

Impla**Station**

Instruction for Use

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TABLE OF CONTENTS

1. INTRODUCTION	4
1.1 Indications for Use.....	4
2. SYSTEM SETTINGS.....	5
2.1 System Requirements	5
2.2 Network Settings	5
3. INSTALLATION AND UPDATE	6
3.1 Update	9
4. USER INTERFACE	10
4.1 Multi-Planar Reconstruction (MPR) Display	10
4.1.1 Axial view	10
4.1.2 Coronal view	10
4.1.3 Sagittal view	11
4.2 How to Adjust the Planes	11
4.3 3D Rendering Window (Volume)	12
4.4 Panoramic Mode	13
4.5 Rotating Slice Window	16
4.6 Buttons and Basic Functions	16
4.6.1 INFO Panel	17
4.6.2 Tool Panel	17
4.6.3 Settings Menu	18
4.6.4 Visualization Tools	21
4.6.5 Tab Panel	21
5. INPUT DATA (DICOM)	22
5.1 DICOM "Cutting".....	23
5.2 DICOM to STL Conversion	24
5.3 DICOM Segmentation	25
5.3.1 Options	27
6. INPUT DATA (STL)	29
7. NERVE CANAL TRACING	36

8. VIRTUAL CROWNS PLACEMENT	37
9. IMPLANT PLANNING	39
10. ANCHOR PIN PLANNING	48
11. SURGICAL GUIDE CREATION	52
11.1 Surgical Guide Based on Prosthesis	57
12. SURGICAL PROTOCOL	58
WARNINGS AND PRECAUTIONS	59
ANNEX A – How to evaluate the quality and accuracy of alignment.....	61
ANNEX B – Dual Scan Technique	62
ANNEX C – Cloud Service	66
ANNEX D – Cybersecurity Hygiene	71

1. INTRODUCTION

ImplaStation is stand-alone software designed for trained qualified dental practitioners. The key scientific concept of the ImplaStation software is the visualization of a patient's medical image data (DICOM file from third-party CT/CBCT scanners) to pre-operative digital implant planning, surgical guide (drill guide) file (output of the pre-operative implant planning) creation.

The data acquired by the optical scanner (scanned surface of the maxilla or mandible) can be aligned to the CT/CBCT reconstruction through a point-based registration technique.

Virtual crown(s) design and nerve tracing can be used as additional tools to assist the specialist during an implant planning process.

The ImplaStation library contains implant, abutment, drill, and sleeve files, which are encrypted files and approved by the corresponding implant manufactures. The software allows designing the surgical guide (drill guide) file and exporting the generated file to a 3rd party external system for manufacturing.

The followings are the major functions of ImplaStation:

- Patient DICOM dataset loading and visualization*
- Data (DICOM, .stl files) input; Data (.stl file) output for manufacturing; Surgical report (drilling protocol .pdf) output.
- Nerve tracing
- Virtual crown(s) positioning
- Virtual implant placement
- Collision detection
- Patient treatment plan creation
- Surgical guide design and creation
- Surgical protocol design and creation
- Project information management and sharing
- Designed surgical guide data can be exported to a third-party system for manufacturing**

*The software is not intended for diagnosis, please use the software offered by the Computed Tomography Scanner manufacturer, on which scanning was performed for the diagnosis and expert opinions. The software does not apply any compression, modifications, or adaptation to the DICOM files and model surface scan STL-files during their upload, alignment, design, and export.

**Paid option

Note!

The software as medical device has no patient contact

1.1 Indications for Use

ImplaStation is stand-alone software designed for trained qualified dental practitioners, including dentists and dental technicians.

The software can be used to visualize a patient's medical image dataset output in DICOM format from third-party CT/CBCT scanners.

ImplaStation is intended for use as a pre-operative tool for the dental implant(s) positioning based on the CT/CBCT image dataset aligned to optical 3D surface scan(s) and for the surgical guide planning result file creation. The surgical guide can be manufactured using a planning result file when used as input to 3D manufacturing systems.

3D manufacturing is out of ImplaStation software control, depends on many external factors and lie within the sole responsibility of the user.

2. SYSTEM SETTINGS

2.1 System hardware and software requirements

	Minimum System Requirements	Recommended
OS	Windows 7 PRO Mac OS 10.12 and higher	Windows 8 Home Windows 8.1 Home Windows 10 Home Windows 8 PRO Windows 8.1 PRO Windows 10 PRO Mac OS 10.12 and higher
Central Processing Unit (CPU)	Intel Core i3	Intel Core i5 Intel Core i7 or equivalent
Memory (RAM)	4GB	8GB or more
Graphics Card	Intel HD Graphics 615 Intel HD Graphics 620 NVIDIA GeForce 1GB	NVIDIA GeForce 2GB or more
HDD	3GB of free space	100GB of free space or more
Monitor resolution	1600 x 900 pixels	1920 x 1080 pixels or higher

2.2 Network Settings

In order to identify user account, import/export order forms, share ImplaStation projects and communicate with customer partner(s), personal computer must be connected to the Internet.

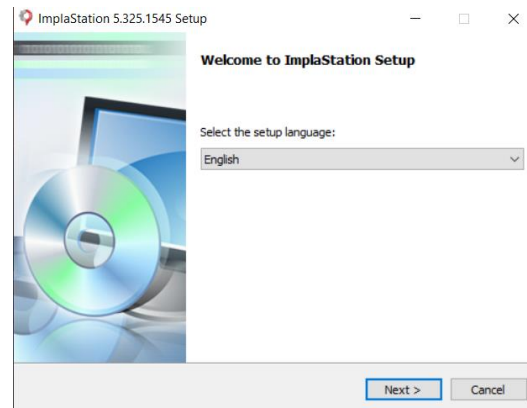
Internet connection is required for the support, help and training provided by Customer Support Service.

3. INSTALLATION AND UPDATE

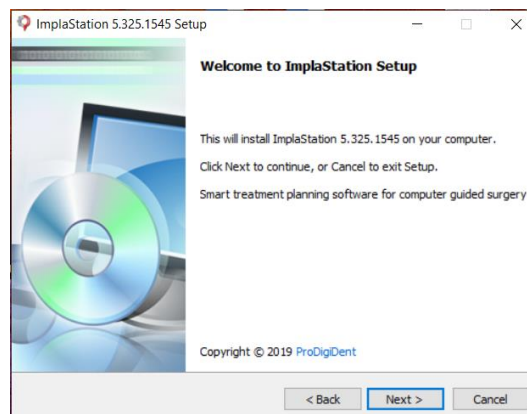
Open download directory on Implastation website (implastation.com), then click on the download link. Start installation process manually by executing the loaded **ImplaStationSetup** file on personal computer.



Choose language settings and click **Next** to move to the next step

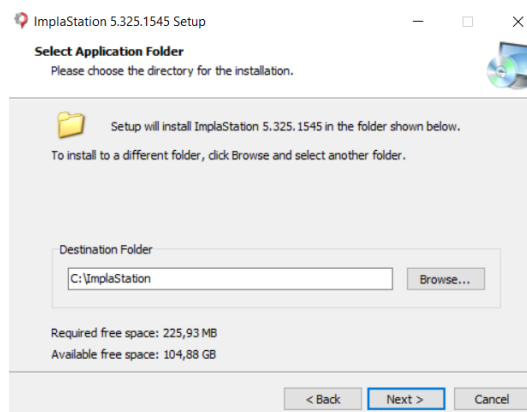


Click **Next** to move to the next step



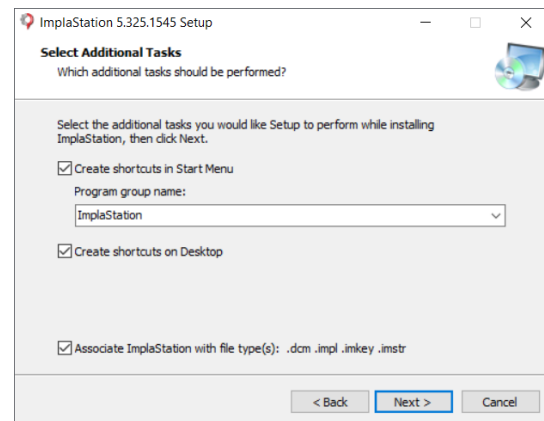
Browse for app location and click **Next** to move to the next step

It is recommended to locate main Implastation folder in the "C:" drive root

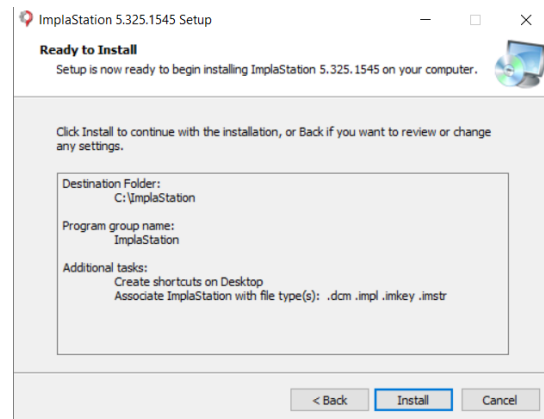


Select the additional tasks you would like setup and click **Next** to move to the next step

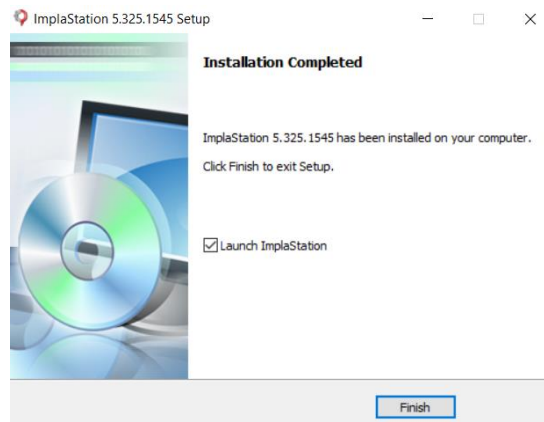
For not experienced user it is recommended to choose all options



Click **Install** to continue with the installation

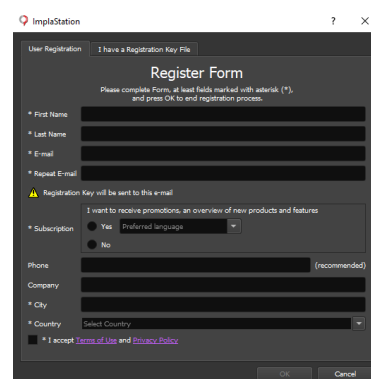


Click **Finish**



Open the software and fill up the registration form.

It is recommended to choose option "I want to receive promotions, an overview of new products and features". It is recommended to enter phone number.



Press **OK**, then software will be automatically closed. Please check your e-mail.

If you already have Implastation License Key find file on your computer, then click **OK**

Open your inbox e-mail folder, save attached key-file to a hard drive, open it by double clicking to complete a registration process

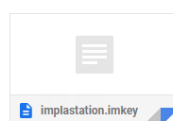
Optionally - you may specify a path to the saved key file using the Registration Form of Implastation app, open "I have a Registration Key File" tab > "Browse" tab, choose saved Key-file in the folder and press OK

Save attached key-file to a hard drive and run it by double click to complete registration process.

Another option - you can specify a path to saved key file in Registration Form of Implastation app - "I have a Registration Key File" - "Browse" and press OK.

Key file "attached" to the specified email and hardware of the PC from which registration was done. It is should not copy the key-file to another PC - it will not activates app installed on another PC. It is done to protect account from theft.

One email address may be specified for unlimited PC quantity (home, work, office etc.) Email owner controls key files transfers.



Note!

Key file(s), "Library" folder and other important information are located in the folder "Implastation" (C:\Users\"user name"\AppData\Roaming\Implastation) for Windows

If the **Implastation License Key** file is not received after registration process, check the SPAM and other folders for incoming messages in your specified email box.

For **technical issues**, email us at support@prodigident.com

Find the video instructions for how to install and activate the software on ProDigiDent YouTube channel.

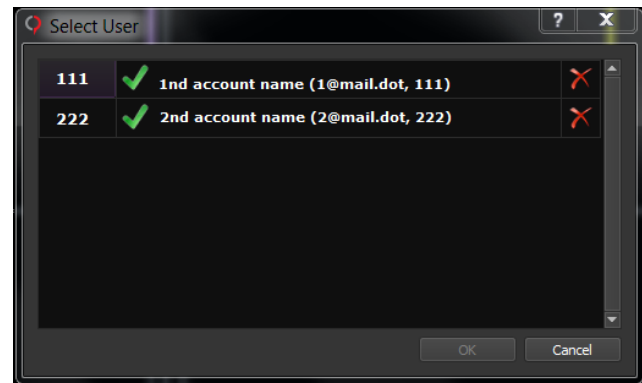
The **Implastation License Key** file is "attached" to the specified email and hardware ID of the PC from which registration was done.

The **ImplaStation License Key** file should not be copied and used with another PC. There is no option to activate app installed on another (non proper) PC in aim to protect the account from thefts and to protect the user's personal information. One email address maybe specified for unlimited quantity of PC (home, work, office etc.) Only an e-mail owner able to control **ImplaStation License Key** files transfers.

The ImplaStation Settings menu enables user to register several accounts, attached to different e-mail addresses. In case of several accounts are registered on one PC the "Select user" window appears.

If your browser automatically converts key-file to text - copy an appropriate string with the code to bookmark "I have a registration key-file"

The window shows all available user accounts. Please select the one you want and press OK.



3.1 Update

To check the current version of the software click the "**Help**" button, then select "**About application**" line



If an update is available, the "**Update Application**" menu pops up automatically when the software starts up. Click "**OK**" to update (recommended), or click "**Cancel**" to continue to work with the current version.

If the update does not occur, or it gives you an error, reinstall the software by clicking the link in the update dialog window.

Warning!

Software installation package or update package is a secured deliverable package. This secure deliverable package is uniquely encrypted and key-hashed to ensure the integrity and authenticity of its origin.

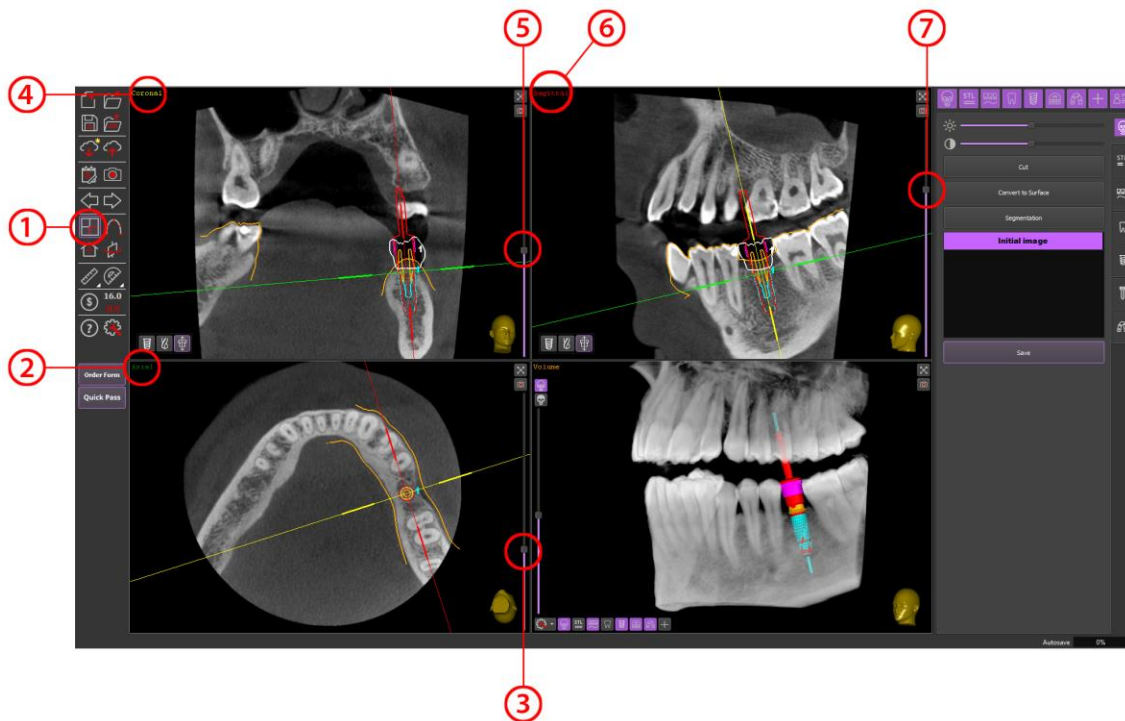
4. USER INTERFACE

The Implastation user interface enables users to visualize the patient's DICOM dataset using the Coronal, Sagittal, Axial, Panoramic, Rotating Slice and 3D view in corresponding windows.

MPR and Panoramic display can be used to generate interactive slices in free, oblique planes.

4.1 Multi-Planar Reconstruction (MPR) Display

The software automatically provides multi-planar windows (coronal, sagittal, and axial) and 3D view. This Multi-Planar Reconstruction **(1)** can be used to work on any spatial plane to obtain different types of high-quality diagnostic images obtained from 3rd parties medical CT or CBCT scanners.



4.1.1 Axial view

Axial view is a horizontal cut away slice of the maxillo-facial area as seen from the bottom **(2)**.

By scrolling the mouse wheel or clicking and dragging the slider **(3)**, It is possible to view the whole sequence of axial images. The name of the axial window and indicator line of the axial slice are marked in **green**. The indicator line of the axial slice appears in the coronal, sagittal, panoramic, and 3D windows.

4.1.2 Coronal view

Coronal View is a vertical cut away slice of the body as seen from the front **(4)**.

By scrolling the mouse wheel or clicking and dragging the slider **(5)**, it is possible to view the whole sequence of cross-sectional images. The name of the coronal window and indicator line of the coronal slice are marked in **yellow**. The indicator line of the coronal slice appears in the axial, sagittal, panoramic, and 3D windows.

4.1.3 Sagittal view

Sagittal View is a vertical cut away slice which divides the body into right and left parts **(6)**.

By scrolling the mouse wheel or clicking and dragging the slider **(7)**, it is possible to view the whole sequence of sagittal images. The name of the sagittal window and indicator line of the sagittal slice are marked in **red**. The indicator line of the sagittal slice appears in the axial, coronal, and 3D windows.

4.2 How to Adjust the Planes

- Free adjustment of the view by moving the center of the crossed planes

To move the center of the view axes intersection, put the cursor on it, then left-click and drag. The intersection of the view axes will move within the given plane. This movement will be synchronized with the change in slice depth in other MPR windows.

Hint	Use the "head" icon in the corresponding window to see the orientation of scans
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- Quick adjustment of the view by clicking the desired point

To move the center of the crossed planes, put the cursor on the desired position and double left-click on it. The center of the axes intersection will move to the selected point immediately.

- Quick adjustment of the view by clicking the implant image

The double left-click on the implant image enables users to set up the coronal axis in the same position with the implant axis and move the center of axes intersection to the implant reference point.

- Adjustment of the oblique view (plane rotation)

Since the maxillo-facial region is difficult to evaluate in standard MPR: axial, sagittal and coronal planes, oblique views become very important in analyzing and planning medical image data on a computer.

To rotate the plane, put the cursor on the plane line of the corresponding plane, left-click, hold and rotate it. The plane will rotate around the center of the crossed planes. By adjusting the only one plane, the other two views in oblique multi-planar will be generated automatically.

- Parallel movement of the planes

To provide the parallel movement of the plane, put and hold the left mouse button on the bulky part of the indicator line of the plane and drag it.

- Move the plane by scrolling the mouse wheel

Put the cursor on any point of the MPR window, and then scroll the mouse wheel.

- Zoom in/out 2D/3D objects

Zoom in/out the views by holding down the right mouse button and moving the mouse forward or backward.

- Moving 2D/3D objects

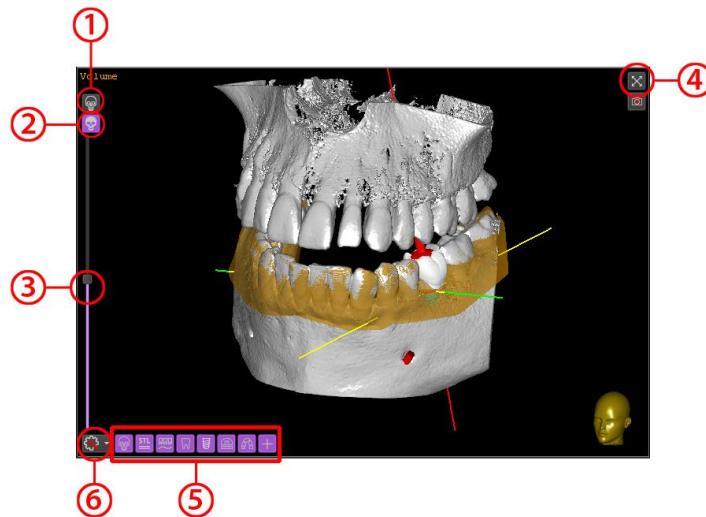
To move the object, press and hold down the mouse wheel, then move the object within the selected window.

- 2D/3D Image rotation

To rotate the image, put the cursor on any point of the desired window, press and hold down the left mouse button and rotate the object.

4.3 3D Rendering Window (Volume)

The 3D volume rendering view can be used to visualize large volumes of data generated by CT/CBCT scanners in three-dimensional space in aim to simplify the spatial orientation and object placement control.



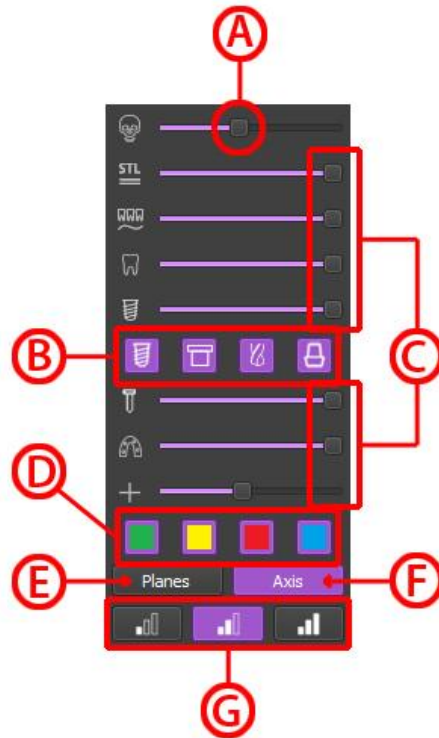
Use the icons located at the top left window corner to switch between MIP mode (Maximum Intensity Projection) (1) and ISO mode (Isosurface) (2).

Use slider (3) to adjust the image opacity threshold.

Click on the top right corner (4) of the 3D Volume Rendering Window to maximize or minimize it.

To switch On/Off (5) the visualization of the DICOM, STL surface, nerve, crown, implant, measurements, surgical guide or axes click on the corresponding buttons.

Settings menu of the 3D Volume Rendering Window (6):



Use the threshold slider **(A)** to change the density of the bone in ISO mode. To switch On/Off the visualization of the implant, sleeve, drill or abutment click on the corresponding buttons **(B)**. To adjust the STL surface, Objects opacity threshold settings, drag slider right to increase opacity or left to make the object(s) more transparent **(C)**. Axis planes visualization settings **(D)**. Switch between "Planes" **(E)** and "Axis" **(F)** to change the orientation line view. The software can be switching between low, medium and high-performance graphics settings, depending on the customer PC graphics card processor capacity **(G)**.

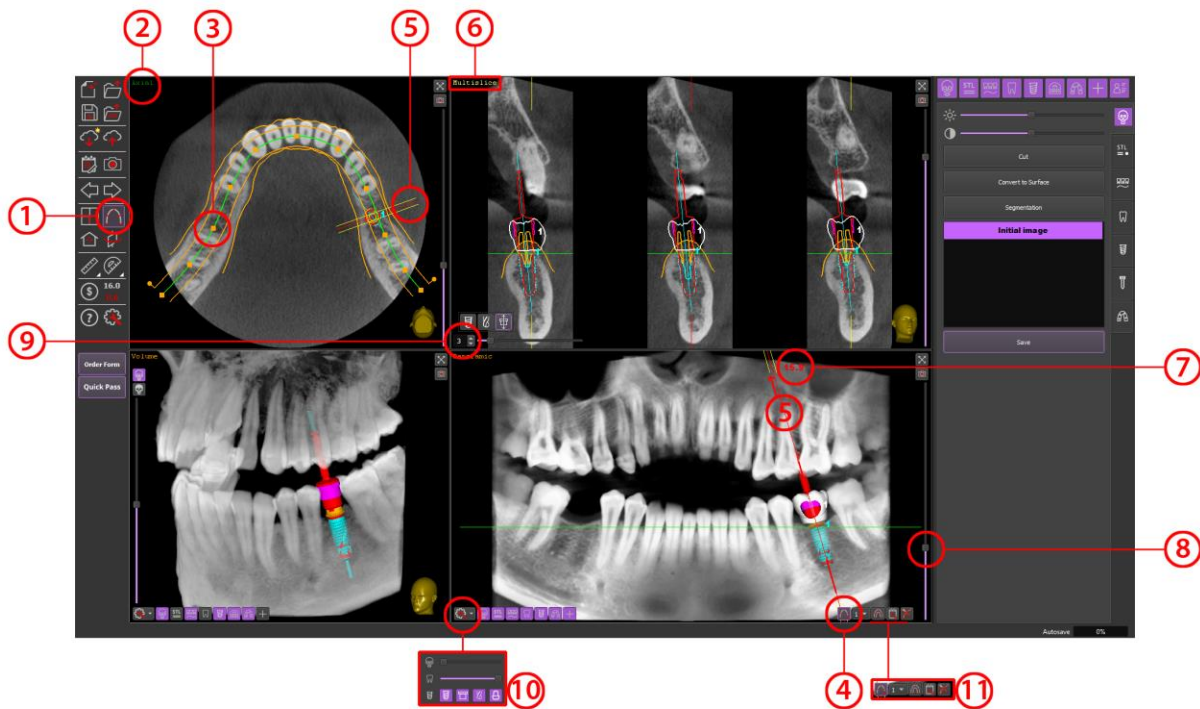
4.4 Panoramic Mode

Serves for general review of the maxillofacial region and allows users make expanded evaluation of the implant(s) position

The **Panoramic Curve** identifies the dental arch position.

Hint

The best area where to place the curve is in the half of the length of teeth roots, where the canals are going to be good markers for the curve tracing



To edit or create the panoramic reconstruction of the CBCT/CT scan click on the **"Switch to PANO mode"** button (1)



Before starting to edit or trace the panoramic curve, select the **Axial Window** (2) containing the dental arch of the upper or lower jaw.

To **edit** existing panoramic curve move the dots by clicking with the left mouse button on each yellow dot (3) and dragging it into the right position.

To trace a **new** panoramic curve, click on the **"Add Panoramic curve"** button (4)



Put the mouse cursor over the image and draw new panoramic curve using the left mouse button by placing points one after another on the arch, then double-click to finish tracing. In case of misplacement, move the dots by clicking with the left mouse button on each yellow dot and dragging it into the right position.

The **Indicator Line** (5) of the panoramic slice appears in the axial and in panoramic window. Put the cursor on the **Multislice Window** (6), scroll the mouse wheel to move the indicator line along the panoramic curve to see the desired cross-sectional slice(s).

Hint

Quick adjustment of the view. To move the indicator line, put the cursor on the desired area in axial or in panoramic view and double left-click on it. The indicator line of the panoramic slice will move to the selected point immediately

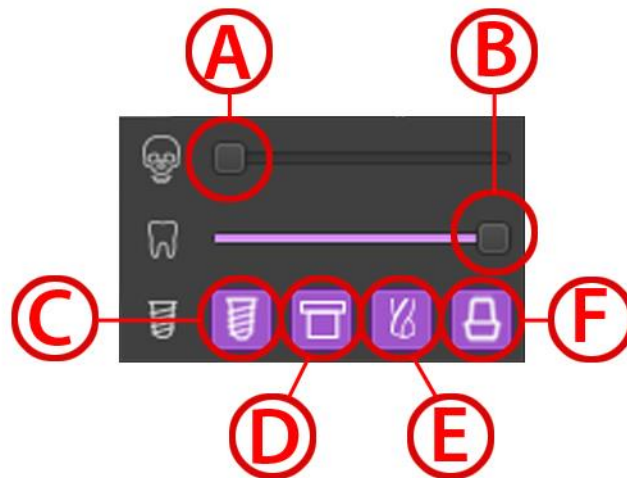
To adjust the inclination of the cross-sections in the panoramic view click on indicator line and tilt it. The numerical value of the **angle of inclination** (7) will appear near the indicator line.

Note! The angle of inclination will be correct only if the occlusal plane of chosen jaw is parallel to axial plan

Click and drag the **slider** in Panoramic Window to change the panoramic curve thickness **(8)**.

The default settings for **Multislice window (6)** assume three separate cross-section images with distance increment of one millimeter. The number of slices can be increased to five and reduced to one **(9)**.

Settings menu of the Panoramic Window **(10)**:



To adjust the image opacity threshold, drag slider left to increase opacity or right to make the image more transparent **(A)**. To adjust the Crown(s) opacity threshold, drag slider right to increase opacity or left to make the crown(s) more transparent **(B)**. To switch On/Off the visualization of the implant **(C)**, sleeve **(D)**, drill **(E)** or abutment **(F)** click on the corresponding buttons.

Control panel of the Panoramic Window **(11)**:

"Add Panoramic Curve" button	
Click on the Panoramic View list button to choose initial or created panoramic view(s)	
Click on the button to switch between Narrow or Wide mode	
Click on the button to add the panoramic image to Surgical Protocol	
"Delete Panoramic Curve" button	

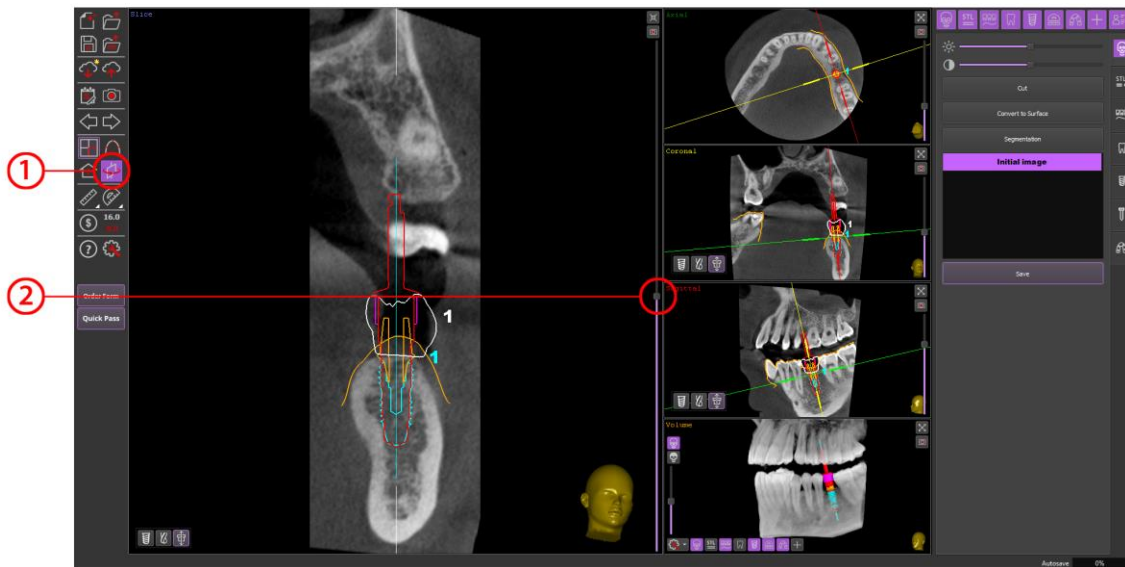
4.5 Rotating Slice Window

Click the **"Open Slice"** button on the Tool Panel to open the Rotating Slice Window (1)

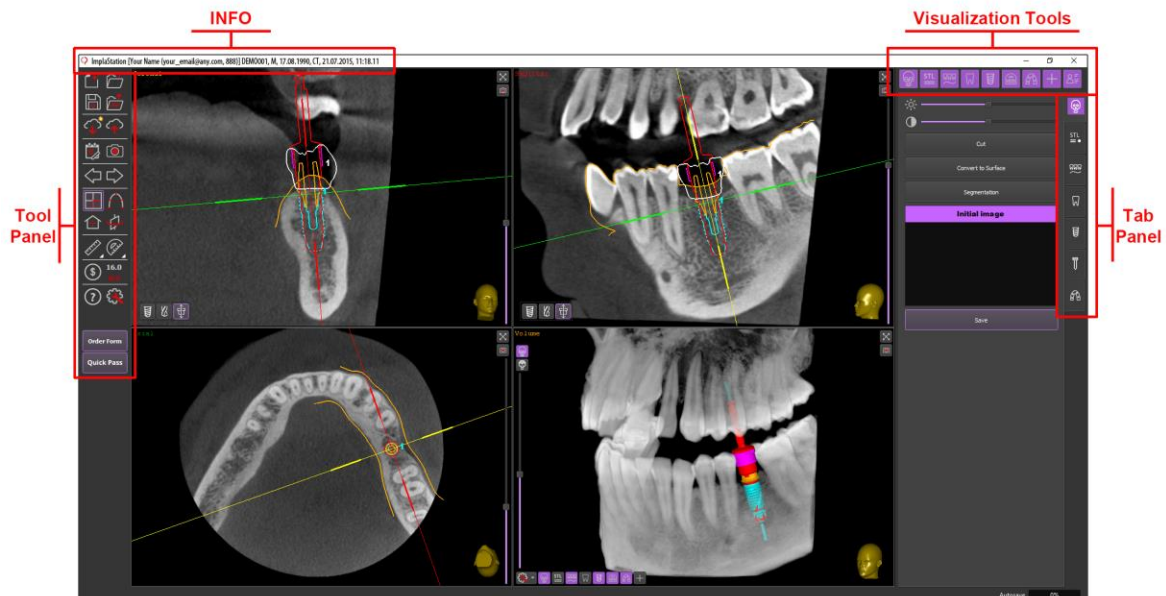


The main purpose of the Rotating Slice View is final control and ability to make a precision correction of the implant and sleeve position.

To rotate the image around the Implant axis, put the cursor on any point of the Rotating Slice window and scroll the mouse wheel or click and drag the slider on the right part of the window (2).



4.6 Buttons and Basic Functions



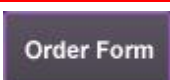
4.6.1 INFO Panel

The INFO panel displays information on the customer name, customer email address and registration number, patient's name, patient's date of birth and gender, CT scan data.

4.6.2 Tool Panel

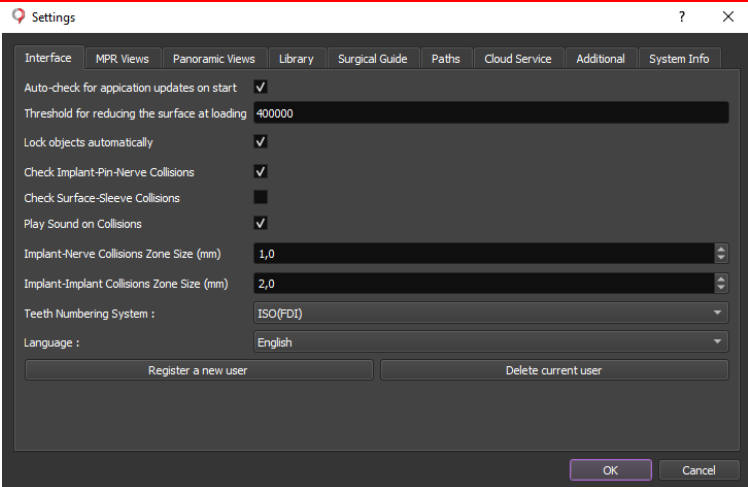
The Tool Panel basically consists of buttons customer needs to manage the case, set up view, make a measurement, purchase exports, etc.

	Click the New Project / Load DICOM button to upload DICOM data
	Click the Open Project button to open the existing project
	Click the Save Project button to save project
	Click the Open Recent Projects button to open the list of the recent projects
	Click the Cloud Service button to manage messages
	Click the Save or Send to cloud button to save the created project to cloud or share it with others
	Click the Edit Notes button to note an information
	Click the Undo button to cancel the last action
	Click the Redo button to reverse the last Undo. Used only after Undo.
	Click the Switch to MRP mode button to
	Click the Switch to PANO mode button to edit or trace the panoramic reconstruction curve
	Click the Open Slice button to open the Rotating Slice Window
	Click the Reset Views button to reset view settings to default
	Click the Take Snapshot button to take a snapshot

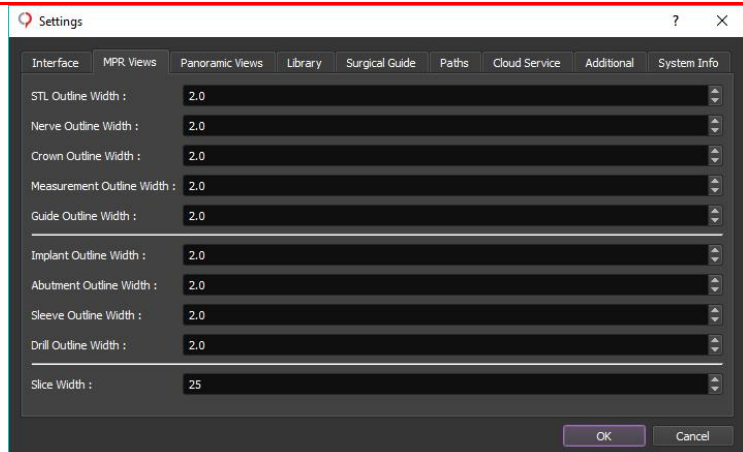
	Click the Measure Distance button to perform distance measurement
	Click the Measure Angle button to perform angular measurement
	Click the Purchase Exports button to order and purchase the export packages
	Regular and Time-limited exports balance
	Help button opens app-specific help sections or links when clicked
	Click the Settings button to open the Settings Menu
	Click the Order Form button to fill out the digital order form
	Click the Quick Pass button to send the current project to previously specified email address

4.6.3 Settings Menu

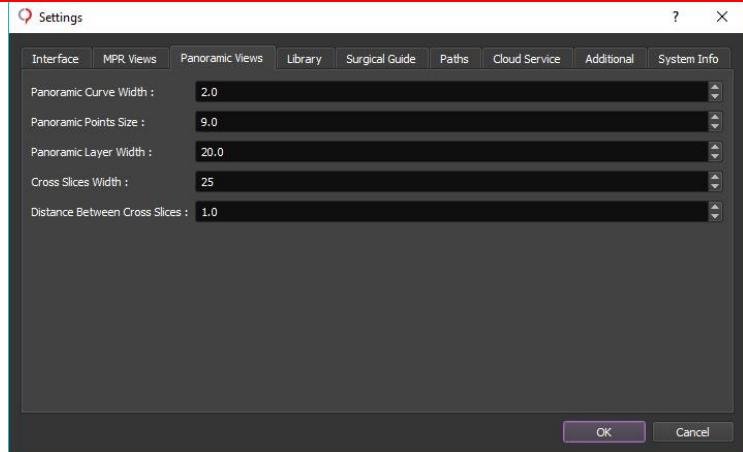
This menu allows setting the preferences for the software.
The following settings can be set from this page:

Interface, language, and user settings There is an option to register a new user or delete current user When collision function is selected, the software checks the collisions of the objects automatically. If collision is detected, the triangular sign "Attention" will appear	
The implant's or pin's safety zone border intersects a nerve	
The implant's safety zone border intersects another implant	
The sleeve intersects a scan STL surface border	

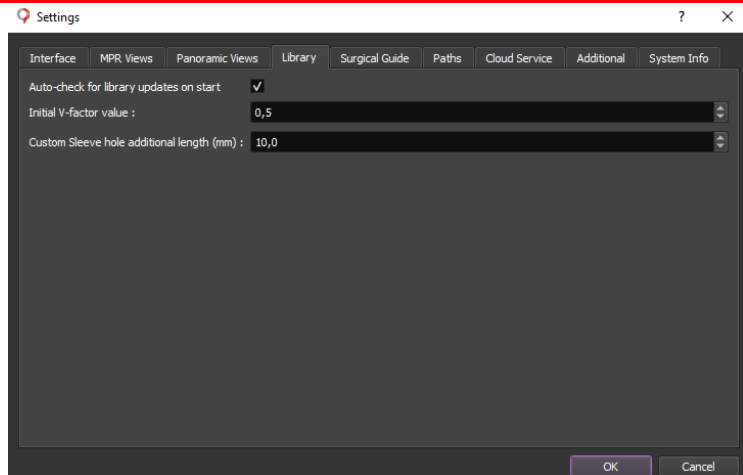
MPR View settings
Outline thickness and slice width adjustment



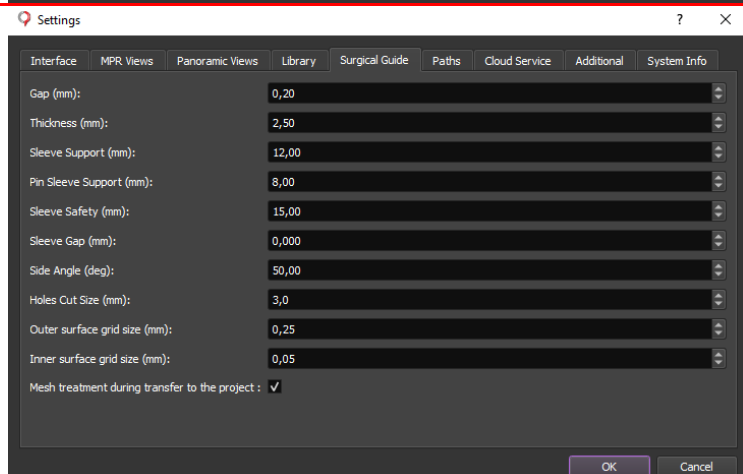
Panoramic View settings
Distance between cross slices adjustment



Library update and Initial V-factor settings



Surgical Guide settings
See chapter "Surgical Guide" for a more detailed explanation

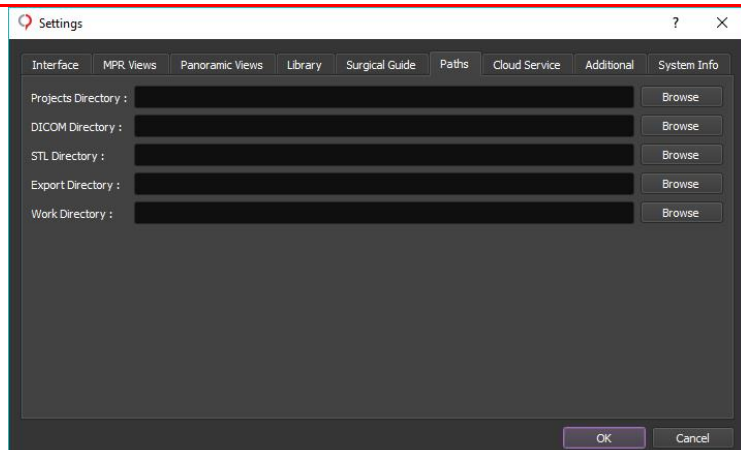


Paths settings

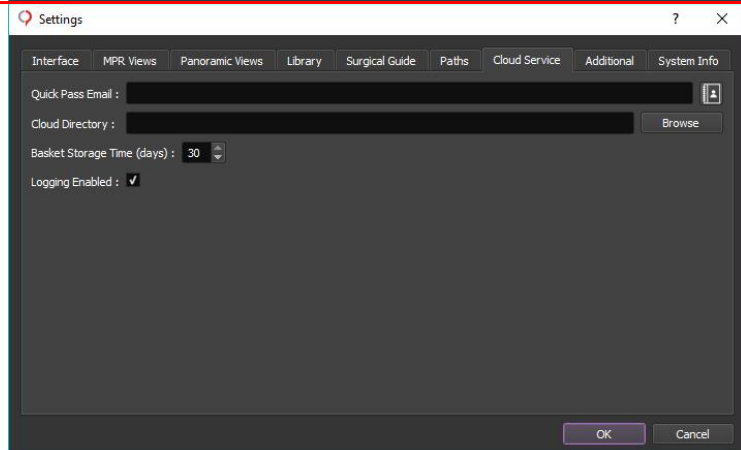
Specify the path for placing the library folder using the "Data Directory" tab.

For example:

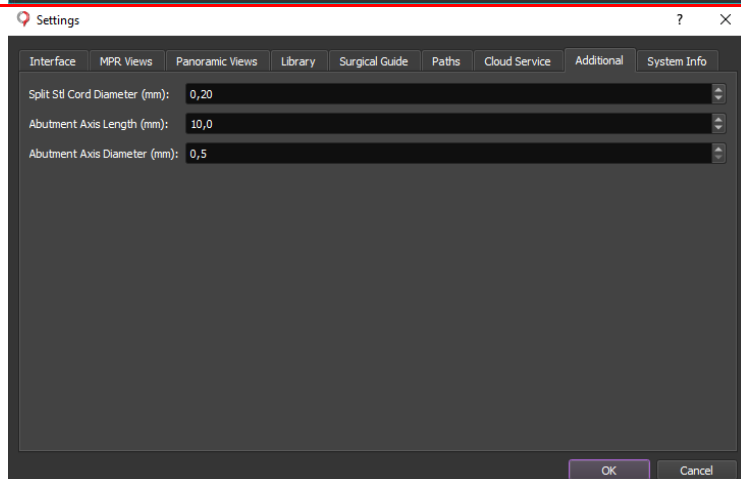
C:/Users/USERNAME/AppData/Roaming/ImplaStation



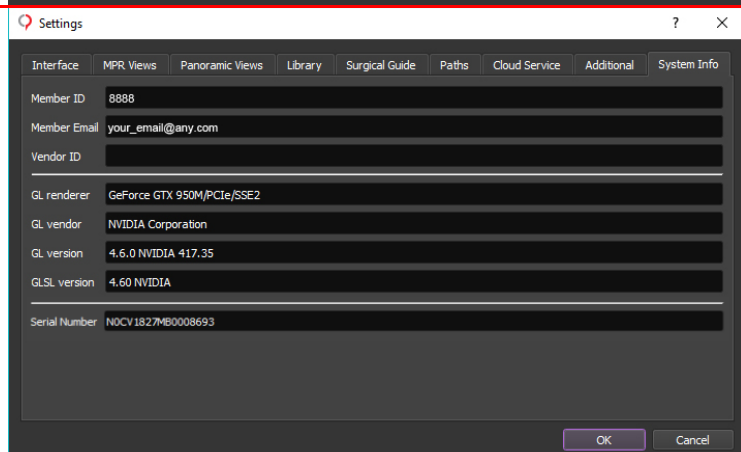
Cloud Service and Quick Pass Email settings



Additional settings



System and User Info (example)



4.6.4 Visualization Tools

	Click the button to enable or disable the visualization of the DICOM
	Click the button to enable or disable the visualization of the STL surface
	Click the button to enable or disable the visualization of the Nerve Tracing
	Click the button to enable or disable the visualization of the Crown
	Click the button to enable or disable the visualization of the Digital Implant
	Click the button to enable or disable the visualization of the Measurements
	Click the button to enable or disable the visualization of the Surgical Guide
	Click the button to enable or disable the visualization of the Axis
	Click the button to enable or disable the visualization of the Patient Data

4.6.5 Tab Panel

Tab panel helps users navigate through the patient's case

	DICOM management
	STL surface management
	Nerve tracing
	Crown design
	Digital Implant, Sleeve, Drill, Abutment management
	Anchor Pin management
	Surgical Guide design

5. INPUT DATA (DICOM)

The **first step** of the planning process is to upload a CT/CBCT dataset of the patient. The software does not modify or compress the input DICOM data during their upload, usage or export. **DICOM Conformance Statement for ImplaStation** is available for download here: <https://implastation.com/documents/upload/dicom-conformance-statement.pdf>

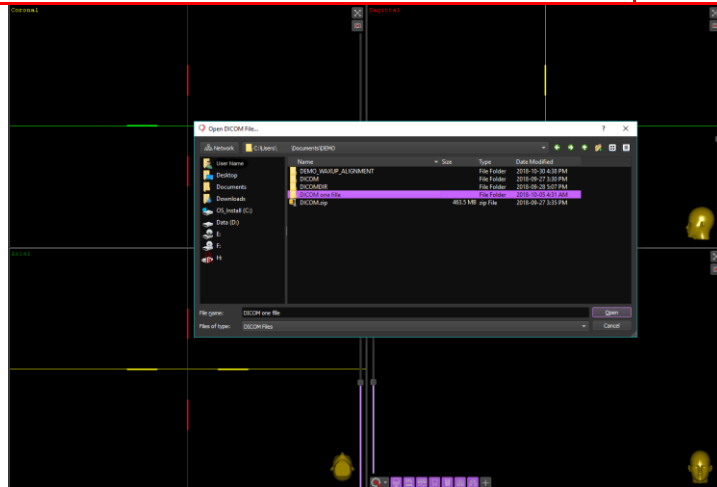
Click the **New Project / Load DICOM** button which is a way either to import a dataset from CD or import dataset from a selected source



In the appeared window to download data, select any object from the following:

- folder with DICOM Data
- multi-slice DICOM file
- single-slice DICOM file, one from the set
- DICOMDIR file

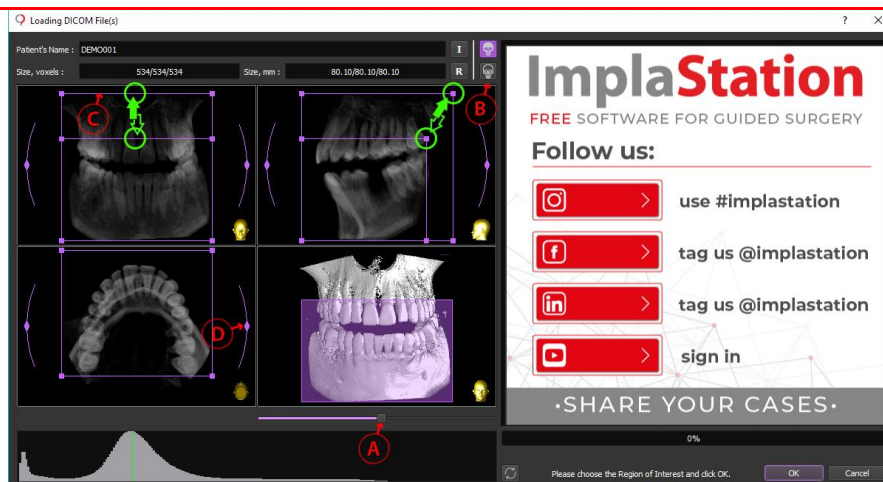
Then click on **"Open"**



To see DICOM-files without extension choose "All files" option.

Ensure to select the correct study and series by comparing them with the patient name in the CT/CBCT data selection dialog. After you have uploaded the relevant dataset, it is displayed in the processing window.

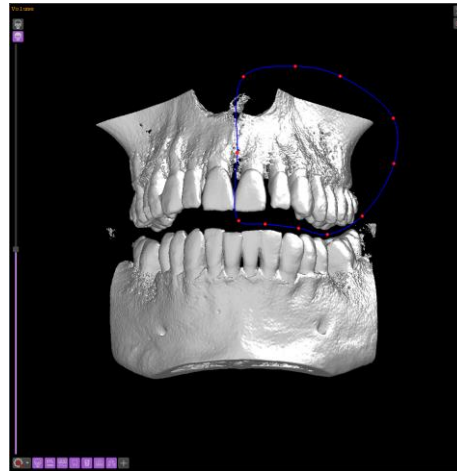
To adjust the visualization of the uploaded CT/CBCT dataset drag the corresponding slider to adjust the image opacity threshold **(A)**, switch between **MIP** mode (Maximum Intensity Projection) and **ISO** mode (Isosurface) **(B)**. With the cropping tool, remove disturbing or unrelated parts of the CBCT/CT scan by left-clicking, holding and dragging the purple cropping box inside the windows and area outside the box will be deleted **(C)**. In case of DICOM is displayed with an incorrect orientation upside down, turn it so that the Maxilla is on top and the Mandible is on the bottom using rotation slider **(D)**. Then click **"OK"**.



5.1 DICOM "Cutting"

The 3D and 2D visualization of the CT/CBCT scan of the patient may be "cut off" by an overlay of the dark mask on a selected area of the DICOM. Created masks can be turned on and off to hide and display fragments of CT/CBCT. This feature is most in demand for working with 3D rendering.

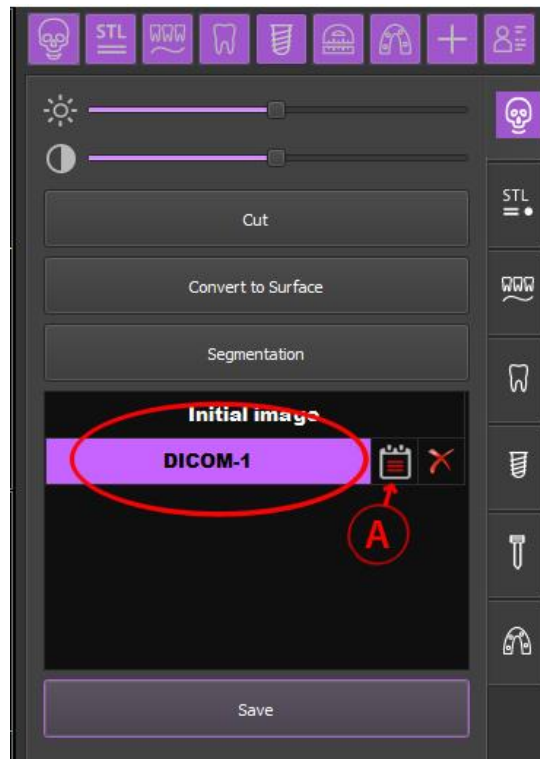
Optionally maximize the "Volume" window. Setup the 3D image position. Click on the **"Cut"** button in DICOM directory in the right part of the screen. To identify the area on which the DICOM mask is going to be cut. Draw the borderline by placing points one after another around the cutting area. Continue to draw the curve that goes back to the starting points and then double-click to finish selection.



Then either click on the **"Cut inside selected area"** button to cut inside or click on **"Cut outside selected area"** button to "cut" outside.



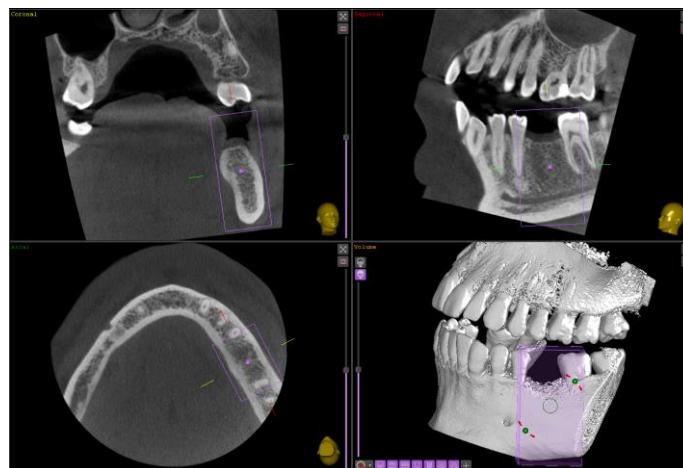
Press the **"Save"** button to save the created DICOM mask and mask name will appear in the list in DICOM directory on the right part of the screen. Optionally, it is possible to change the name of the saved DICOM mask by pressing the "Edit Title" button **(A)**. During the design process choose any saved DICOM mask by left-clicking on it.



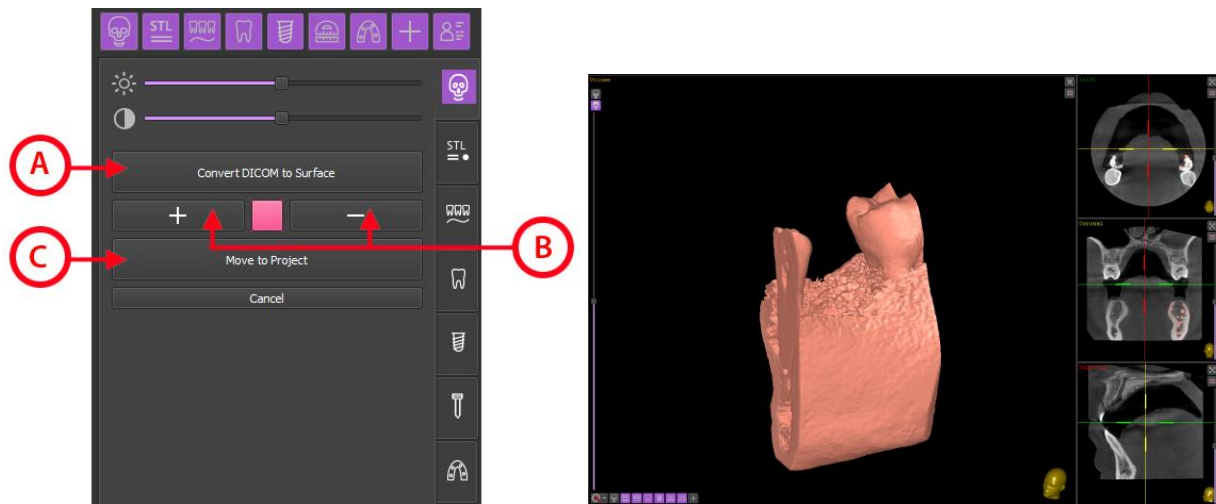
5.2 DICOM to STL Conversion

Click on the "**Convert to Surface**" button to start the conversion process of the DICOM file to STL surface. Adjust 3D rendering threshold by clicking "+" and "-" buttons (**B**) (see next page).

Adjust the size and position of the working area which is outlined by a purple line. Expand or compress the working area by left-clicking, holding and dragging the purple converting box of the working area. To rotate the whole working area left-click, hold and drag the red, yellow and green marks. To move the whole working area left-click, hold and drag the square located at the central part of the converting box.



Click on the "**Convert DICOM to Surface**" (**A**) button and If everything is OK click on (**C**) "**Move to Project**" button.

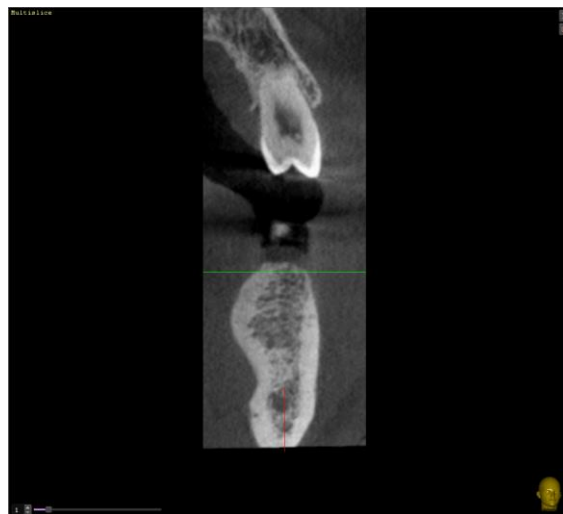


Note! The final view of the converted surface depends on the pre-adjusted 3D-rendering threshold

5.3 DICOM Segmentation

The "**Segmentation**" tool can be used in panoramic mode for bone segmentation (cross-sectional view), and in MPR mode (axial view) for segmentation of bones and teeth. The Segmentation tool is intended for slice reconstruction of the segmented area. Each slice can be edited manually.

Switch on the "**PANO mode**", set up the panoramic curve and adjust the view of the working cross-sectional area in Multislice window.



This example of using "Segmentation" is one possibility, among many. Click on the "**Segmentation**" button to start the segmentation process of the DICOM file. Setup the brightness and contrast. Unmark the "**Use mask**" checkbox.

Adjust the size and position of the working area which is outlined by a purple line. Expand or compress the working area by left-clicking, holding and dragging the squares located at the corners of the working area, or just move the whole working area left-clicking, holding and moving the square located at the central part.

Click on "**Receive segment**" button. The appeared green contour in Multislice window outlines the structures of the patient CBCT scan to be segmented.

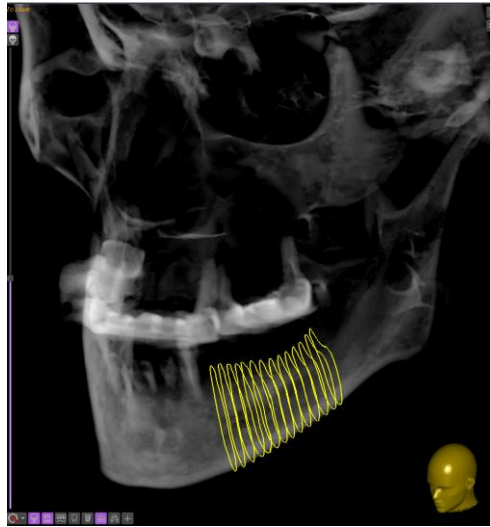


There are two ways how to draw or adjust the boundaries of the zone to be segmented. Place the round cursor into the green zone or outside the green zone, click and hold the left mouse button and the software automatically fill in or fill out the segmented area gradually oriented on the bone density.

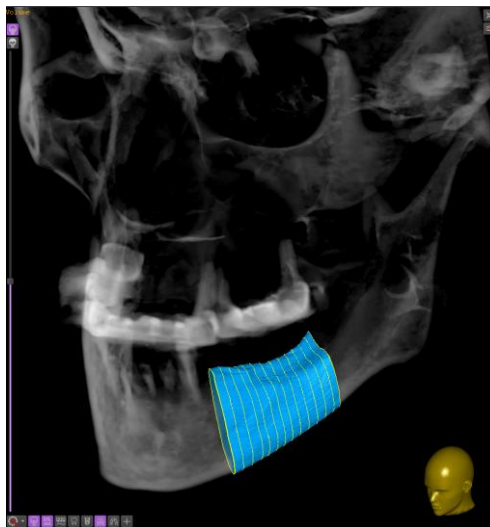
Or place the round cursor into the green zone or outside the green zone, click and hold the right mouse button and push off the borders of the segmented area manually. To maximize or minimize the size of the round cursor just scroll the mouse wheel forward or backward. Finalize the slice segmentation by left-clicking on any part of the Multislice window outside of the purple working zone. The green color of the segmented area will be changed to the yellow one.



To proceed with the next area to be segmented, just scroll the mouse wheel outside of the purple working zone and repeat the steps above.

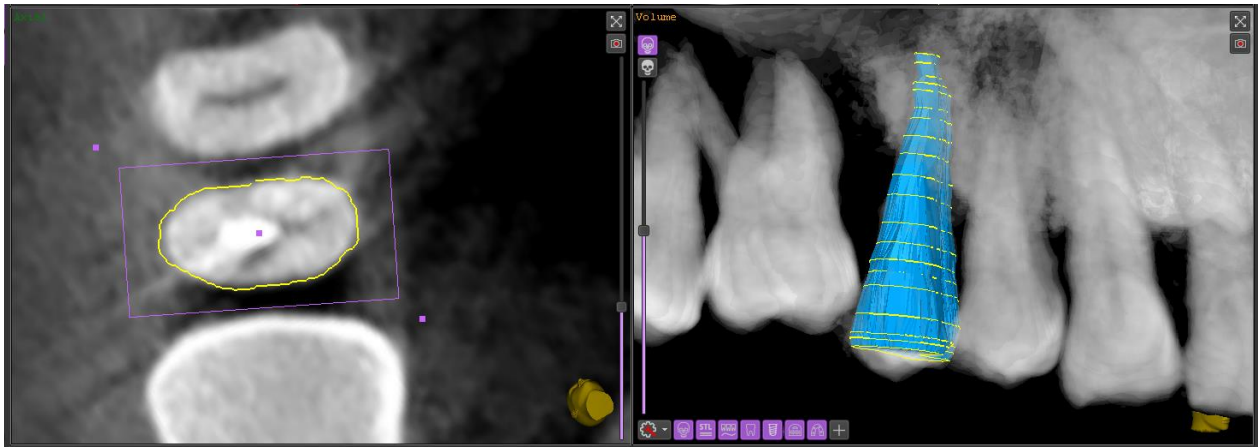


Step by step mark the entire volume of the required bone block. Press the **"Convert"** button to build a surface from selected contours. Check the result and save the segmented block into the project by clicking the **"Move to Project"** button.

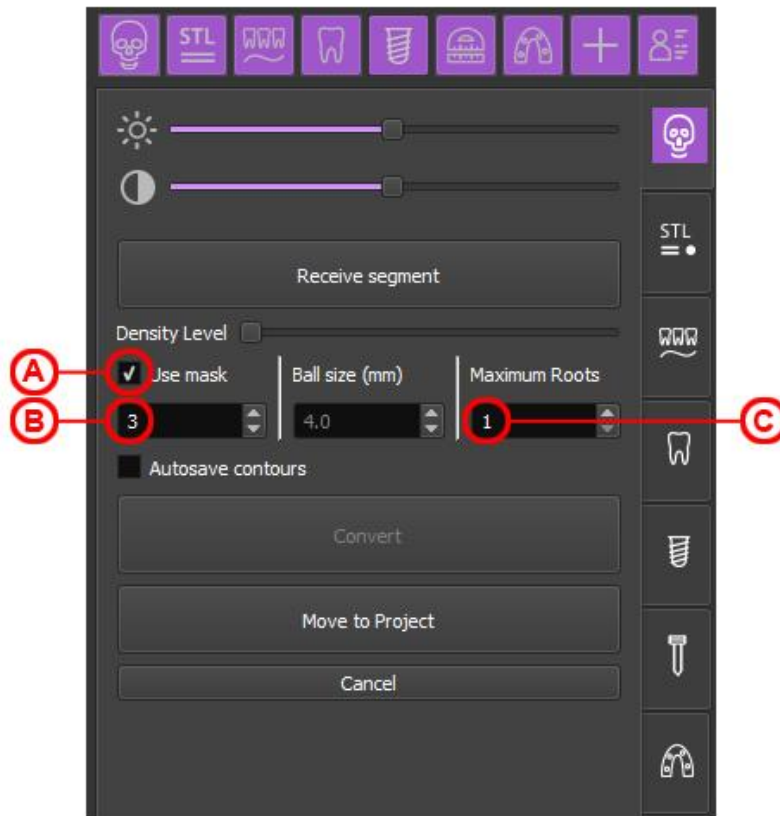


5.3.1 Options

The software allows you to segment DICOM using **"MPR mode"**. This option is most preferred for tooth segmentation. The difference with the method described above is that the process is carried out in the Axial window.



For the accurate and precise segmentation of the small structures such as a tooth and root(s) use the Mask mode. Mark the **"Use mask"** checkbox (A). This feature controls the contour size changes of the segmented zone within the value in pixels set by the user. For example, if the number of pixels in the corresponding window (B) is marked as 3, then the difference in the size of each subsequent zone will not exceed ± 3 pixels. To start tooth segmentation, mark the "Use mask" checkbox, choose the number of roots in the corresponding window (C) and proceed with the segmentation process described above.



6. INPUT DATA (STL)

Surface scans of the patient's mouth can be obtained from 3rd party intraoral scanner or any 3D lab scanner, provided in an open .stl or .obj format. Optionally you can scan the stone model of the patient jaw using CT/CBCT scanner and convert obtained DICOM file to STL surface (see APPEX B - Dual Scan Technique). The accuracy of the double scanning method is doubtful.

Click the **STL Surfaces** button in the tab panel on the right part of the screen.



Click on **"STL+"** button and select the patient STL file on your computer. Press OPEN and wait for it to finish loading.

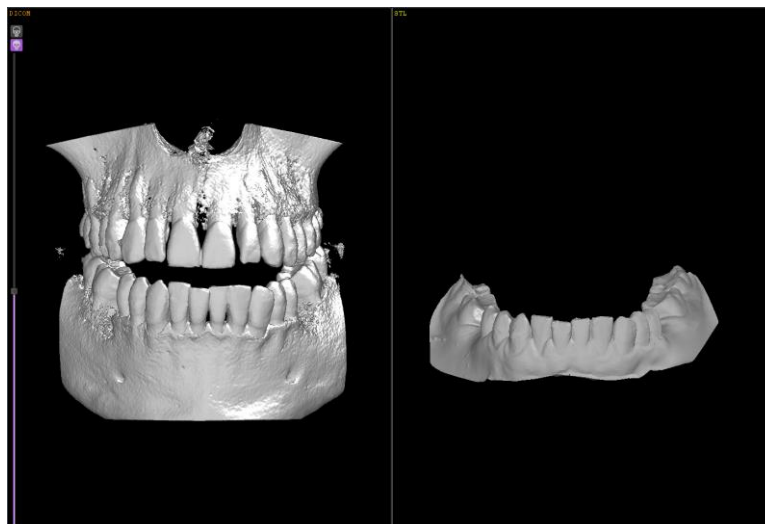
Note!

If the amount of triangles in an STL file is exceeding a threshold (400000 triangles on default. May be adjusted in the settings menu), the software would propose to reduce the number of triangles in the file

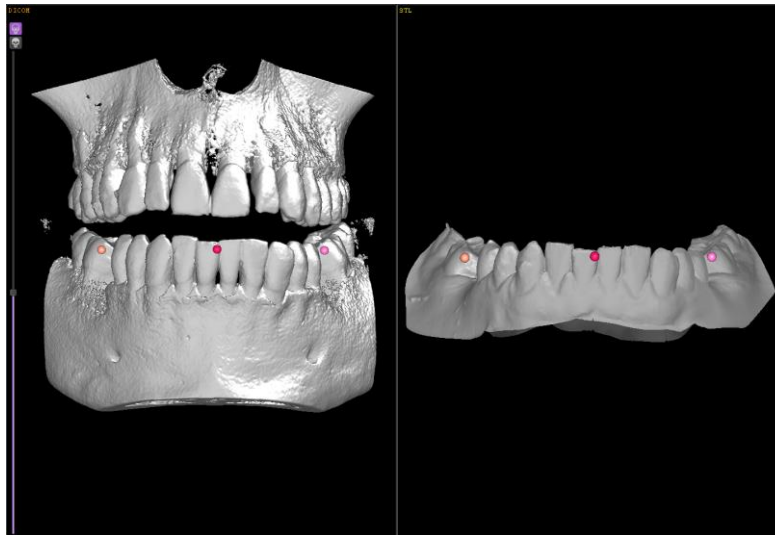
- Alignment.

Mark the **"Align to DICOM or to another STL file"** checkbox and press OK to start an alignment process. Or Mark either the **"Put to the center of coordinates"** checkbox to place the STL model at the center of coordinates, or mark **"Put to original coordinates"** checkbox to place STL model at the original coordinates. The "Put to original coordinates" is the most convenient mode to import several STL surfaces previously mapped together in the third-party CAD programs.

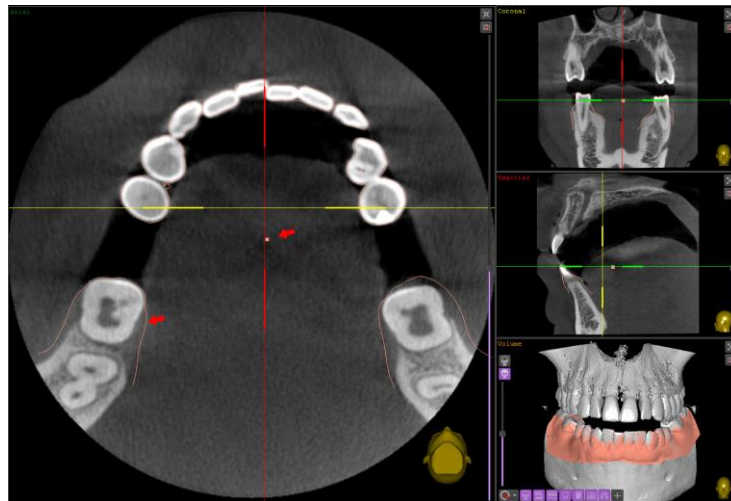
Mark the **"Align to DICOM or to another STL file"** checkbox and press OK. Bring the two images into view so that they are similar.



Pick a point on DICOM surface as a landmark by left-clicking, then click a point on the corresponding region of the STL surface. Select at least 3 equal regions and click on the **"Align to selected object"** button.



To adjust alignment manually, click on STL surface center (the square point which is marked in color of corresponding STL surface) and drag it or click on the STL surface borderline and tilt it.



- Click on the **"Group"** button in the Tab Panel on the right part of the screen and select two or more STL file in the appeared window to group them for further design and alignment and press "OK".

The main purpose of this feature is an ability to move selected and grouped up STL objects together. The mutual position of the grouped up STL surfaces remains unchanged.

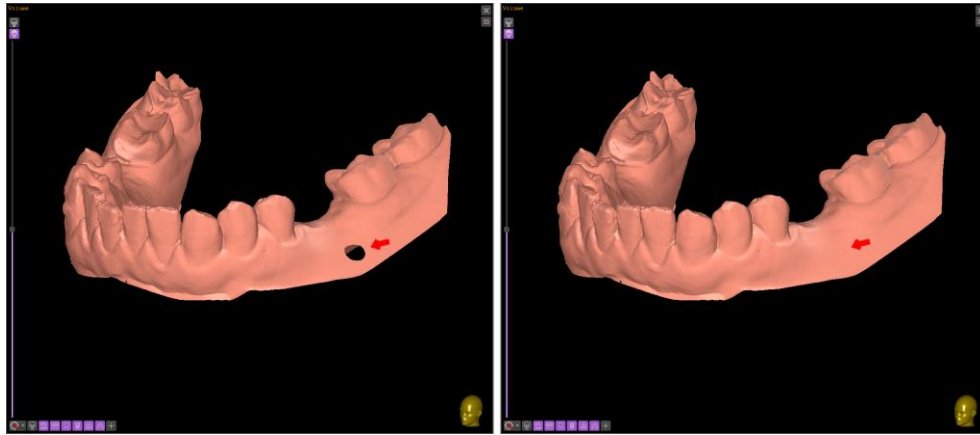
- To realign STL files or STL and DICOM files press on **"Align"** button.

- Click on **"Fix"** button to repair STL file.

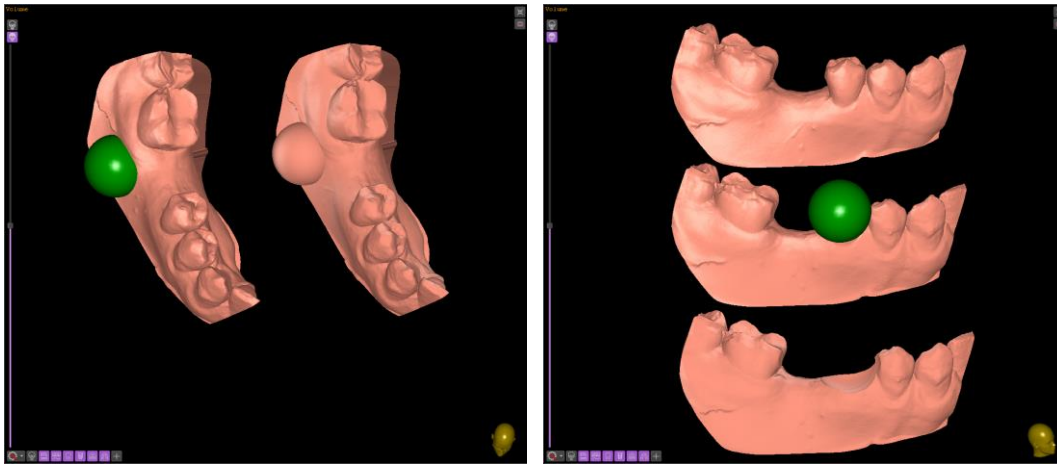
This feature enables the software to analyze STL files automatically and repair the various defects in 3D meshes, such as holes, self-intersections.

In case you are not satisfied with the result, you may try to fix the STL file again by clicking the "Fix" button. But the upshot is you get the repaired file in an instant.

ATTENTION! Using this tool, unclosed surfaces can be closed if no errors are found



- To export STL file choose the STL file to be saved in the list of STL mode, then click on **"Export"** button. In appeared window either press "OK", or select additional objects (Implant(s)/Pin(s), Abutments, Sleeve(s), Drill(s))to be combined and saved with STL file), then press "OK". **Please be advised your account will be charged for one export.**
- To reduce the number of triangles in the STL file mesh, in other words, to simplify the file, click on the **"Edit"** tab, then on the **"Simplify"** button.
- To split STL, click on **"Split"** button in **"Edit"** submenu and draw the split line, then click on "Split Surface" button and add the SLT file to the project clicking **"Keep BLUE surface"** button to save blue-colored surface to the project, or click on **"Keep RED surface"** button to save red-colored surface to the project.
- Click on **"Edit"** button, then choose the **"Remesh/Change"** line, then click on the **"Spheres"** button to open a menu. Define the planning area by setting the green sphere in the center of the planning zone either using the MPR view or the 3D view. The center of the sphere glides over the STL surface in a 3D rendering view. Once the planning zone is defined, adjust the size of the sphere by scrolling the mouse wheel.
The sphere can be used for both purposes - to add "tissue" to the STL surface by clicking the left mouse button or to remove the corresponding selected part of the STL surface by clicking the right mouse button.

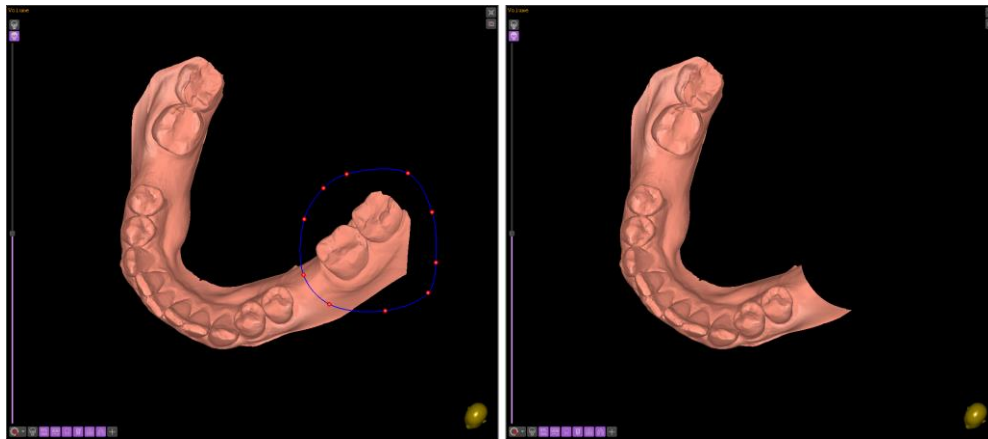


There is an option to press and drag the cursor to draw a strip of spheres. If necessary, after drawing apply function "**smoothing**".

Note!

Most of the STL surfaces can be split, but small defects such as through holes can trip up the split process

- To cut the STL file, maximize the "Volume" window. Setup the STL surface position. Click on "**Edit**" button, then click the "**Cut**" button. To identify the area on which the STL surface is going to be cut. Draw the borderline by placing points one after another around the cutting area. Continue to draw the curve that goes back to the starting points and then double-click on this line. Or use a round or square frame with a variable size to highlight the desired cut-off area. Then click on the "Cut Inside" or "Cut Outside" button.

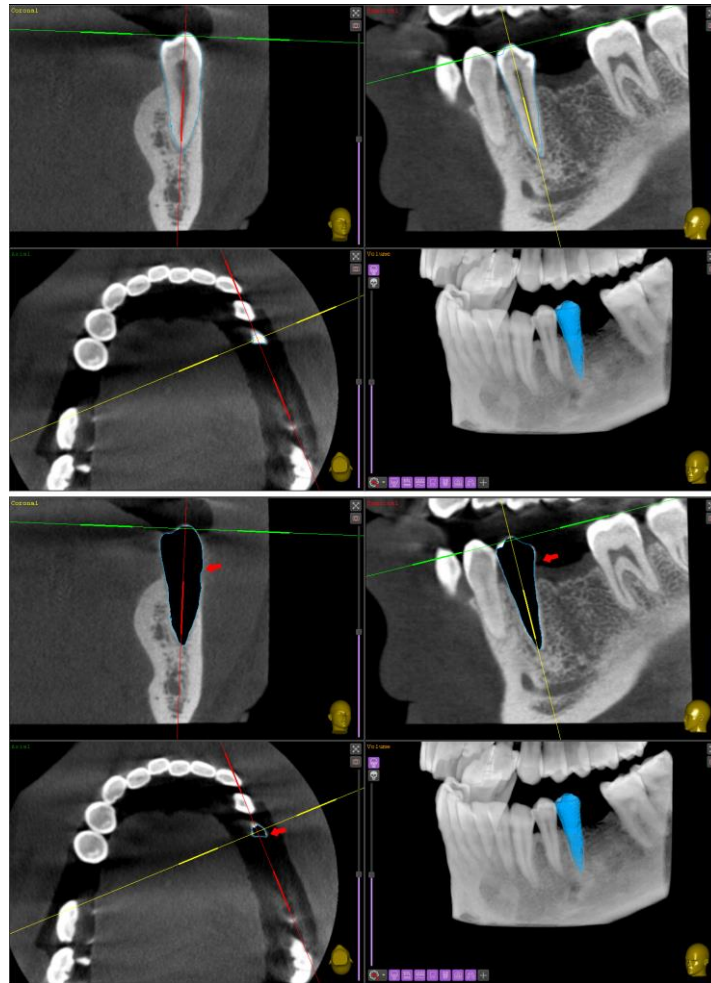


Note!

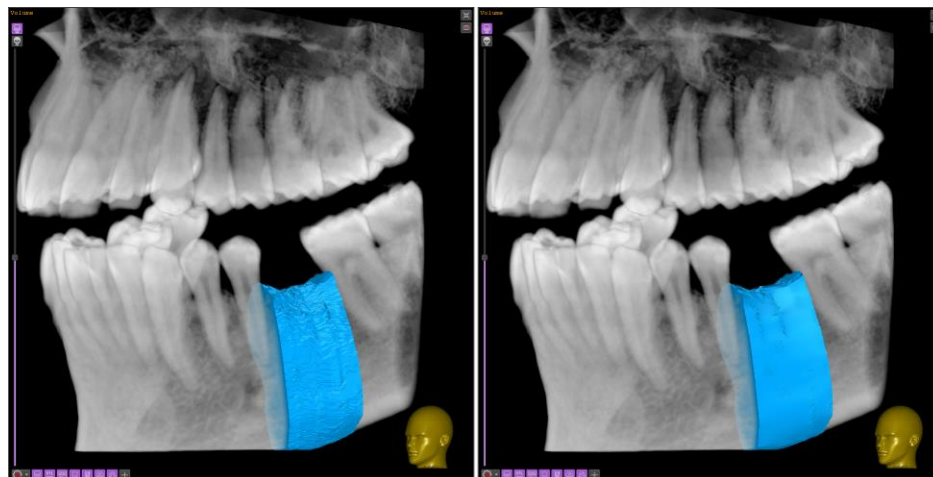
The direction of the cutting is perpendicular to the plane of the screen

- To invert the working surface of the STL file, choose the STL file to be inverted in the list, and then click on "**Edit**" button, then click the "**Invert**" button.
- To "remove" (actually the software makes a black mask) the STL volume from DICOM file, select the appropriate STL file, click on "**Edit**" button, then click the "**Delete**" button.

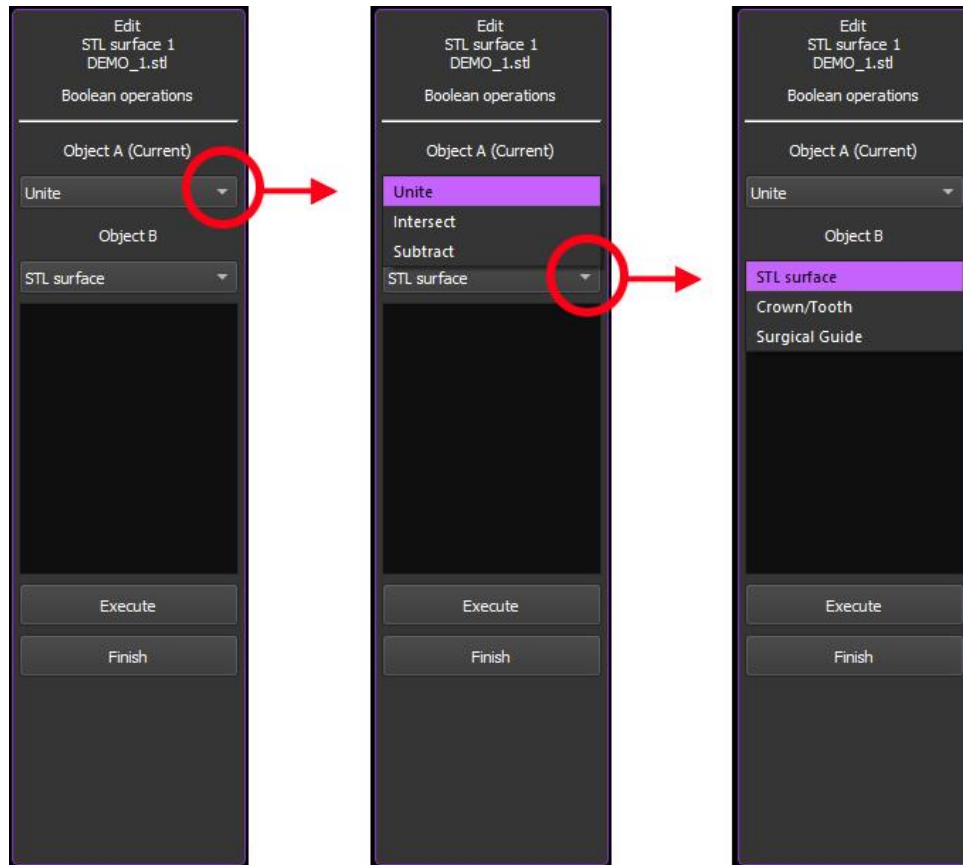
from DICOM" button and cut the volume bounded by the STL-surface from the DICOM image.



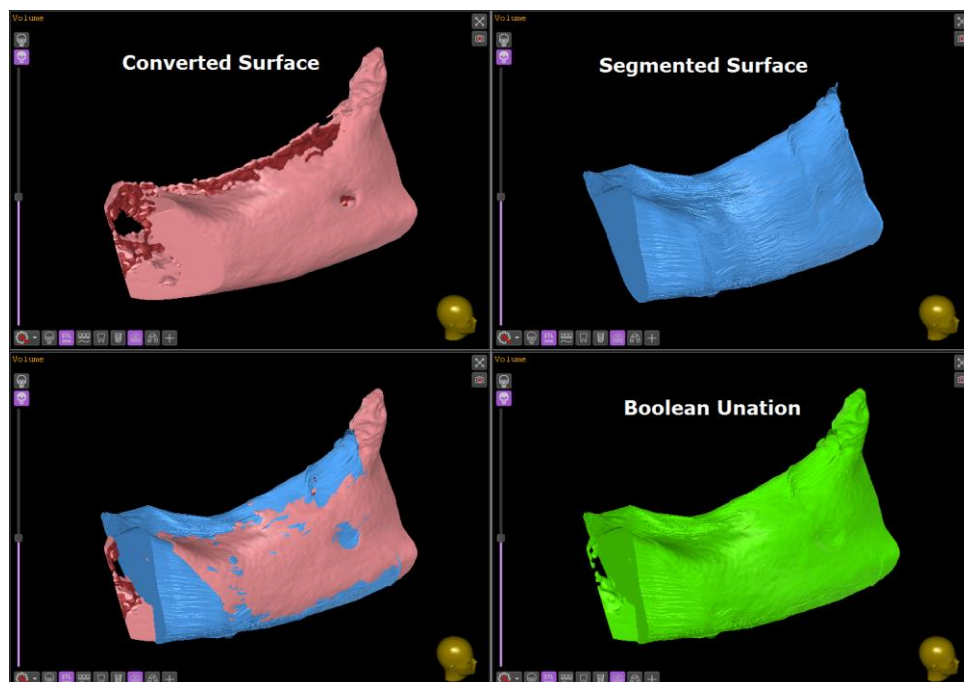
- To smooth segmented STL file (as well as any other preloaded STL) choose the STL file to be smoothed in the list of STL mode, and then click on "**Edit**" button, then choose the "**Remesh/Change**" line, then click on the "**Smooth**" button. It is assumed either to smooth the local part of the surface, using the green circle cursor. Smoothing intensity can be adjusted. Using "**Smooth all**" button smooth the entire surface.



- Click on "**Edit**" button, then click on the "**Boolean operations**" button and in the appeared window choose the type of Boolean operation: Unite, Intersect, Subtract. To merge Object A (current STL) and Object B (STL Surface, Crown/Tooth, Surgical Guide) press "**Execute**" button.

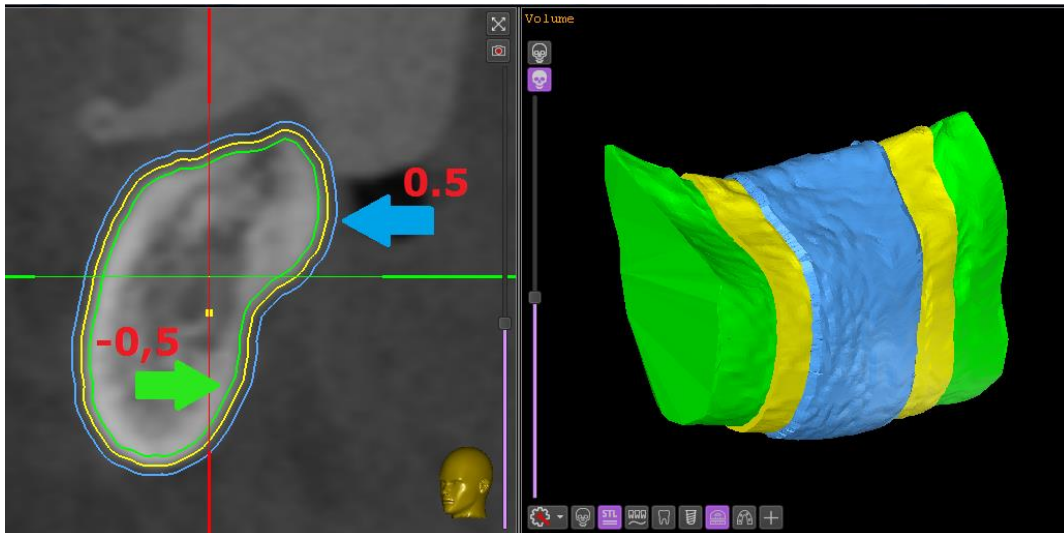
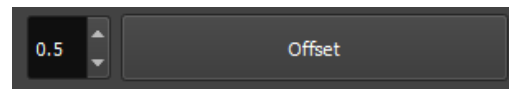


New STL surface will appear in the STL list.



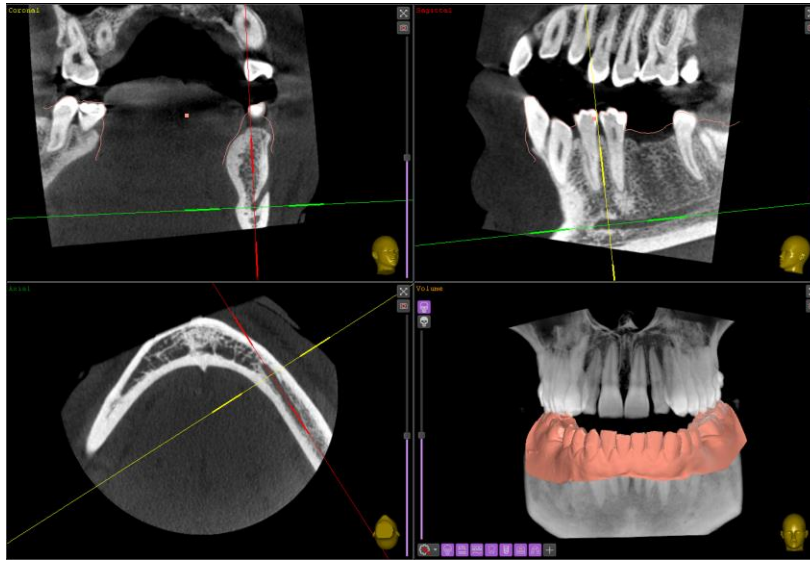
Note! Boolean operations are performed correctly only with “closed” surfaces

- To expand or shrink the surface by a certain value in millimeters, click on "**Edit**" button, then select the offset value in the window opposite the "**Offset**" button, then click on the button.



7. NERVE CANAL TRACING

Select MPR mode. Setup the slice planes to visualize nerve canal clearly in axial, cross-sectional and sagittal view.

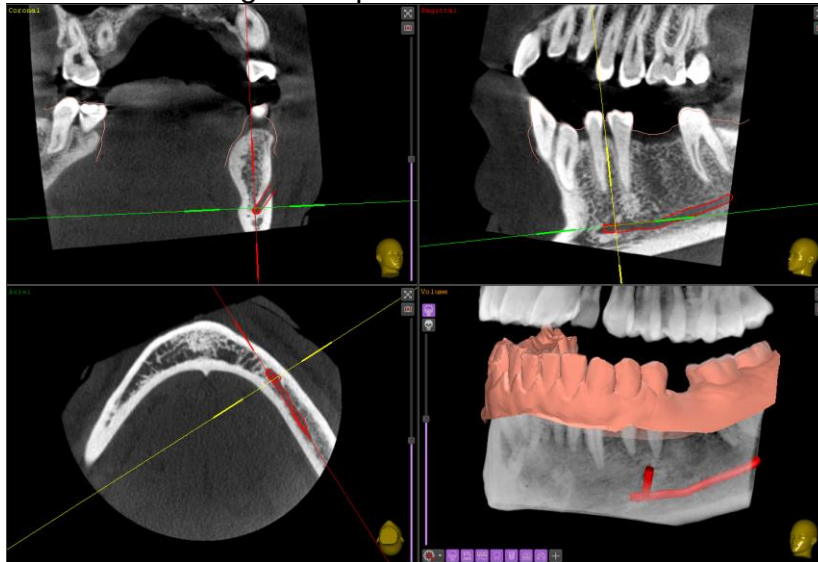


Click on "**Nerve**" button in the workflow panel on the right part of the screen



Click on "**Draw new Nerve**" button and cursor is going to be a red spot. Trace nerve canal using the left button of the mouse points one after another from frontal part to distal part in the Sagittal window.

Or trace the nerve canal by clicking and scrolling through the Cross-sectional view. Complete the operation either by double-clicking the left mouse button or by clicking the "**lock**" button in the nerve tracing menu panel.



Warning!

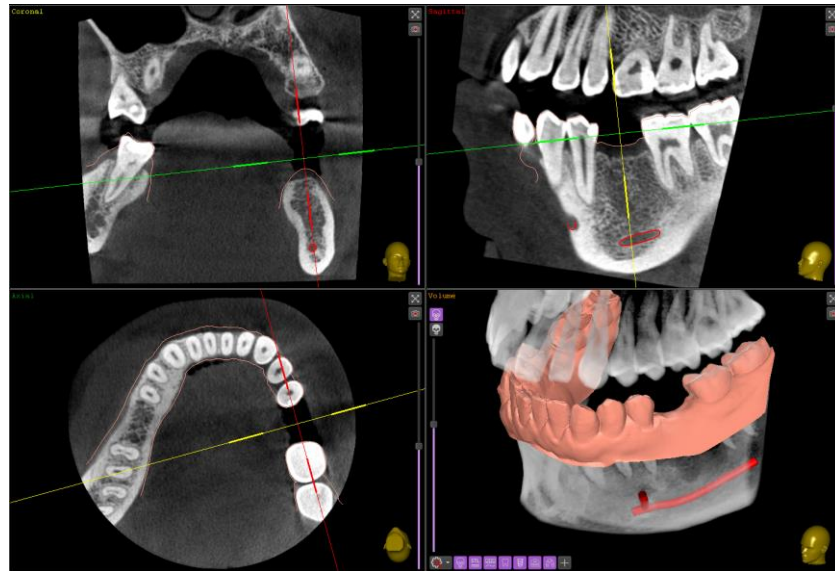
Make sure that the nerve is correctly traced. Always maintain an appropriate safety distance to the nerve canal

Warning!

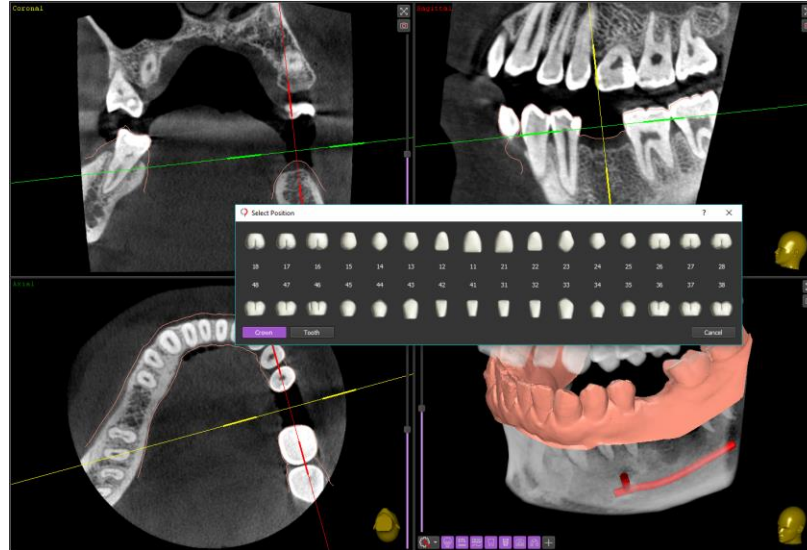
The pathway of imaged nerves is for display only, location accuracy of the traced nerve is not tested, and pathways of imaged nerves can not be used as sole information for the clinician to make clinical decisions

8. VIRTUAL CROWNS PLACEMENT

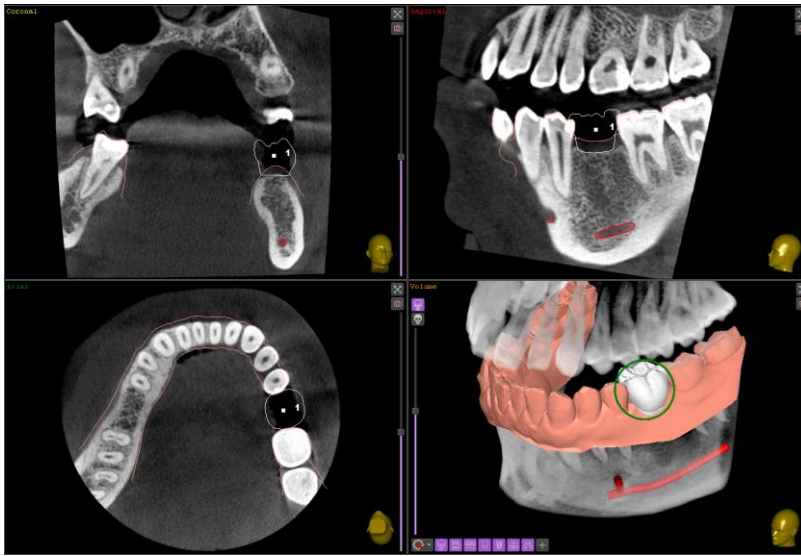
Select MPR mode. Set up the slice planes to visualize the tooth/teeth position to be planning in axial, cross-sectional and sagittal view.



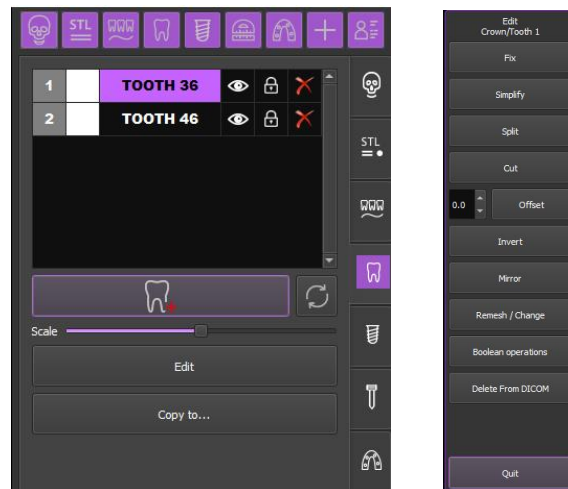
To add a virtual tooth click on **"Crown"** button in the workflow panel on the right part of the screen. Click on **"Place new Crown or Tooth"** button. In appeared **"Select Position"** window select the crown or tooth mode, click on the desired tooth in the virtual OPG, and the virtual crown or tooth is going to appear in the pre-set area.



To change the tooth position in axial, cross-sectional and sagittal view just click on and hold central square and drag it or click on and hold the line tilt it.



To change the size of the tooth/crown, use "Scale" slider below the "Place new Crown or Tooth" button. To edit a crown or tooth, press the "Edit" key, and in the window that appears, select the function to change. All the presented change functions are described in the STL chapter.



To change the tooth position in 3D mode, maximize the "Volume" window, click on the tooth. The green round line is going to appear. Left-click, hold and drag this green line to tilt the tooth. Right-click, hold and move the mouse forward to increase the tooth size or move the mouse back to decrease tooth size.



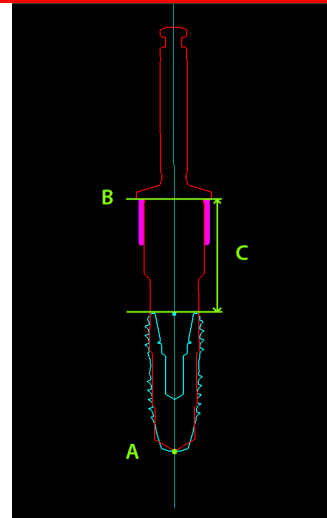
Click on "**Lock On/Off**" button in the "Crown" tab panel or go to the next step.

9. IMPLANT PLANNING

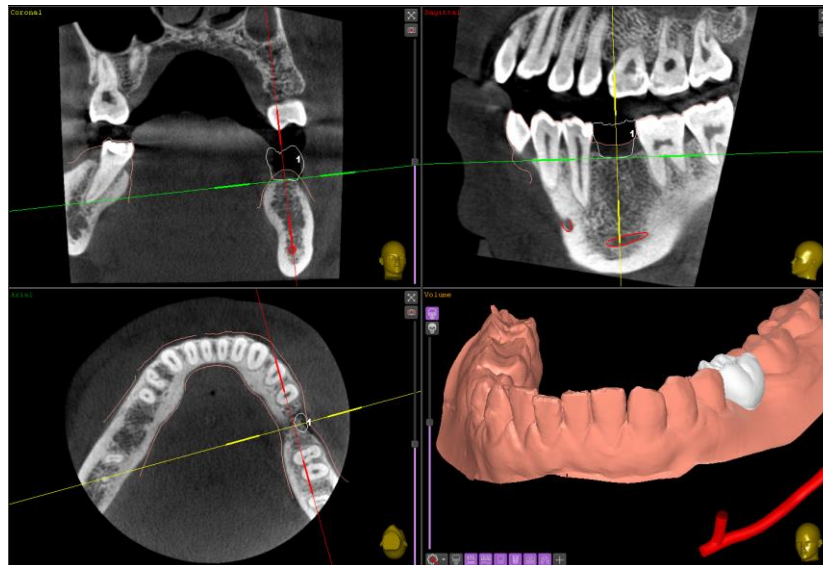
The software allows users to perform implant planning using Panoramic, MPR or Rotation Slice mode.

There is a concept, which software uses to calculate the position of every single element such as an implant, drill, and sleeve.

The general idea of the concept is the implant is the primary object. The drill tip is connected to the implant apex (**A**) and occlusal surface of the sleeve is connected with a drill stopper surface (**B**). And if the drill length is changed, the sleeve position will be changed equally increasing and decreasing sleeve offset (**C**)



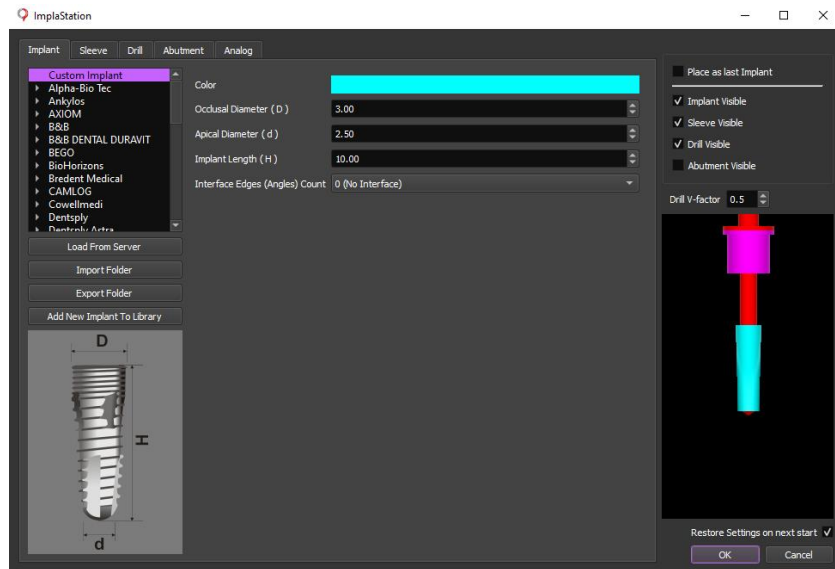
Select MPR mode. Set up the slice planes to visualize the further implant position to be planning in axial, cross-sectional and sagittal view.



To add a virtual implant click on **"Implant"** button in the workflow panel on the right part of the screen. Click on **"Place new Implant"** button and at the appeared window, choose the **"implant"**, **"sleeve"**, **"drill"** and **"abutment"** corresponding submenu by left-clicking.

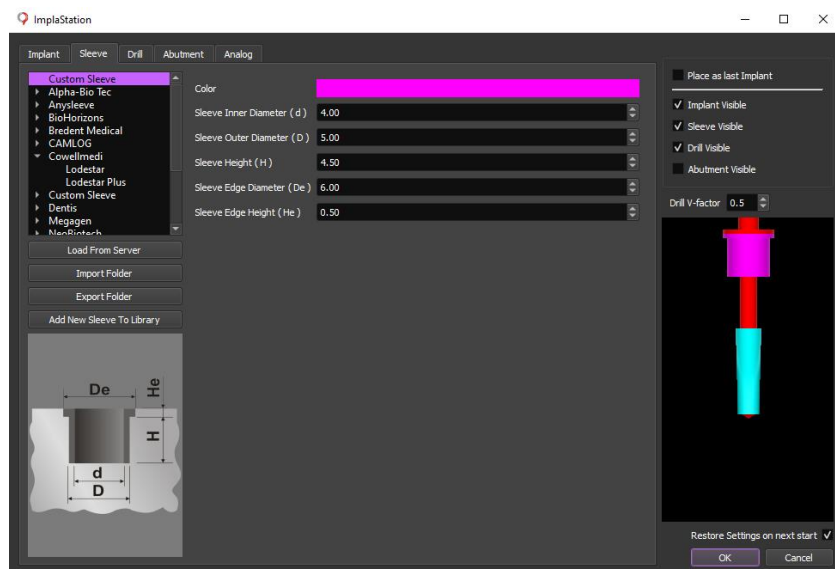
To place an implant that does not show up on the implant library list, click on the **"Implant"** submenu, select **"Custom Implant"** option, choose the implant color and enter relevant dimensions for **"Occlusal Diameter"** (D), **"Apical Diameter"** (d), **"Implant Length"** (H) and **"Interface Edges (Angles) Count"**. Mark the **"Place as a last Implant"** checkbox to save settings for the next implant(s) to be placed. To restore settings for the next start

of the software, mark the appropriate checkbox in the lower right of the submenu window.

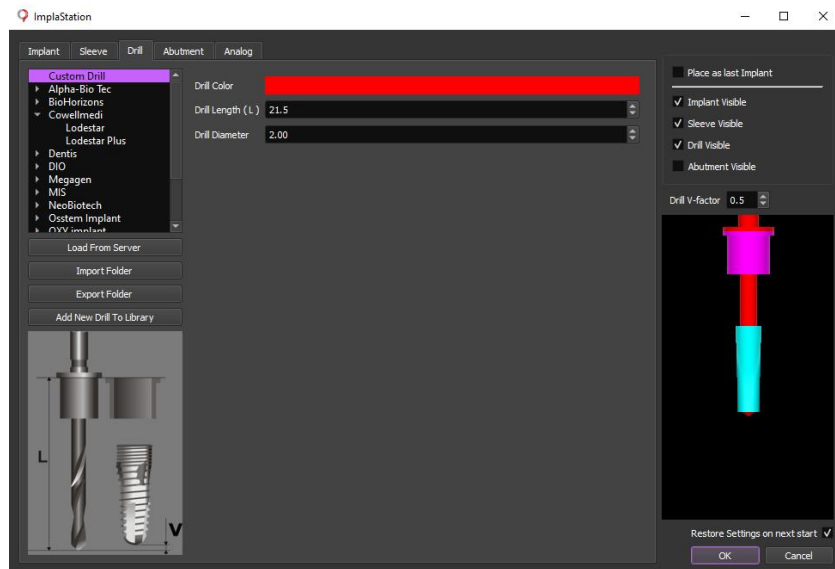


Add the V-factor depth by scrolling the mouse wheel, or writing the number, or by clicking on the arrows. Increasing or decreasing the value of the V-factor leads to the drill tip shifts down or shifts up relative to the implant apex.

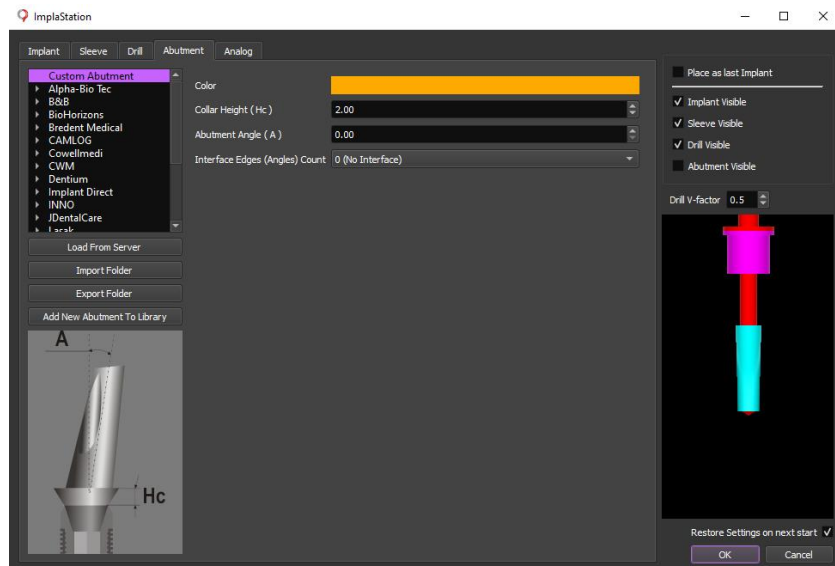
The same can be performed for custom sleeves. Click on the "Sleeve" submenu, select "Custom Sleeve" option, choose the sleeve color and enter required dimensions for "Sleeve Inner Diameter" (d), Sleeve Outer Diameter (D), Sleeve Height (H), Sleeve Edge Diameter (De), Sleeve Edge Height (He).



Custom Drills. Click on the "Drill" submenu, select "Custom Drill" option, choose the drill color and enter required dimensions for "Drill Length" (L), "Drill Diameter".

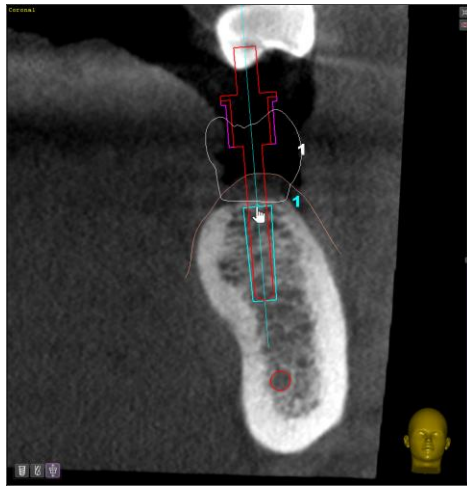


Click on the "Abutment" submenu, select "Custom Abutment" option, choose the abutment color and enter required dimensions for "Collar Height" (H_c), "Abutment Angle" (A).

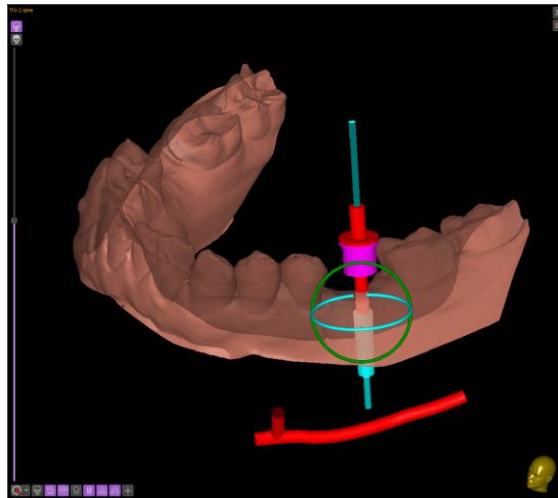


Press "OK" and select the tooth position.

To change the implant position in axial, cross-sectional and sagittal view just click on and hold square mark at the occlusal line of the implant and drag it, or click on and hold the contour line and tilt it.



To change the Implant position in 3D mode, maximize the "Volume" window, click on the implant. The green and blue round lines are going to appear. Left-click, hold and move this green line to tilt the implant. Left-click, hold and move the blue line to rotate the implant.

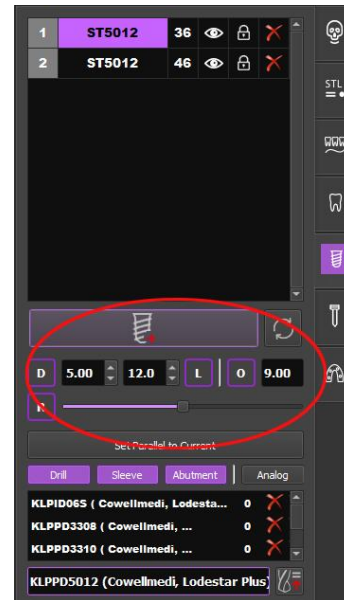


There are three ways to change the size and type of the Implant:

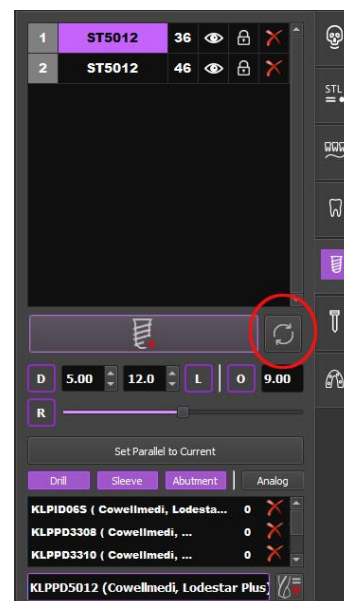
- Use the quick menu at the left lower corner of cross-sectional and sagittal windows. Click on "implant" sign, and change the implant diameter and length by clicking on the "+" or "-" sign. Click on "drill" sign and change the drill diameter and length by clicking on the "+" or "-" sign. Click on the "sleeve" sign to lock offset of the sleeve. Use the slider to rotate the implant around the central axis.



- Go to the menu below the "Place new Implant" button in the right part of the screen to change the size of the implant by clicking on the number and scrolling the mouse wheel, or writing the number into the appropriate windows, or using the arrows.



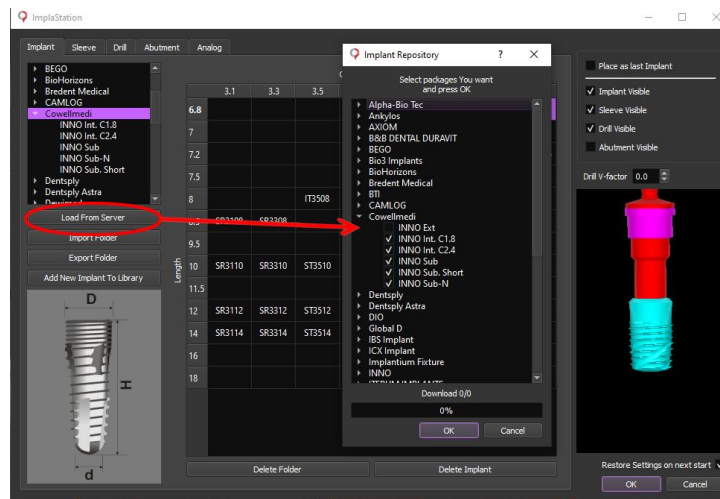
- Press on "Replace Implant" button and set the Implant, Drill, Sleeve, and Abutment settings up



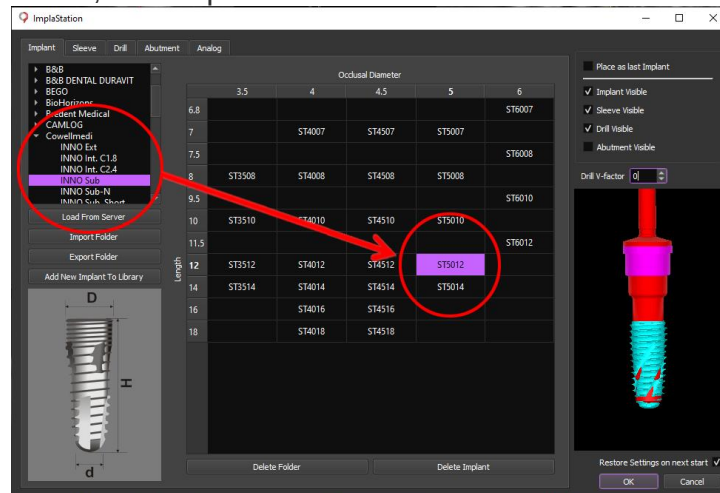
Click on "**Lock On/Off**" button in the "Implant" tab panel or go to the next step.

To load implant libraries from the server click on "**Replace Implant**" button and then click on the "**Load From Server**" button. In appeared window select the system of the implant by marking checkbox and press "**OK**" and the chosen library will be downloaded into the software Implant list.

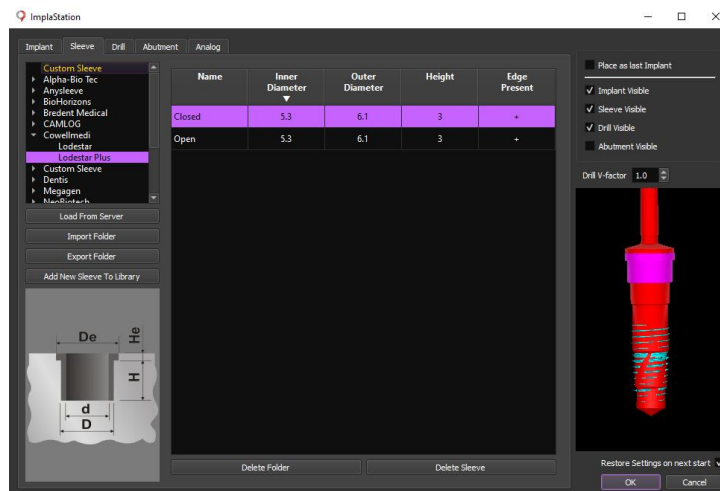
The same downloading procedure can be performed for drills, sleeves, and abutments libraries.



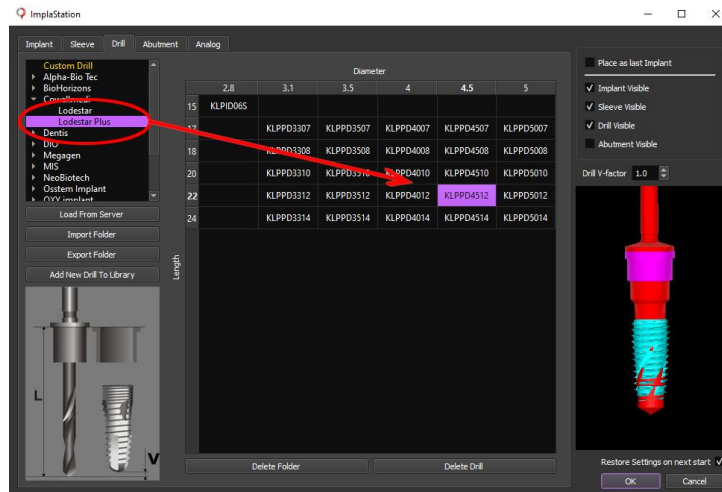
Now there is a possibility to use the implant, drill, sleeve, and abutment provided by manufacturer. (Be advised – some libraries created by backward engineering method)
To place preloaded elements click on the **"Place new Implant"** button or on the **"Replace Implant"** button, in the appeared menu choose the implant manufacturer name, implant line name, and implant size.



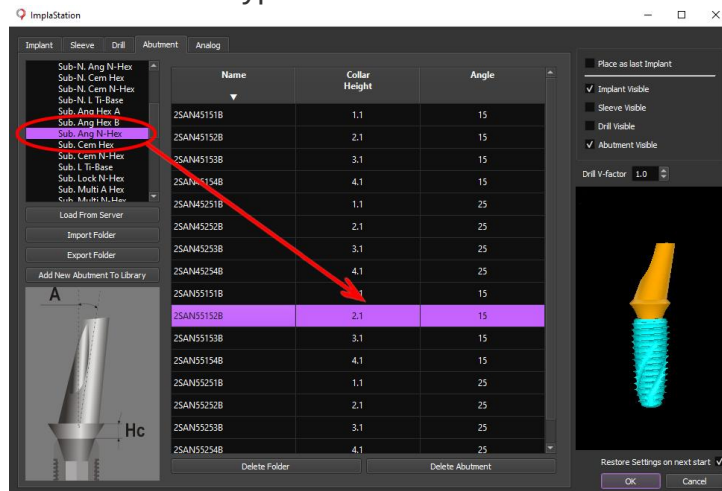
Click on the "Sleeve" submenu, choose the sleeve manufacturer name and sleeve line name.



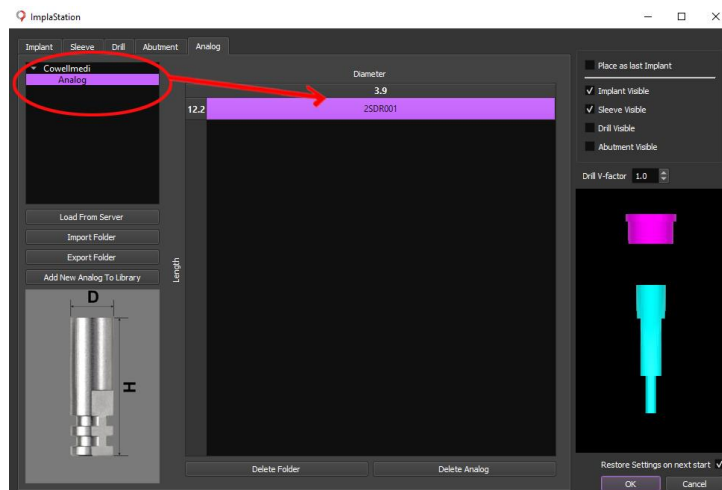
Click on the **"Drill"** submenu, choose the drill manufacturer name, drill line name, and drill size. Set up "V-factor" depth, then press "OK".



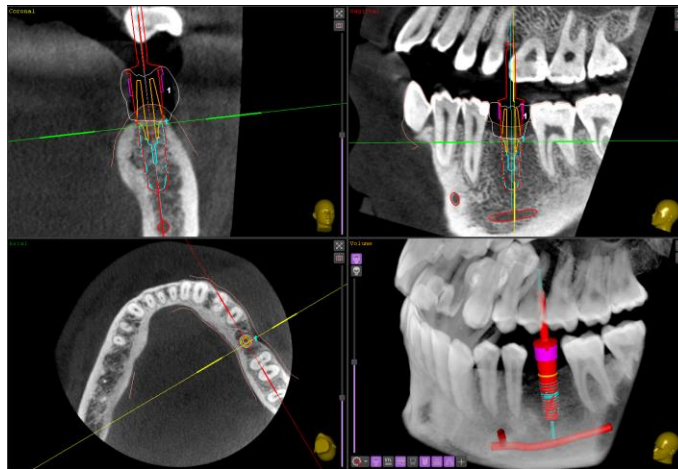
Click on the **"Abutment"** submenu, choose the abutment manufacturer name, abutment line name, and abutment size and type.



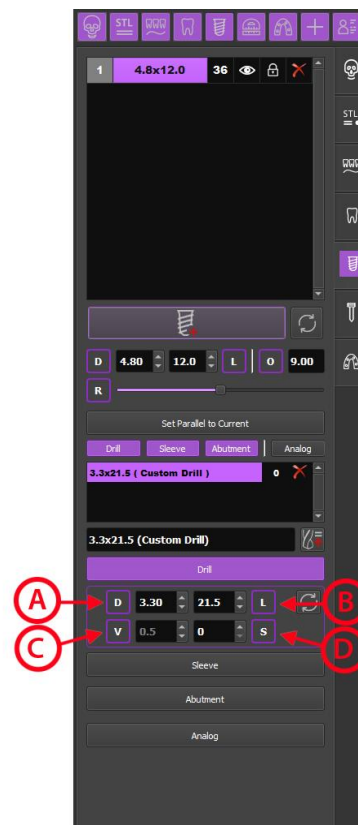
Click on the **"Analog"** submenu, choose the analog manufacturer name, analog line name, and analog size and type.



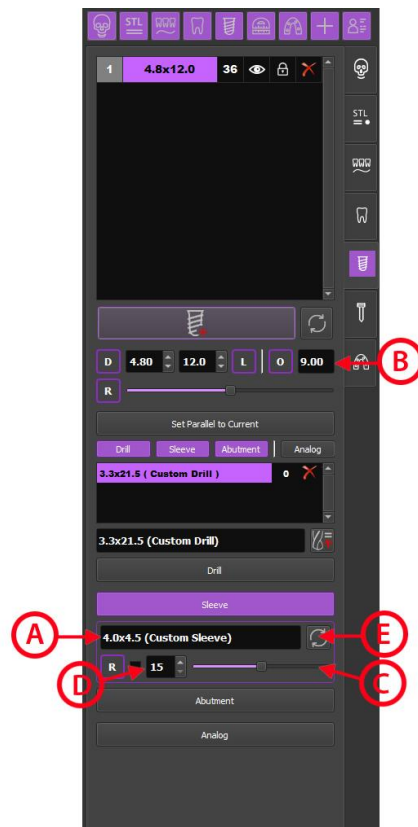
Check the implant position and press **"Add Drill"** to add a final drill to the drilling list.



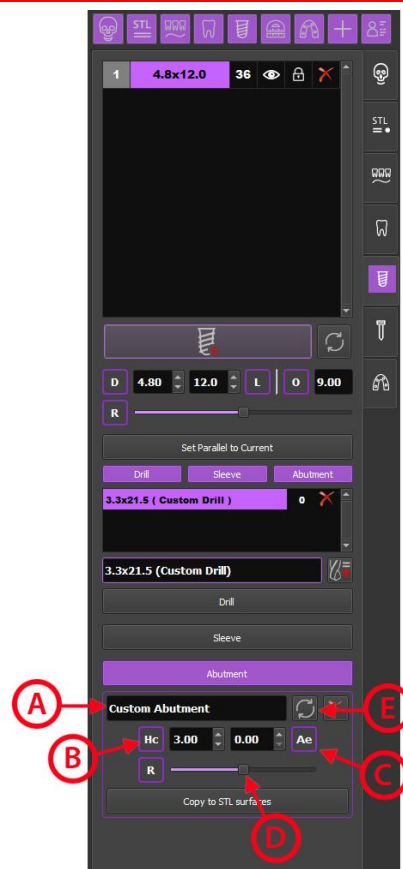
Click on **"Drill"** submenu in the right part of the screen and set up the drill diameter "D" (A), drill length "L" (B), drill V-factor (C), the drill spacer "S" (D) is an option to add the regulated space between stopper of the drill and contacted surface of the sleeve to change a position of the sleeve and decrease the sleeve offset during digital implant planning.



Click on the **"Sleeve"** submenu in the right part of the screen and check the name of the sleeve **(A)**, offset length "O" **(B)**. To rotate a sleeve click on the slider and drag it **(C)** to rotate a sleeve by an angle multiple of 15, 30, 60, 90 degrees, choose the rotation angle checkbox "R" and select one of the four options: 15, 30, 60, 90 **(D)**. To change the current sleeve, click on the "Replace Sleeve" button **(E)**.



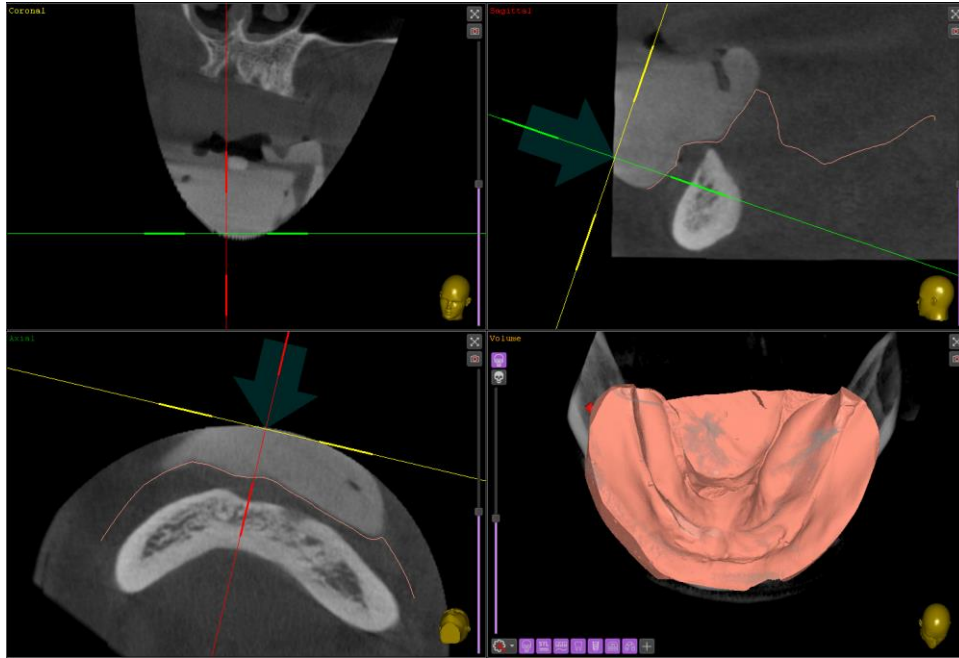
Click on the **"Abutment"** submenu in the right part of the screen and check the name of the abutment **(A)**, collar height "Hc" **(B)** and extension angle "Ae" **(C)**. To make a rotation of the abutment click on the slider and drag it **(D)**. To change the current abutment, click on the "Replace Abutment" button **(E)**.



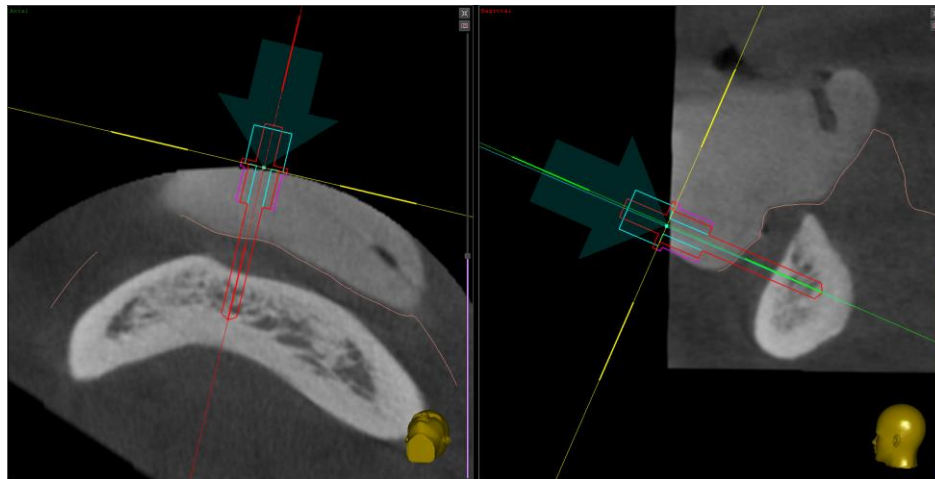
10. ANCHOR PIN PLANNING

The pin planning using Implastation has the same concept as an implant positioning.

Select **MPR** mode. Setup the slice planes to visualize the further pin position to be planning in axial, cross-sectional and sagittal view.

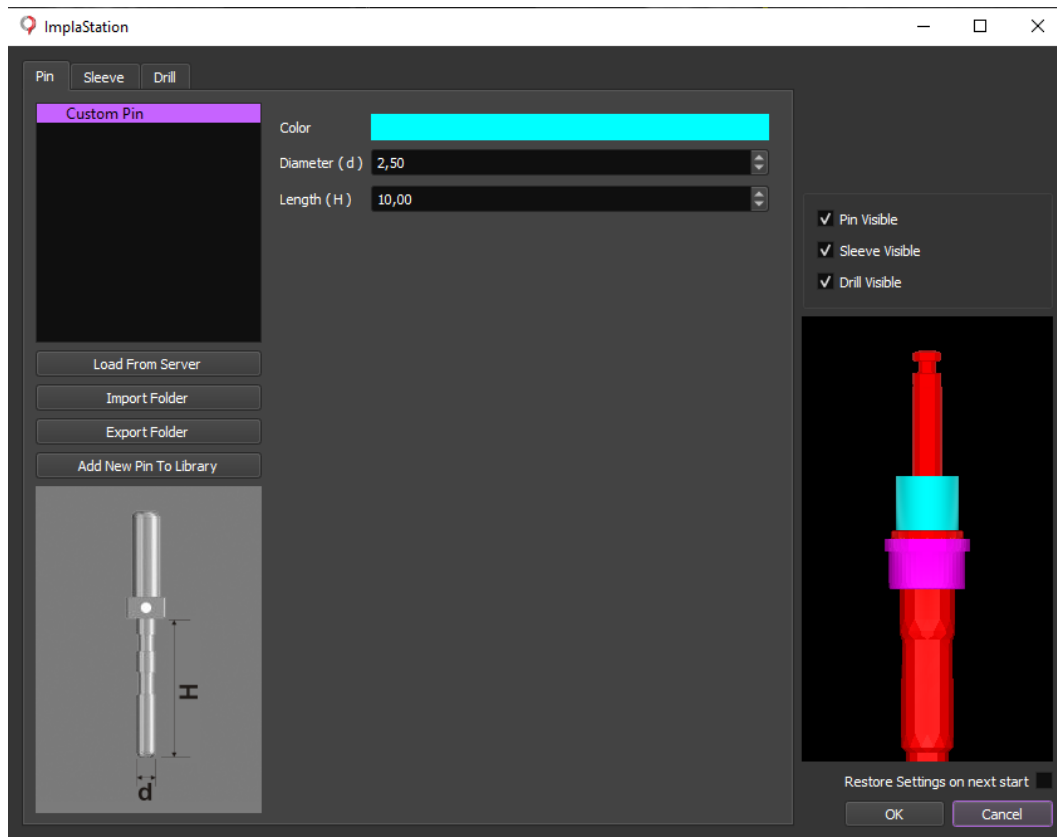


To add a virtual pin click on "**Pin**" button in the workflow panel on the right part of the screen. Green transparent arrow will appear in Axial and Sagittal windows in an aim to show the position and direction of the pin.



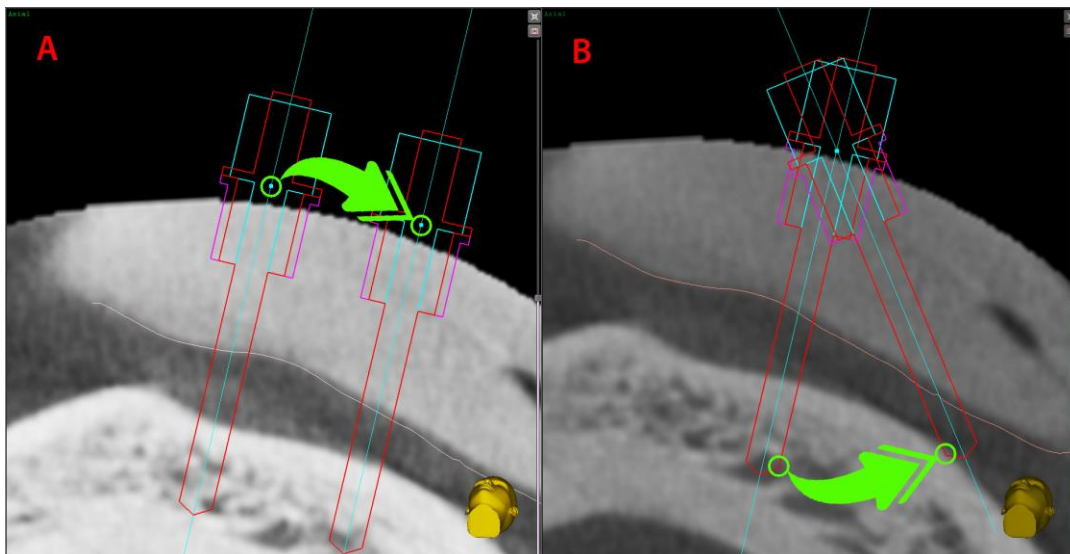
Click on "**Place new Pin**" button and at the appeared window, choose the "pin", "sleeve", and "drill" corresponding submenu by left-clicking.

To place a pin that does not show up on the pin library list, select "Custom Implant" option, choose the pin color and enter relevant dimensions for "Diameter" (d), and Length" (H). To restore settings for the next start of the software, mark appropriate checkbox in the lower right of the submenu window.

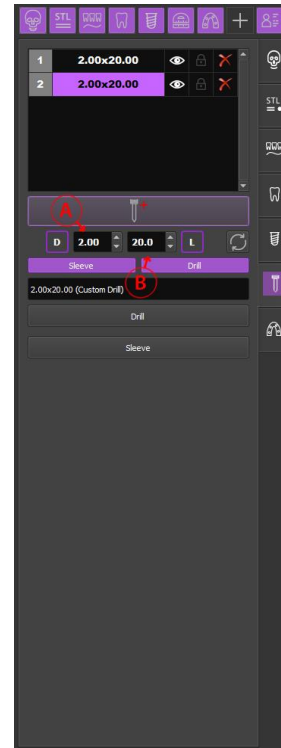


The same can be performed for custom sleeves and custom drills (see Implant settings part). Then press the "OK" button.

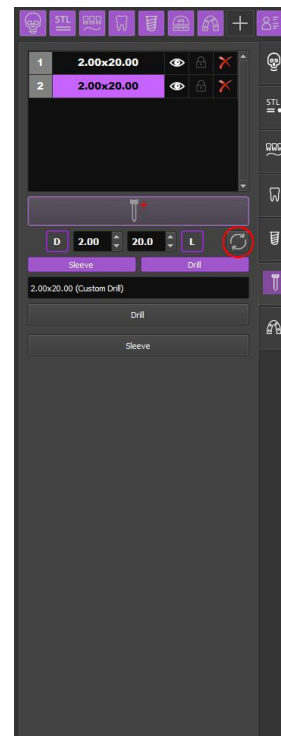
To change the pin position in axial, cross-sectional and sagittal view just left-click on and hold square mark at the stopper-contact surface area of the pin and drag it **(A)**, or click on and hold the contour line and tilt it **(B)**.



Use menu below the **"Place new Pin"** button in the left part of the screen to change the type of the pin or adjust pin diameter (**A**) and length (**B**) by clicking on the number and scrolling the mouse wheel, or writing the number into the appropriate windows, or by clicking on the arrows.



Click on the **"Replace Pin"** button and set up the Pin, Drill, and Sleeve settings.

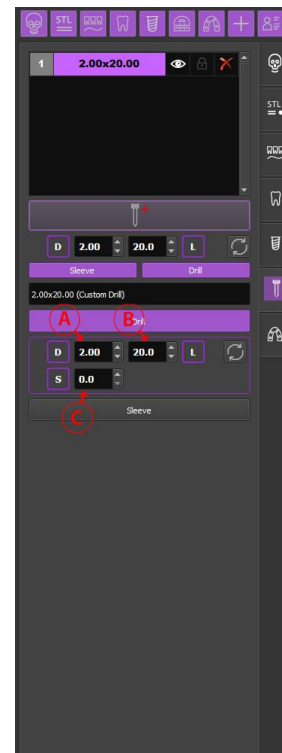


Click on **"Lock On/Off"** button in the **"Pin"** tab panel or go to the next step.

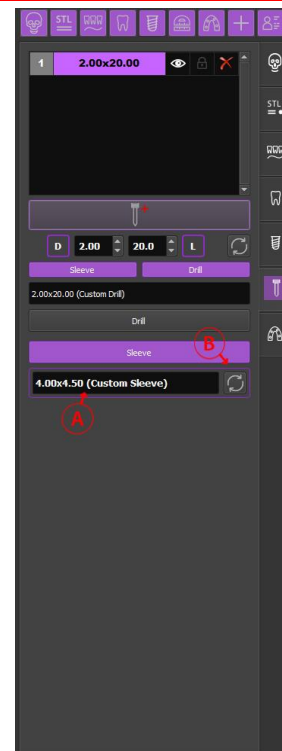
To load Pin libraries from the server click on the **"Replace Pin"** button and then click on the **"Load From Implant Server"** button. In appeared window select the system of the pin by marking checkbox/es and press "OK" and the chosen library will be downloaded into the software Pin list. The same downloading procedure can be performed for drills and sleeves libraries.

Now there is a possibility to use the pin, drill, and sleeve provided by a manufacturer. To place preloaded elements click on the **"Place new Pin"** button or on the **"Replace Pin"** button, in the appeared menu choose the pin manufacturer name, pin line name, and pin size.

Click on the **"Drill"** submenu in the right part of the screen and set up the drill diameter "D" (A), drill length "L" (B), the drill spacer "S" as an option to add the regulated space between stopper of the drill and contacted surface of the sleeve to change a position of the sleeve and decrease the sleeve offset during digital pin planning (C)



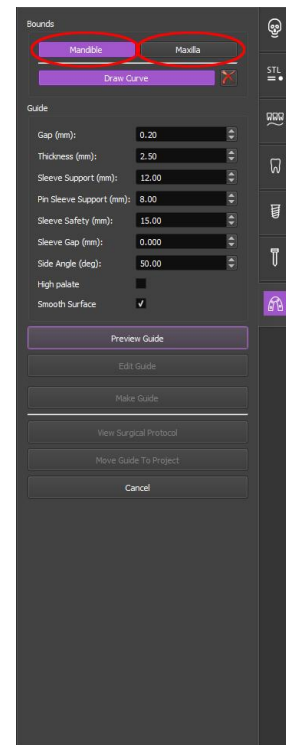
Click on the **"Sleeve"** submenu in the left part of the screen and check the name of the sleeve (A). To change the current sleeve, click on the **"Replace Sleeve"** button (B).



11. SURGICAL GUIDE CREATION

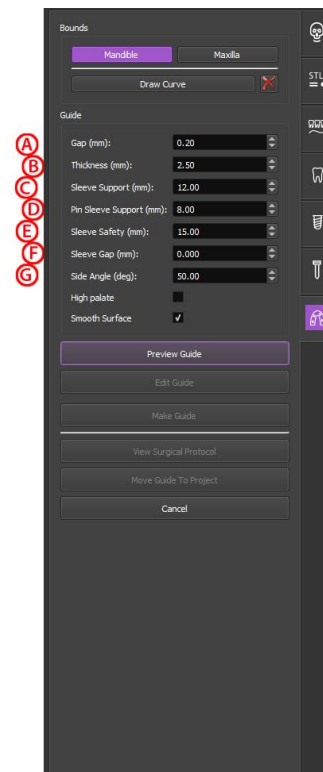
To start a virtual surgical guide creation click on "**Surgical Guides**" button in the workflow panel on the right part of the screen. Click on "**Make Surgical Guide based on Surface**" button and at the appeared window setup the STL surface position.

If the direction of the surgical guide is suggested by the program incorrectly, select the Surgical Guide orientation - "Maxilla" or "Mandible".



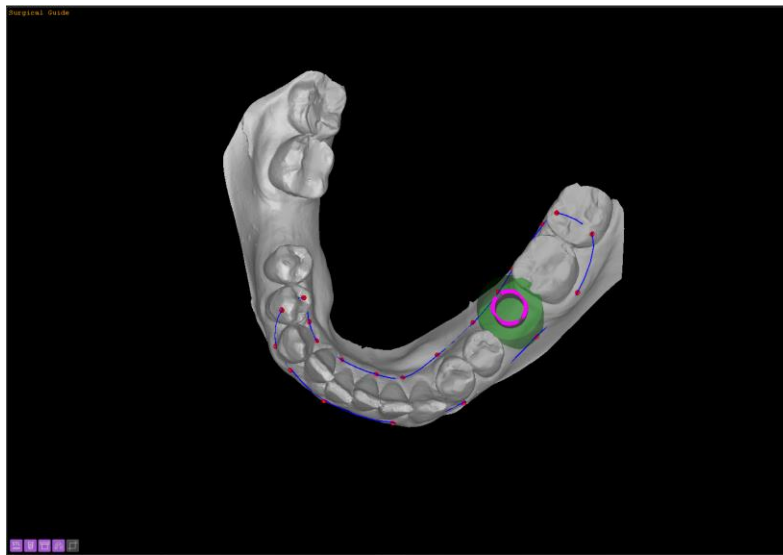
Set up the Surgical Guide settings for printing:

- A Gap** (mm) (set up an additional compensation value for the expansion or shrinkage of the guide material during the printing process. The settings of this parameter avoid difficulties during the process of placing and removing the surgical guide, and are necessary to compensate for scanning errors or other aggravating factors.);
- B Thickness** (mm) (surgical guide wall thickness settings);
- C Sleeve Support** (mm) (set the diameter of the sleeve supporting block);
- D Pin Sleeve Support** (mm) (set the diameter of the pin sleeve supporting block);
- E Sleeve Safety** (mm) (set the diameter of the dental handpiece head safety zone around the sleeve);
- F Sleeve Gap** (mm) (set the positive radial offset between a sleeve and surgical guide);
- G Side Angle** (degrees) (set the value of the angle of the slope of the guide edge).



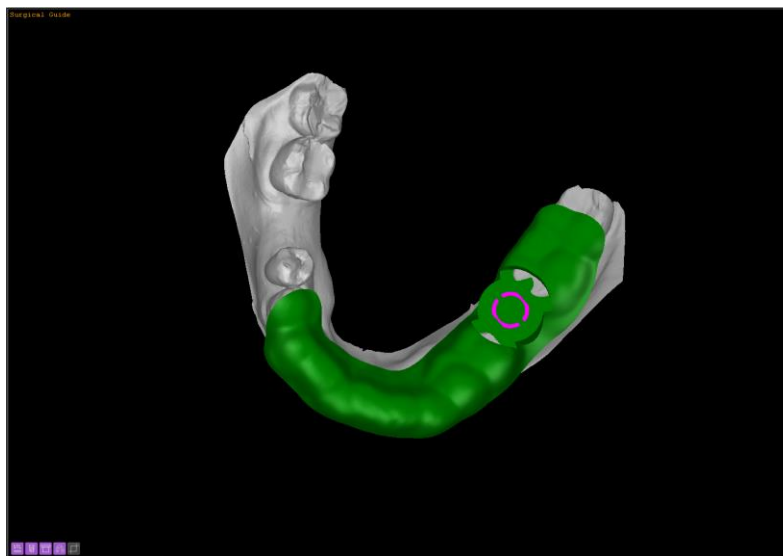
Default settings can be changed in the Settings Menu.

To identify the area in which the Surgical Guide is going to be created, draw the borderline by placing points one after another around the Surgical Guide area. Continue to draw the curve that goes back to the starting points and then double-click on this line or click on the **"Draw Curve"** button.



Note!

Before generating the guide, set up the insertion direction from the view perpendicular to the screen. So set the view to provide minimum undercuts, and then click on the **"Preview Guide"** button and software will go ahead and create the preview model of the surgical guide.

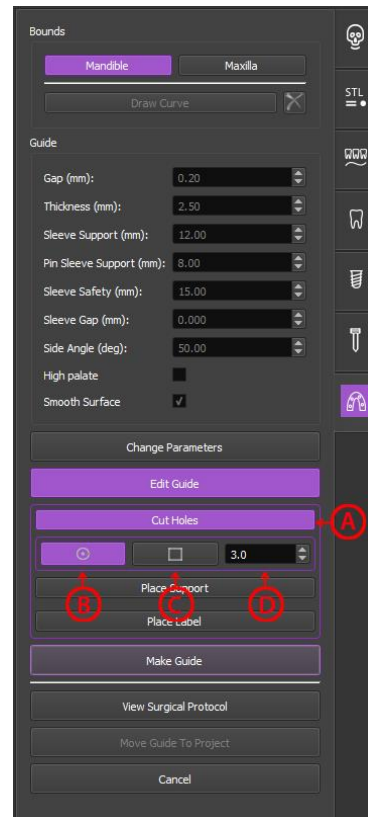


Click the **"Edit Guide"** button to open the Surgical Guide Edit Menu.

Click “**Cut Holes**” button (A).

To cut viewing windows either click on the round window button or click on the square window button, set up the size of the window by scrolling with the mouse wheel (C-D).

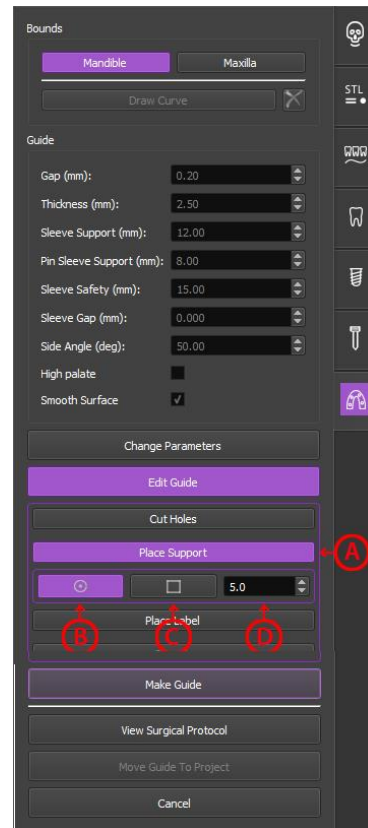
The cursor is going to be round or square shape cutter, move the cursor over the STL surface of the generated surgical guide then left-click to make a hole.



Click “**Place Support**” button (A).

To add a round/square support bar from the menu either click on the round button or click on the square button, set up the size of the support bar by scrolling with the mouse wheel (C-D).

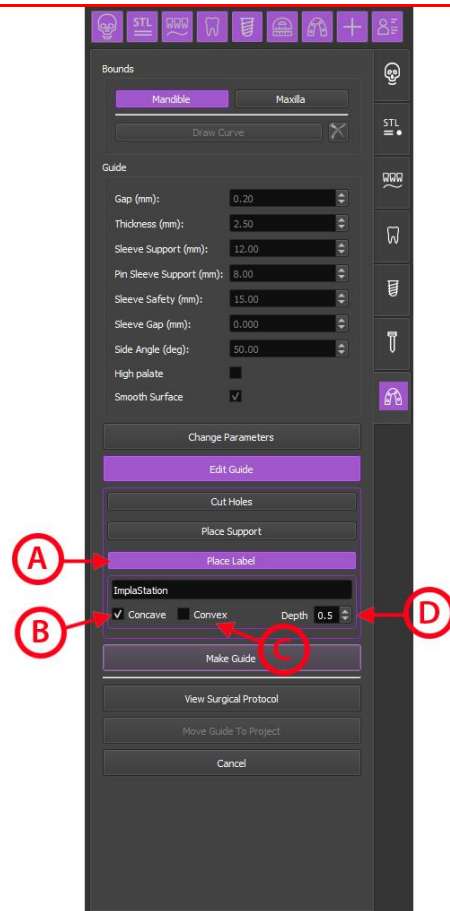
Place a support bar on the guide surface and modify it by using the points for rotation and size adjustment.



Select the **"Place Label"** button (A).

Type in the desired text in the label field.
Modify the desired label text depth (D) by scrolling with the mouse wheel.

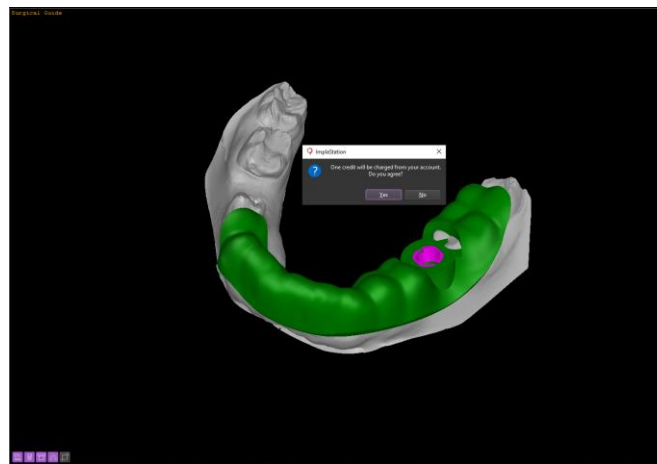
To add a label to surgical guide move cursor over the guide and left-click where you wish to place tag. Click on the **"Concave"** (B) or **"Convex"** (C) checkbox to modify the way a Label imprints on the surgical guide surface.



Check the surgical protocol by clicking the **"Surgical Protocol"** button in the Surgical Guide menu on the right part of the screen.

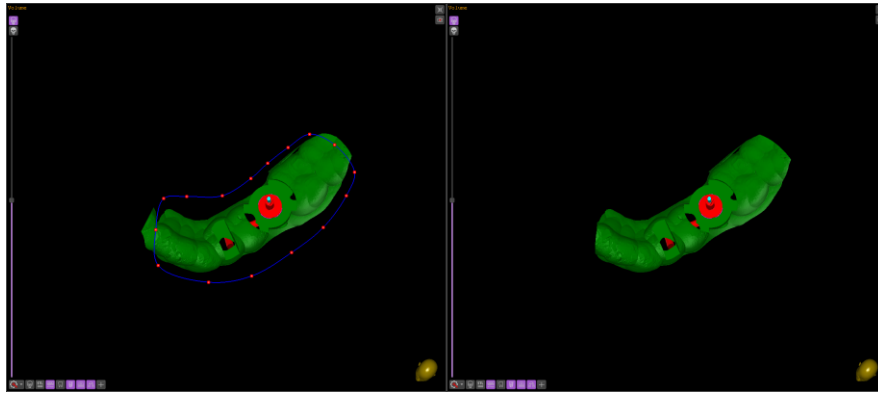
Check Surgical guide settings and modifications then click **"Make Guide"** button to achieve the final view of the generated guide.

To save created Surgical Guide on your computer press **"Move Guide to Project"**, then in the appeared window, click **"Yes"**.

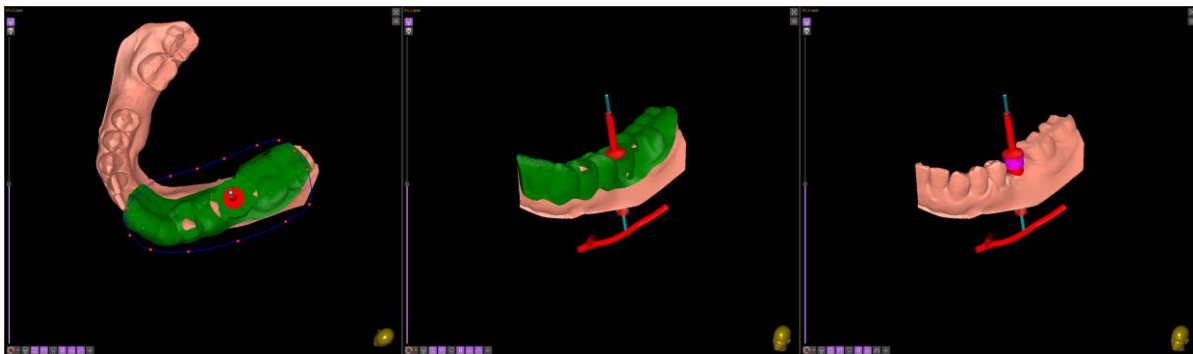


Note! Paid option. One credit will be charged from your account

To cut a Surgical Guide, maximize the "**Volume**" window. Setup the Surgical Guide surface position. Click on the "Cut selected Surgical Guide" button to cut only Surgical Guide.



Click on the "Cut selected Guide and it base Surface" button to cut Surgical Guide and STL surface.



To identify the area on which the Surgical Guide surface is going to be cut. Draw the borderline by placing points one after another around the cutting area. Continue to draw the curve that goes back to the starting points and then double-click on this line. Then click on the "Cut inside" or "Cut outside" button.

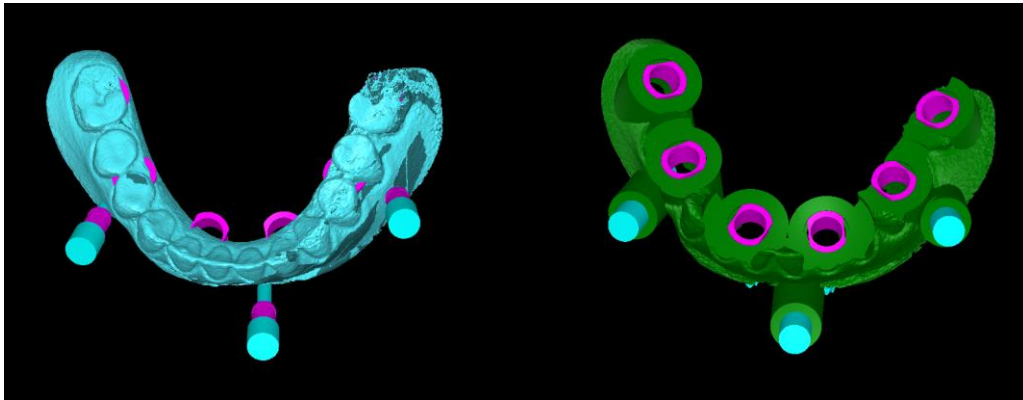
Note! Set up the direction of the cutting from the view perpendicular to the screen

To copy generated Surgical Guide to STL surfaces list click "**Copy to STL Surfaces**" button in the Surgical Guide menu on the right part of the screen.

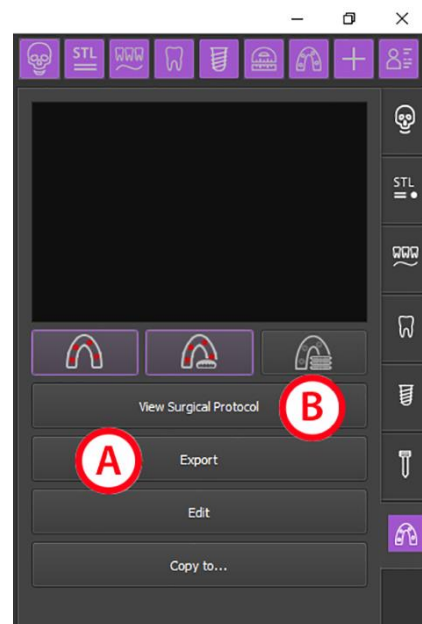
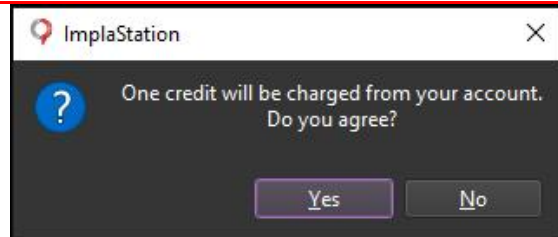
11.1 Surgical Guide Based on Prosthesis

To start the creation of the surgical guide based on the denture click on the **"Surgical Guides"** button in the workflow panel on the right part of the screen. Click on the **"Make Surgical Guide based on Prosthesis"** button and at the appeared window setup the STL surface position. Select the Surgical Guide orientation - "Maxilla" or "Mandible". Set up the Surgical Guide settings for STL printing.

Before generating the guide, position it taking into account that the pass of insertion of the planning surgical guide is perpendicular to the plane of the screen. Then click on the **"Generate Guide"** button and software will go ahead and create the surgical guide.



To get file of the Surgical Guide saved on your PC press **"Yes"** in the appeared window, one credit will be charged from your account, then click on **"Export"** button **(A)**. To get file of the Surgical Protocol saved or printed, press **"View Surgical Protocol"** **(B)**.



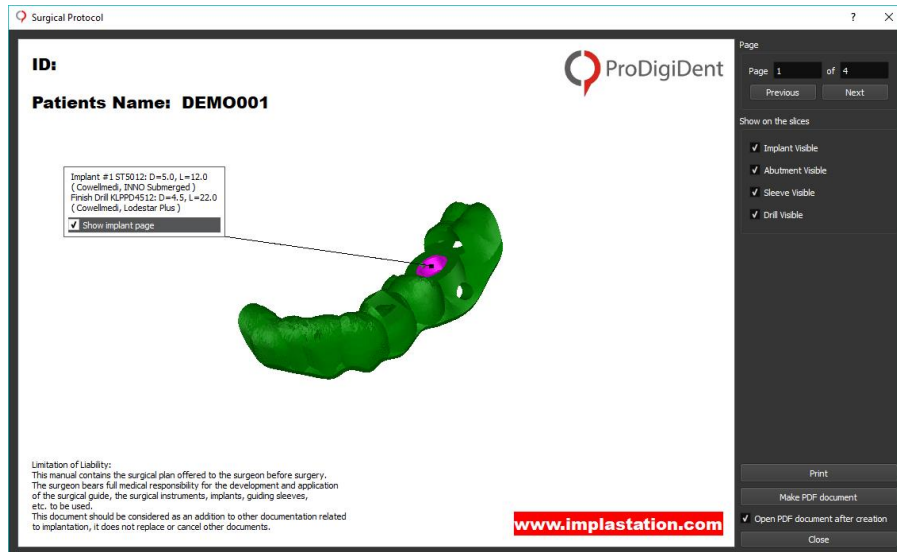
12. SURGICAL PROTOCOL

The Implastation creates a surgical protocol together with the surgical guide based on virtual implant planning, sleeve(s) position and selected surgical drill sequence.

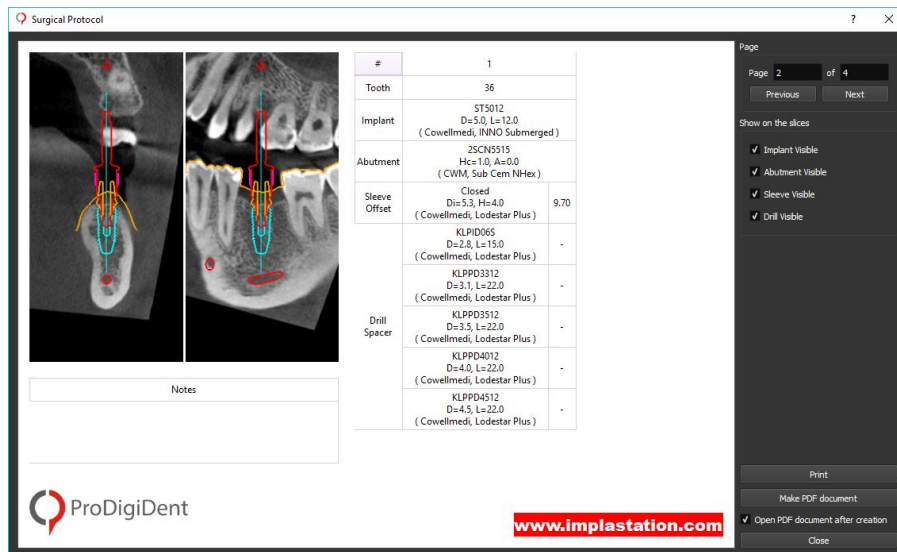
Click the "**View Surgical Protocol**" button in the right part of the screen to open the Surgical Protocol Window

View Surgical Protocol

The following image shows an example of a surgical protocol.



The surgical protocol is available per implant providing detailed information together with the images of the planning view. Adjust the guide position as you need. To get more info select the option "**Show implant page**".



To add a panoramic image to the Protocol select the option "**Add to surgical protocol**" see Page 15 (11).

WARNINGS AND PRECAUTIONS

There are no chemical, physical, electrical, mechanical, electromagnetic and biological hazards to the ImplaStation software.

However, there are several warning functions designed to remind the user of his legal responsibility to verify implant planning stages and results.

- **INDICATIONS FOR USE**

Warning!

The ImplaStation software must be used in accordance with their accompanying instruction for use

Warning!

This device is not tested on the pediatric patient population

Warning!

Prior to working with software, please make sure to have received appropriate training and instructions in software operation. Prodigident offers regular online webinars for ImplaStation which is open for all users

Warning!

Correct design of the surgical guide lie within the sole responsibility of the user

Warning!

3D manufacturing is out of ImplaStation software control, depends on many external factors and lie within the sole responsibility of the user

Warning!

The manufactured surgical guides for implant placement are classified as medical devices by the FDA (under 21 CFR 872.3980). Surgical guides are subject to legal requirements such as registration and listing as a manufacturer of medical devices, validation of production equipment, processes and quality system regulations

Warning!

In the US. 3D printed surgical guide is a medical device to be manufactured at an FDA registered and listed manufacturing location

- **DICOM**

Warning!

The user is solely responsible to ensure that the quality of the loaded patient CT/CBCT data is sufficient for proper planning the case

Warning!

The production of CT/CBCT scans lies within the full responsibility of the clinicians or appropriately qualified personnel. The CT/CBCT scanner should be maintained within original manufacturer specifications

- **NERVE CANAL**

Warning!

Make sure that the nerve is correctly traced. Always maintain an appropriate safety distance to the nerve canal

Warning!

The pathway of imaged nerves is for display only, location accuracy of the traced nerve is not tested, and pathways of imaged nerves can not be used as sole information for the clinician to make clinical decisions

- **IMPLANT PLACEMENT**

Warning!

During implant placement, please assure that an implant/pin does not collide with an existing implant/pin, tooth root(s) or nerve canal. A collision of the implant/pin with another implant, nerve, or any other main anatomical structure can cause severe damage

Warning!

The user must be able to recognize the triangular sign "Attention" to detect warnings such as "Collision between implant/pin and implant/pin", "Collision between sleeve and scan STL surface", and "Collision between implant/pin and nerve canal"

- **SURGICAL GUIDE**

Warning!

Make sure that created STL file of the surgical guide or produced surgical guide is intended to be used only by trained qualified dental practitioners

- **ALIGNMENT**

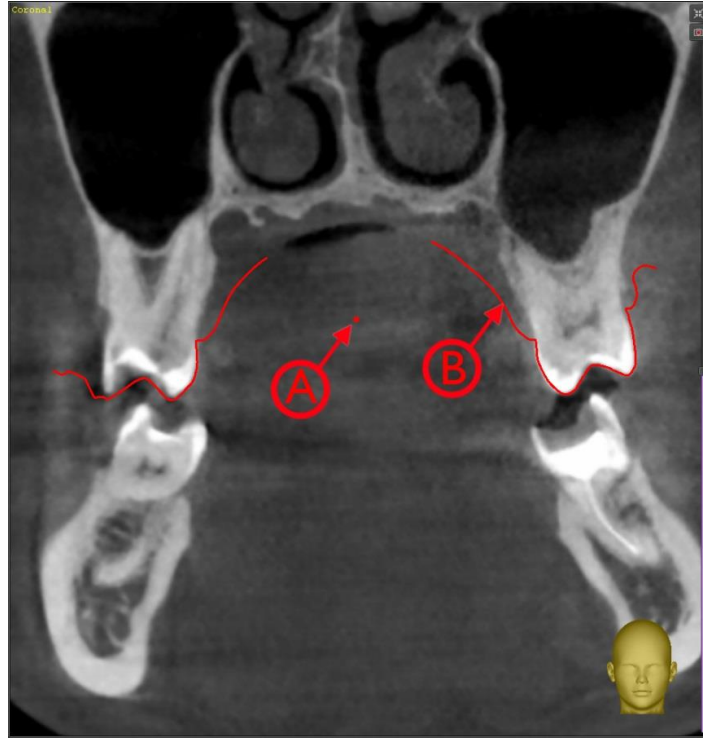
Warning!

Make sure that CBCT/CT and STL surface scans are well aligned in all relevant areas, particularly in the implant placement area

ANNEX A - How to evaluate the quality and accuracy of alignment?

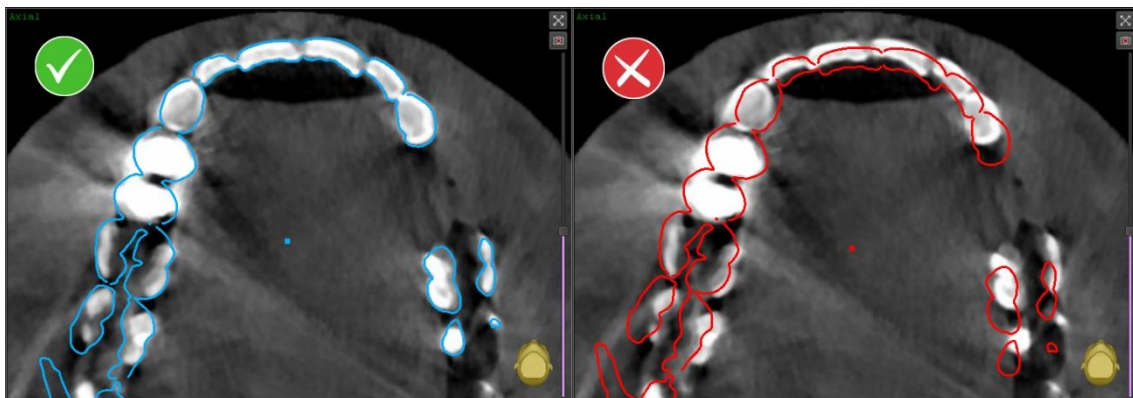
The software enables users to overlay and align DICOM visualization to the STL surface by picking points on both surfaces as a landmark (see part 6, p.28).

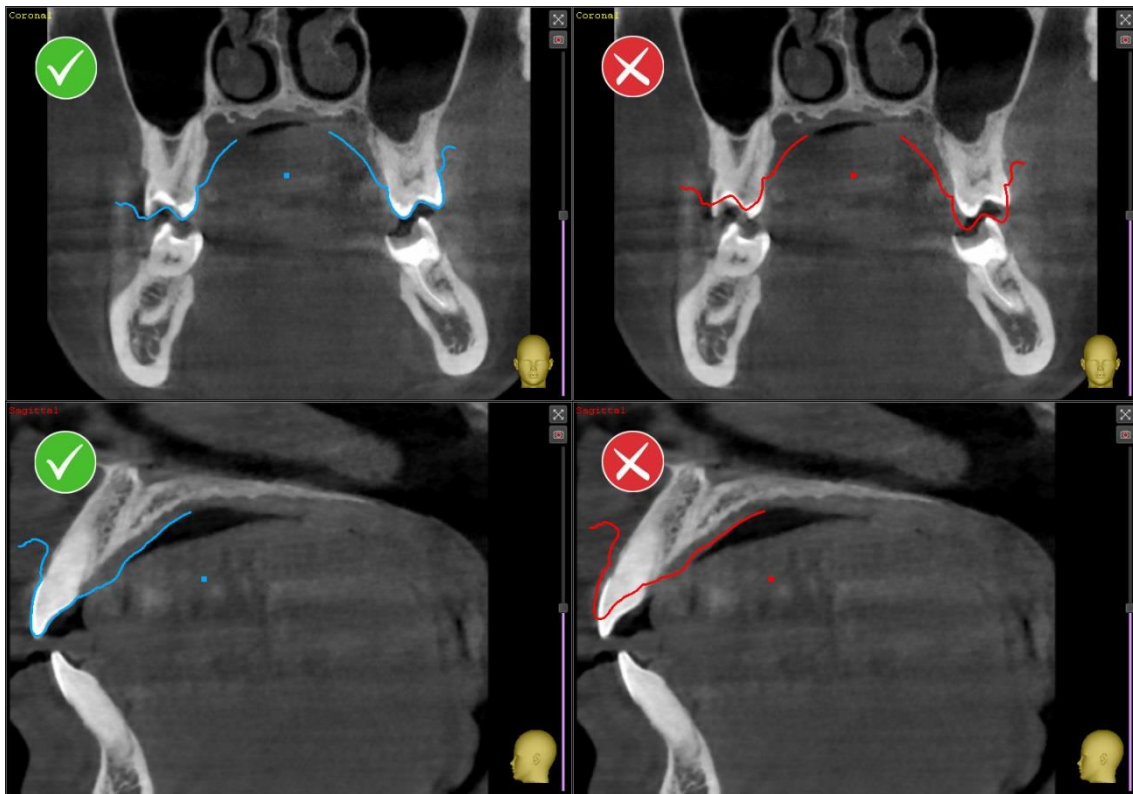
There is a tool to correct an alignment manually in MPR or Panoramic mode. Dragging the scan with the square point (**A**) or rotating the scan using the control point on contour line (**B**) of the scan provides your movement to one dimension in Axial, Coronal, and Sagittal views (see picture).



The aim is to get the contour of the STL surface scan to coincide with the corresponding object on the CT scan. Teeth are a good landmark for alignment.

Example of the alignment:





ANNEX B - Dual Scan Technique

Full Digital Workflow for the Treatment Planning of an Edentulous Patient with Guided Surgery using Dual CBCT/CT Scanning Technique.

Definitions:

Dual Scan Technique (DST). The dual scan (dual CBCT scanning technique) is the term used when a dental appliance, such as a set of dentures, is superimposed over the patient CBCT/CT scan.

Scan Appliance is a denture with temporary radiopaque markers that are applied directly to the inside and outside of the denture.

DST Patient CBCT/CT Scan is a head CBCT/CT scan of the patient wearing the denture prepared with temporary radiopaque markers. The patient's dentures should be in occlusion when the scan is taken.

ImplaStation Dual Scan Technique Workflow:

1. Create new project:

You can either import an existing project (see section 4.6.2 - Tool Panel) or create a new project.

2. Import Patient's CBCT/CT scan data:

Click the **New Project / Load DICOM** button to upload the patient's DICOM data (see Chapter 5. Input Data (DICOM)).



3. Import Scan Appliance DICOM data:

To use the Dual Scan Technique, you need to import DICOM data of the Scan Appliance(s) with radiopaque markers.

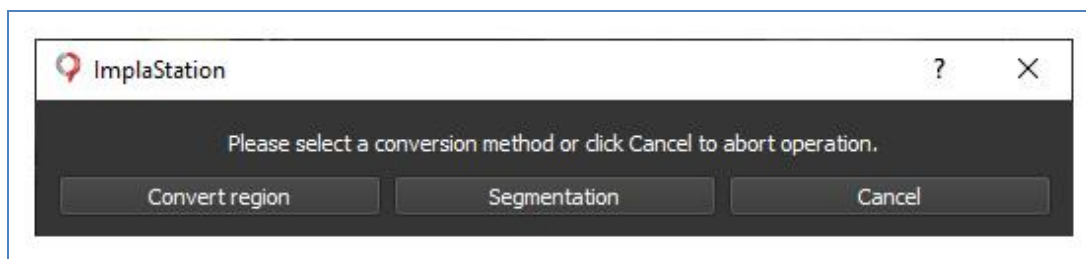
Click the **STL Surfaces** button in the tab panel on the right part of the screen.



Click on  button and select the Scan Appliance DICOM file on your computer. Press "OPEN" and wait for it to finish loading.

4. Segment/Convert of the dental appliance:

Choose the action you plan to apply to the downloaded file. The software offers the following options: Segmentation or Conversion of the dental appliance data (DICOM) into the surface (STL).



To convert Dental Appliance scan data, follow the instruction described in Chapter 5.2 – "DICOM to STL Conversion" of this User Manual.

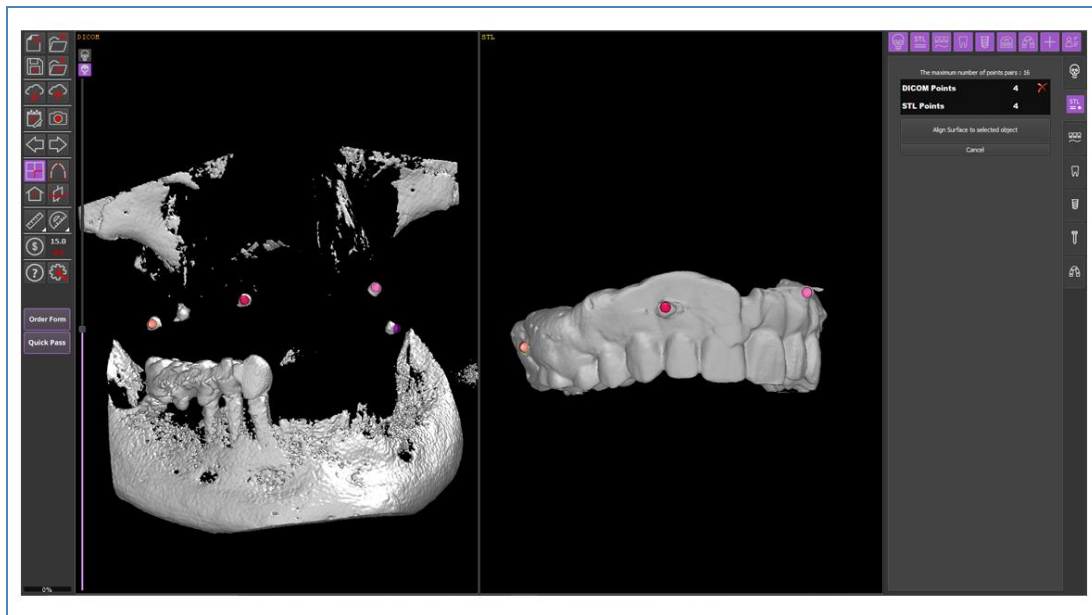
To segment Dental Appliance scan data, follow the instruction described in Chapter 5.3 – "DICOM Segmentation" of this User Manual.

Once DICOM is converted/segmented into STL set, you can proceed to the alignment of the CBCT/CT scans.

5. Align Scans:

Check the box "Align to DICOM or to another STL" and click OK to start an alignment process. Or Mark either the "Put to the center of coordinates" checkbox to place the STL model at the center of coordinates or mark the "Put to original coordinates" checkbox to place the STL model at the original coordinates.

Use the sliders to adjust the density of the bone/denture. Place points on the radiopaque markers scan in the left 3D pane and corresponding points on the Surface Scan in the right 3D pane. Then click the "Align Surface to selected object" button.



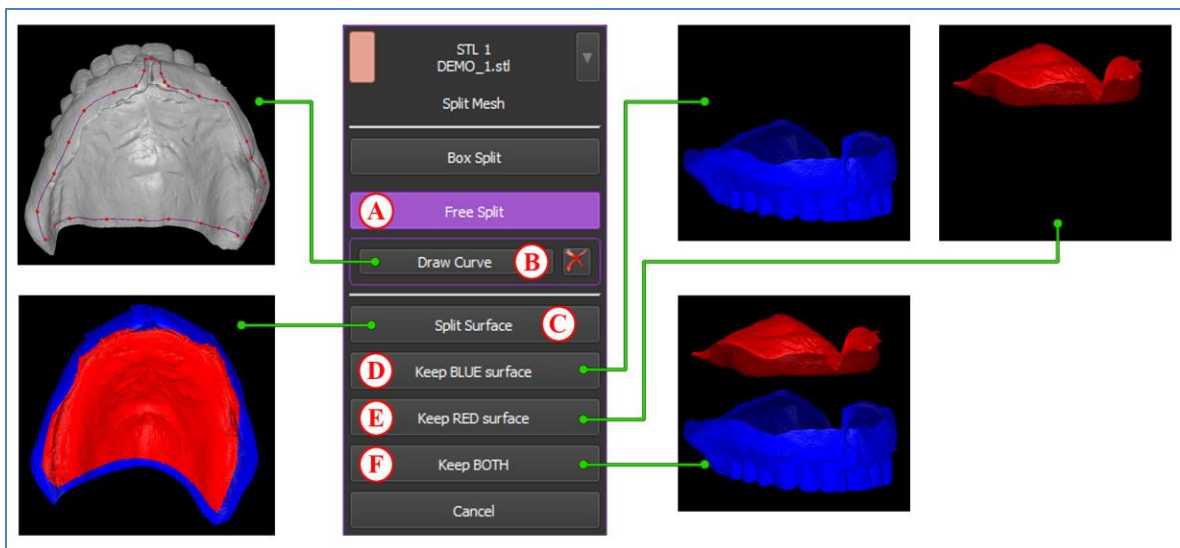
To adjust alignment manually, click on the STL surface center (the square point which is marked in color of corresponding STL surface) and drag it or click on the STL surface borderline and tilt it. (See Chapter 6. - INPUT DATA (STL)).

6. Create a soft tissue surface (Split and Invert):

Once the CBCT/CT scans are aligned, you can proceed to the soft tissue surface detection step. Open the STL submenu, click the “Edit” button, then click the “Split” button, choose “Free slit” option.

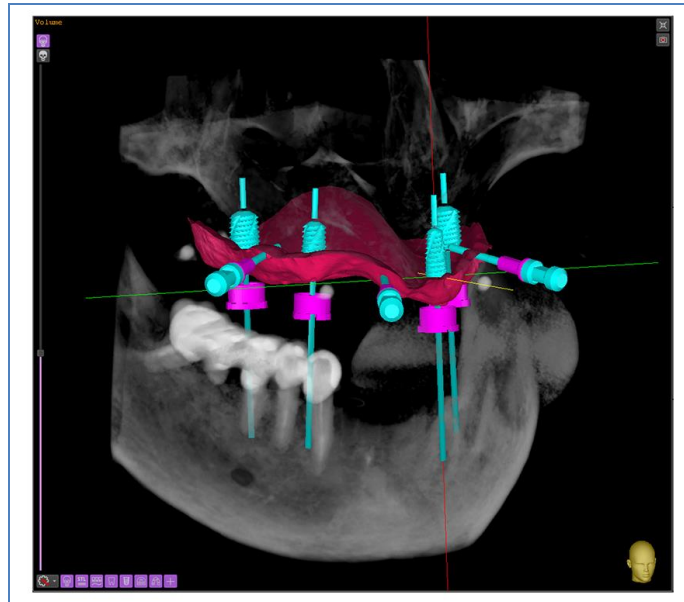
Set up the 3D object position, click on the "Draw Curve" button (B) (see picture below), the application switches to drawing mode, and draw the borderline by placing points one after another around the area of interest.

To split the surface into two objects you need to click on the Split Surface button (C), and then add the SLT object to the project by clicking the "Keep RED surface" button (E) to save a red-colored object. Click the “Invert” button, then click the “Quit” button and save new STL surface.



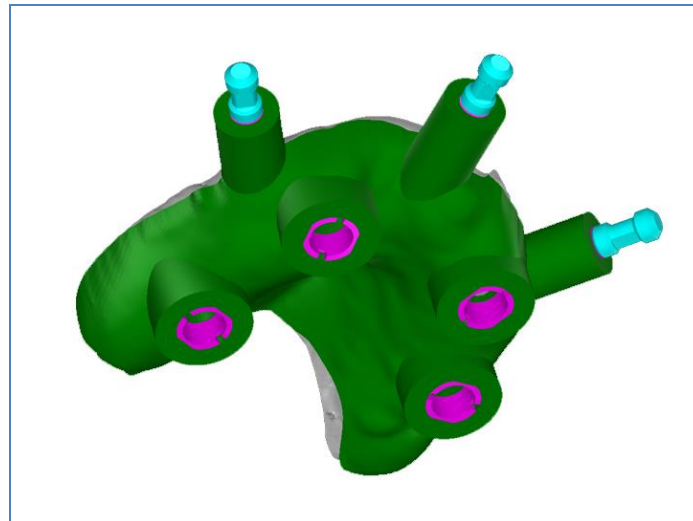
7. Perform Implant planning:

Once the soft tissue surface is created, you can proceed to the Implant planning, follow the instruction described in Chapter 9 – “IMPLANT PLANNING” of this User Manual.



8. Create the surgical guide:

Follow the instruction described in Chapter 11. SURGICAL GUIDE CREATION.



9. Create the surgical guide based on prosthesis

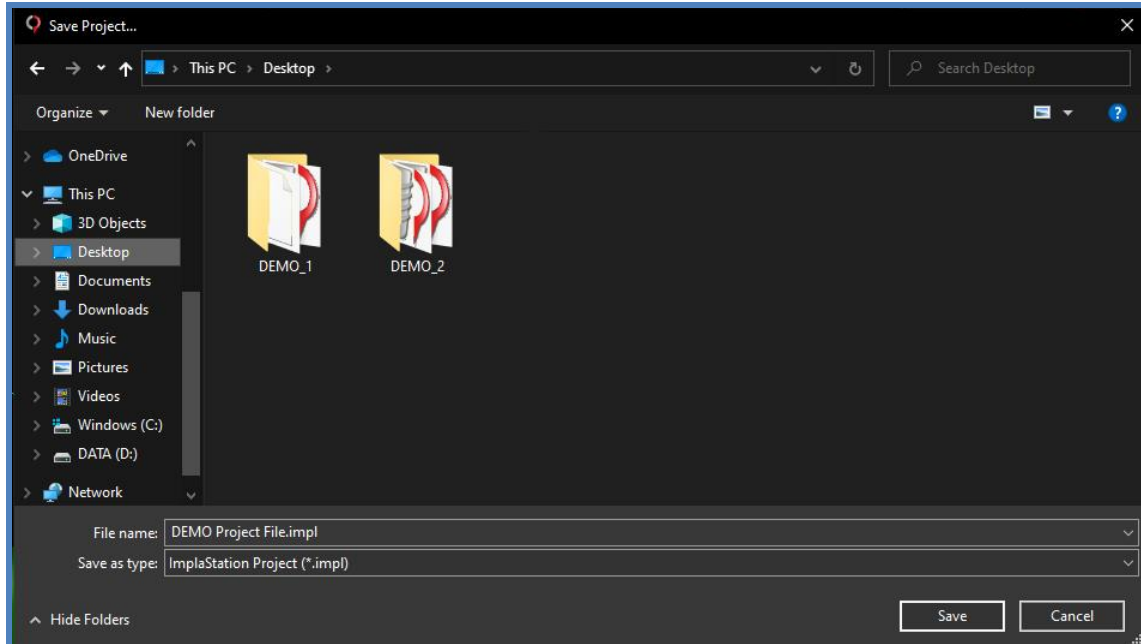
Optionally you can proceed to the surgical guide creation exactly after the CBCT/CT scans alignment step. (see Section 11.1 Surgical Guide Based on Prosthesis).

ANNEX C - How to anonymize your project file.

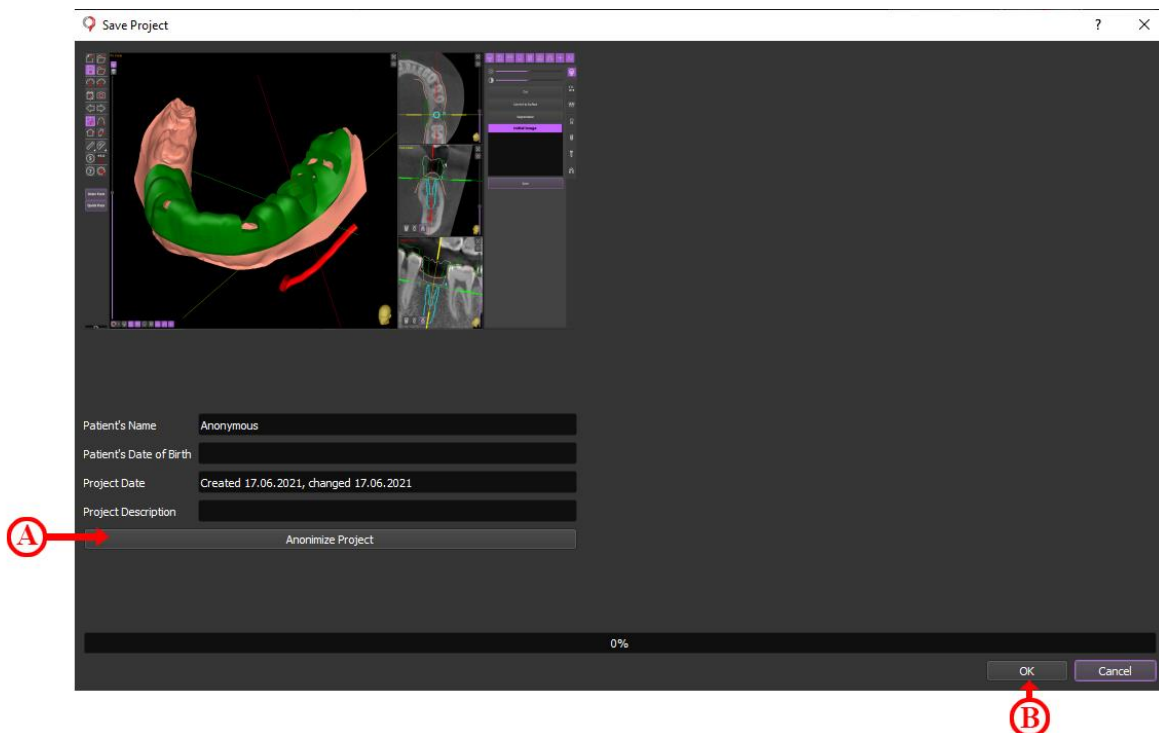


To anonymize your Project file, click the "**Save**" button. The button is located in the upper left-hand corner of Implastation's interface.

Under the "Save File" submenu, decide on your save location. In the "**File Name**" field, type in your preferred Project file name (do not use patient name in project file name). Click "**Save**" to save your file.



Under the next "Save Project" submenu, click "**Anonymize Project**" (A) and "**OK**" (B).



ANNEX D

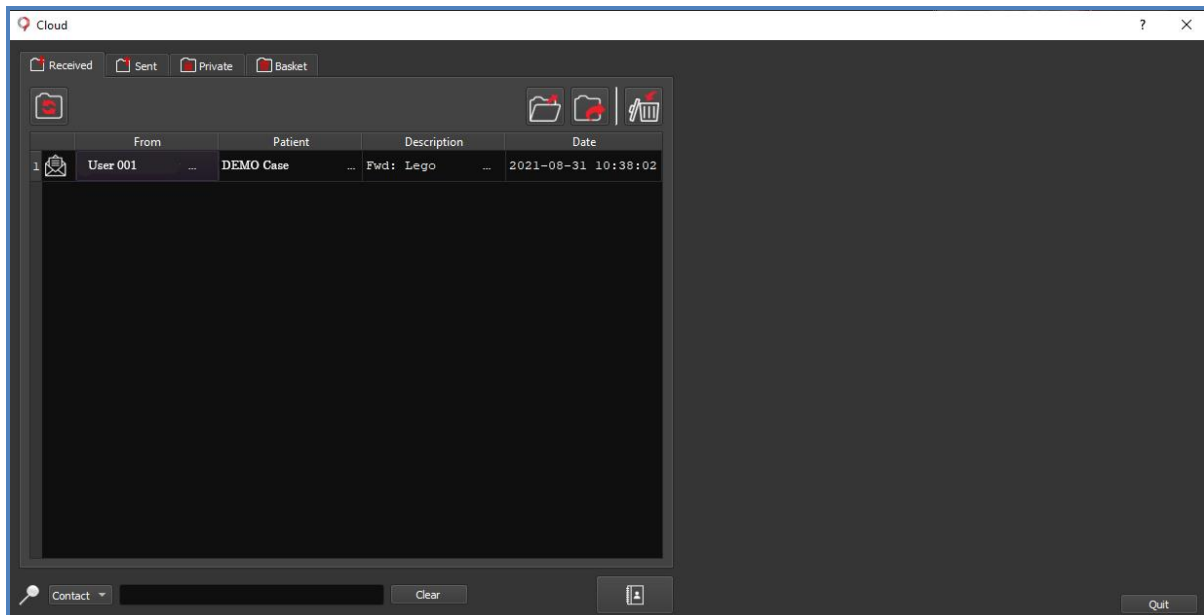
Cloud Service.

A-D.1 Inbox.

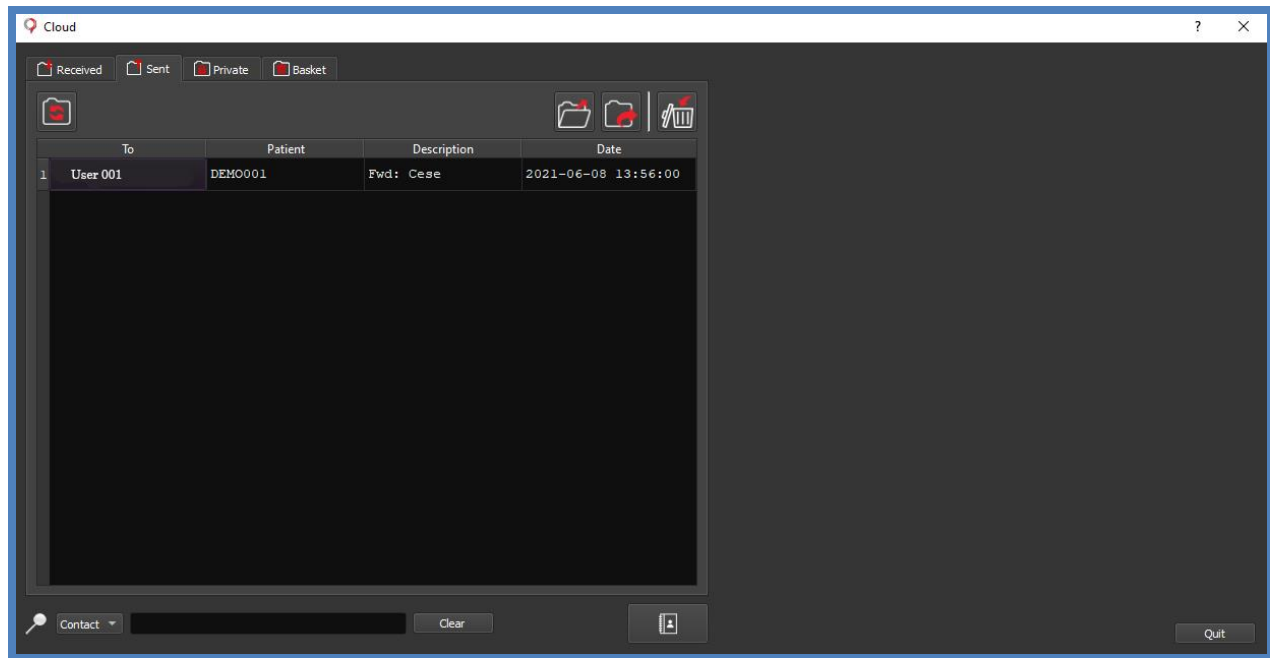
Click the "**Cloud Service**"  button. It's in the top-left corner of the Implastation's interface. Doing so prompts a "Cloud Service" window.

	Refresh
	Open project
	Forward project file
	Delete file
	Restore deleted file
	Contacts
Add New Contact	Add new contact

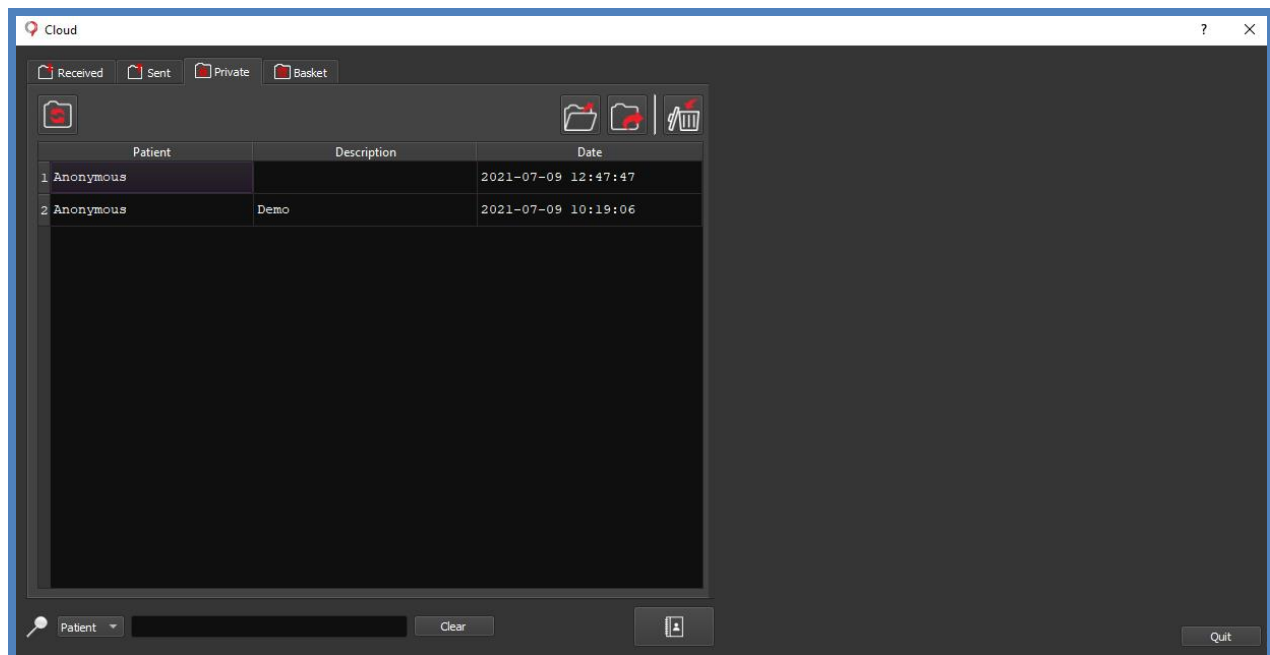
Find the "**Received**" tab. "Received" is located in the upper left-hand corner of the Cloud Service interface. Double-click a received project file to open the project or select received project file and click .



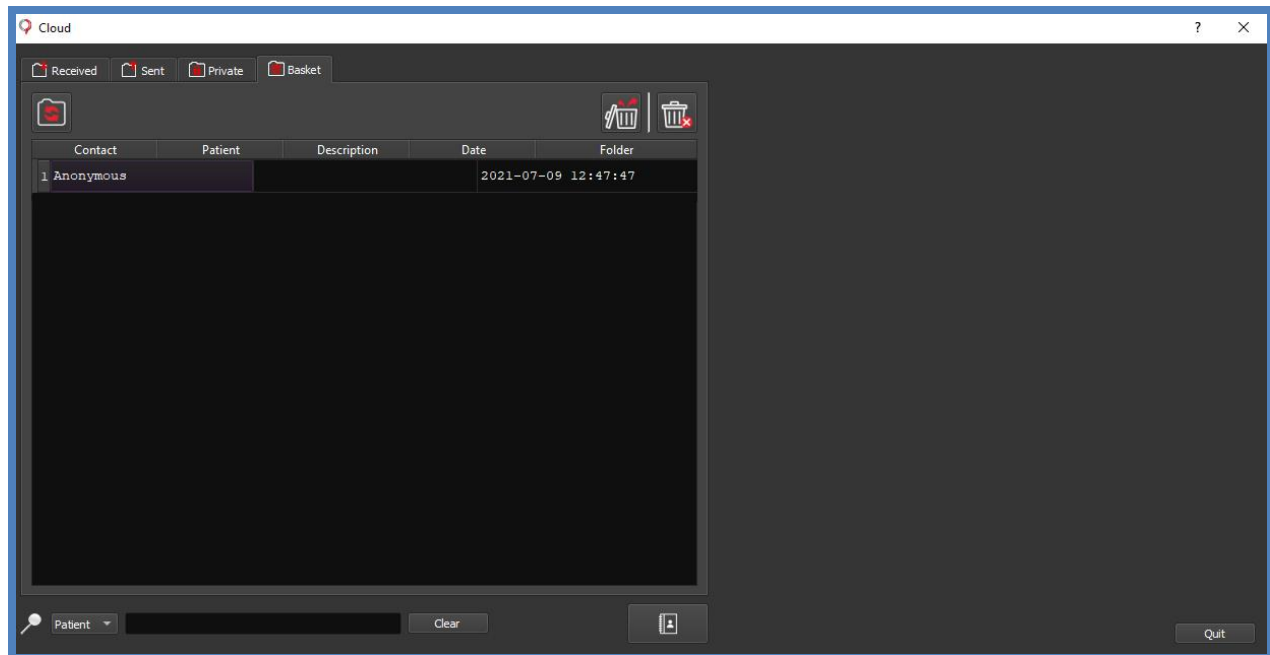
Find the "**Sent**" tab. Click a "sent" project file to open the project, you sent before.



Find the "**Private**" tab. Click an "Anonymous" project file to open the anonymous project.



Find the "**Basket**" tab. Deleting project files from your inbox doesn't permanently delete them immediately - they'll move to the "Basket" folder where they'll remain for 90 days before being deleted automatically.

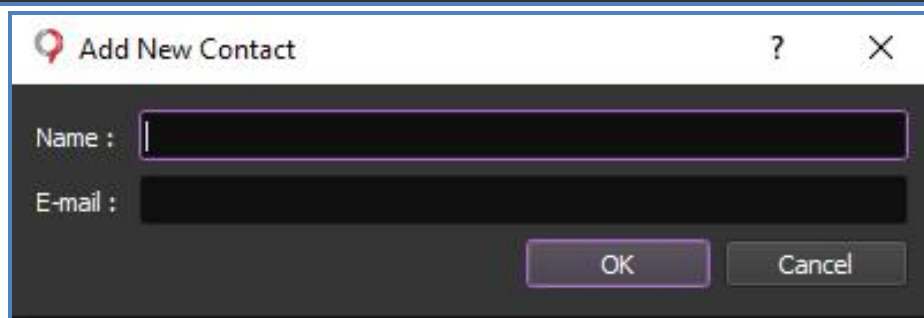
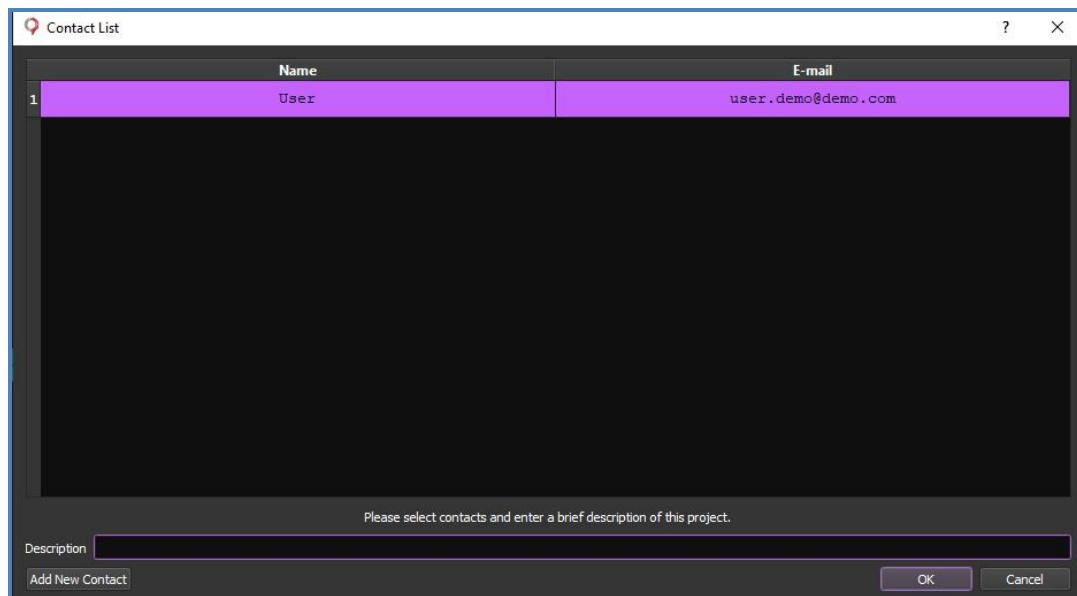


A-D.2 How to send a case.



Click . It's in the top-left corner of the Implastation's interface. Doing so prompts a "**Contact List**" window.

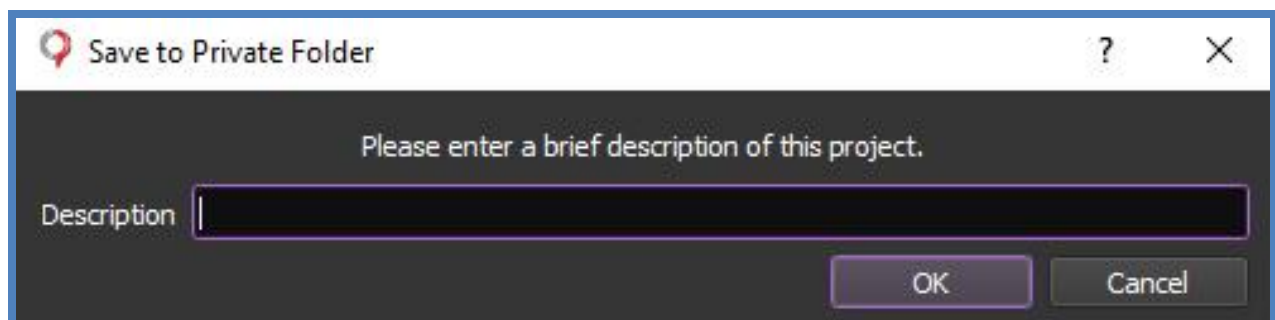
Enter/select your recipient's email address. In the "**Add Contacts**" text box, type in the email address or select the existing recipient's email in the list.



A-D.3 How to save in the cloud.

Saving your Project File in the cloud lets you access them from anywhere. To save

Project File online with Prodigident Cloud, click  make a brief description of the case and click OK.



Warning!

Prodigident Inc. uses AWS's utility-based cloud services to process, store, and transmit encrypted Project Files.

AWS's utility-based cloud services stores data (Project File) for at least one year after data generation completes. Prodigident will send user an alert email one month before removing data from the server.

ANNEX E

Cybersecurity Hygiene

The Implastation software does not store patient personal data, medical information, PII and non-PII data directly. All the data is stored on the user PC. User is responsible for data protection on the user side.

To protect data against loss or unauthorized use, several security mechanisms have been implemented in Implastation:

- Restrict user access to the storage media, operating system by setting up a strong user password;
- Create a unified way of working. Installation / Upgrade of product security patches and software packages by an authorized user and/or possibly authorized HDO or Dental Lab staff.
- Configure the operating system to prevent further access to the system by initiating a session lock after 10 min of inactivity or upon receiving a request from a user;
- Configure the operating system to restrict the access to security features of the PC;
- Use data encryption to secure Patient data, Project Files, Drilling protocols on your computer system and storage media;
- Use the anonymization function to protect patient personal data if required;
- Backup your data regularly and always backup before updating or uninstalling the software;
- Use anti-virus software, firewall.

REVISIONS

Revision	Date	Section	Paragraph	Summary of change	Authorized by
0	Oct 25, 2018	N/A	N/A	Initial Issue	Andrii Gromov
1.0	Mar. 30, 2020	Warnings and Precautions	N/A	Section updated and supplemented	Andrii Gromov
2.0	June 3, 2020	N/A	N/A	Company mailing address changed from Miami, FL to Roselle, IL	Andrii Gromov
3.0	March 16, 2021	N/A	N/A	The name and address of the authorized representative within the European Market changed	Andrii Gromov
3.1	July 12, 2021	Annex D,E	N/A	New sections added	Andrii Gromov
3.2	November 29, 2021	7. NERVE CANAL TRACING; WARNINGS AND PRECAUTIONS	N/A	New warnings added	Andrii Gromov
3.3	December 2, 2021	1. INTRODUCTION	1.1 Indications for Use	Indication for use added	Andrii Gromov
3.4	December 2, 2021	WARNINGS AND PRECAUTIONS	N/A	New warnings added	Andrii Gromov

ImplaStation

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