contour around the selection representing the crown and bridge base.

By pressing the Ctrl key and left clicking with the mouse, you can remove the selection.

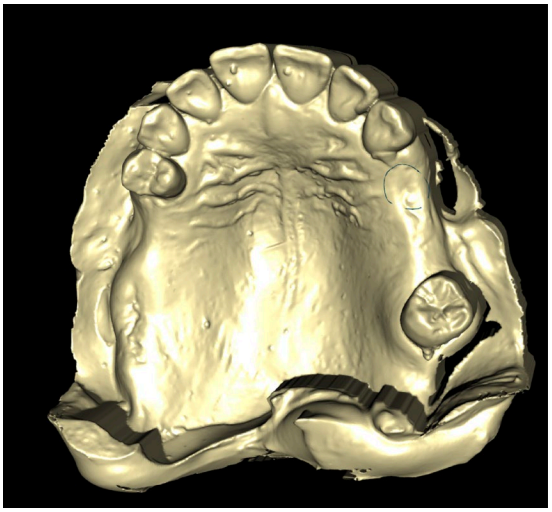
The “*Tool size*” slider is used for brush size selection.

Step 3 – Margin detection

Step 3 detects the tooth margins used for crown creation. Pressing the Shift key and holding the left mouse button allows the margin to be edited.

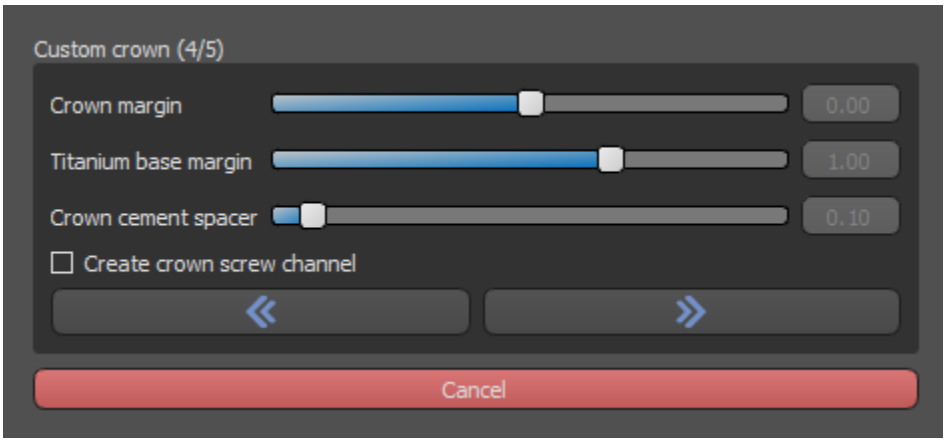


The Project Margin button projects the curve defined by the user on the deformed tooth.



Step 4 – Tibase editing

Step 4 is used for crown upgrading and the creation of a crown screw channel.



"*Crown margin*" can be used for setting the crown margin.

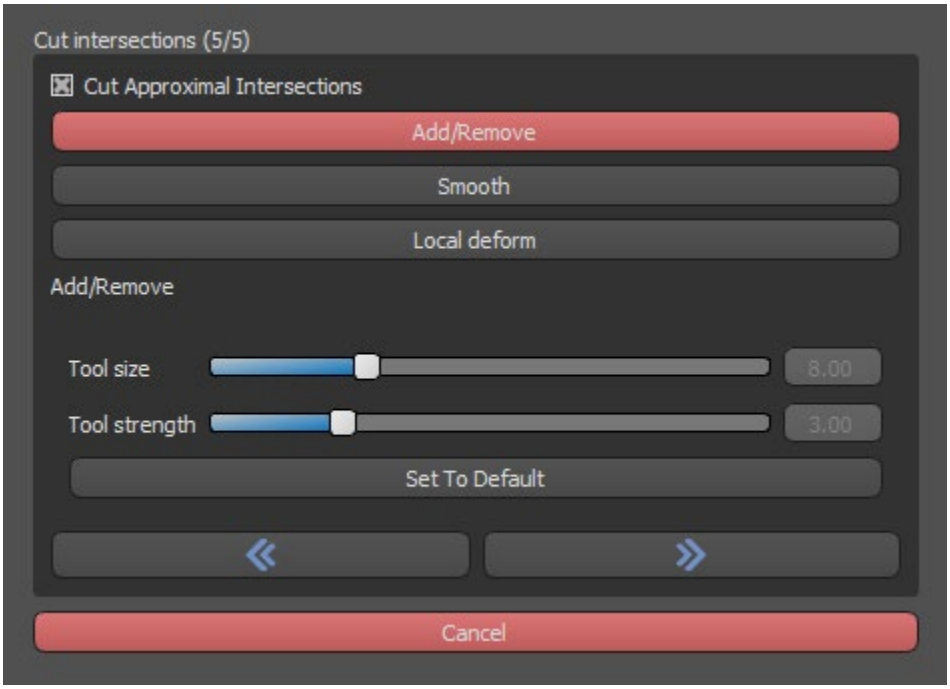
"*Titanium base margin*" can be used for setting the base margin.

"*Crown cement spacer*" is an extra space for the glue between the crown and abutment.

The create crown screw button creates a hole going through the crown so that the user can access the abutment screw and screw the abutment into the implant.

Step 5 – Crown editing

Step 5 is used for adjusting the created crown.



"*Add/Remove*" is used for the addition/removal of the crown material.

“*Smooth*” smooth the crown surface.

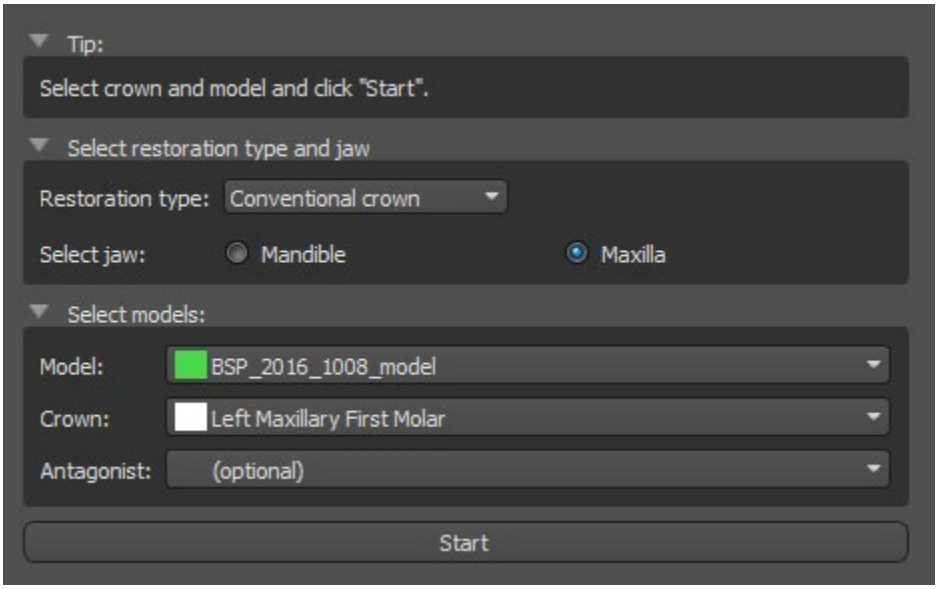
“*Local deform*” Tool that deforms the tooth at a local point.

The “*Tool size*” slider is used for tool size selection, and “*Tool strength*” defines the strength of the tool. The original values can be restored by clicking on the “*Set to Default*” button.

The relevant checkbox can be used for hiding Cut Approximal Intersections and Cut Occlusal Intersection.

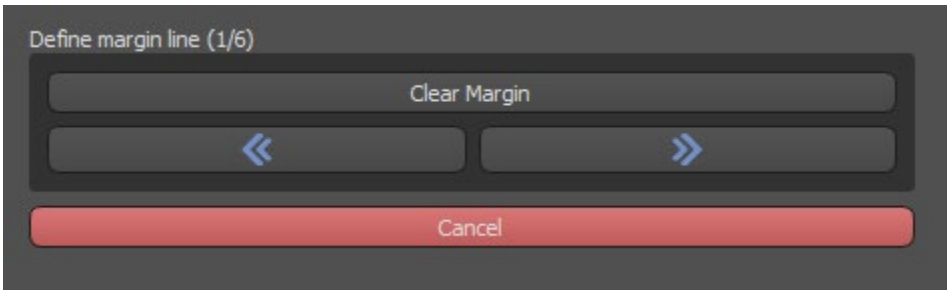
22.5. Restoration type selection – Conventional crown

Conventional crown selection can be chosen in the menu in the right panel. This requires selecting a restoration type, jaw, model and confirming by clicking “Start”. The crown and antagonist models are optional.
If a user selects the (no crown) option, the crown is added in the third step.



Step 1 – Margin line definition

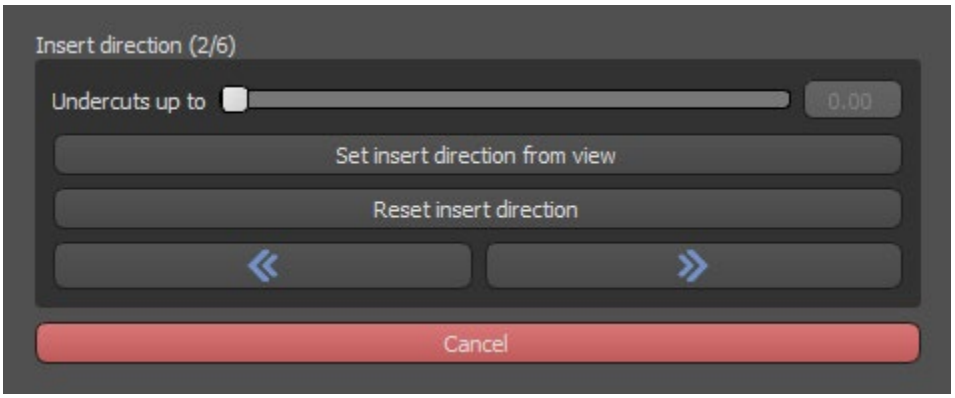
Step 1 is used to define a closed margin line along the remaining tooth structure.



The margin can be deleted by selecting "*Clear Area*".

Step 2 – Undercuts

Step 2 is used to define the initial parameters for the crown.



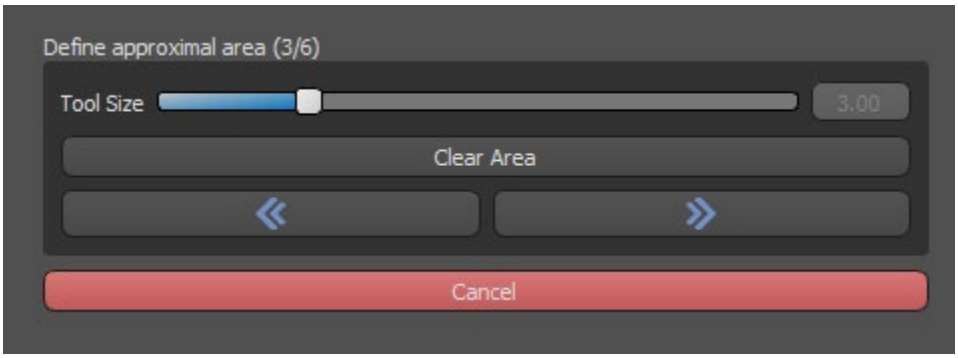
The slider can be used for setting the values for the undercut.

"*Set insert direction from view*" is used to set the insert direction according to the current viewing angle in the 3D view.

"*Reset insert direction*" restores the original insert direction.

Step 3 – Define approximal area

Step 3 is used to select/colour the existing adjacent teeth so the crown can be resized by the software to fit.

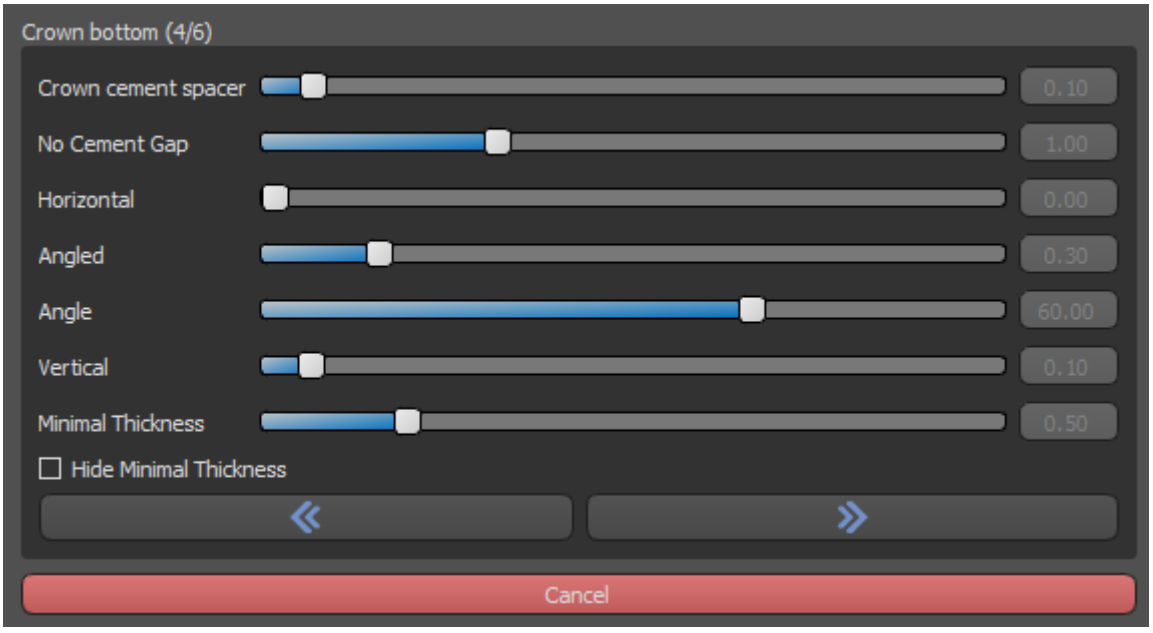


The approximal area can be deleted by selecting "*Clear Area*". Pressing the Shift key and holding the left mouse button will define the approximal area and create a brown contour around the selection representing the crown and bridge base. By pressing the Ctrl key and left clicking with the mouse, you can remove the selection

The "*Tool size*" slider is used for brush size selection.

Step 4 – Crown bottom editing

Step 4 is used for editing the crown bottom.



"*Crown cement spacer*" is an extra space for the glue between the crown and abutment.

"*No cement gap*" allows the user to edit the crown margin.

"*Horizontal*" defines the horizontal crown border width.

“*Angled*” defines the length of the angled part of the border.

“*Angle*” defines the angle of the angled part.

“*Vertical*” defines an additional vertical border.

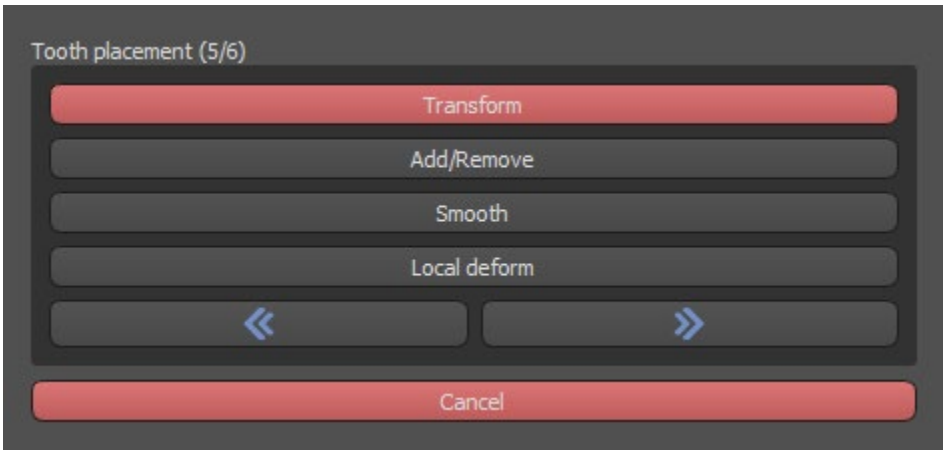
“*Minimal Thickness*” is used to edit the minimal thickness.

The relevant checkbox can be used to hide the minimal thickness.

If the user selected the (no crown) option in the restoration panel, the “*Add New Tooth*” dialog is available to select the tooth by clicking on the “*Next*” button. Only one tooth can be selected. The tooth is added by clicking on the “*OK*” button. Cancel closes the “*Add New Tooth*” dialog.

Step 5 – Tooth placement and editing

Step 5 is used for tooth placement and tooth editing.



“*Transform*” activates the widget for tooth placement.

“*Add/Remove*” is used for the addition/removal of the crown material.

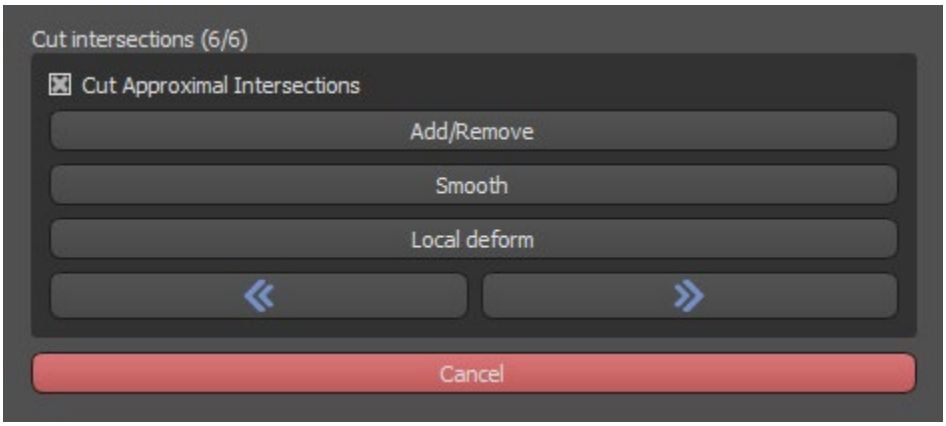
“*Smooth*” smooths the crown surface.

“*Local deform*” allows the creation of ups and downs.

The “*Tool size*” slider is used for tool size selection, and “*Tool strength*” defines the strength of the tool. The original values can be restored by clicking on the “*Set to Default*” button.

Step 6 – Crown editing

Step 6 is used for additional crown editing.



"*Add/Remove*" is used for the addition/removal of the crown material.

"*Smooth*" smooths the crown surface.

"*Local deform*" Tool that deforms the tooth at a local point.

The "*Tool size*" slider is used for tool size selection, and "*Tool strength*" defines the strength of the tool. The original values can be restored by clicking on the "*Set to Default*" button.

The relevant checkbox can be used for hiding Cut Approximal Intersections and Cut Occlusal Intersection.

22.6. Create Bridge

The create bridge function is available in the Restoration Design Panel but only if you select Bridge process flow in the Main screen. It allows the user to design a bridge for missing teeth.
By clicking on "*Create Bridge*", the user starts a new process flow.

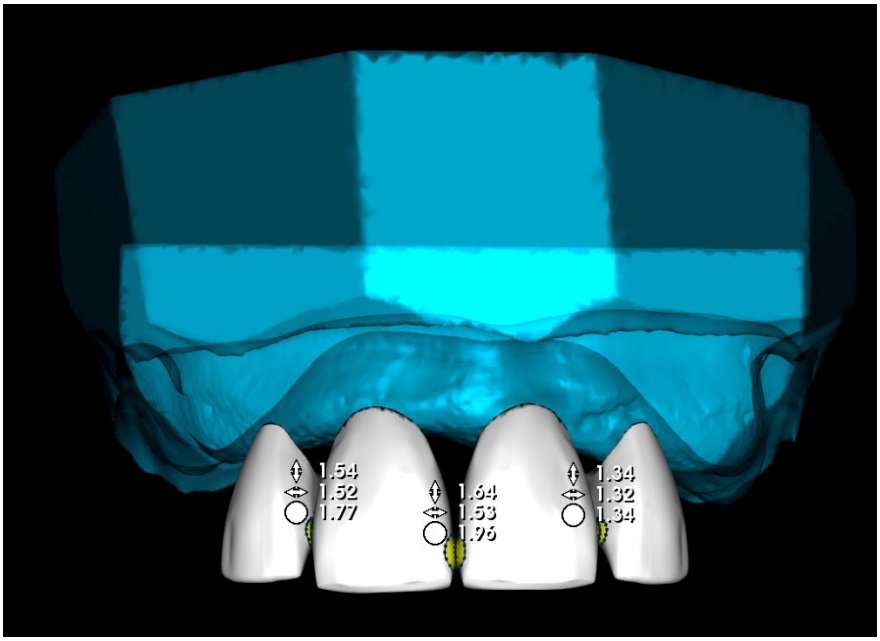
Step 1 – Unit Bridge

Step 1 is used for setting the points between the teeth to unit them. If the teeth are intersecting, the blue points are not created.

The blue points can be dragged along the teeth to set the bridge according to the user's preferences.

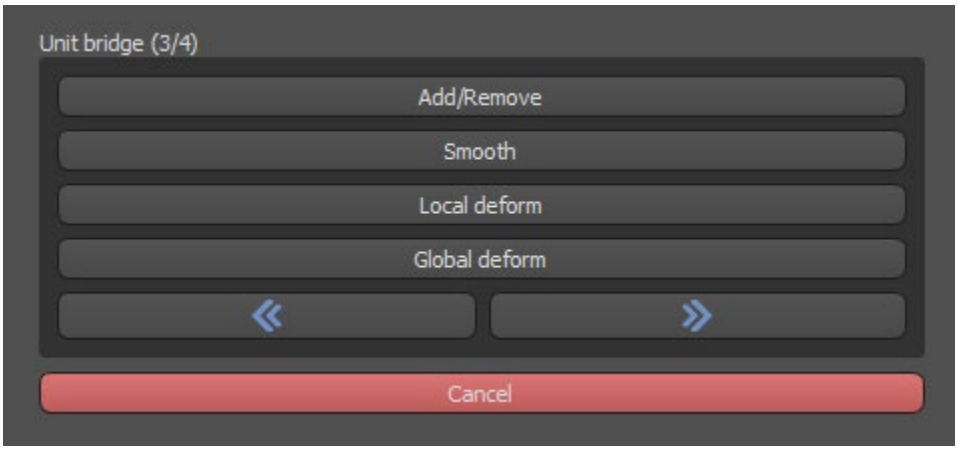
Step 2 – Editing connections

The blue points allow the user to edit the connections between the crowns or teeth.



Step 3 – Bridge editing

Step 3 is used for editing the bridge.



"*Add/Remove*" is used for the addition/removal of the material.

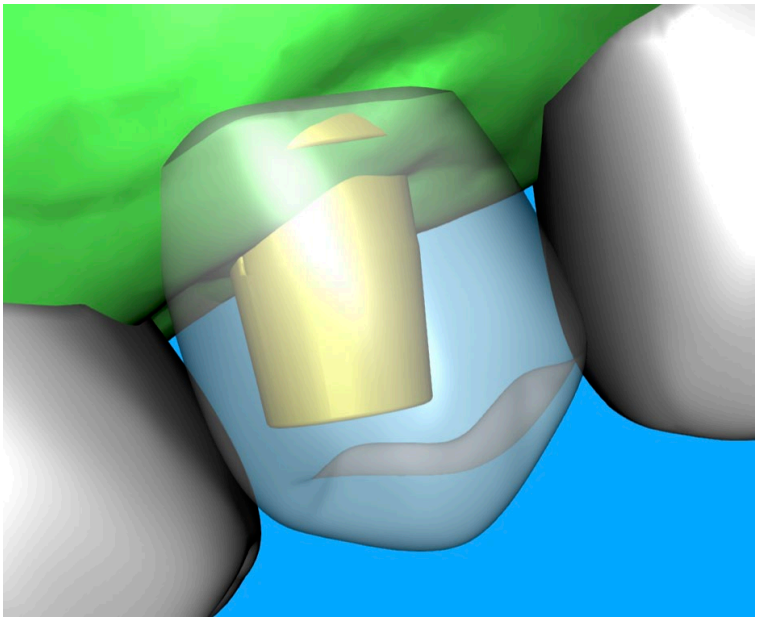
"*Smooth*" smooths the bridge surface.

"*Local deform*" allows the creation of ups and downs.

"*Global deform*" creates ups and downs on a global scale.

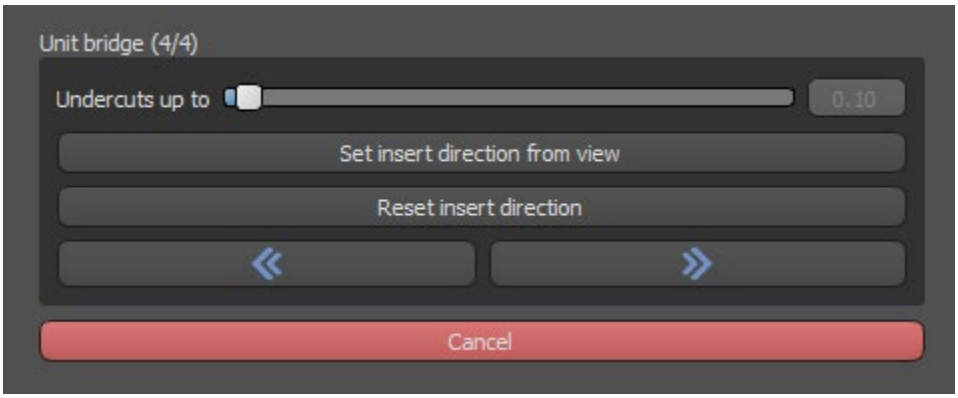
The "*Tool size*" slider can be used to change the brush tool dimension, and "*Tool strength*" defines the strength of the tool. The original values can be restored by clicking on the "*Set to Default*" button.

If the teeth are overlapping, the union operation between teeth is being performed and the first two steps are skipped.



Step 4 – Undercuts

Step 4 is used to define the initial parameters for the bridge.



The slider can be used for setting the values for undercut.

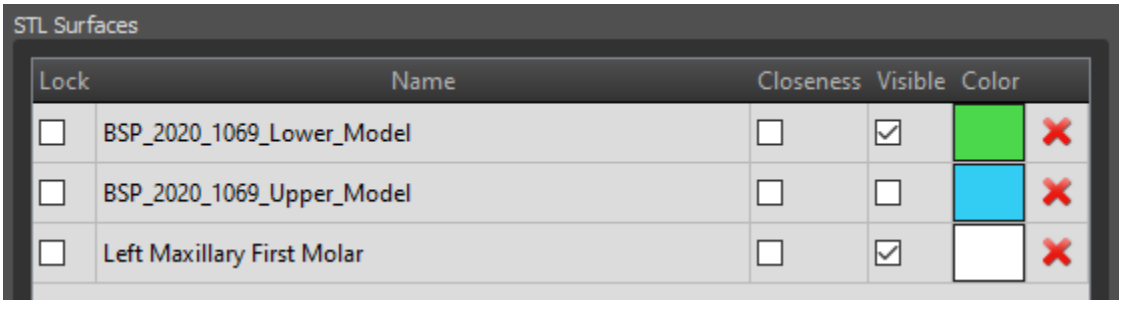
"*Set insert direction from view*" is used to set the insert direction according to the current viewing angle in the 3D view.

"*Reset insert direction*" restores the original insert direction.

Bridge creation is finalized by clicking on the "*Next*" button.

22.7. Teeth Surfaces panel

Teeth Surfaces lists the imported patient's STL models, placed virtual teeth and their reduced versions, and the newly generated crown base:



The table includes the following attributes:

"*Lock*" – surface locking controlled with a checkbox.

“*Name*” – surface name.

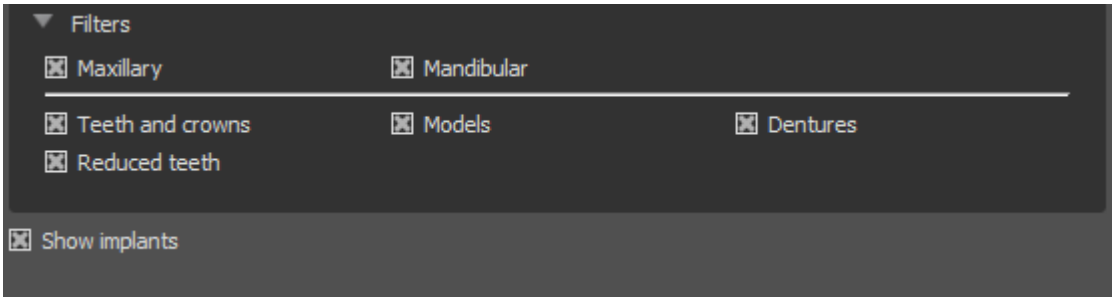
“*Closeness*” – surface closeness controlled with a checkbox.

“*Visible*” – surface visibility or hiding with a checkbox.

“*Colour*” – surface colour.

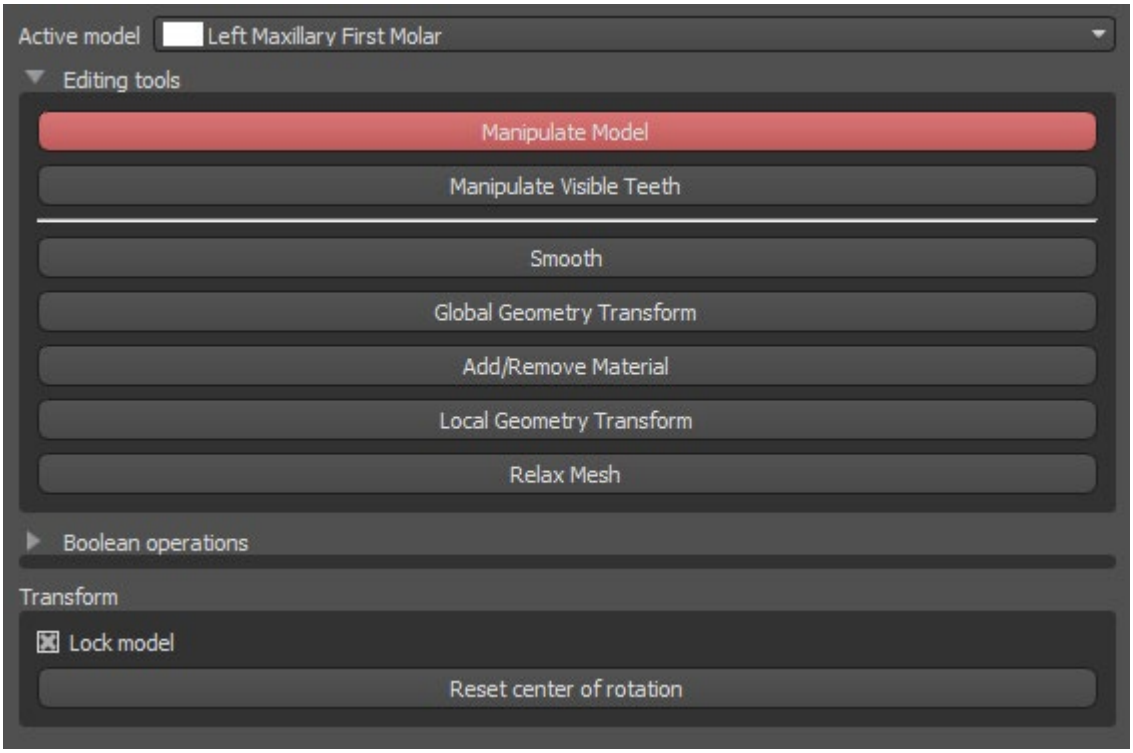
– surface removal.

Filters can be used to display either the maxilla or the mandible only, or selected object types:



22.8. Teeth Edit panel

The Teeth Edit panel allows the user to edit the shape of a tooth by using different editing tools:



“*Manipulate Model*” allows the user to change the position of the tooth.

“*Smooth*” smooths the tooth surface.

“*Global Geometry Transform*” creates ups and downs on a global scale.

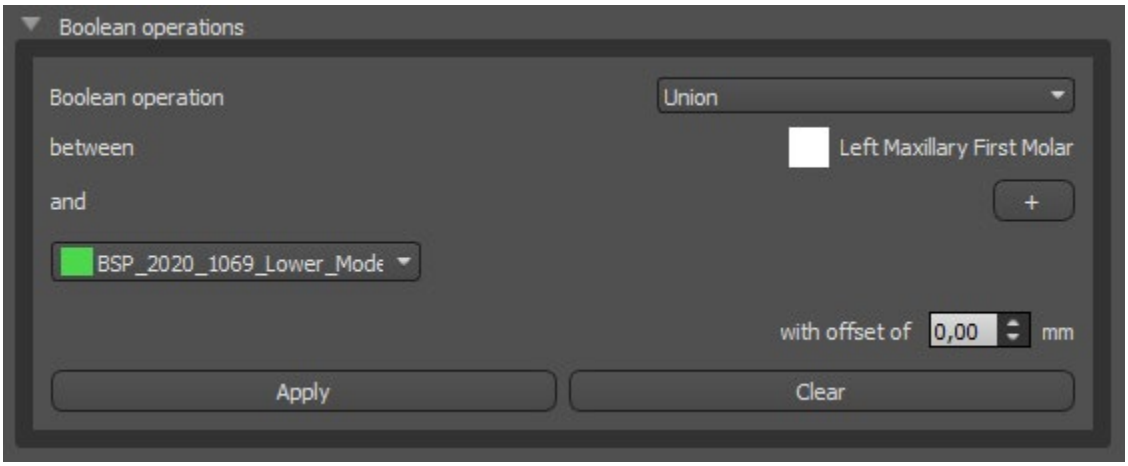
“*Add/Remove*” is used for the addition/removal of the material.

“*Local Geometry Transform*” creates ups and downs on a local scale.

“*Relax Mesh*” is similar to smoothing while it respects sharp edges to some degree.

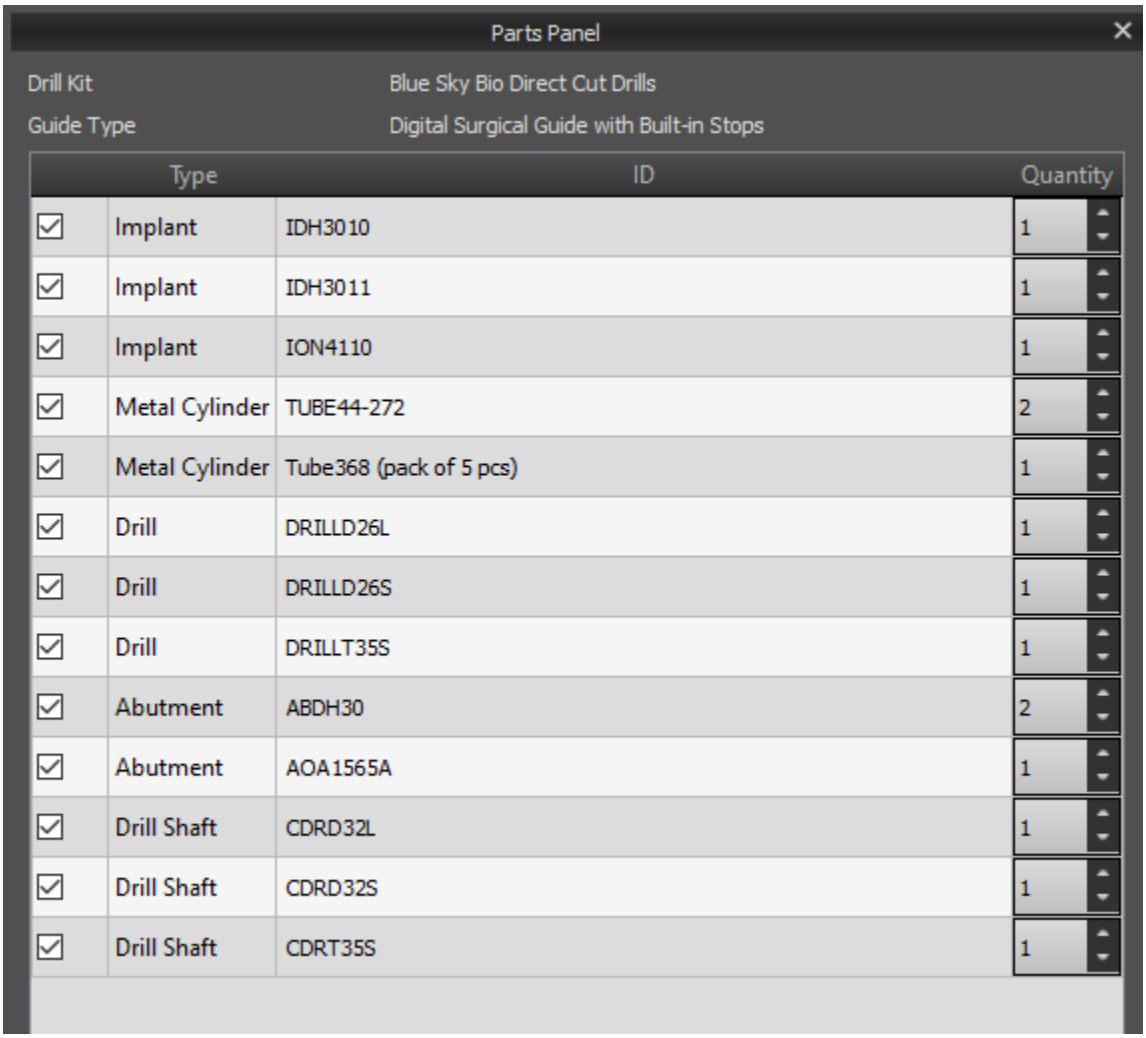
The “*Tool size*” slider can be used to change the brush tool size. The original values can be restored by clicking on the “*Set to Default*” button.

Boolean operations allow the user to join and subtract 3D models.



22.9. Parts panel

The Parts Panel lists the imported patient’s drill kit and guide type and quantity of each part, which can be added to the shopping cart.

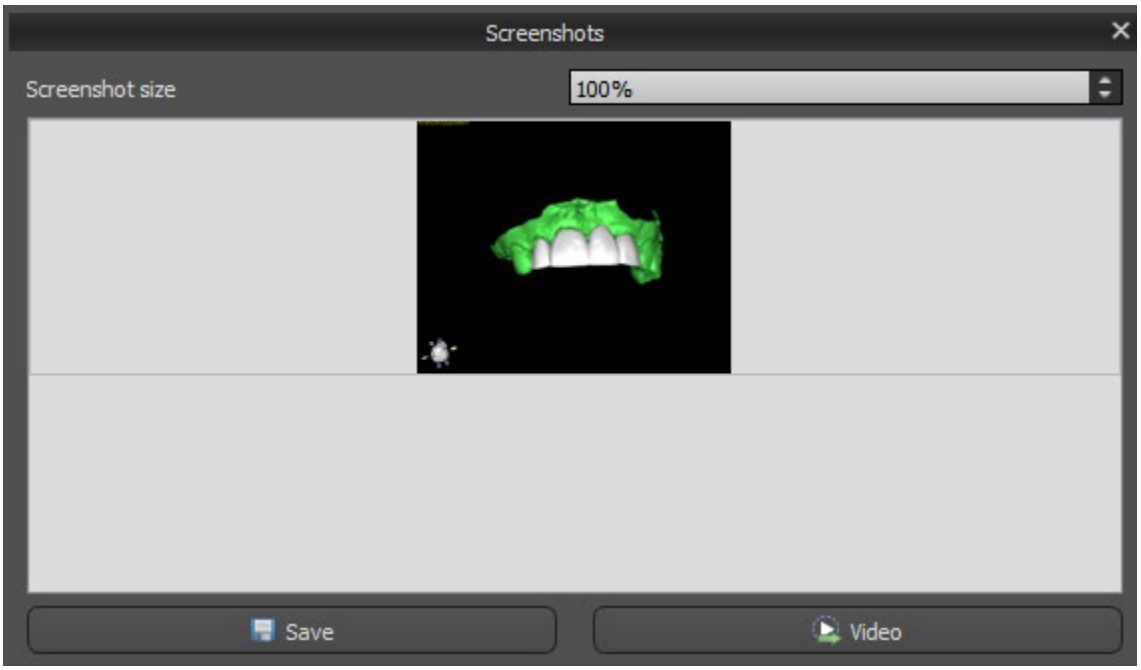


The user is taken to the Blue Sky Plan official webpage after clicking on the "*Add Parts to Cart*" button. The original values of the quantity of parts can be restored by clicking on "*Clear user Adjustments*".

22.10. Screenshots panel

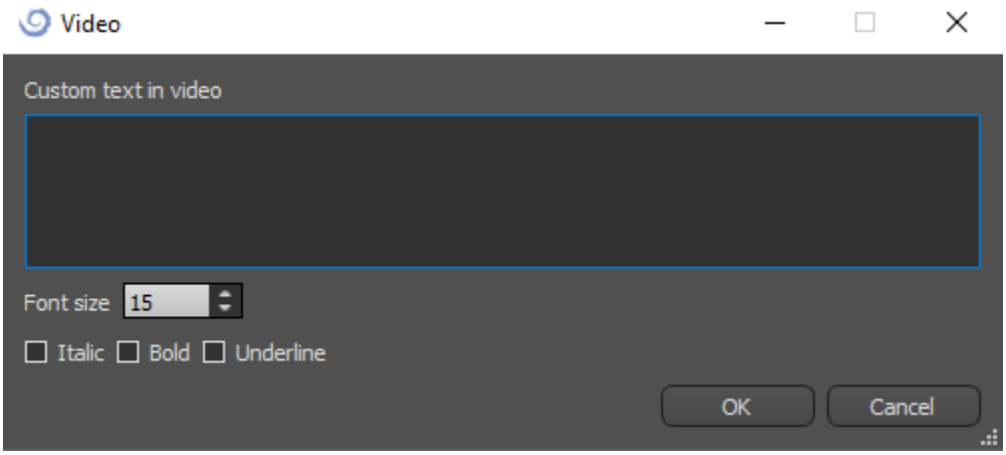
The Screenshot panel can be used for taking a screenshot with the button located in the top right corner of the workspace.

After clicking the button, the "Save screenshot" message appears, and the screenshot is included in the column in the right panel.



The arrows on the right are used for changing the screenshot size.

Video allows the screenshots to be exported as an AVI video or animated gif with custom text and selected font size and type.



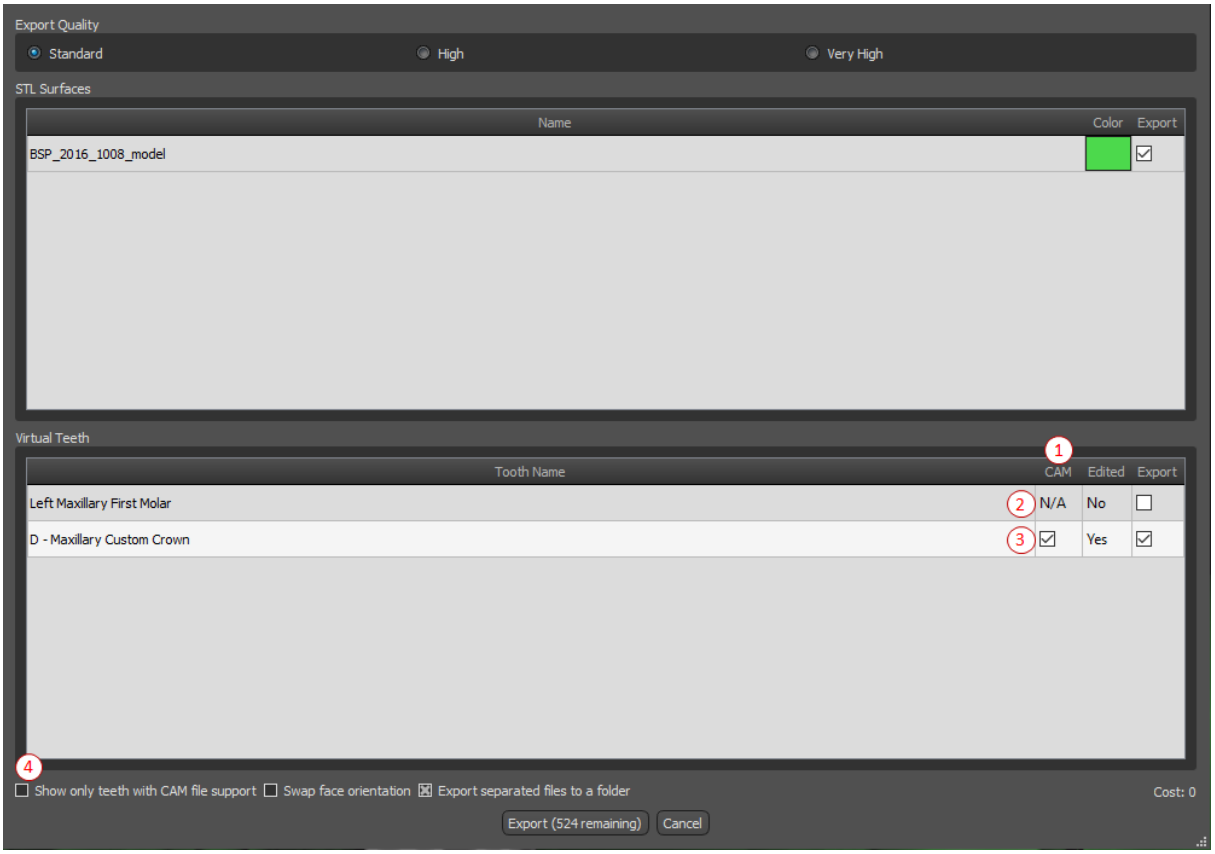
22.11. CAM Export

In addition to the normal export of models, the software allows you to create a CAM export.

In order to export, you need to create at least one crown or one bridge. Once you complete this step, you can choose which models you want to export in the CAM column (1) inside of the export dialog.

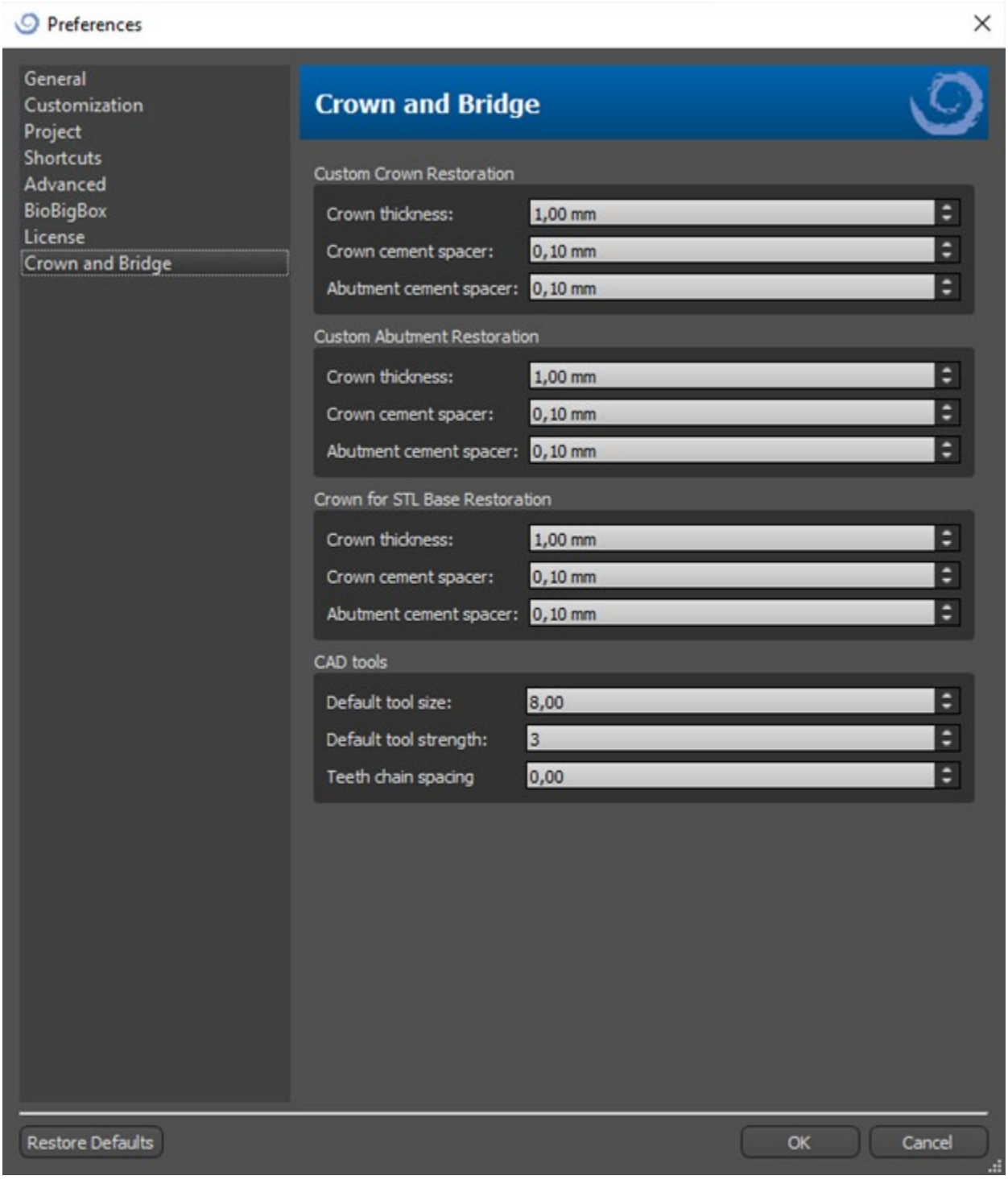
If the model is not CAM exportable the value will be “N/A” (2), otherwise there will be a checkbox for selection (3).

If you want to see only models which can be CAM exported, you can use the button on the bottom left called “Show only teeth with CAM file support”.



The final product of the CAM export is a file called <name>.constructionInfo where all the information about the model are stored.

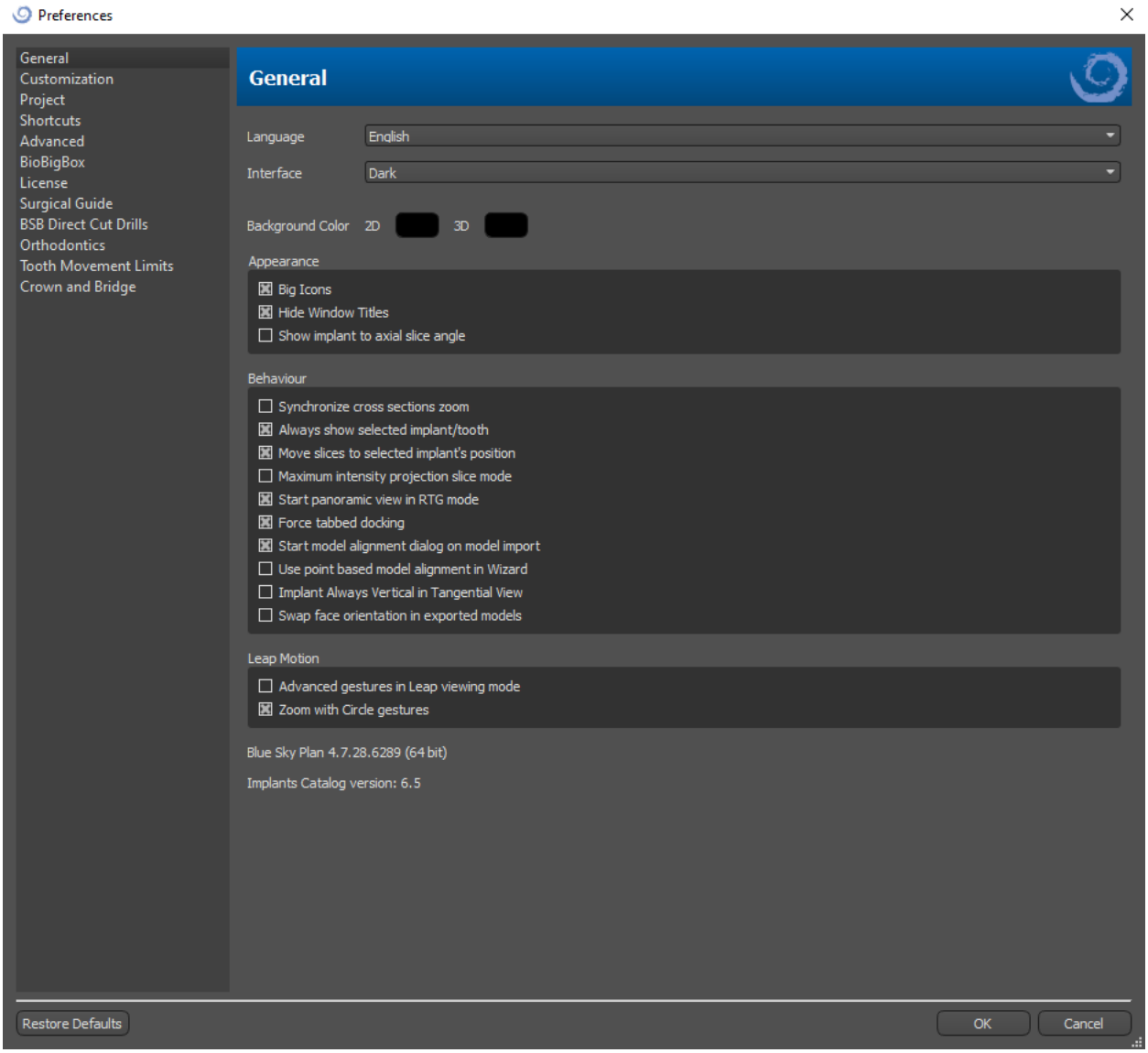
22.12. Crown and Bridge Preferences



In “Preferences > Crown and Bridge” the user can set the Crown thickness, Crown cement spacer and Abutment cement spacer for different types of restoration available in the Restoration Design panel. CAD tools are available for the Denture module. The “Default tool size” is used for selecting the default tool size, and “Default tool strength” defines the default strength of the tool. “Teeth chain spacing” allows the user to set the spacing between the teeth in the teeth chain.

23. Preferences

Blue Sky Plan® makes it possible to save user settings for the program and its environment. You mark the settings selection with the *"Tools > Preferences..."* menu option.



23.1. General

Dragger delay – the time until the dragger disappears after the mouse cursor moves away from the implant or tooth

Big icons – sets the size of the icons in the tool bars

Hide window title – sets the visibility of the titles of windows with visualization data

Synchronize cross-sections zoom – if this option is turned on, moving and changing the ruler in any cross-section of the slice also changes the ruler in the other cross-sections of the slice

Maximum intensity projection slice mode – this button for switching the slice display mode offers two variants: MIP (maximum intensity projection) and X-ray.

Always show selected implant/tooth – ensures visibility of the active implant when implants/teeth are fully transparent

Drill Depth Correction – a correction factor for the distance of the Drill Guide from the implant when exporting.

Move slices to selected implant's position – clicking on the implant sets the positions of the orthogonal and normal slices on the selected implant.

Advanced gestures in Leap viewing mode – enables advanced scene manipulation gestures in Leap viewing mode. A Leap controller is required.

Zoom with circle gestures – toggle the effect of the circle gesture between slider control and zoom control.

23.2. Project

Autosave project – automatically saves the project at the time interval entered

23.3. Advanced

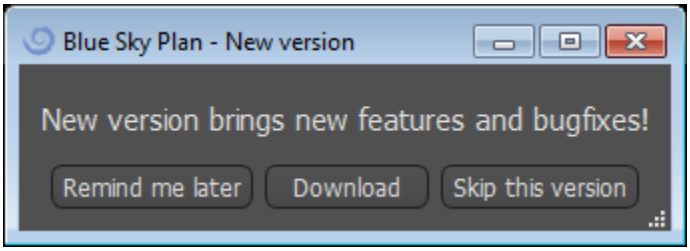
Rendering mode – the multi-threaded mode provides somewhat better display performance but may lead to program instability with inappropriate graphics card drivers.

Logging – allows information about the execution of the program to be stored in a log The log can be displayed by clicking the *"Show Log"* button, and its content can make it easier for the program manufacturer to solve problems that arise when running the program on specific hardware configurations.

Automatically check for updates – every day when it first starts up, the application checks whether you are using the newest release and, if not, offers to install the update for you.

24. Automatic updates

Blue Sky Plan® supports the option of automatically checking the availability of a newer version of the program. It does this once a day when it first starts up; this can be turned off in the program settings dialog in the *"Advanced"* tab with *Automatically check for updates.* This feature can be invoked manually with the menu selection "*Help > Check For Updates…*"



If a new version is available, the program offers the user the options of postponing the update till later, downloading and installing the update immediately, or skipping this update completely. The update download runs directly in the application environment, and to install it, Blue Sky Plan® must shut down and then start the installation, so please close open projects before checking for a new version and installing the update.

25. Footnotes

25.1. Blue Sky Bio Aligners Prescriber Instructions for Use

Caution: *US federal law restricts this product for sale by or on the order of a dentist or physician.*

Indications for Use

Blue Sky Bio Aligners are a series of clear, lightweight, plastic appliances indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e., all second molars). Utilising a series of incremental tooth movements, it sequentially positions the teeth by way of continuous gentle force.

Device Description

Blue Sky Bio Aligners are a series of clear plastic aligners that offer a solution for aesthetic orthodontic treatment by utilising a set of removable aligners to correct tooth malocclusions. A dental health professional (e.g. orthodontist or dentist), using a standard personal computer, prescribes the Blue Sky Bio Aligners based on an assessment of the patient's teeth, determines the course of treatment with the system, takes moulds of the patient's teeth and then imports a digital version of the mould (or model) into the ordering software, then in the ordering software aligns the teeth as they want them at different phases of treatment. The phase models are exported from the ordering software and sent to Blue Sky Bio. Blue Sky Bio then prints a series of plastic trays intended to gradually realign the patient's teeth in accordance with the physician's prescription in the ordering software. The prescribing physician creates the models used to print the aligners. Blue Sky Bio produces trays which are formed of clear, thermoformed plastic. The trays are sent back to the dental health professional who then provides them to the patient, confirming their fit and design. Over a period of time, additional trays are provided sequentially to the patient by the dental health professional to gradually move the target teeth to the designed position. The dental health professional monitors the treatment from the moment the first aligner is delivered to when the final aligner is delivered. The trays are held in place by pressure and can be removed by the patient at any time.

Storage and Handling

Store the devices in a dry, clean and dust-free environment in the original packaging at modest temperatures (5°C to 40°C / 41°F to 104°F).

Contents of the Box

The box contains the aligners for the patient identified by the stickers on the plastic bags containing the aligners. These were made from the models you sent to Blue Sky Bio. If at any office visit the aligner fits incorrectly, scan the patient, go through the

construction/ordering process again and send Blue Sky Bio a new model for aligner re-fabrication.

The aligners are delivered clean but NON-STERILE in a plastic bag. The plastic bag has a sticker on it which identifies the patient and which number of aligner is in the bag. The patient should be instructed to clean the aligner with toothpaste and a toothbrush each day. The teeth should be brushed before inserting the aligner.

25.2. Computerised Orthodontic Bracket System Instructions for Use

Caution: *US federal law restricts this product for sale by or on the order of a dentist or physician.*

Indications for Use

The Blue Sky Bio Computerised Orthodontic Bracket System is a software system intended for use as an aid in orthodontic treatment planning to correct malocclusions in orthodontic patients. For use by dental professionals trained in orthodontic treatment, including radiographic analyses and treatment planning. The Blue Sky Bio Computerised Orthodontic Bracket System is intended for use with commercially available brackets currently used in standard orthodontic treatment. The end product is an indirect bonding tray for use by the dental professional to place multiple brackets at the same time. The additive printing of the indirect bonding trays should only occur at a validated printing centre. Each validated printing centre is to be a registered and listed contract manufacturer with Blue Sky Bio, as documented to the FDA per the Device Establishment Registration and Listing (see CFR Part 807).

Device Description

The device consists of proprietary software that allows the placement of virtual orthodontic brackets on 3D models supplied by the clinician. The physical models are scanned and converted into virtual models in the software. An indirect bonding tray made out of resin is produced. The physical orthodontic brackets are inserted into the indirect bonding tray. The tray aids in the accurate bonding of the brackets, duplicating the position of the virtual brackets in the planning software. The tray is produced using two alternative methods.

One method utilises the virtual model of the patient model with virtual brackets. The indirect bonding tray is designed and printed as a negative of the virtual model with the brackets in place. The printing of the indirect bonding tray should only occur in an FDA registered establishment.

The second method utilises a printed patient model with markers indicating the position of the brackets. The brackets are glued to the model on the marked areas and the indirect bonding tray is pressure thermoformed over the model capturing the brackets.

Both methods result in a resin indirect bonding tray with brackets attached to the tray according to the bracket position planned in the software. The clinician inserts the tray with the brackets on the patient's dentition, allowing the accurate positioning and bonding of the brackets. Commercially available brackets are used as part of the system but are not part of the submission.

The software is available for download on the Blue Sky Bio website and it is used by Blue Sky Bio and authorised users. The download includes the instruction manual, which can also be downloaded separately on the Blue Sky Bio website. The software requires activation for authorised users.

25.2.1.User Identification

The clinician creates the patient models to be scanned into the software. The clinician either creates or reviews and approves the virtual orthodontic treatment plan, including the bracket positions. The software is intended to be used by Blue Sky Bio and authorised entities manufacturing the indirect bonding tray based on the clinician-approved positioning of the brackets.

How to use the Computerised Orthodontic Bracket System

The dental professional creates a model of the patient's dentition. The model is scanned and converted into digital model using any legally marketed scanner for dental applications which will export STL files. Scanning a physical impression to make a virtual patient model is also possible. The model data is imported into an activated copy of the Computerised Orthodontic Bracket System on a standard personal computer with the following specifications:

- OS: Windows 10 Home/Professional 64 bit or OS X 10.10 (Yosemite) or newer
- Processor: Quad Core Intel i7 or comparable
- RAM: At least 16 GB
- Video card: dedicated NVidia or AMD card, at least 3 GB video RAM, (e.g. NVidia GeForce GTX 650, AMD Radeon HD 7750, ...)
- Monitor: 21 inches, resolution at least 1920 X 1080
- Hard Disk: 5 GB of free space

An authorised user is required to activate the software. The authorised user is either a Blue Sky Bio employee or an authorised purchaser. Authorised users follow the specification requirements guidelines determined by Blue Sky Bio for using their computer and printer with the Computerised Orthodontic Bracket System.

The software has a database of 3D models of commercially available orthodontic brackets. Based on the patient's 3D models and treatment plan the software operator identifies the ideal placement of the brackets. The bracket placement is reviewed and

approved by the dental professional. The dental professional can adjust the final position of the bracket if desired.

Manufacturing of the Indirect Bonding Tray (IBT)

Two alternative methods are used to manufacture the indirect bonding trays.

1. The virtual model of the patient's dentition with the virtual brackets in place is utilised to create a negative of the model. This virtual model fits on top of the dentition of the patient and has also cavities matching the shape of the brackets. The user defines the outline of the indirect bonding tray in the software and a virtual model of the tray is created. This model is printed using a new and not recycled legally marketed material for short term use in the mouth called NextDent Ortho IBT utilising a 3D printer satisfying the specifications of Blue Sky Bio described in section 16.11.4. The tray is delivered to the clinician.

2. In an alternative method, a model of the patient's dentition with bracket positioning markers is printed utilising a 3D printer satisfying the specifications of Blue Sky Bio described in section 16.11.1.

The actual brackets are temporarily attached on the markers of the model. A legally marketed thermoplastic resin sheet such as Dentsply Essix Ace is pressure formed on top of the model capturing the patient's dentition and brackets. Any standard thermal pressure forming machine can be used following the guidelines of the manufacturer of the resin sheets. A pressure forming machine is sold by the manufacturer of Essix Ace. The sheet is trimmed to the middle of the brackets. Excessive undercuts are removed and the tray is made suitable to be used as an indirect bonding tray and delivered to the clinician.

Use of the Indirect Bonding Tray (IBT)

IBT's are patient-specific devices intended for short term use in the patient's mouth. The indirect bonding tray is a placement guide to allow a dentist to place orthodontic brackets in a precise manner. Manufacturing the tray using the two alternative methods does not change the way it is used. The key to the tray's clinical use is the fit on the patient's dentition and the location of the spaces holding the brackets during the bonding process. The clinician verifies the accurate fit of the tray on the dentition. In addition, the position of the brackets in the patient's mouth is verified to ensure that the location of spaces for the brackets matches the virtual treatment plan. Once the shape of the tray has been verified, the clinician inserts the brackets into the tray and places a legally marketed bonding agent. The final step is placing the tray back in the patient's mouth to bond the brackets onto the patient's dentition following the instructions of the manufacturer of the bonding agent. If necessary, the clinician can adjust the bracket position removing one or more brackets and using traditional manual bracket placement. The procedure is the same for a printed or thermoformed indirect bonding tray.