SMART Guide software module user manual

SGSS 3.0

CE

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1. Introduction

SMART Guide surgical planning software module for dental implantology (henceforth: SMART Guide planning software or software) is part of SMART Guide Software System 3.0 (SGSS 3.0), a software developed to manage a state-of-the-art dental treatment workflow. Within this workflow and using the software, the user can prepare a virtual plan of the implant surgery by defining the position and size of the implants to be inserted. The software uses anatomical input information generated by a CBCT device and/or an intraoral/tabletop surface scanner. Based on the virtual plan, a surgical template (or guide) is manufactured, which allows the user to perform the implant surgery as planned, in an easy and rapid manner.

1.1. Overview

The workflow is summarized in Figure 1. By default, the dentist takes an impression of the patient's dentition and then the patient and the impression both undergo CBCT imaging. Intraoral or tabletop scans are also accepted input formats if the dentist does not wish to have a CBCT scan taken of the impression. The input images are then uploaded to dicomLAB Dental via the Internet. DicomLAB Dental prepares the images for planning, generating a ready-for-planning case. The case can be opened and used for surgical planning by the user in the web-based SMART Guide planning software. The output of planning is the surgical plan, which is the basis of the digital plan of the surgical guide. The surgical guide is then 3D-printed with a state-of-the-art printer developed especially for dental applications. The guide, complete with guiding sleeves, is delivered to the dental office by postal delivery or courier, ready to be used for implant surgery after the necessary preparations. The software is intended to be used with dicomLAB Dental Ltd.'s own products, Universal Guided Kit (surgical instrument kit) and SMART Guide Dental Surgical Guide (3D printed surgical guide).

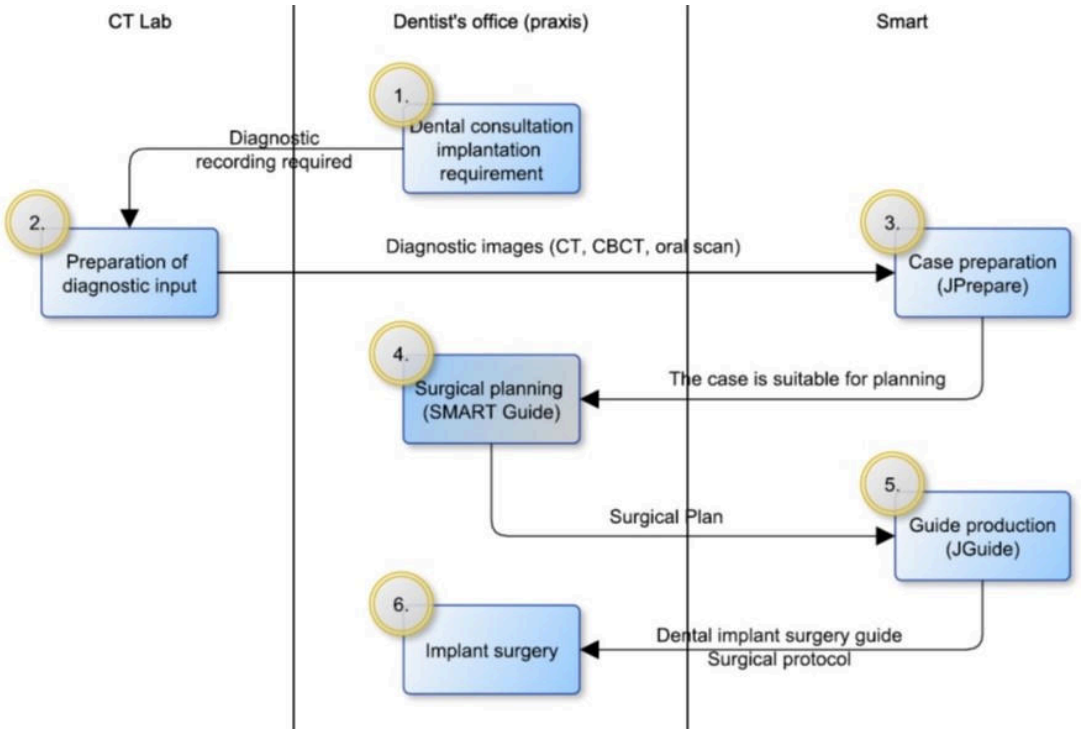

Figure 1: An overview of the workflow

SMART Guide surgical planning software allows the user to prepare a surgical plan in a ready-for-planning case (see above). The software is used in 4 main steps, which are as follows (Figure 2):

1. Opening a case,
2. Adding implants,
3. Adding fixation pins,
4. Finalizing the plan.

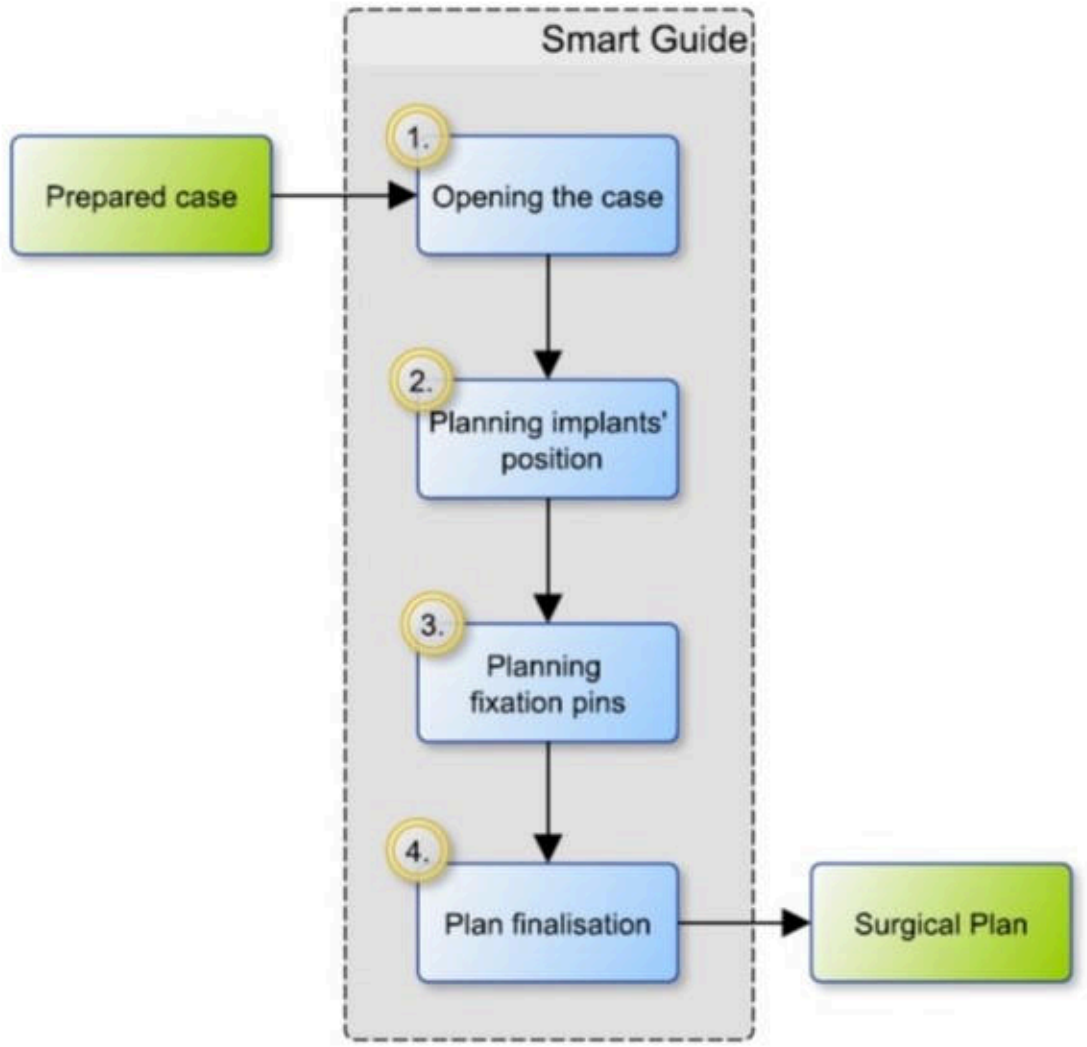

Figure 2: The main steps of using the software

Protection against unauthorized access: this software module is accessible only to registered users with a password-protected personal account in dicomLAB Cloud.

1.2. Expected clinical benefits

- Smart Guide Software System 3.0 (henceforth: System) is a system to support dental implant surgery by increasing the accuracy of dental implant placement, especially regarding angle deviation. In a large, four-arm, randomized, controlled clinical trial, the System's clinical equivalent, SMART Guide Software System improved angular deviation in a stepwise manner, in comparison with the conventional freehand approach. The highest mean deviation (7.03° ± 3.44) was achieved by freehand surgery. This was followed by the pilot protocol (5.71 ± 3.68°) and the partially guided

protocol (4.30 ± 3.33°), while the best results were achieved with the fully guided protocol (3.04° ± 1.51). The application of the System also enhanced coronal and apical deviation.[1]

- The System allows the user to make a digital surgical plan based on the unique anatomical conditions of the patient. From the surgical plan, a patient-specific surgical protocol is generated to enable the placement of the planned implants. This surgical protocol is to be used with a) a surgical toolkit defined by the user during planning, which consists essentially of bone drills and b) a surgical template manufactured to fit the individual patient. The surgical plan, the protocol and the template are the outputs of the System.
- The use of the tools of the surgical toolkit as prescribed by the surgical protocol allows the user to place implants in the patient's mandible and/or maxilla as per the surgical plan.
- This means that the three-dimensional position of the placed implants in the patient's bone will correspond to their planned positions within the error margins allowed by professional consensus, as detailed in the all-time international literature.

1.3. Indications and contraindications

Indications:

- The indication of the use of the SMART Guide planning software is the need for dental implantation because of edentulousness over 18 years of age.

Contraindications:

- The contraindications are the same as those for conventional freehand implant surgery.[2]
- Absolute contraindications: any serious condition or untreated disease including diseases of the bones, their metabolism, disorders of blood coagulation, diseases of the cardiovascular system, immune diseases, neoplasia, etc., treatment with bisphosphonates, immunosuppressed states, alcohol or drug abuse, poor compliance of the patient and/or relatives (or a complete lack thereof) due to pathologically altered mental functioning or otherwise.
- Relative contraindications: radiotherapy (for 2 years after irradiation), uncontrolled diabetes, hemorrhagic diathesis or anticoagulant therapy, heavy smoking.
- Temporary contraindications: untreated periodontal disease, retained root in the intended implantation site, local infection, untreated potential foci (untreated caries, periapical processes, etc.), poor oral hygiene, transient infective diseases (bacterial or viral), other contraindication of surgery in general (e.g. acute infection with fever), age under 18 years, pregnancy.
- Relative local contraindications: erosive or bullous disease of the oral mucosa (because of local or systemic reasons), bruxism, parafunction, advanced atrophy of the jawbone.

1.4. Users and training requirements

This documentation is intended for users who are qualified as medical doctors, dentists or dental technicians and have undergone proper training to allow them to perform the described procedures.

[1]Varga E Jr, Antal M, Major L, Kiscsatári R, Braunitzer G, Piffkó J. Guidance means accuracy: A randomized clinical trial on freehand versus guided dental implantation. Clin Oral Implants Res. 2020 May;31(5):417-430.

[2]From the implantology guidelines of the Implantological Society of Hungarian Dentists

Please note that the procedures described in this documentation may not be performed in lack of such qualification(s).

1.5. Adverse events and side effects

For the purposes of this documentation, an adverse event is any event, putatively related to the use of the System, which has an adverse effect on the health of the user or the patient. There are no known adverse effects or side effects related specifically to the use of the System, and neither have adverse events been reported. According to the manufacturer's best knowledge and the international literature on similar systems, the use of the System does not carry any significant additional risks or specific side effects as compared to the situation when implant surgery is performed without the use of the System. Should, however, an adverse event occur, it must be reported to the competent authority of the member state where the event occurred, in case of Hungary:

Nemzeti Népegészségügyi és Gyógyszerészeti Központ, Orvostechnikai Főosztály
1097 Budapest, Albert Flórián út 2-6.
Phone: +36 1 886 9300
E-mail: info@egeszsegvonal.gov.hu

1.6. Residual risks

The preparation and manufacturing of the surgical guide involves human intervention, so human error during preparation and manufacturing cannot be excluded. However, in our experience, its chance is extremely low.

The three-dimensional space displayed in the software is a limited representation of reality. Its accuracy depends on the resolution of the applied input images and the resolution applied in the software. See Chapter 1.7 for maximum accuracy.

The user shall be liable for any risk or damage stemming from ignoring the software's notifications regarding potentially hazardous situations (see Chapter 5.6).

To minimize cybersecurity risks, please observe Chapter 1.8.

Should the surgeon become uncertain regarding the accuracy of the surgery while performing it with the surgical guide or if the surgical guide gets damaged before or during the surgery, it is recommended to fall back on the conventional freehand procedure. The application of the surgical guide does not exclude the possibility of returning to the conventional procedure at any point.

1.7. Accuracy

The accuracy of the CT image corresponds to that of the raw CT input. The criterion for input resolution is a voxel size of 0.2 to 0.4 mm.

The algorithm that calculates the optimal distance between the guiding sleeve and the tissues (as represented by an intraoral scan or the CT image of an analog impression) is accurate to 7 decimal places.

The safety zones to prevent the collision of objects are accurate to 7 decimal places. The safety zones have been determined individually for each instrument group, based on expert opinion.

1.8. Cybersecurity

Password protection

- Use a long and possibly complex password.
- The password should not contain the name of the user, not even its parts.
- Never give your password to anybody, do not write it in a clearly visible or easily accessible place and do not enter it while somebody is watching.
- Do not send your password in either regular mail or email.
- Change your password immediately if you suspect unauthorized access.
- The password should not be easily guessed and it should not contain information related to the user.
- Allow the web browser to remember your password only if you are using your own computer and nobody else has access to the computer.

Antivirus software

- Use antivirus software for your own safety.
- Keep the antivirus software updated.
- Never use an unknown data medium or one of uncertain origin (pendrive, external drive, etc.)

Firewall

- If your software environment is protected by a firewall, add dicomLAB Cloud platform to the exceptions.

Network in a practice or clinic

- If you use the software through the network of a dental practice or clinic, ask the system administrator to set up the antivirus software and firewall for you.

Public or shared networks

- Do not use the planning software module and dicomLAB Cloud on a public computer/through a public Wi-Fi network (e.g., airport Wi-Fi, internet café).
- If you access the planning software module and dicomLAB Cloud through a local area network (LAN), be aware that the computers of the network may share data with each other.

Physical security

- Never leave your computer logged in if there is a chance that someone else can access it.

Other software

- Do not install software that can have a potentially detrimental effect on performance or security (e.g., games can affect performance while remote desktop applications pose a security risk).

Notify the manufacturer

- Notify dicomLAB Dental Ltd. immediately if you have detected or suspect a security breach.

Environmental security

- If you share a computer with others, always log in with your own user account.
- Always keep your operating system and browser up to date.

Phishing

- Never respond to suspicious email and never open attachments in such emails. DicomLAB Dental Ltd. will never ask you for your username and password.
- Always make sure that you are really on the website of DicomLAB (check the URL in the browser's address bar).
- Always make sure that the connection is secure (this is indicated by a small padlock icon at the beginning of the address bar).

1.9. How to use this manual

Please read this manual carefully before you start using SMART Guide planning software. Make sure that the version number indicated in the manual corresponds to the software version you use. Several images in this manual show screens from the software. To indicate possible mouse actions in any given screen, we use schematic mouse icons as shown in Figure 3. These icons do not appear in the software, they serve only the purposes of illustration in this manual. The red rectangles marked A, B, C, etc. (used to highlight parts of a screenshot in this manual, see for instance Figure 4) are not parts of the software either. They are used only in this manual to ease the understanding of the explanations.

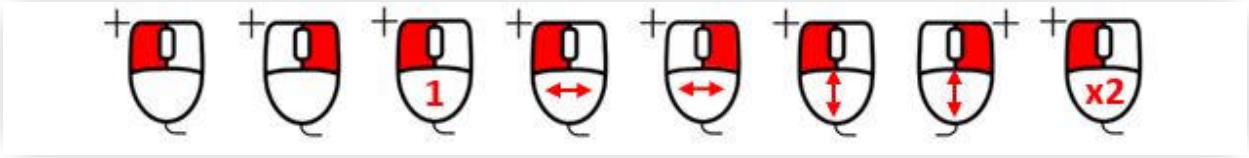

Figure 3: Mouse actions as symbolized by the icons used in the manual. Left to right: single click with the left button, single click with the right button, indication of the number of the click in a series of clicks (1st, 2nd, etc.), horizontal click and drag with the left button, horizontal click and drag with the right button, vertical click and drag with the left button, vertical click and drag with the right button, double click with the left button.

1.10. Symbols

The following table provides the explanation of the symbols on the label.

Symbol	Symbol title	Symbol explanation	Source of Symbol
	Read the user manual	It indicates that the user must read the user manual	ISO 15223-1
	Medical device	It marks the product as a medical device	MDR (EU) 2017/745
	Name and address of manufacturer	It identifies the manufacturer of the medical device, in accordance with European Union Directives 90/385/EEC, 93/42/EEC, and 98/79/EC. This symbol is accompanied by the name and address of the manufacturer.	ISO 15223-1

CE	Conformité Européenne or European Conformity	Products marked with the CE symbol are declared by the manufacturer to be in compliance with EU regulations. Where applicable, the identification number of the Notified Body must be indicated after the symbol.	MDR (EU) 2017/745
UDI	Unique device identification	It indicates the primary manufacturing identifier of the device	MDR (EU) 2017/745

2. Launching and system requirements

SMART Guide planning software can be launched from the case management system in cases that have reached the planning phase.

2.1. Installation

The application runs within a web-based backend system, so there is no need to install it on the user's computer.

2.2. Launching

SMART Guide planning software module is not a standalone application. It can be launched from within the online case management system of dicomLAB Cloud (henceforth: Cloud) once a case has entered the planning stage. Cases can be created after registration to the Cloud. To create a case, it is required that the user enter essential information about the patient and the planned surgery. The Cloud helps the user through this process with information bubbles. Once the essential information has been entered, the user is instructed to upload input diagnostic images. Information on the format of these images, minimum criteria, and imaging protocols are provided in information bubbles. After uploading the diagnostic images, the case enters the preparatory stage. At this stage, the trained dental technicians of dicomLAB Dental Ltd. process the input data and prepare the case for planning. In the planning stage, the user can open the case in the planning software module to prepare the surgical plan.

2.3. Minimum system requirements

SMART Guide planning software may be used only in a system environment that meets the following minimum requirements:

CPU (processor)	i5 (4th generation: 45xx) or any other x86 processor of identical performance
Video card	Any card with WebGL 2.0 support or integrated video card
Memory	8 GB
Browser	Google Chrome (version 56 or higher) or Microsoft Edge (version 79 or higher)
Free disk space	5 GB

Display	Full HD 1920 × 1080
Internet connection	Upload: 256 kbps, Download: 2048 kbps

3. Views

There are three main views: the planning view, the 3D view and the panorama view (Figure 4).

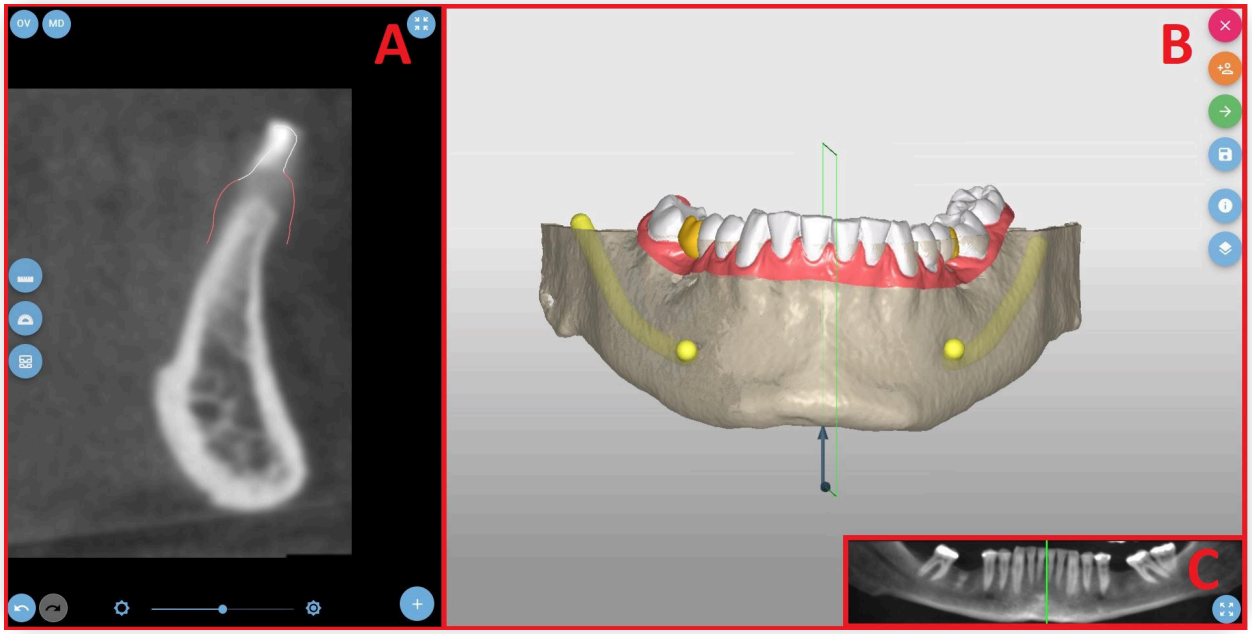

Figure 4: Views. Planning view(A), 3D view (B), panorama view (C).

3.1. The Planning View

The planning view occupies the left side of the main window. This is where implants and fixation pins are added and modified. By default, this view shows a sagittal (orovestibular) section. The section plane can be moved along the dental arch by adjusting the position of the section plane indicator (see later) in the panorama view. The section plane can be also rotated around its axis by clicking and dragging with the right mouse button as shown. (Figure 5, Figure 6).

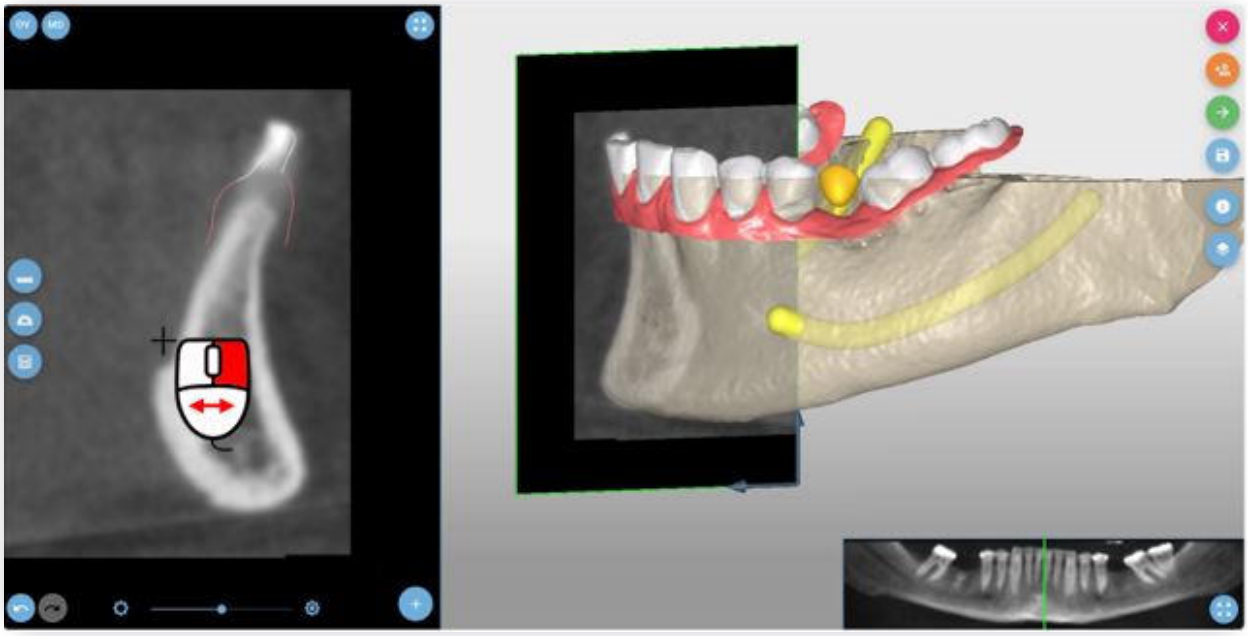

Figure 5: The planning view. The section plane can be rotated by clicking and dragging horizontally with the right mouse button.

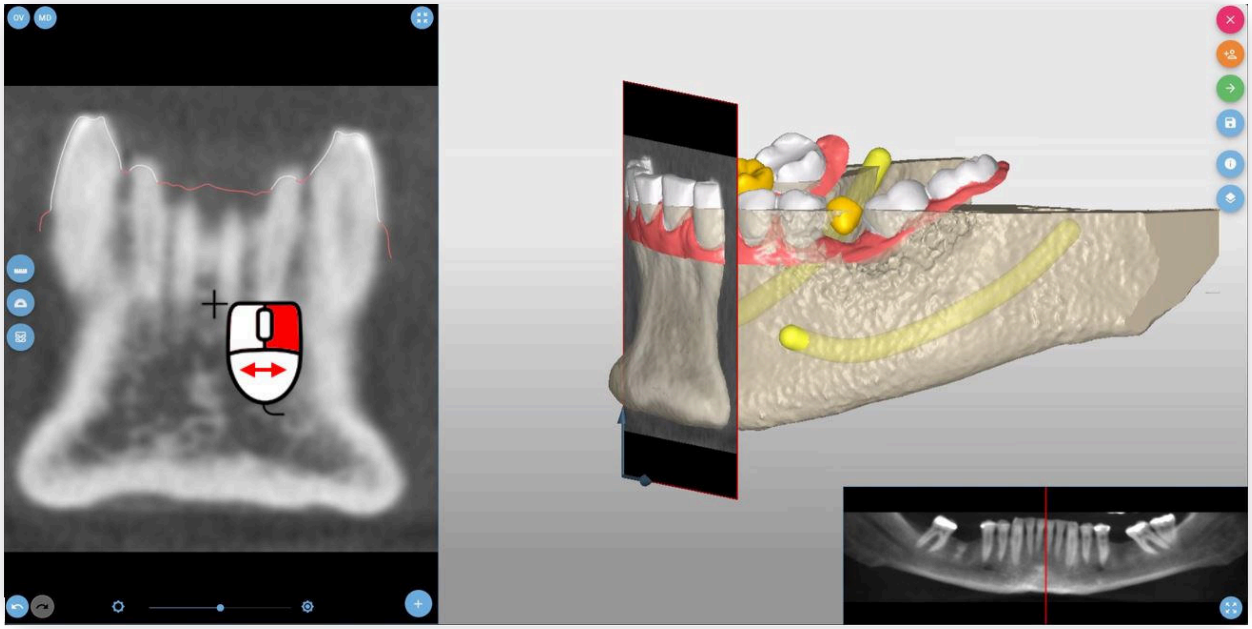

Figure 6: The planning view. Horizontal clicking and dragging with the right mouse button has rotated the section plane

Note that if an implant or fixation pin is selected, the axis of the selected object is the axis of rotation.

3.1.1. Tools

At the top and the bottom of the planning view, various tools are found to support easy and comfortable planning.

These tools are as follows: Figure 7.

Default section planes: These buttons allow switching between the default orovestibular and mesiodistal section planes.

Resize view: Increase or decrease the size of the planning view.
Undo/Redo: Undo/Redo planning actions such as adjusting the position of an implant or a fixation pin, rotating the section plane, etc.
Gamma: Darken or lighten the image.
Ruler: A virtual tool used for measuring distances, which allows us to measure the distance between two points on the design plane. The starting point of the segment to be measured is fixed on the plane with a left mouse click, and then the endpoint is fixed with another left mouse click at the desired point. After fixing the starting point, the current length of the segment is displayed with an accuracy of two decimal places in the upper-middle third of the design plane. When the mouse cursor approaches the endpoints of the ruler, a circle appears, and by clicking the left mouse button and holding it down, the given endpoint can be moved. In this case, the distance display is updated in real-time with the current distance measured by the ruler. Due to the straight projection of the design plane, the measured distance is also the 3D spatial distance between the two points. The ruler allows measurement with an accuracy of two decimal places, within a margin of error of ±0.2 mm.
Protractor: A virtual tool used for measuring angles, which allows us to measure the angle between two segments originating from a single point on the design plane. With three left mouse clicks, you can successively designate one side of the angle, the vertex of the angle, and the other side of the angle. When the angle is placed, the angle enclosed by the two sides is displayed with an accuracy of two decimal places in the upper-middle third of the design plane. When the mouse cursor approaches the endpoints of the angle, a circle appears, and by clicking the left mouse button and holding it down, the given endpoint can be moved. In this case, the angle value display is updated in real-time with the currently measured angle value. Due to the straight projection of the design plane, the measured enclosed angle is also the 3D spatial enclosed angle between the two segments. The protractor allows measurement with an accuracy of two decimal places, within an arctan(|AB|±0.2) degree margin of error, where AB is the shorter side of the angle, and ±0.2 is the ruler's—i.e., the line drawing's—margin of error. If the shorter side of the angle is at least 10 mm long, then the margin of error is ±1.14 degrees. To stay within the margin of error, please ensure that both sides of the angle are at least 10 mm long.
Kit settings: Launch the kit settings window (Figure 25)
Implant settings: Launch the implant settings window (Figure 29)
Add object: Add an implant or a fixation pin.
Delete object: Delete an implant or fixation pin (one by one or all at the same time).

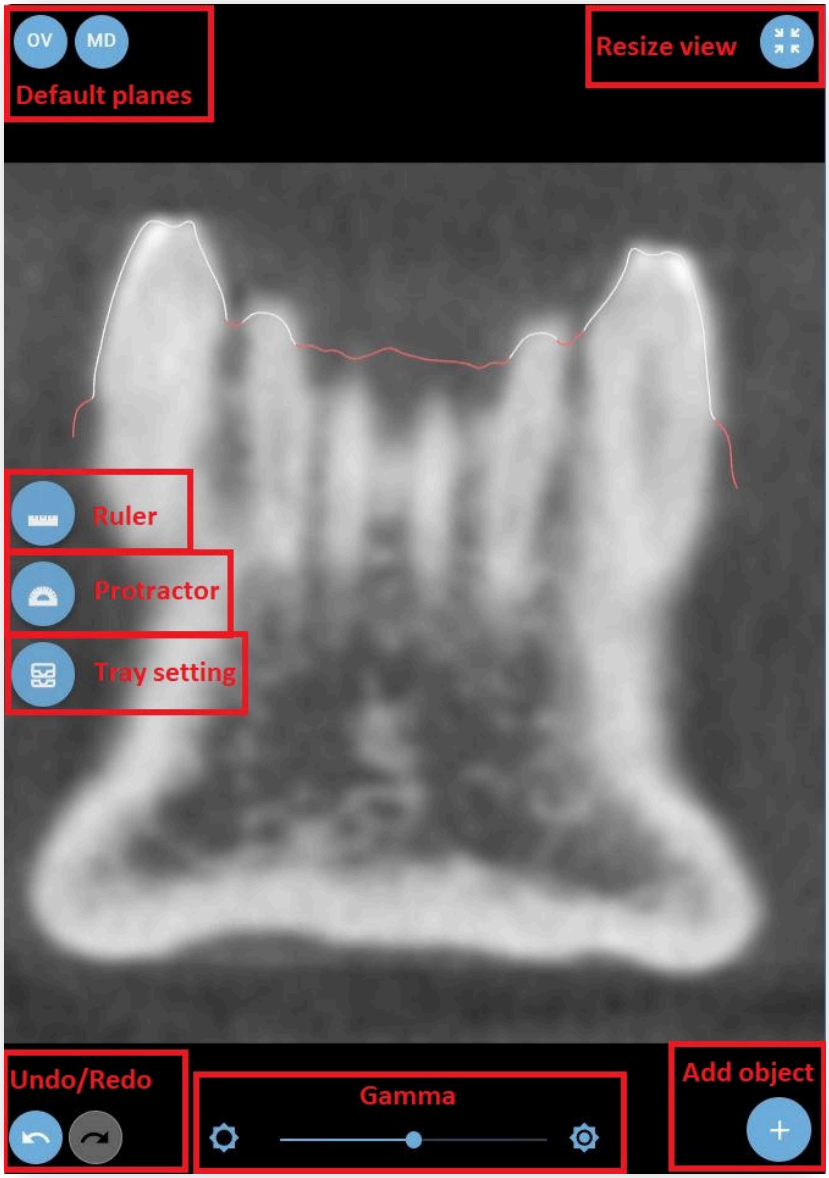

Figure 7: Tools of the planning view.

When an object (implant or fixation pin) is selected, the “add object” button is not available, and the default plane selector buttons use the axis of the selected object as the reference axis (i.e. mesiodistal and orovestibular are defined as related to the selected object). Furthermore, selecting an object opens an object toolkit at the top of the view (discussed later in Chapter 5).

3.2. The 3D View

The 3D view shows a three-dimensional digital model of the patient’s anatomy, generated from the input images discussed in the Overview. Furthermore, this view displays all planned objects (implants, fixation pins, etc.), their name, axis, and the guiding sleeves as they will be positioned in the surgical template according to the planned position of the corresponding implants. Move the contents of the view by clicking and dragging with the left mouse button. Rotate by clicking and dragging with the right mouse button. Click on any planned object to select it. Hovering the mouse pointer over any object that can be selected will highlight the contours of the object (Figure 8).

In the 3D view, the frame of the section plane is color-coded as follows:

- Blue: the position and orientation of the plane is neither a default setting nor is it locked to an object
- Green: the plane is oriented in the orovestibular direction (default setting)
- Red: the plane is oriented in the mesiodistal direction (default setting)
- Light blue: the plane is locked to an implant or fixation pin

The color coding corresponds to that of the section plane indicator in the panorama view.

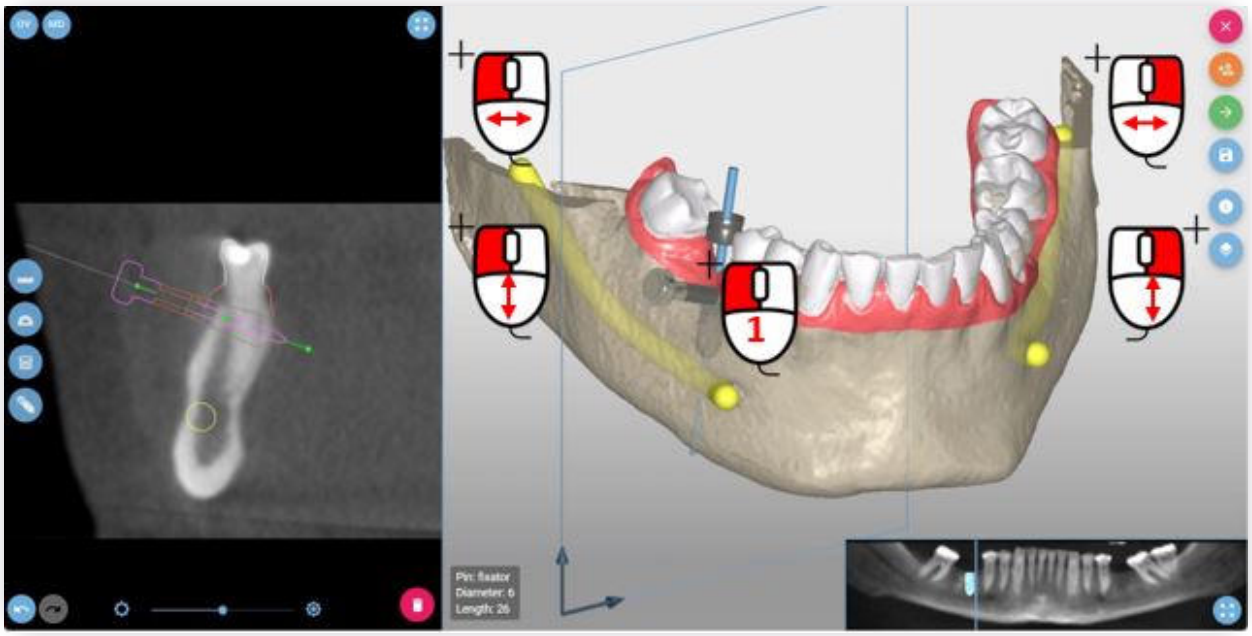

Figure 8: Actions in the 3D view.

3.2.1. Settings of the 3D View

The 3D settings menu can be opened by clicking on the blue icon in the top right corner of the view as shown in Figure 9.

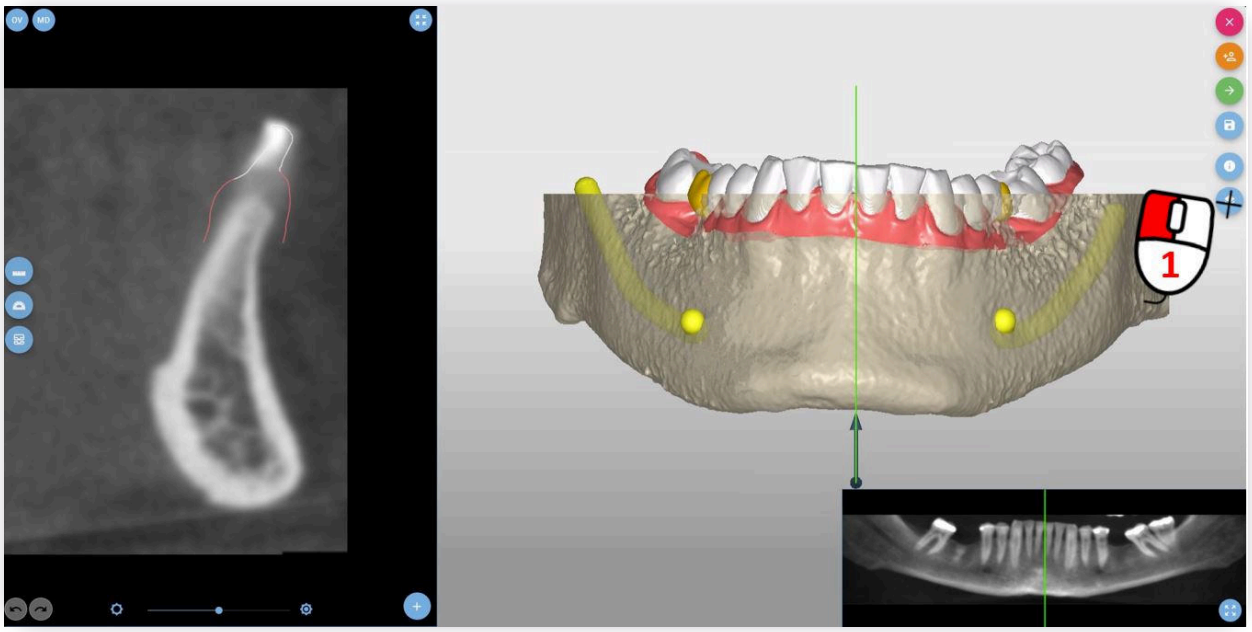

Figure 9: The location of the 3D settings view.

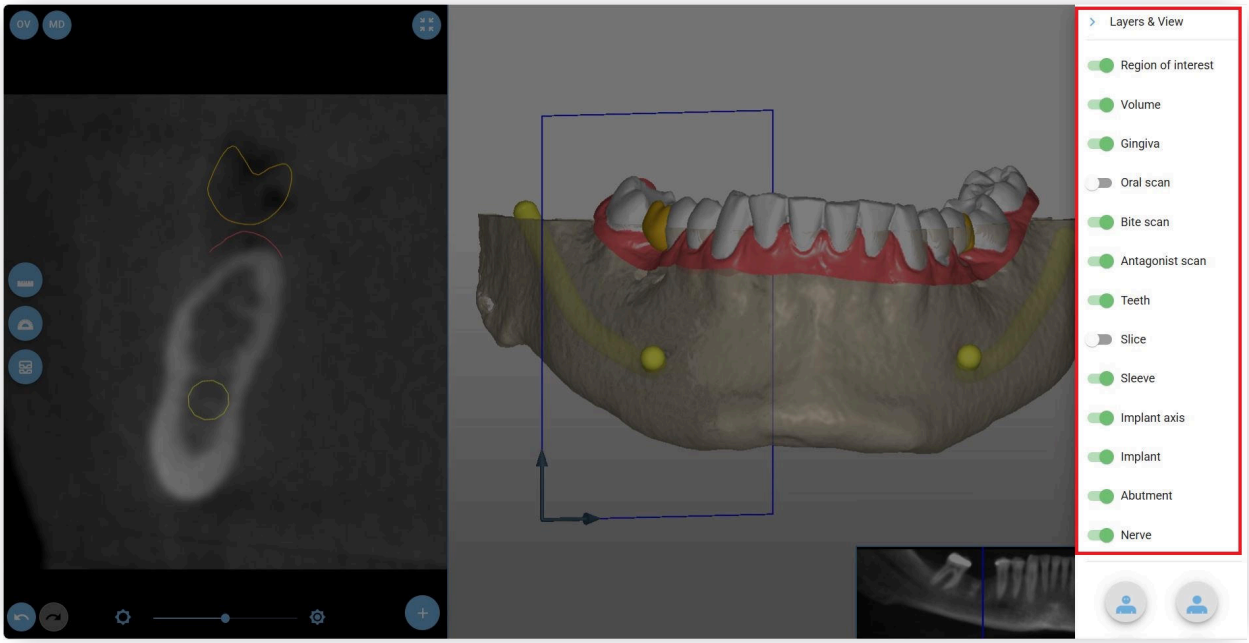

Figure 10: The 3D settings panel. Visibility switches.

As shown in Figure 10, the 3D settings panel contains visibility switches for the following elements:

- Region of interest (hide skull)
- Volume (hard tissue)
- Gingiva
- Impression (or oral scan)
- Bite (only in case of a 3 oral scan protocol)
- Antagonist (only in case of a 3 oral scan protocol)
- Tooth (digital prosthetic visualization)
- Slice (toggle cross-sectional image on and off)
- Sleeves
- Implant axis
- Implants
- Nerve canal

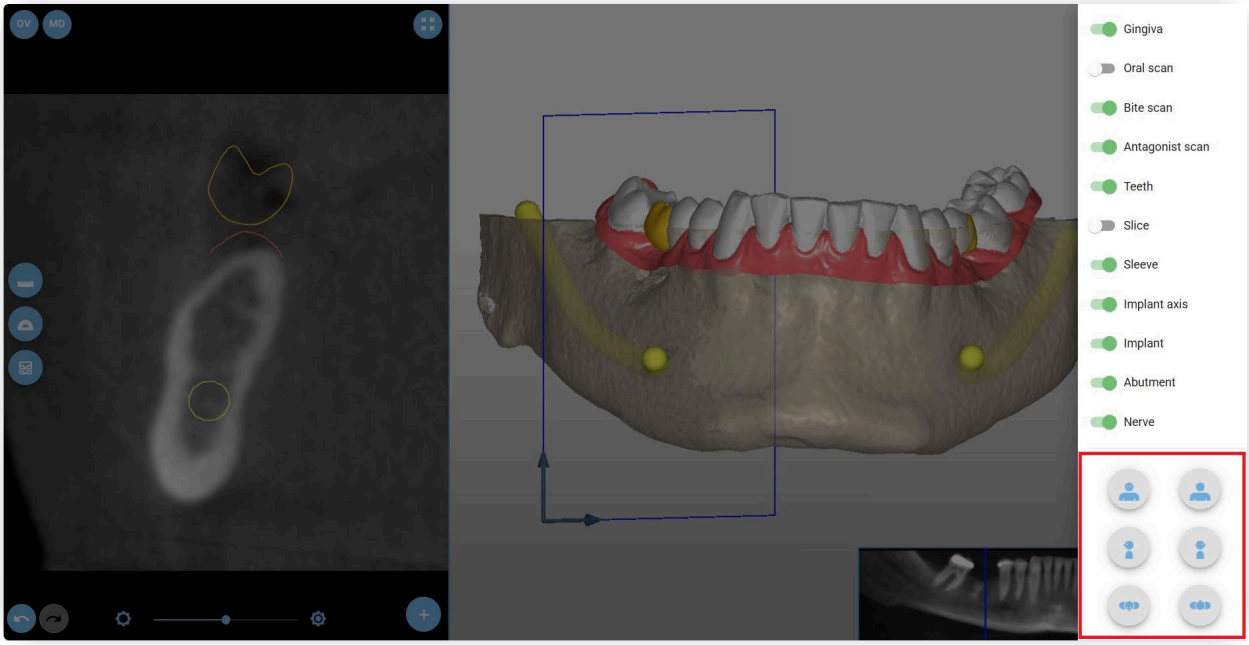

Figure 11: The 3D settings panel. Buttons for the default views.

The bottom of the panel contains buttons to switch between six default views (Figure 11). The views themselves are shown in Figure 12 and are as follows (right to left, top to bottom): front, back, left, right, top, bottom.

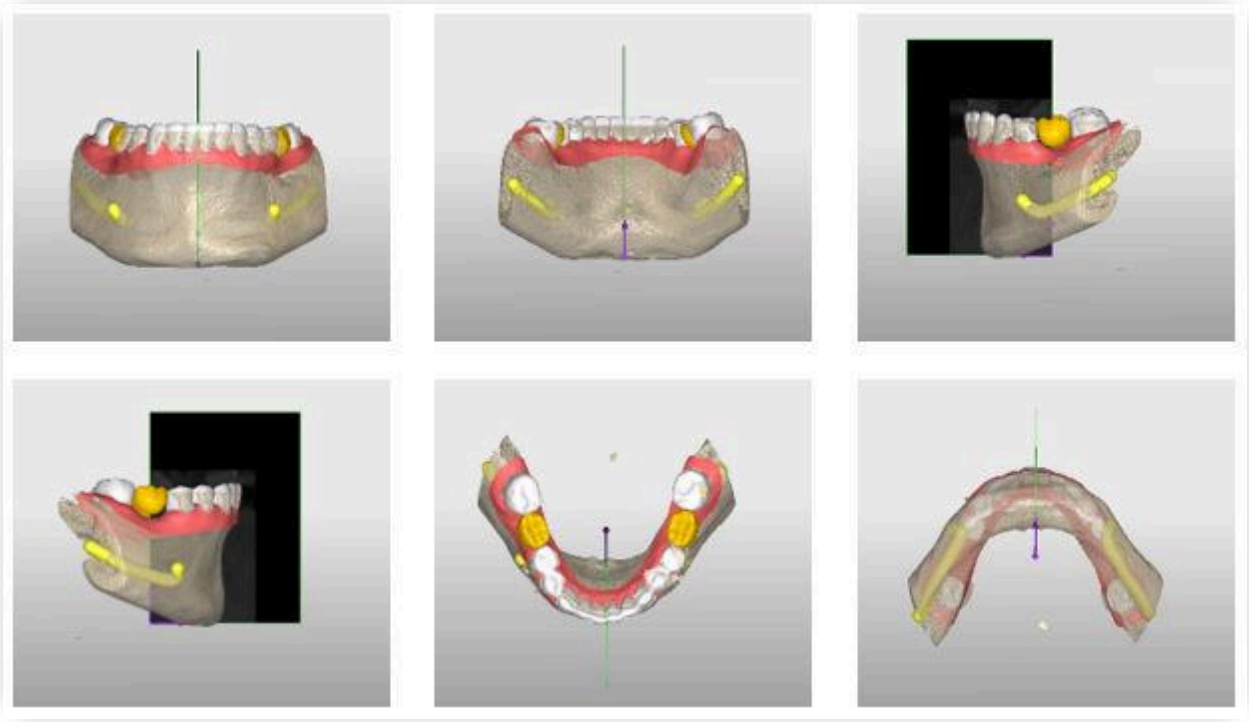

Figure 12: Default 3D views: front, back, right, left, top, bottom

3.3. The Panorama View

The panorama view shows a quasi-panoramic X-ray image generated from CBCT images along the planning arch with the planned implants.

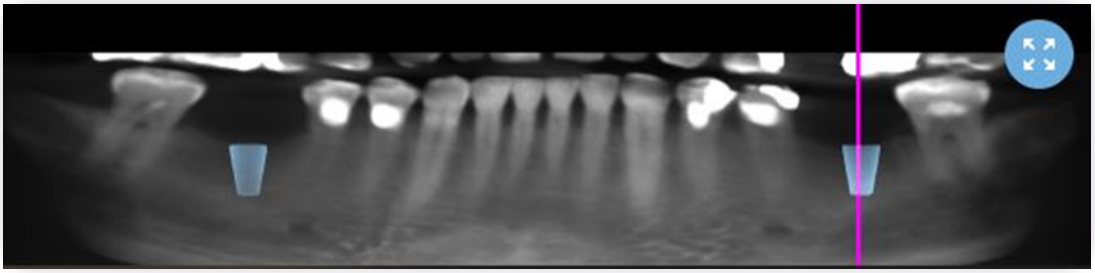

Figure 13: Panorama view with implants

The position of the section plane (planning plane) can be defined in this view with the help of the section plane indicator (purple vertical line). Either click on the desired position with the left mouse button or click and drag with the left button. Clicking on an implant selects the implant.

In the panorama view, the section plane indicator is color-coded as follows:

- Blue: the position and orientation of the plane is neither a default setting nor is it locked to an object
- Green: the plane is oriented in the orovestibular direction (default setting)
- Red: the plane is oriented in the mesiodistal direction (default setting)
- Light blue: the plane is locked to an implant or fixation pin

The color coding of the indicator corresponds to the color coding of the frame of the section plane in the 3D view.

4. Close, finish planning, request mentor

The buttons are located in the upper right corner of the 3D view (Figure 14).

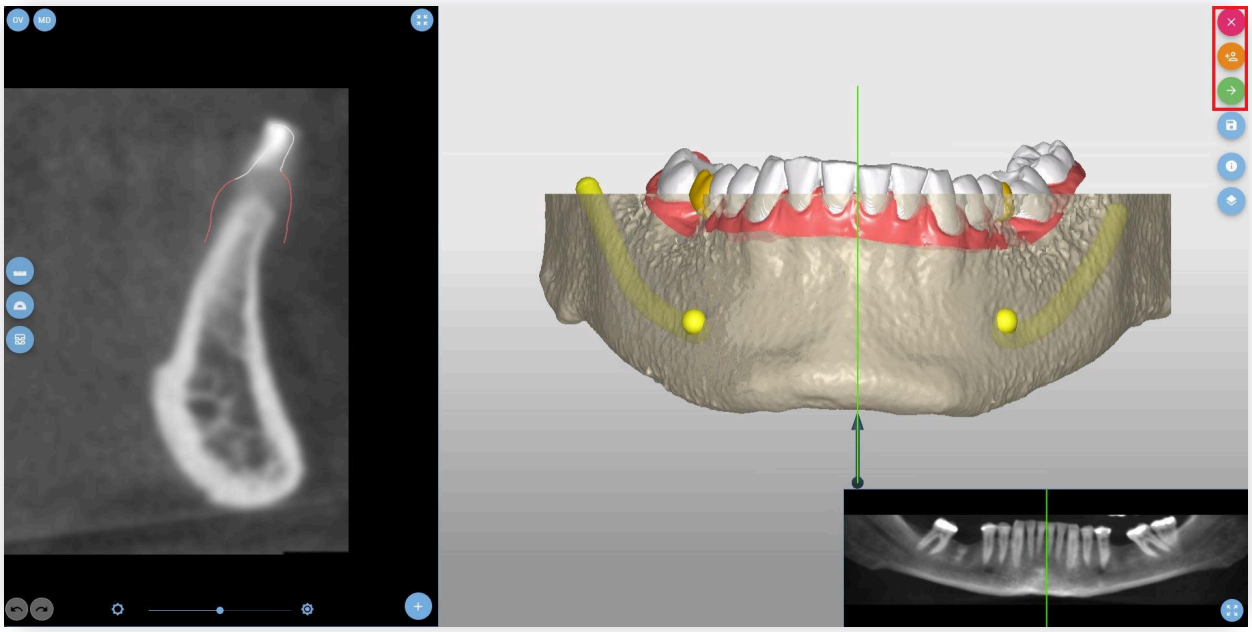

Figure 14: The location of the close, finish planning and request mentor icons

4.1. Close

- Clicking the “Close” button will close the surgical planner without saving. Any changes made since the last save or the plan’s opening will not be recorded.

- By clicking the “Save and Close” button, the current state of the plan is saved, and then the planner is closed. The plan is not finalized in this state and cannot be ordered. Finalization of the case is necessary for ordering. (Figure 15, Figure 16)

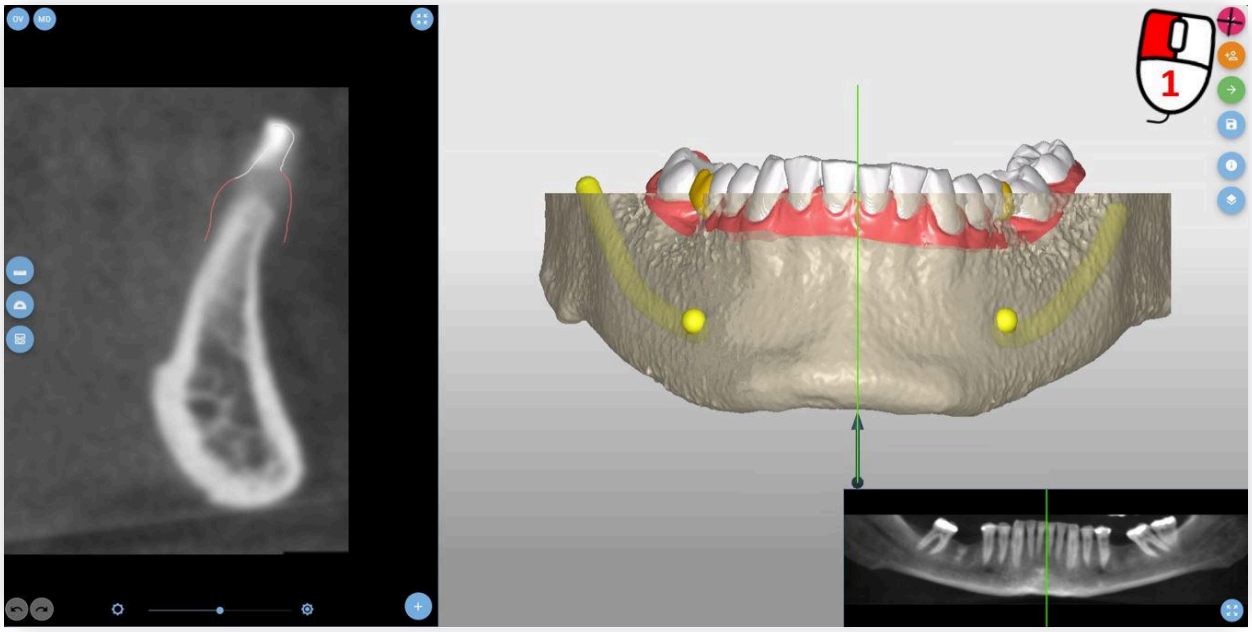

Figure 15: Use the Close button by left-clicking on it

Figure 16: Options in the Close pop-up dialog

4.2. Finish planning

The completed plan needs to be finalized, which can be done by clicking the “Finish Planning” button.

- Clicking the “OK” button will save and finalize the current state of the plan, and then the planner will close. After this, the plan can only be opened for viewing, it cannot be edited further.
- Planning may be continued by clicking the “Cancel” button.

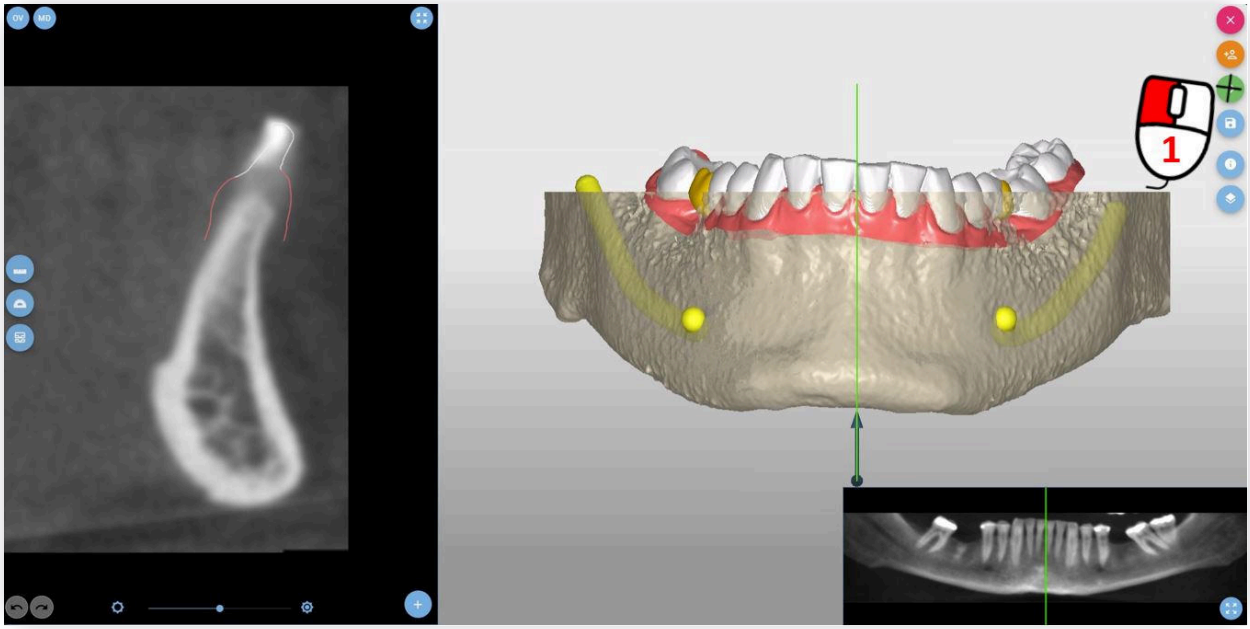

Figure 17: Use the Finish planning button by left-clicking on it

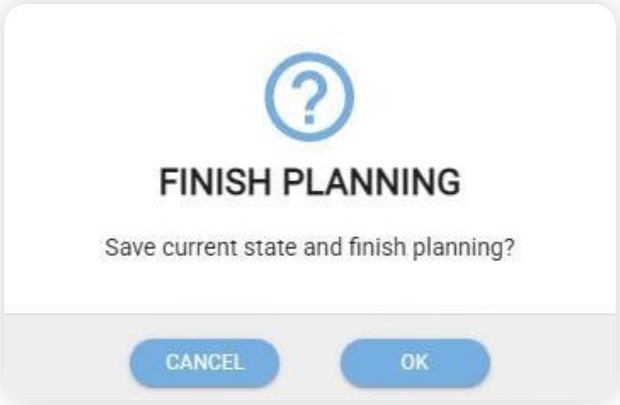

Figure 18: The Finish planning pop-up dialog

4.3. Request mentor (plan recommendation)

4.3.1. Initiating a plan request

During planning, it is possible to request assistance or plan recommendation. This request can be initiated by clicking the “Request mentor” button (Figure 19). After clicking the button, the Request mentor window appears, where you can review the case information and message history, and also have the opportunity to send a message to the mentor doctor. By pressing the “Send request” button, the current state of the case is saved, and then the planner closes (Figure 20). Until the completion of the mentor planning, the person who initiated the request can only open the plan for viewing.

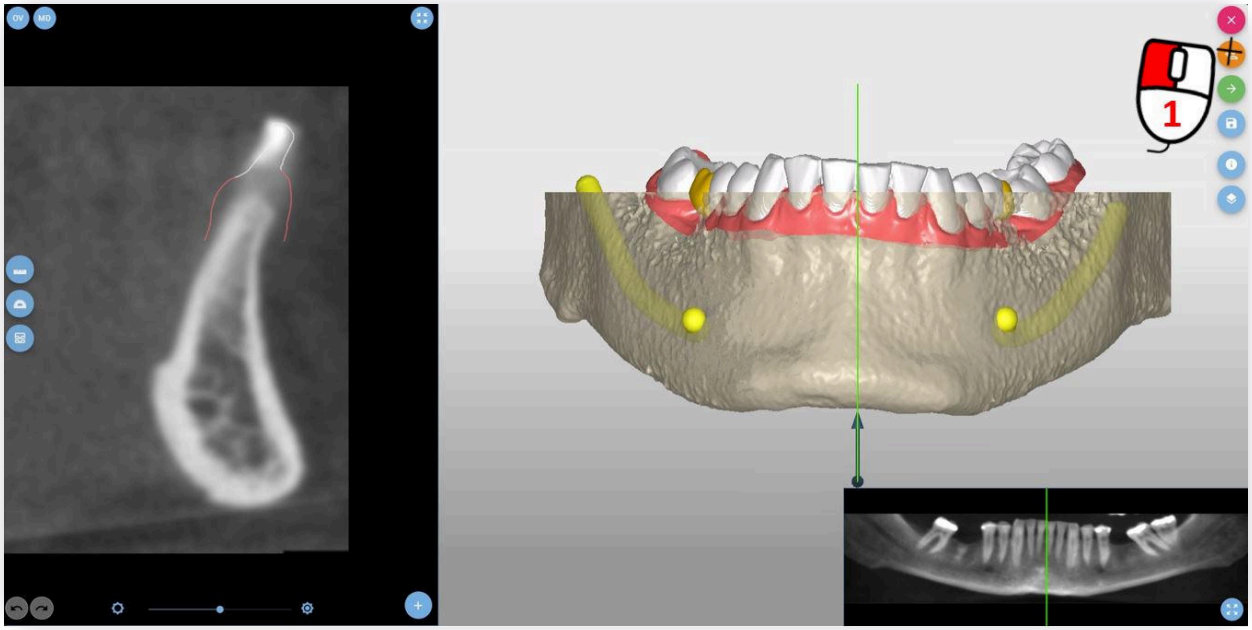

Figure 19: Use the Request mentor button by left-clicking on it

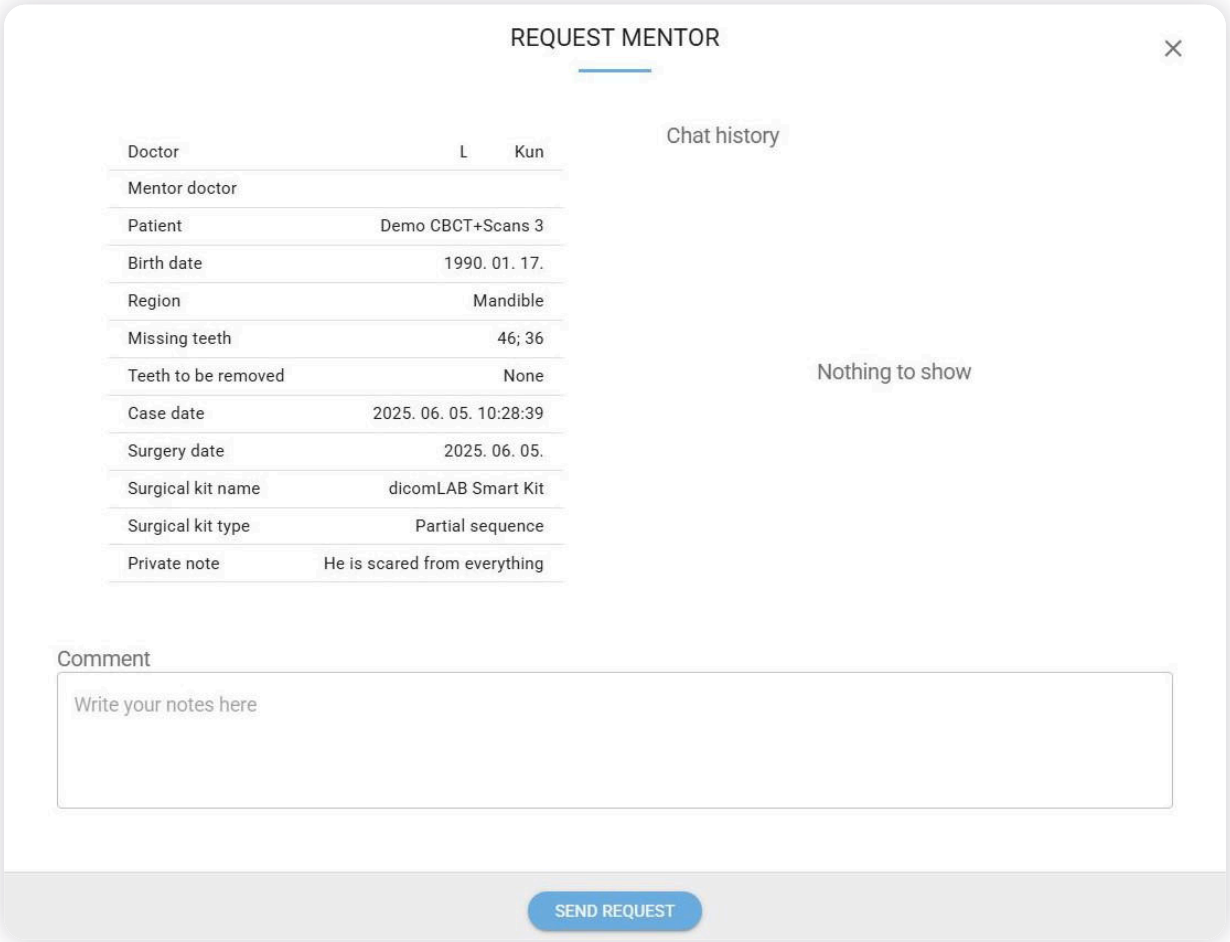

Figure 20: The Request mentor pop-up window

4.3.2. When the requested plan arrives

The plan created by the mentor is returned to the user who requested the recommendation. The plan becomes editable again, and the user can decide whether to accept it or send it back for further planning. In case of re-planning, using the “Send back to mentor” button (Figure 21) will open the Send back case window. Here it is possible to review the case information and message history and send a message to the mentor. By clicking the “Send back to mentor” button, the current state of the case is saved, and then the planner closes (Figure 22). Until the completion of the mentor planning, the plan can be opened for viewing only.

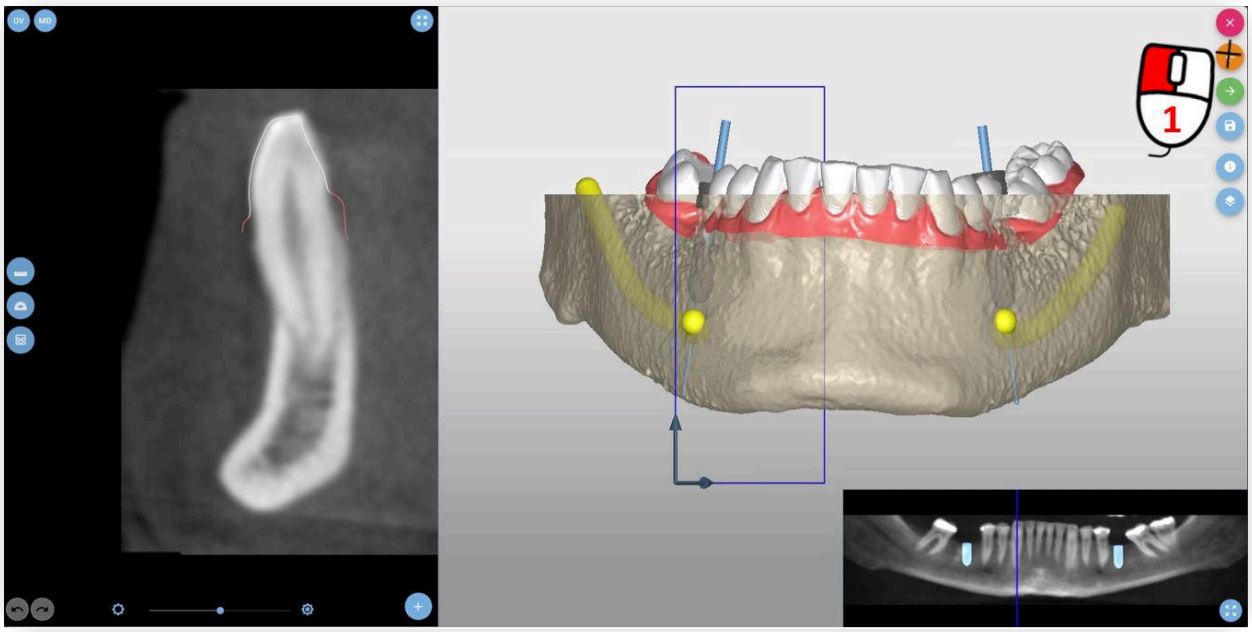

Figure 21: The Send back to mentor button.

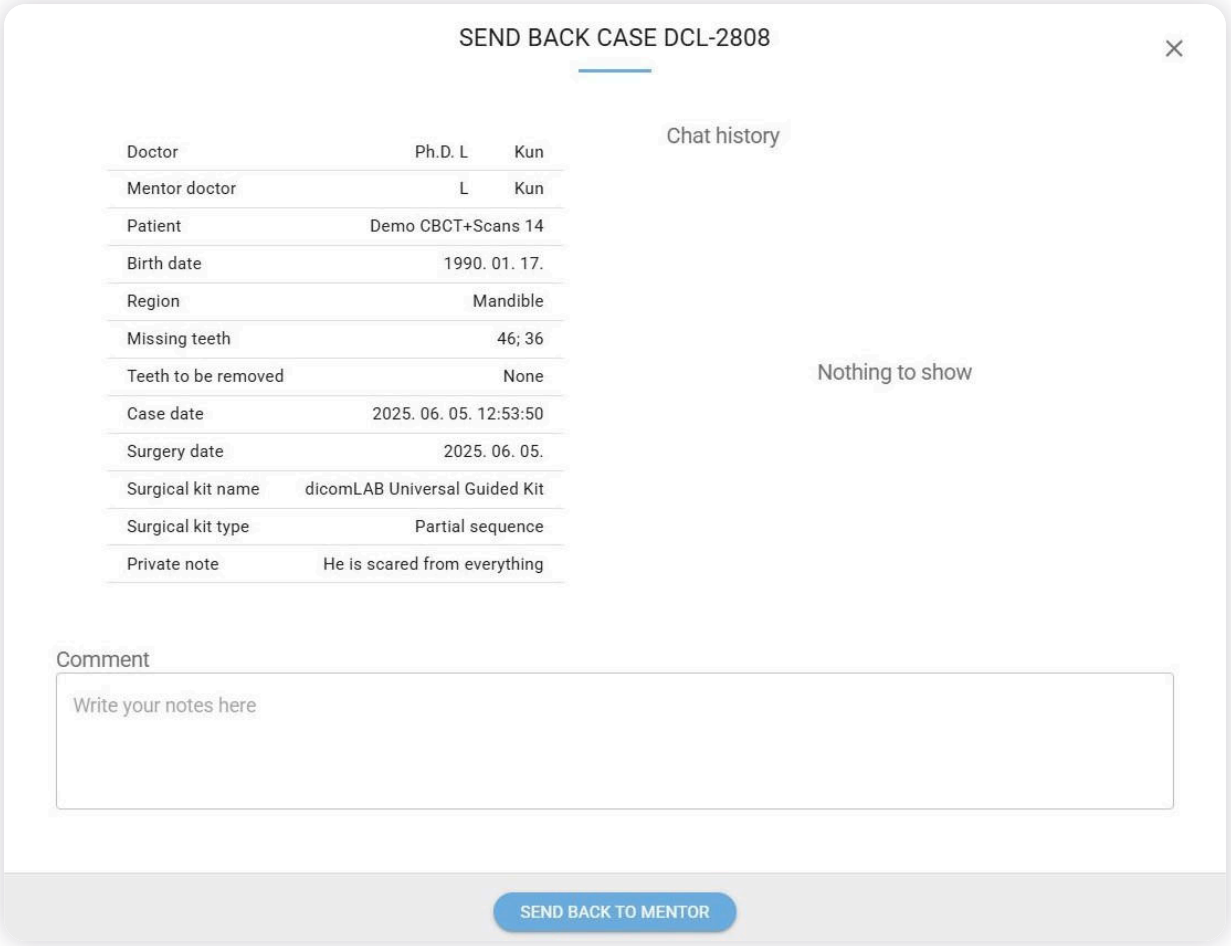

Figure 22: The Send back case pop-up window

4.3.3. Accepting a plan recommendation request (for mentors only)

After the opening of the cases for which a plan recommendation has been requested, the mentor may decide whether to undertake the preparation of the plan recommendation. By clicking the “Take it” button (Figure 23), the plan becomes editable. The completed plan recommendation can be returned for review using the finish planning button (Chapter 4.2). After completion, as a mentor, the plan can only be opened for viewing. An exception is if the requester of the plan recommendation sends back the case for further planning.

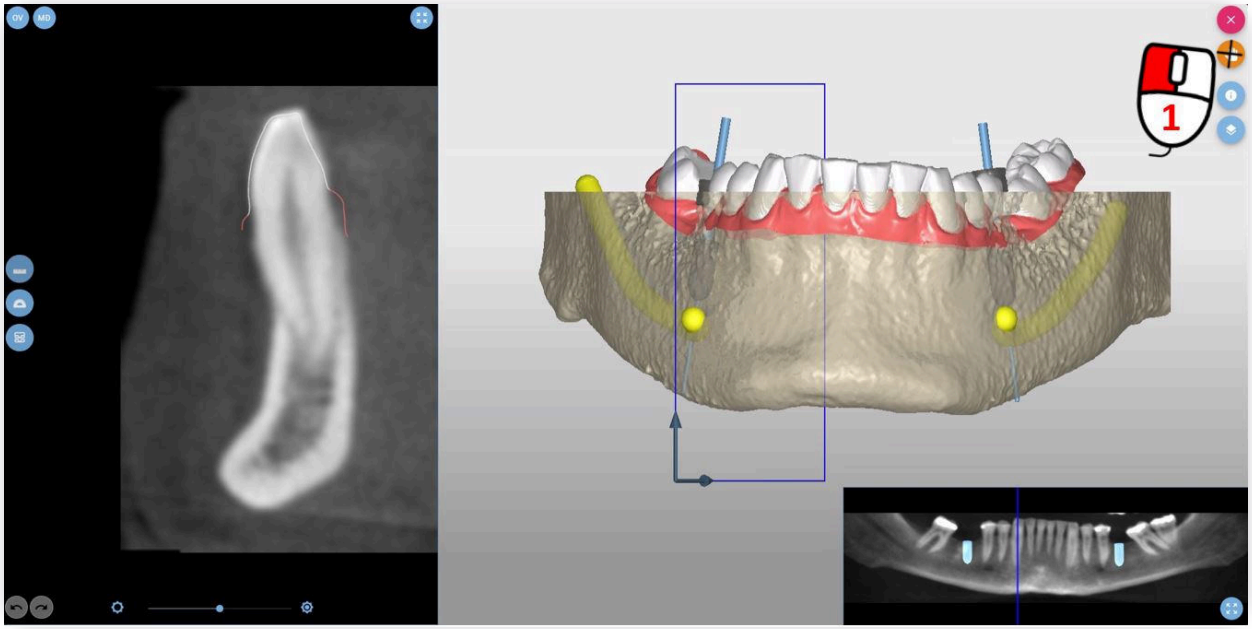

Figure 23: The Take it button

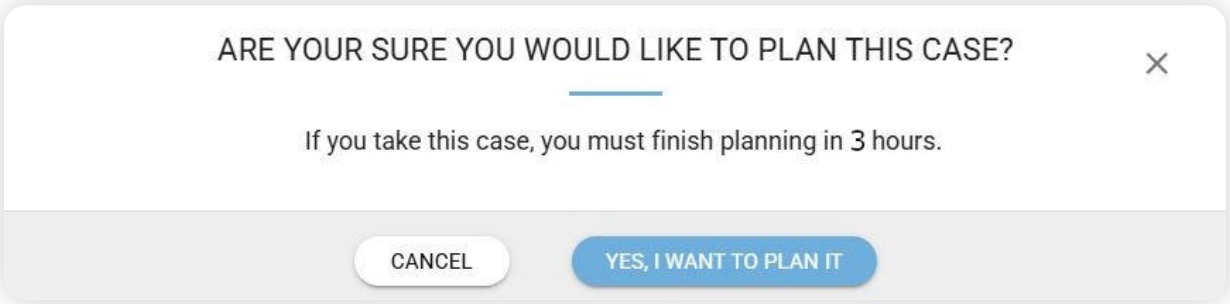

Figure 24: Confirming the acceptance of a plan request

5. Planning

Implants and fixation pins can be inserted in the planning view. The desired plane (location) of planning can be selected in the panorama view

5.1. Kit settings

With the help of the Kit Settings tool (Figure 25), the type of surgery, the type of surgical kit to be used during the operation, implant manufacturer, and implant family can be set. During planning, only one surgical kit can be selected for a case, however, a case can contain implants from multiple implant families, provided that the selected kit supports it.

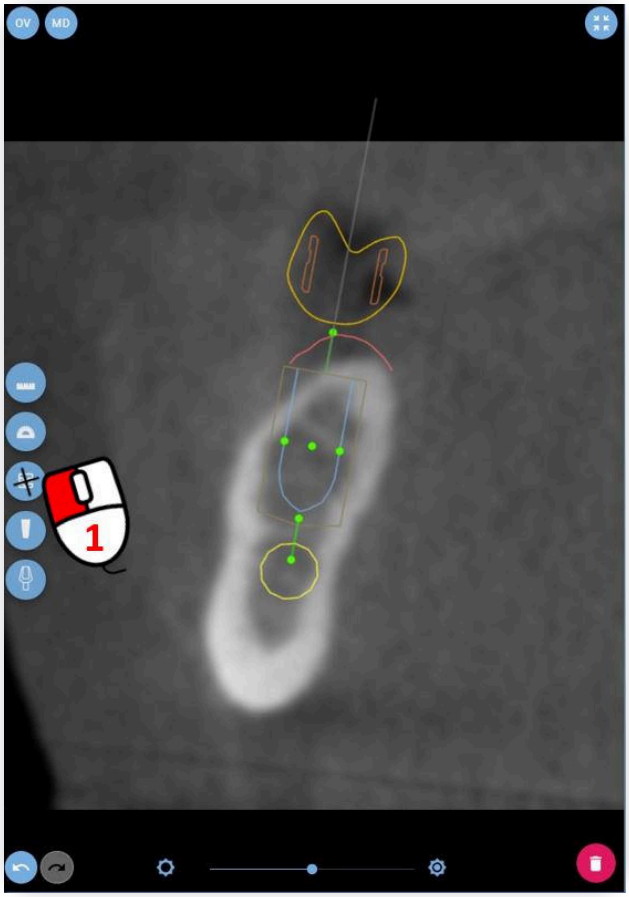

Figure 25: The Kit Settings button in the planning view

By clicking on the Kit settings button, the kit settings dialog box appears (Figure 26). From the dropdown menu, the desired type of surgery, kit, implant manufacturer, and implant system can be selected.

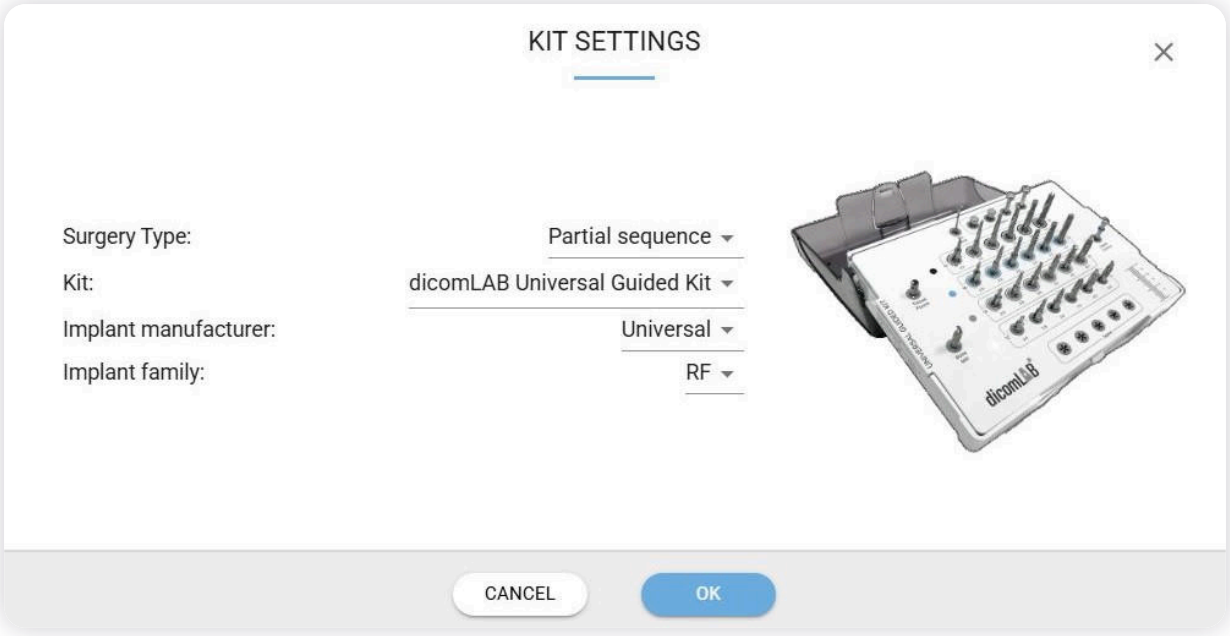

Figure 26: The Kit Settings dialog

5.2. Add & edit an implant

In the panorama view, upon positioning the section plane to the desired position, the “Add implant or pin” menu appears in the bottom right corner of the planning view (Figure 27).

Figure 27: Adding an implant

By clicking on the plus sign, the add implant button appears, which upon clicking adds an implant with default parameters to the plan at the center of the cross-sectional image, visible in all three views. The appropriate sleeve is also selected for every implant placed in the plan.

5.2.1. Implant settings

The Implant settings button appears on the left side of the planning view after selecting a given implant (Figure 28). After adding an implant, this implant is selected by default, while the implants already in the plan can be selected with a left mouse click in the 3D or panorama view. By clicking the button, the Implant settings window opens (Figure 29), where the desired implant manufacturer and family can be chosen, as well as the intended length and diameter of the implant to be planned. The Implant Settings window can be displayed by double-clicking on a given implant in the panorama and planning view. To delete an implant from the plan, click on the Delete implant button that appears in the bottom right corner of the planning view, which then offers the option to delete either the selected implant or all implants (Figure 30).

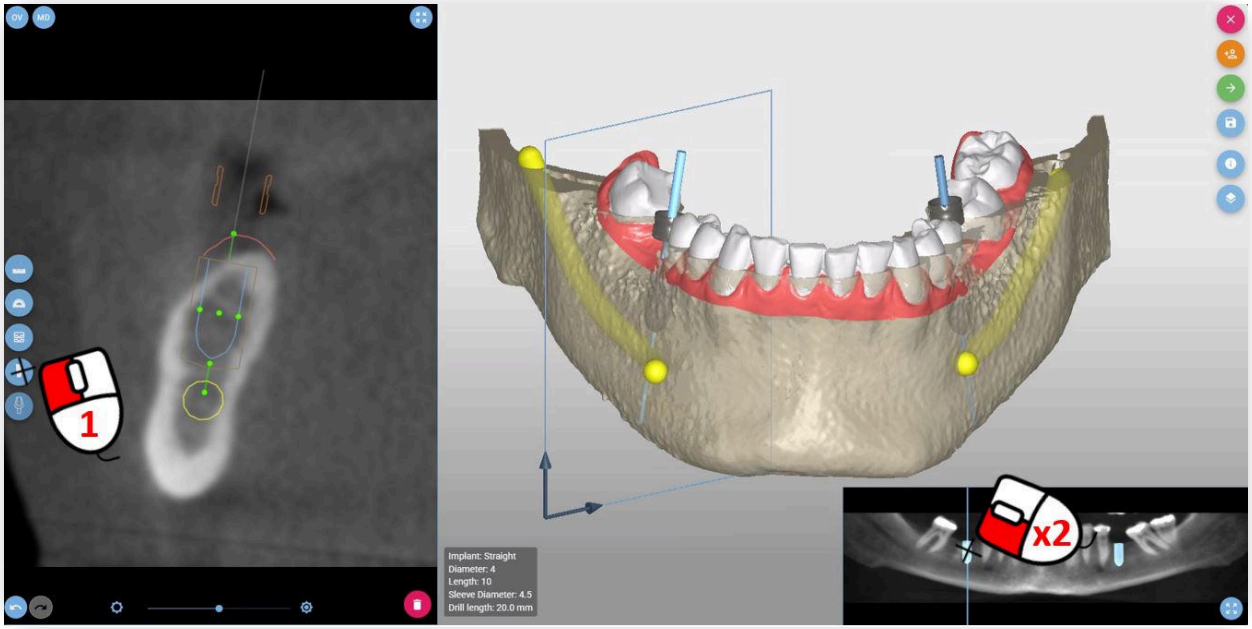

Figure 28: Implant settings

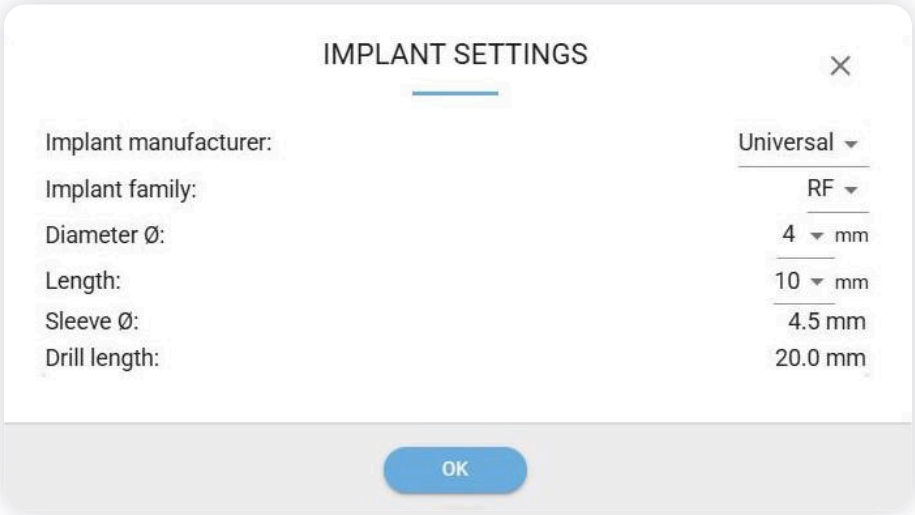

Figure 29: The Implant settings dialog

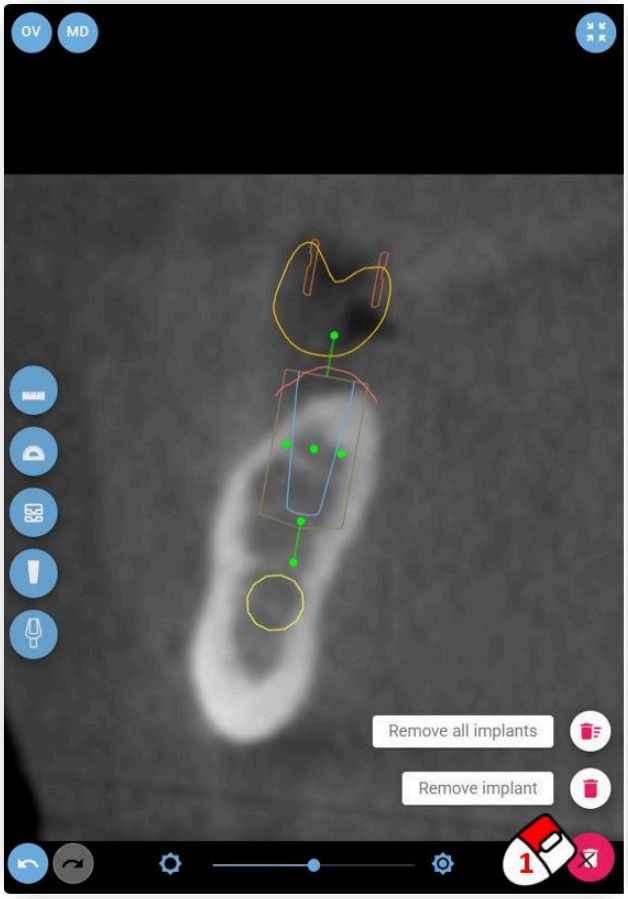

Figure 30: Deleting options

5.2.2. Move, rotate, resize

The selected implant is centered and focused in the planning view, at which point green control points appear around and in the middle of the implant. By holding down the left mouse button on the middle helper point and moving the mouse, the implant can be positioned; it can be rotated with the top and bottom points. Control points for resizing are found on both sides and at the bottom of the implant. The diameter of the implant can be adjusted with the lateral resizing control points, and its length can be adjusted with the control point at the bottom of the implant (Figure 31).

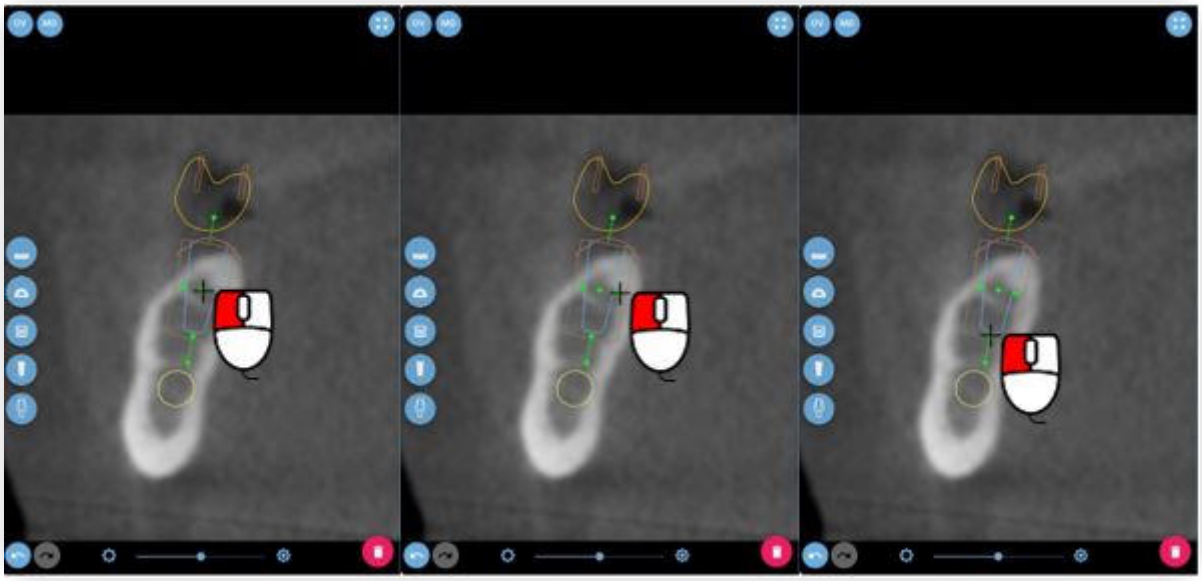

Figure 31: Left to right: move, adjust diameter, adjust length

With the upper control point, the implant can be rotated around its apex, and with the lower control point, around the center of its platform (Figure 32, Figure 33).

Figure 32: Rotation around the center of the platform

Figure 33: Rotation around the apex

5.3. Parallel aligner

With the parallel aligner tool, the rotational values of a given implant can be copied to one or more other implants. The tool (Figure 34) requires the panorama view to be set to a large size. After selecting the starting implant, the parallel aligner becomes active, and the function can be activated by clicking the “Parallel aligner” button (crosshair cursor). By clicking on the implant you wish to align, its rotational values will change to match those of the starting implant. The function remains active until you click on an empty area or the tool button. During the alignment process, the position of the central point of the implant does not change.

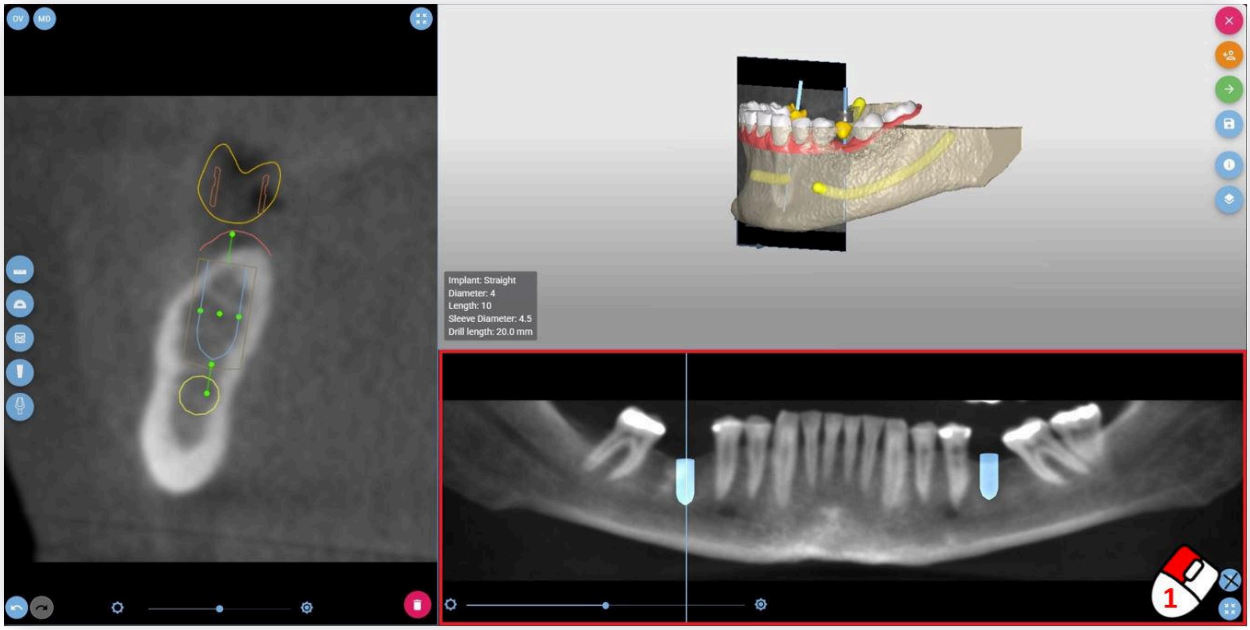

Figure 34: The button of the parallel aligner tool.

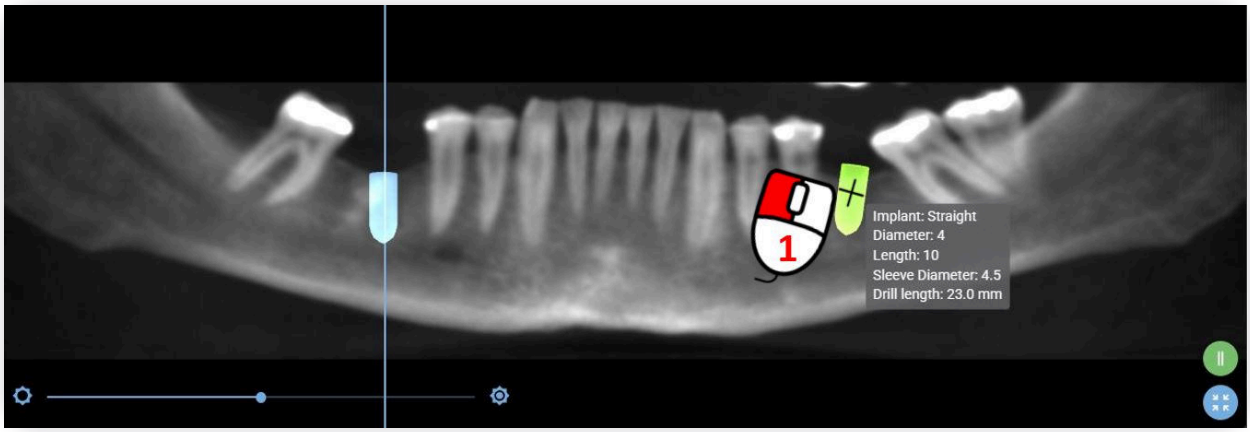

Figure 35: The tool can be used in the larger panorama view. While the tool is active, its button is green.

5.4. Visualization of prosthetic abutments

For each implant library, regardless of the selected surgical kit, a universal prosthetic abutment visualization is available to ensure more convenient and accurate surgical planning. The abutment can be displayed after selecting the implant by clicking the Abutment Settings button located on the left toolbar (Figure 36).

After pressing the button, a pop-up window appears (Figure 37), where the abutment properties can be freely adjusted.

The available parameters are:

- Abutment angle (°): for displaying angled abutments.
- Abutment neck diameter (mm): for modeling the shoulder width of the abutment.
- Abutment neck height (mm): for visualizing the gingival height of the abutment.

Note: When designing a stackable guide (multi-level surgical guide), the use of abutments is mandatory. The system automatically issues a warning if abutments are missing. See the relevant chapter (Chapter 5.6) for details.

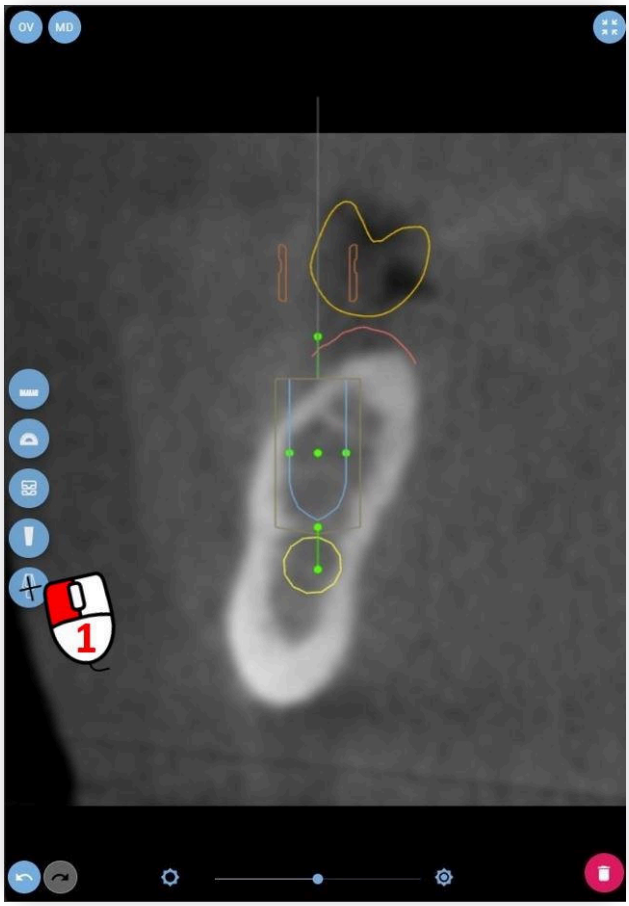

Figure 36:

Figure 37:

5.5. Add & edit a fixation pin

In the panorama view, by positioning the section plane to the desired position, the “Add implant or pin” menu appears in the bottom right corner of the planning view (Figure 38).

Figure 38: Add implant or pin: the add pin button.

By clicking on the plus sign, the add fixation pin button appears, which upon clicking adds a default fixation pin to the plan at the center of the cross-sectional image, visible in both 3D and planning views. A sleeve is also selected for every fixation pin placed in the plan. The sleeve occupies a fixed position on the fixation pin, marking the location of the physical sleeve that will be placed in the eventual template.

The addition of a fixation pin is only available if the case settings (kit, manufacturer) allow the use of fixation pins.

5.5.1. Pin settings

The Fixation pin settings button appears on the left side of the planning view after selecting a given fixation pin (Figure 39). After adding a fixation pin, the newly added pin is selected by default, and the fixation pins already in the plan can be selected with a left mouse click in the 3D view. By clicking the button, the Fixation pin settings window opens (Figure 40), where the type of fixation pin can be selected. The Fixation pin settings window can be displayed by double-clicking on a given fixation pin in the planning view. To delete a fixation pin from the plan, after clicking the Delete fixation pin button that appears in the bottom right corner of the planning view, the option to delete either the selected fixation pin or all fixation pins appears (Figure 41).

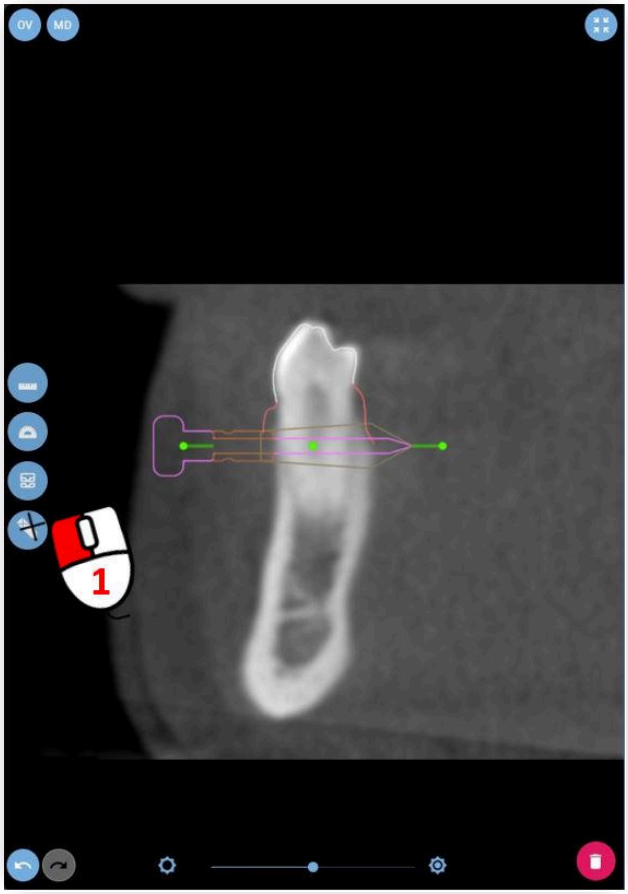

Figure 39: The Pin settings button

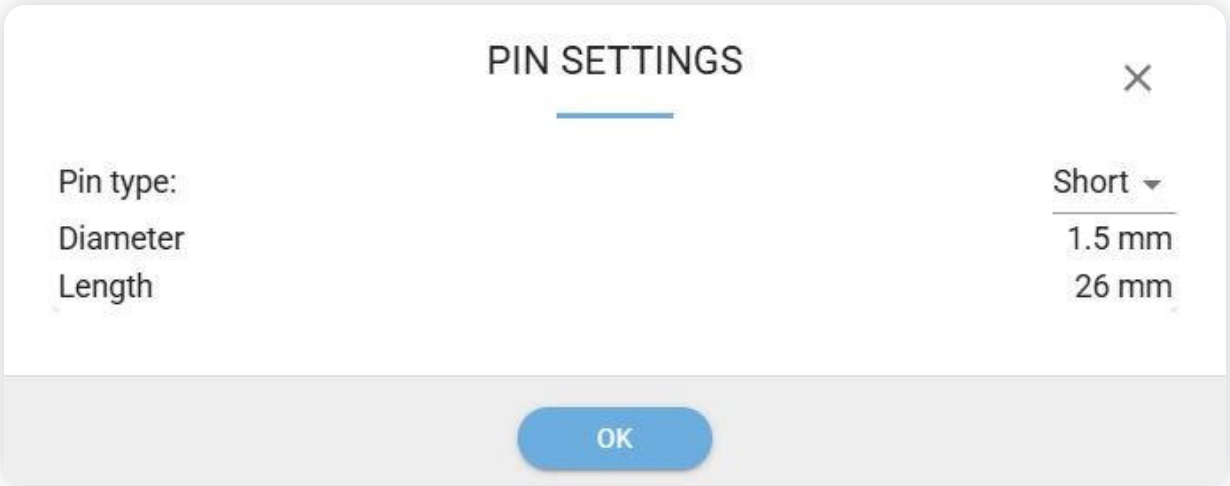

Figure 40: The Pin settings dialog

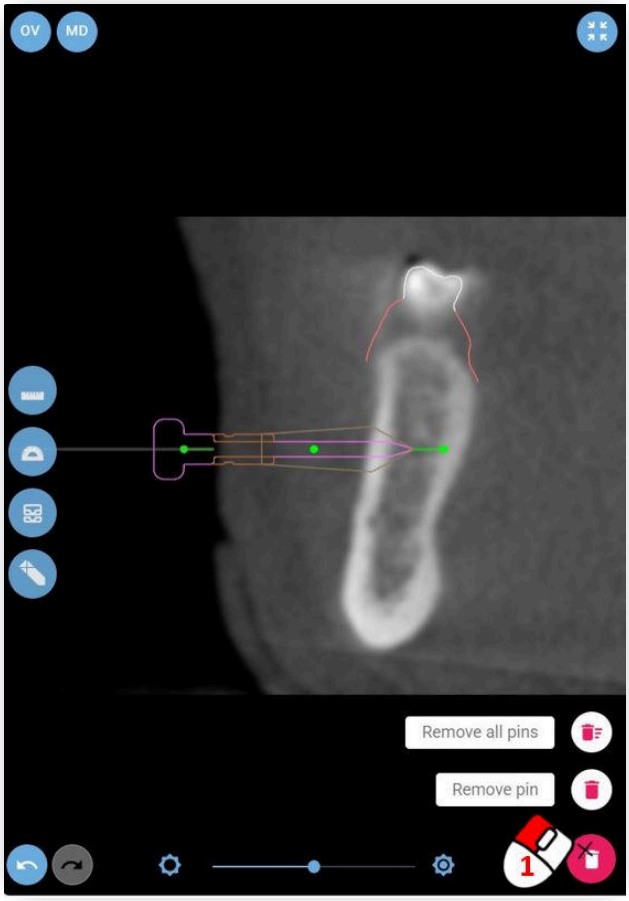

Figure 41: Deleting options

5.5.2. Move and rotate

The selected fixation pin is centered and focused in the planning view, at which time green control points appear at the center and both ends of the fixation pin. By holding down the left mouse button on the middle control point and moving the mouse, the fixation pin can be positioned, and it can be rotated with the top and bottom points. With the upper control point, the fixation pin can be rotated around a pre-set center in the neck of the pin (Figure 42, Figure 43).

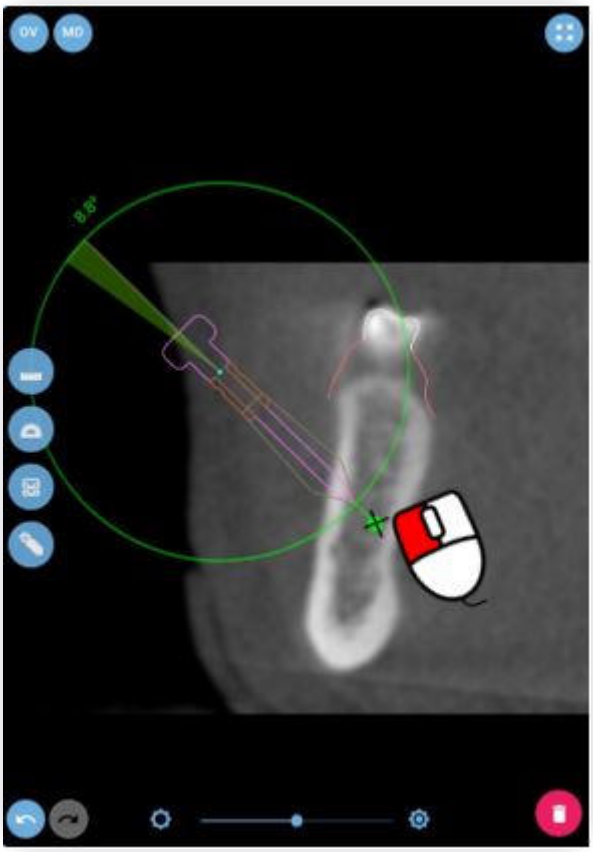

Figure 42: Rotation around the rotation center in the neck

Figure 43: Rotation around the axis

5.6. Notifications and warnings

The software automatically indicates potentially significant problems both during the planning process (in real-time) and when the plan is finalized. These may stem from the relative positioning of objects to one another and/or anatomical structures, and the limitations of the instruments of the applied surgical kit.

The digital models of implants and fixation pins are surrounded by a safety zone, which serves to prevent that these objects are positioned hazardously close to each other or an anatomical structure (especially the canal of the alveolar nerve). The software differentiates between relative and absolute errors. A relative error triggers a notification: the safety zone of the object or objects turns orange, and the notification also appears in a textual format in the planning view and a separate window when the plan is about to be finalized.

A notification does not prevent either the finalization of the plan or placing an order. These messages call the user's attention to a potential problem that requires professional consideration.

A warning indicates a situation when the manufacturing of the surgical template is impossible due to planning error (e.g. guiding sleeves planned in a conflicting position). Warnings appear in red. Plans that contain warnings may be saved but may not be finalized and it is not possible to place an order based on such plans.

WARNING! The safety zone around the instruments has been defined in accordance with the general safety requirements for implantation found in the literature. Although, due to the operational characteristics of the software, the color of the boundary of the zone changes only when the above-described collisions occur, always consider the safety zone during the planning process to avoid damage to various anatomical structures (neighboring healthy roots, the maxillary sinuses, etc.).

The software indicates a relative planning error (orange notification) if:

- Two implants are in a conflicting position (Figure 44).
- An implant and a fixation pin are in a conflicting position (Figure 45).
- The implant may penetrate the canal of the alveolar nerve (Figure 46).
- The sleeve collides with anatomical structures (Figure 47).
- Two fixation pins are in a conflicting position (Figure 48).
- A fixation pin may penetrate the canal of the alveolar nerve (Figure 49).
- The Implant length exceeds drill limit (Figure 50).

The software indicates an absolute planning error (red warning) if:

- The guiding sleeve is outside the boundaries of the impression. Such cases are physically impossible to manufacture (Figure 51).
- The guiding sleeves are in a conflicting position. A typical cause is that the sleeves are planned in a way that they occupy overlapping positions. This, again, renders manufacturing physically impossible (Figure 52, Figure 53).
- In a stackable guide case, no prosthetic abutment has been configured for the implant (Figure 54).

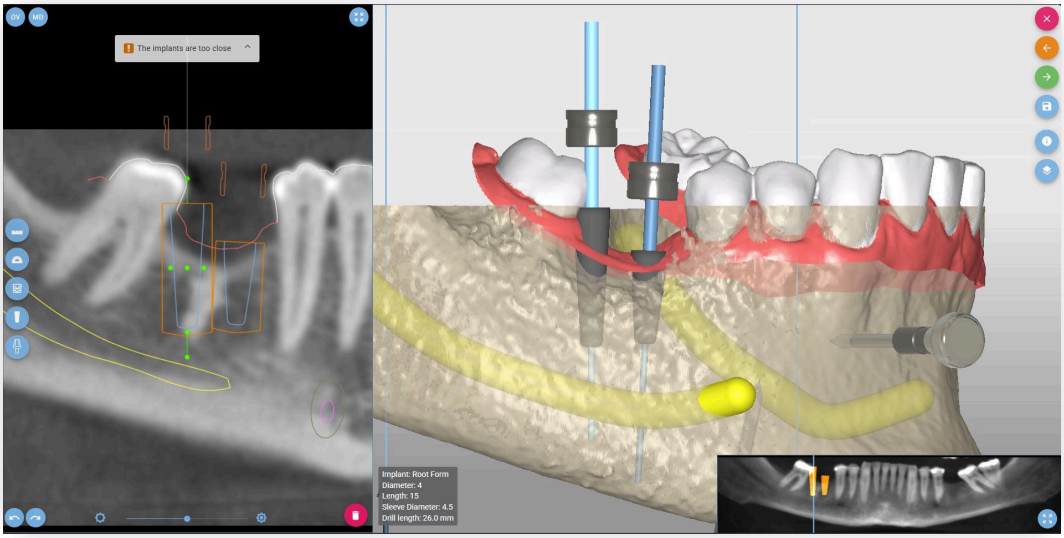

Figure 44: Two implants are in a conflicting position.

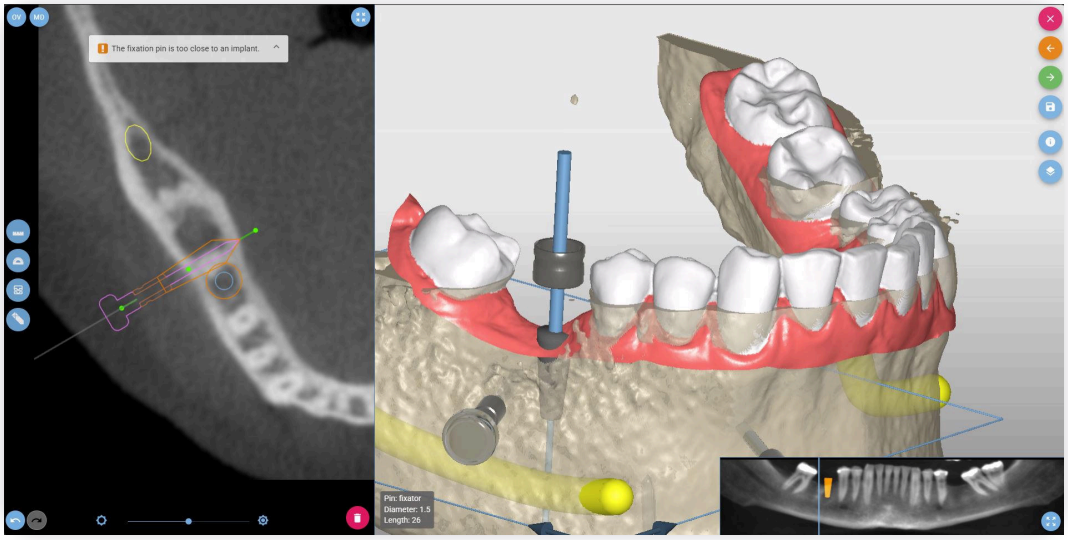

Figure 45: An implant and a fixation pin are in a conflicting position.

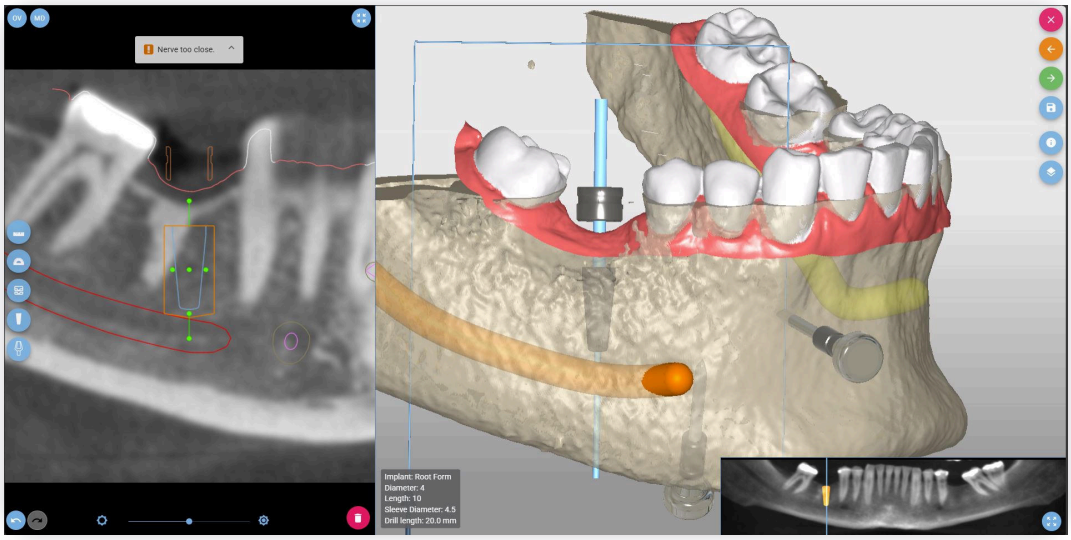

Figure 46: The implant may penetrate the nerve canal.

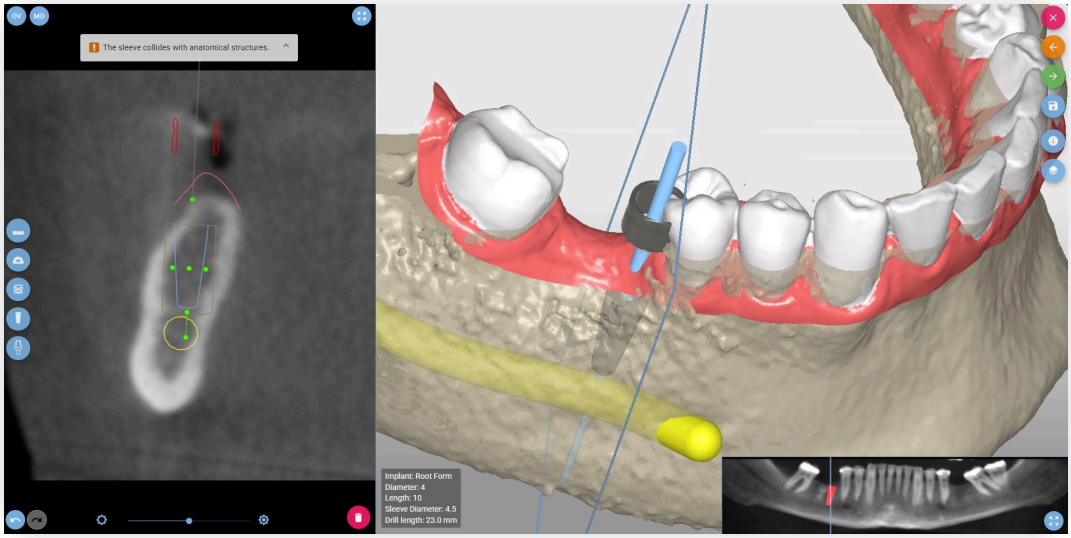

Figure 47: The sleeve collides with anatomical structures.

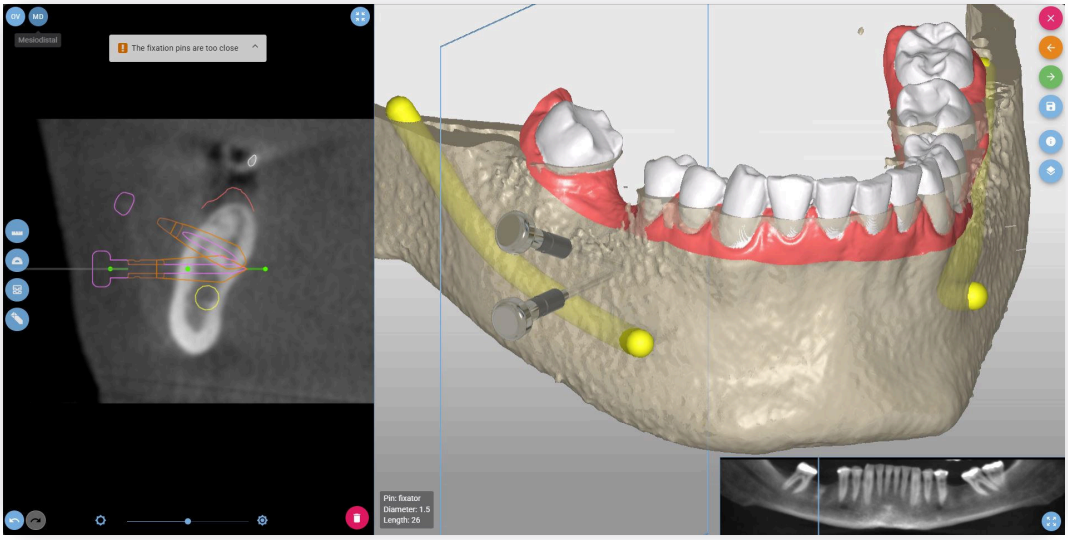

Figure 48: The fixation pins are in a conflicting position.

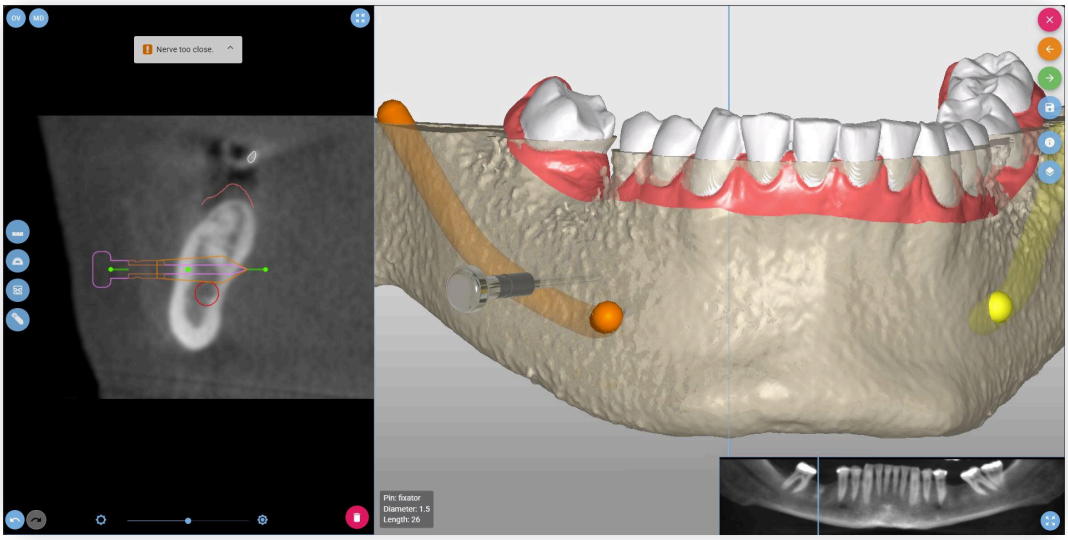

Figure 49: The fixation pin may penetrate the nerve canal.

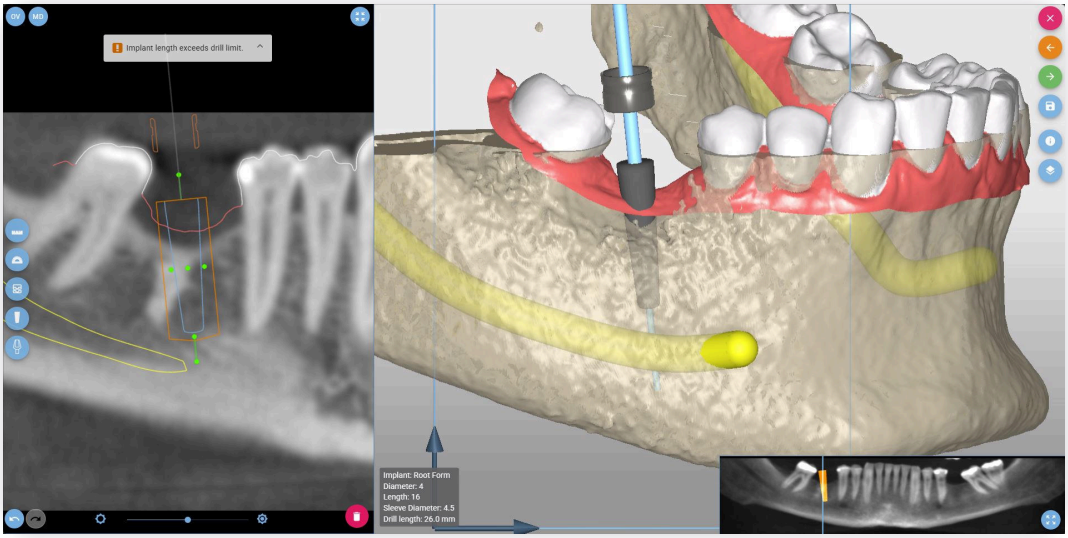

Figure 50: The Implant length exceeds drill limit.

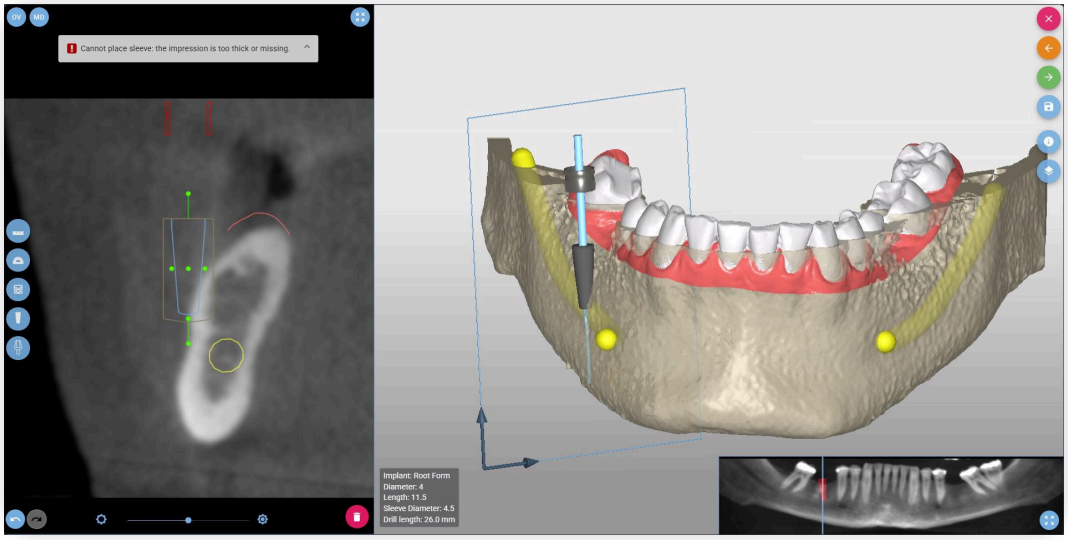

Figure 51: The guiding sleeve is not within the physical boundaries of the impression.

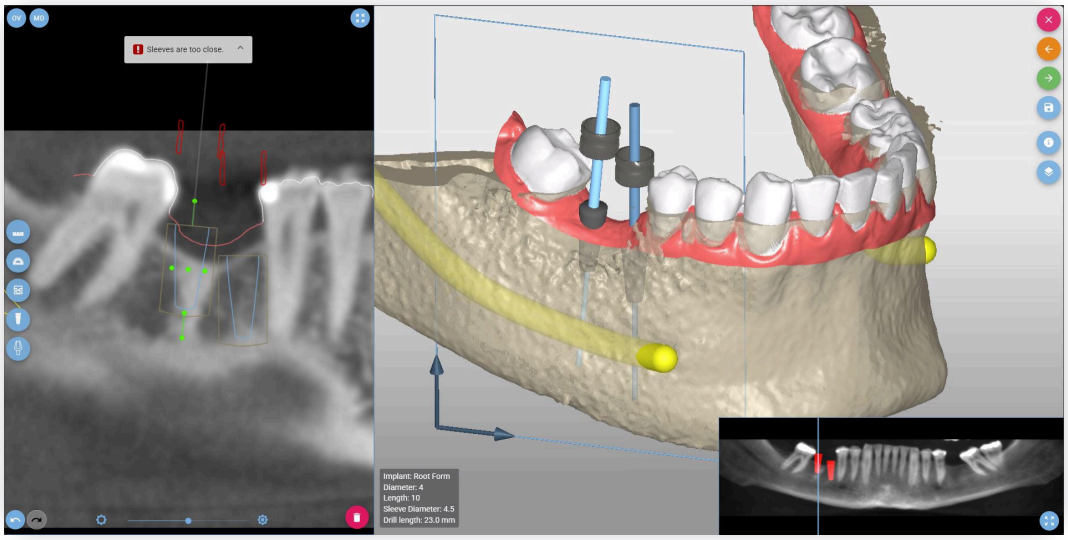

Figure 52: The guiding sleeves are in too close.

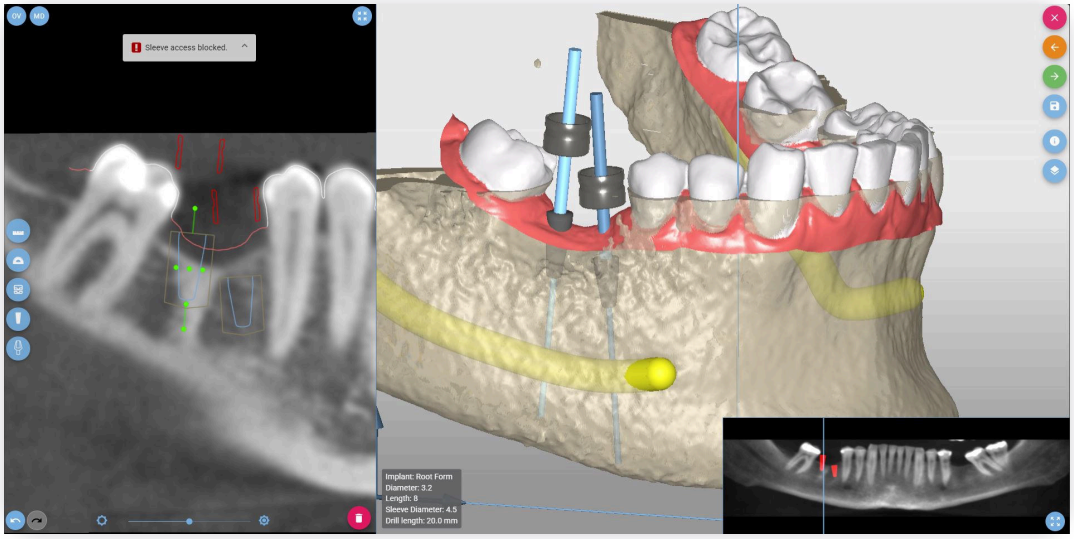

Figure 53: The guiding sleeves access blocked.

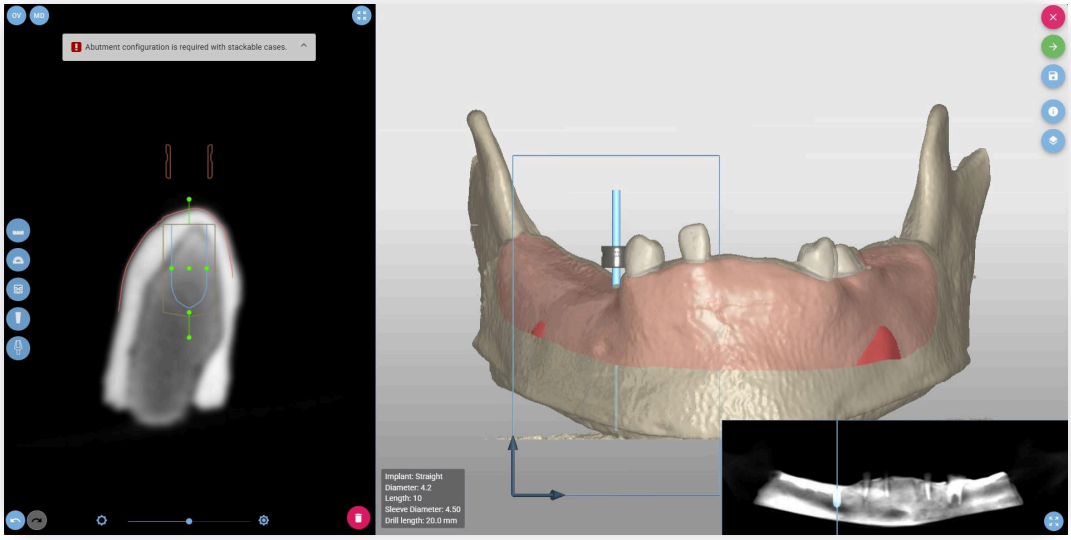

Figure 54: Abutment configuration is required with stackable cases.

6. Product information and customer support

6.1. Contact information

Should you have any questions regarding this piece of software or any other element of the SMART Guide system, please contact the Customer Support Service.

The Customer Support Service is available at:

E-mail: info@dicomlab.com

Phone: +36 30 624 99 70

6.2. Claim a copy of this manual

A printed copy of this manual is available on request by email or phone (above). Upon receiving your request, we provide your copy within 7 workdays.