Diagnocat

Dentist's virtual assistant in implant planning

Segmenton Implant

User Manual

Version 1.0

Diagnocat

Diagnocat

1. USER MANUAL INFORMATION

This user manual is used solely for the purpose of explaining the use of Segmentron Implant. This document cannot be printed or reproduced without the permission of the copyright holder. Users are recommended to read this manual carefully before starting using Segmentron Implant. In addition, this manual may be modified without notice.

1.1. SYMBOLS AND MARKS USED IN THE MANUAL AND IN THE LABELING

	Manufacturer
	Follow instructions for use
	Caution
	Medical device
	Authorized representative in the European Union
	Patient information website
	Unique device identifier
	CE marking

1.2. CONTACT

http://www.diagnocat.com

1.3. DEVICE INFORMATION

Name: Segmentron Implant
Device Version: 1.0

1.4. REGULATORY REQUIREMENTS

Segmentron Implant complies with the following regulatory requirements:

- ISO 13485:2016 Medical devices — Quality management systems. Requirements for regulatory purposes;
- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices
- Canadian Medical Devices Regulations SOR 98-282

Compliance - this Software as a Medical device complies with relevant international and national standards and laws. Information on compliance will be supplied on request; manufacturer contact details are written below.

This medical product software must be installed on appropriate IT equipment that complies with relevant international and national laws and standards on EMC (Electro-Magnetic Compatibility) and Electrical Safety. Such laws and standards define both the permissible electromagnetic emission levels from equipment and its required immunity to electromagnetic interference from external sources.

1.5. MANUFACTURER INFORMATION

DGNCT LLC

333 Southeast 2nd Avenue, 20th Floor#563,

Miami, Florida 33131, USA

Phone: + 1 519 619 4212

https://www.diagnocat.com/

UDI-DI: 860010268032

AUTHORIZED REPRESENTATIVE IN EUROPE

Freyr Life Sciences GmbH

Marie-Curie Str 8

79539

Lörrach,

GERMANY

Phone: +49 6181 707 9007

E-mail: sales@freyrsolutions.com

EU NOTIFIED BODY

SGS House, Noorderlaan 87, 2030 Antwerpen,

Belgium,

CE1639 (SGS Belgium NV)

1.6. PAPER COPY

Note! The User Manual is supplied in an electronic format and not in a paper copy. To receive a paper copy of this manual, please send an email to support@diagnocat.com. Our team will be happy to provide you with a paper copy of the manual to you via the postal service at no additional cost, within 7 days from requesting.

1.7. CUSTOMER NOTICE

This Instructions for Use is intended to assist users in the safe and effective use of the medical device software described herein. The “user” is considered to be not only the body with authority over the medical device software but also those persons who use the medical device software.
This Instructions for Use does not describe the use of the IT equipment on which the medical device software is installed. Refer to the documentation of the IT equipment concerned.

Before attempting to use this medical device software, you must read these Instructions for Use thoroughly, paying particular attention to all **WARNINGS,** and Notes it contains. You must pay special attention to all the information given, and procedures described, in this Instruction of Use. In addition, you must pay special attention to on-screen Messages and On-line Help information containing **WARNINGS** and Notes that may be related to the function being executed.

Directions which if not followed could cause fatal or serious injury to a user, patient or other person, or could lead to clinical misdiagnosis, and/or loss/damage of patient-related data.

Additional information:

- Segmentron Implant may improve the function and performance of the product without notifying the user.
- Some features of the product may not be available in all countries, languages and currencies.
- It is illegal to reproduce and distribute the product without the consent of Segmentron.
- Users should read this manual thoroughly before using this product.
- In order to use the full functions of Segmentron Implant, please follow the specifications described in this manual.
- Backup - Backup is the responsibility of the user and it should never be assumed that any backup is taking place unless it is actively monitored by the user.

2. PRODUCT DESCRIPTION

Segmentron Implant is a pre-planning software for dental implant placement and guided implant surgery. The device combines the proprietary AI algorithms and manual tools for the precise planning of the implant and surgical guide by the dentists. Segmentron Implant allows to visualize the patient's anatomy in 3D based on the superimposition of CBCT and optical scan data, segment all key anatomic objects in the oral cavity, detect the missing or problematic teeth where the implant shall be placed, suggest the approximate placement and the suitable characteristics of the crown, implant and the surgical guide - in an automated way. The manual tools allow dentists to adjust the position and properties of the crown, and the implant according to their choice. The planning results can be exported as a 3D model of the designed guide. Segmentron Implant is intended to be used only by dental professionals with sufficient knowledge in dental implantology and surgical dentistry.

2.1. INTENDED USE

Segmentron Implant is a software device intended for guided implant surgery planning.

It is intended for use as a pre-operative planning software for the placement of dental implant(s) based on imported CBTC image data, aligned to an optical 3D surface scan. Virtual Crowns can be used for optimized implant positioning under the prosthetic aspect. The digital three-dimensional model of a surgical guide for guided surgery can be designed based on the approved implant position. This 3D data can be exported to manufacture a separate physical product.

Segmentron Implant is intended to be used only by dental professionals and surgical dentists who are skilled in implant dentistry

2.2. INDICATION FOR USE

Segmentron Implant software provides tools for clinicians to determine suitable locations for implants taking into account surgical aspects, as well as desired functional and esthetic results. This software shall be used only for the planning of tooth-supported guides.

Segmentron Implant software functionality includes:

- Reading and 3D visualization of CBCT and STL images
- Automated and manual tools for Implant planning
- Segmentron Implant Library: A comprehensive selection of implants
- Generating and downloading surgical guide file and surgical report

2.3. THE INTENDED USERS

Segmentron Implant is intended to be used only by dental professionals and surgical dentists who are skilled in implant dentistry.

2.4. INTENDED PATIENT TARGET GROUP

Adult patients (older than 22) with intraoral conditions such as missing teeth who are being considered for treatment with dental implants

2.5. CONTRAINDICATIONS

The Software cannot be used for direct diagnosis and clinical decision making.

Segmentron Implant shall not be used for any purpose other than planning dental implant placement or design of surgical guides.

The performance of Segmentron Implant depends on the quality and accuracy of the CBCT or CT scan as well as the model scan imported. Relevant anatomical structures must be visible in the scans.

Segmentron Implant can be used only for tooth supported guides.

2.6. POTENTIAL ADVERSE EFFECTS AND SAFETY OF THE MEDICAL PRODUCT

This software is completely safe for use by people, provided that it is used according to the user manual.

2.7. WARNINGS, PRECAUTIONS AND LIMITATIONS

Diagnocat

It is forbidden to download or transmit any messages or content of any type that may disregard or violate any of the rights of any party.

It is forbidden to use this Software for any purpose in violation of local, state, national or international laws.

You may not use this application to publish or transmit any material that is illegal, obscene, threatening, abusive, slanderous, hateful or embarrassing to any other person or organization

Segmentron Implant does not give any guarantees regarding the time required for processing any request; and if you are faced with an emergency, you should not seek assistance from this guide but instead should call emergency medical service immediately.

Segmentron Implant is an adjunct tool and does not replace the role of the clinician.

The user needs to ensure that the surface scan is of the required quality for planning the case, and that the relevant areas for the implant planning fully exist.

Make sure that the quality of the loaded CBCT or CT scan is sufficient for planning the case and that the relevant areas on the image for the analysis are adequate in order to make an accurate and sustainable decision for implant planning! CBCT or CT devices have to comply with the recommendations of ICRP (International Commission on Radiological Protection).

The CBCT and STL studies used for ordering the report must each contain at least 3 teeth (with the same number).

Please check that the scan data is correctly and completely loaded. Also check that the visualization of the CBCT/CT and Surface Scan is working correctly to allow a secure and accurate placement of the implant during the navigated planning and surgical guide design process.

Segmentron Implant should be used according to the manual.

Segmentron Implant is not involved in the implant surgery. All surgical treatment should be done only by clinicians.

Diagnocat

Segmentron software allows for surgical guides to be exported to a validated manufacturing center or to the point of care. Manufacturing at the point of care requires FDA cleared or legally marketed 3D printing fabrication methods and compatible material (biocompatible and sterilizable).

2.8. REQUIRED TRAINING AND QUALIFICATIONS

Training requirements for this type of product will vary from country to country. It is the responsibility of users to ensure that they receive adequate training in accordance with local laws or regulations which have the force of law. If you require further information about training in the use of this medical product software, please contact the Segmentron team.

3. DEVICE SECURITY AND PRIVACY

3.1. Customer Role in the Product Security Partnership

Security of Segmentron products is an important part of each healthcare institution's overall security strategy. However, these benefits can only be realized in combination with a comprehensive, multi-layered strategy that includes policies, procedures and technologies to protect information and systems from external and internal threats.

In accordance with security and industry best practices, security strategies should address:

- Physical security restricts unauthorized access to the servers where the Segmentron Implant product is running.
- Operational security, for example, access / authorization controls and change management.
- Procedural security, for example, locking unattended workstation, no sharing of access credentials, termination checklists, etc.
- Continuous monitoring of security protection effectiveness.
- Security risk management.
- Security policies, for example, ensuring that client systems are in line with the institution's IT security policies.
- Awareness Training.
- Contingency planning.
- Backup

The practical implementation of technical security elements varies by the institution and may employ a number of technologies, including firewalls, virus scanning software, authentication technologies, etc. As with any computer-based system, firewalls and other security products must be in place between the medical system and any externally accessible systems or users.

CAUTION: Segmentron is not responsible for security of institution managed systems (servers, including servers of hosting applications, desktop PCs, laptops)

that are used for running the software of the product and access to information managed by the product.

3.2. Regulatory Controls

Protecting Personal Information

One of the most important assets to protect with security measures is the patient health information (PHI). Many governments require maintaining the confidentiality of this information. Therefore, strict security measures must be taken to guard this protected information. (Users in the USA may find guidelines at http://www.hhs.gov/ocr/hipaa/).

Protecting Personal Health Information

Protecting personal health information is a primary component of a security strategy. Considering the nature of the Segmentron Implant software, the information processed is highly personal and sensitive and should be protected in accordance with local legislative requirements (HIPAA security and privacy rules for US, or European General Data Protection Regulation for EU).

Segmentron Implant does not store the patient's health information. However, the information transferred to the product is not encrypted. Unencrypted patient health information will be present in transferred DICOM data and algorithm analysis results.
Thus, particular care must be taken with this information to ensure the utmost security and confidentiality in data transferring to and from the product.

Removable media, such as paper, may be used for purposes of Segmentron Implant analysis results transfer and long-term storage. Patient data written to removable media is identifiable. Treat removable media containing patient data as confidential and take appropriate measures to protect this information, so that unwanted access by unauthorized individuals is avoided. Procedures to maintain removable media must be part of the institution's security policy.

CAUTION: It is the whole responsibility of the user to guard removable media, which contains sensitive private information, at all times.

CAUTION: Dispose media such as printouts in a secured manner when the media are no longer needed, since the media may contain sensitive private information.

Malware Prevention and Detection

The server(s), on which Segmentron Implant is running, must be placed on a secure local computer network that has protections against viruses and other harmful computer system intruders.

Make sure the equipment is connected to a local network that uses appropriate protection, such as a virus scanner.

When using removable media like USB storage products, CDs, DVDs, be aware that inserting removable media can introduce a virus to the medical product.

Prevent Unauthorized product Modification
Segmentron is required to follow government-regulated quality assurance procedures to verify and validate modifications to Segmentron Implant software.

Users and owners of this medical equipment must permit only Segmentron authorized changes to be made to this product, either by Segmentron personnel or under Segmentron explicit published direction.

Logical Access Control
Regular users do not have direct access to Segmentron Implant. Only authorized specialists (like institution's IT specialists/administrators, Segmentron Implant software administrators) have access to the product. However, they have privileged access which requires strict control.

Implement stringent control of access to the system:

- Allow access only to the personnel who is responsible for service and administration of the product;
- Ensure use of strong passwords by the users;
- Ensure that the users keep their password secretly;
- Ensure periodic change of passwords.

Product Environment
External circumstances can influence the availability of the product and its operation, e.g. network failures, power failures, environmental disasters, etc.

Take appropriate controls to ensure the reliability of the environment in which the product is used.

Information Security Incident Reporting
Although Segmentron Implant incorporates state-of-the-art security and privacy protection, a remote possibility remains that a security or confidentiality breach may occur.

Advise the users of the product and analysis results to contact Segmentron promptly and report about occurred security events to allow Segmentron to respond to the incident with no delay.

4. COMPATIBILITY

The medical product software described in this Instructions for Use should not be used in combination with other software, equipment or components unless such other software, equipment or components are expressly recognized as compatible by Segmentron Implant.

Changes and/or additions to the software as a medical device should only be carried out by Segmentron Implant or by third parties expressly authorized by Segmentron Implant to do so. Such changes and/or additions must comply with all applicable laws and regulations which have the force of law within the jurisdiction concerned, and with best engineering practice.

5. SYSTEM REQUIREMENTS

Segmentron software requirements:

- Any operating system capable of running the required Google Chrome version
- Browser: Google Chrome 92+ and should be updated

Segmentron hardware requirements:

- Minimal processor with at least 2 CPU cores
- 4 GB RAM or more
- Recommended: Processor: 4 core. Memory: 8 GB RAM
- 50 Mbps Internet speed or faster

If you use a browser other than the one specified here, the results may be unpredictable

Please note! To obtain optimal results, please use the Segmentron Implant guidelines. Please do not upload DICOM files with limitations on size more than 1GB and images containing severe artifacts for reasons of improper calibration of the CBCT unit, technical distortion due to machine malfunction.CBCT volume, 50 cm3, which is applied if the height dimension (axial) is less than half the width/length dimension.

6. TECHNICAL PARAMETERS

Segmetron Implant is constituted by software available via Web Application with the use of Chrome web browser. The address of Web Application where the service is available is provided together with the software license.

7. START WITH Segmentron Implant

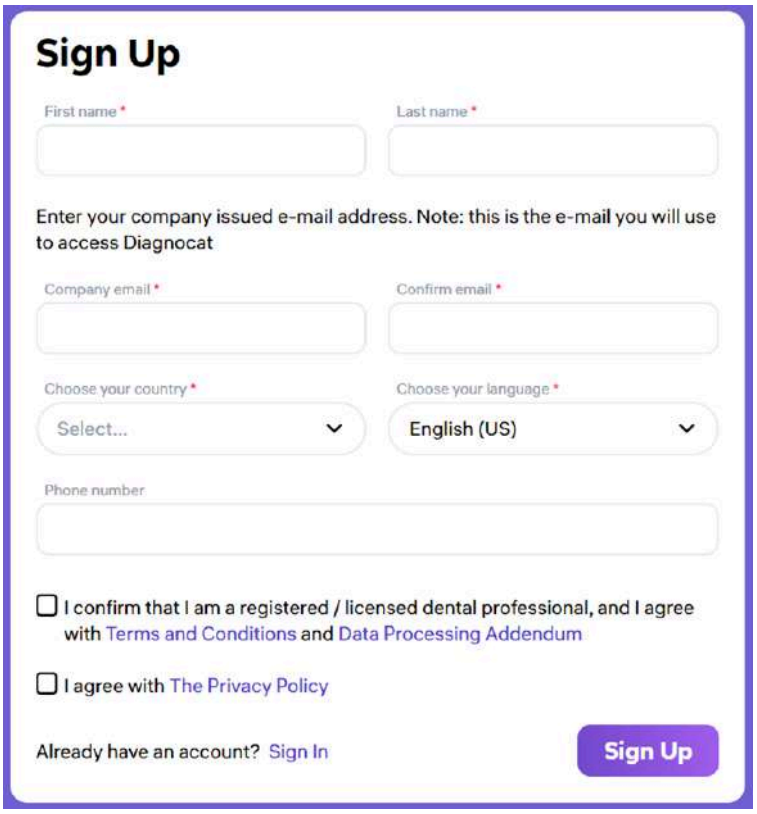
To access Segmentron Implant software, you need to have a valid Diagnocat account.

7.1. Start with Diagnocat

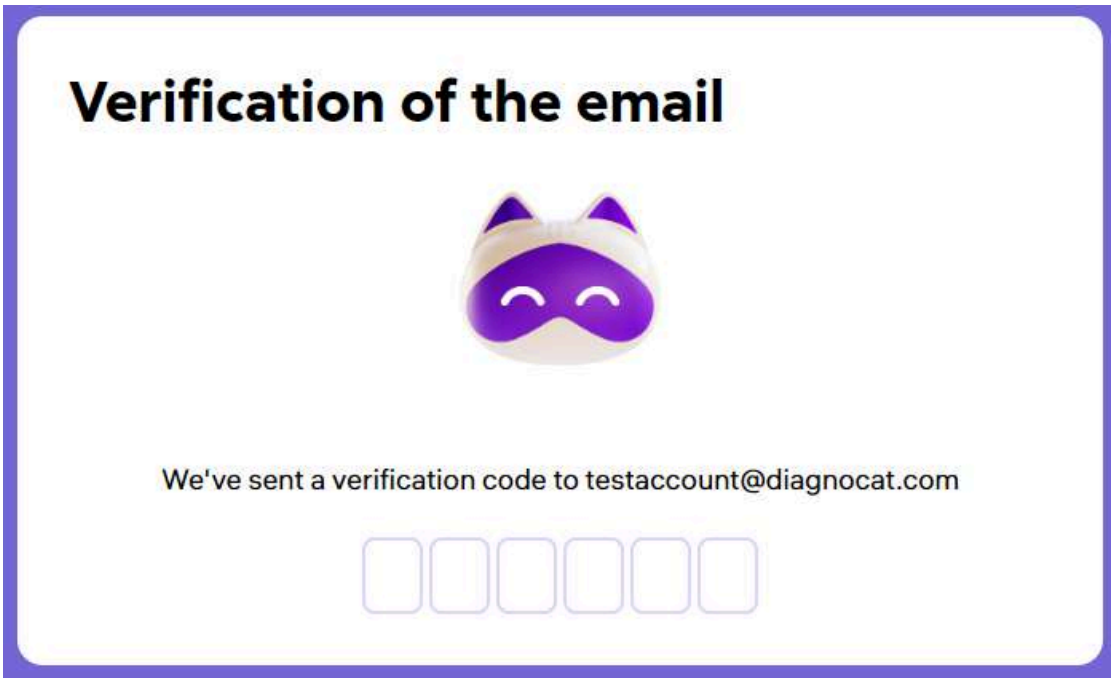
7.1.1. Sign up

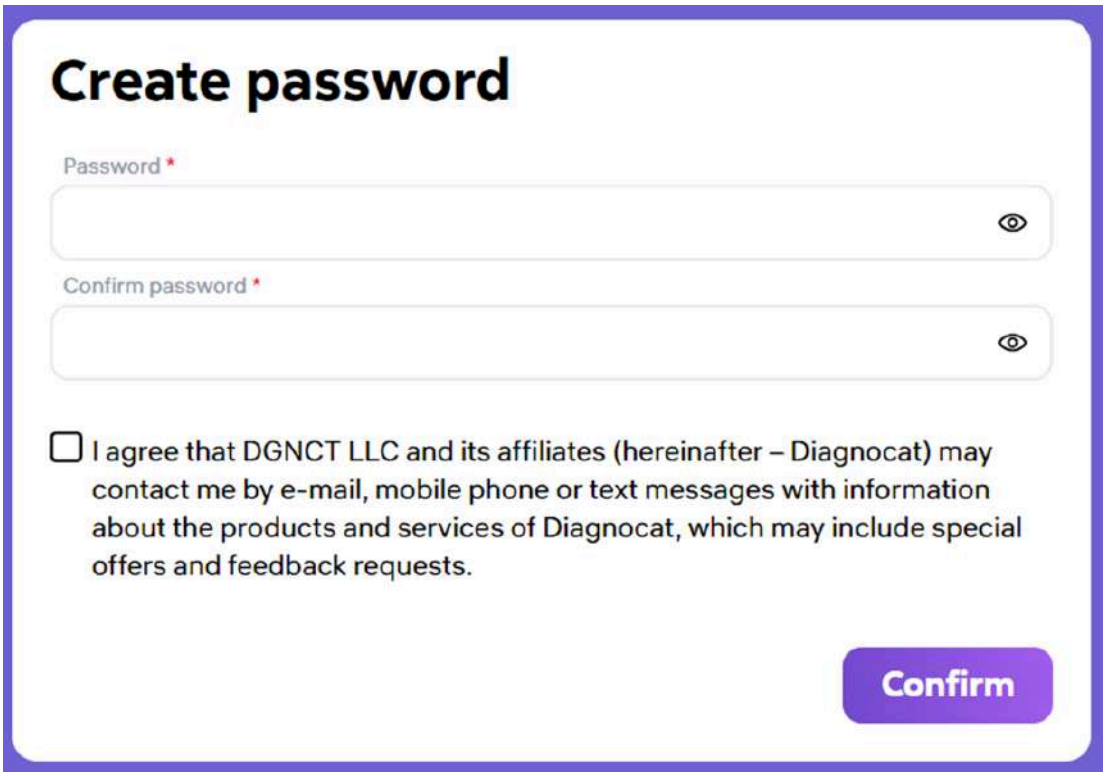
Your sales manager can provide you with a link to registration.

You will be prompted to the account creation screen where you need to provide account details and click the “Sign Up” button.



After that, you will receive an email with a verification code. You should enter this code and set your password.



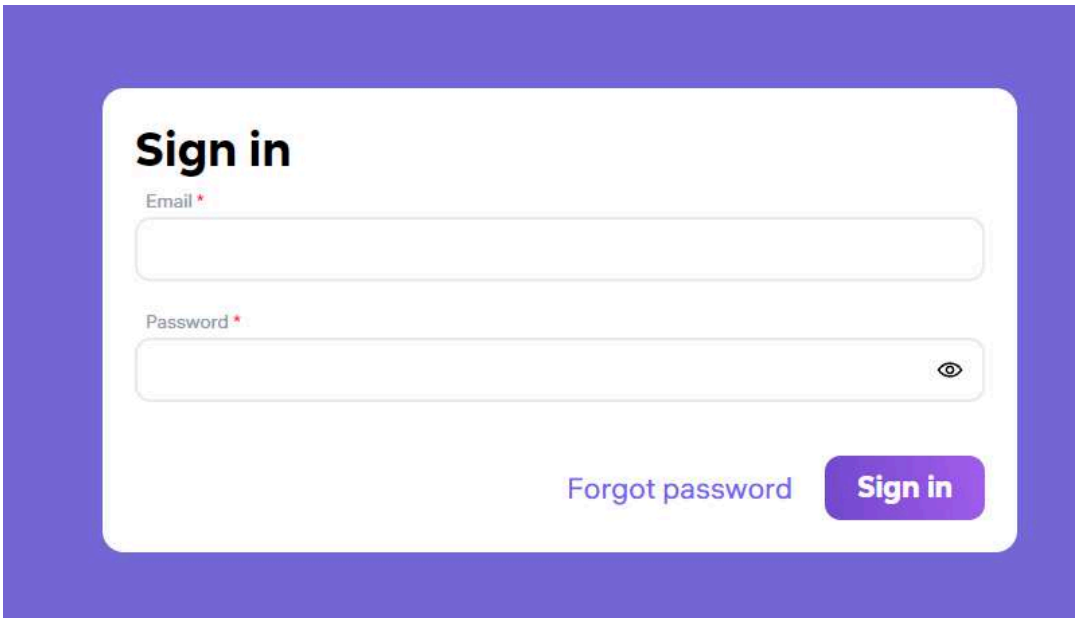


After the registration Diagnocat will ask you some questions about your experience and equipment to better understand your needs.

7.1.2. Sign in

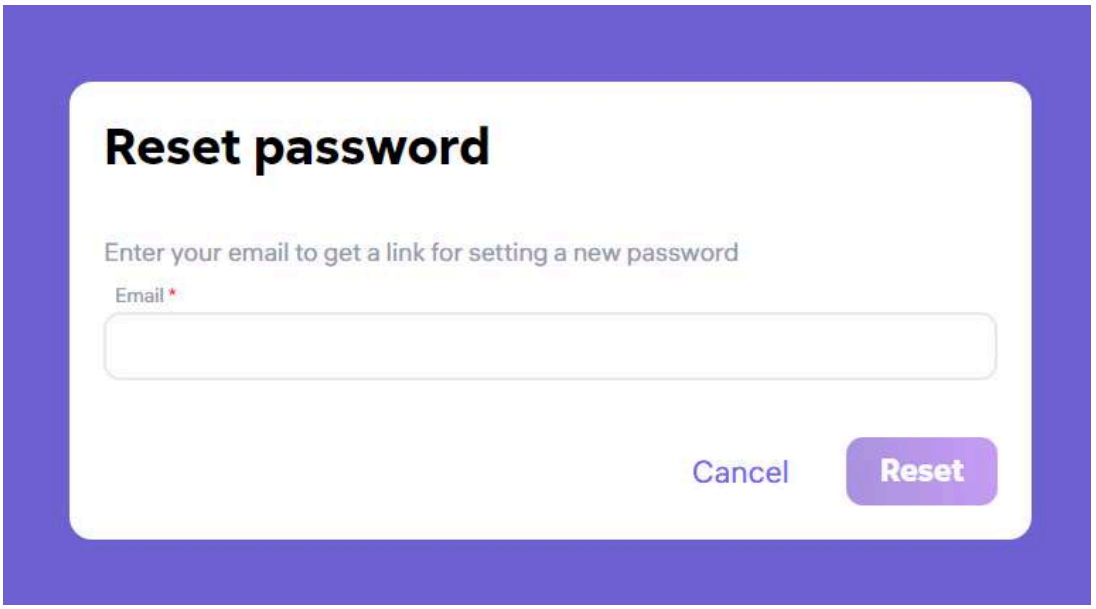
Open the Chrome browser and go to Diagnocat based on your region: for Europe, visit https://app.diagnocat.eu; for Canada, visit https://app.diagnocat.ca.

You will be able to log in to the Diagnocat application by providing your email and password.

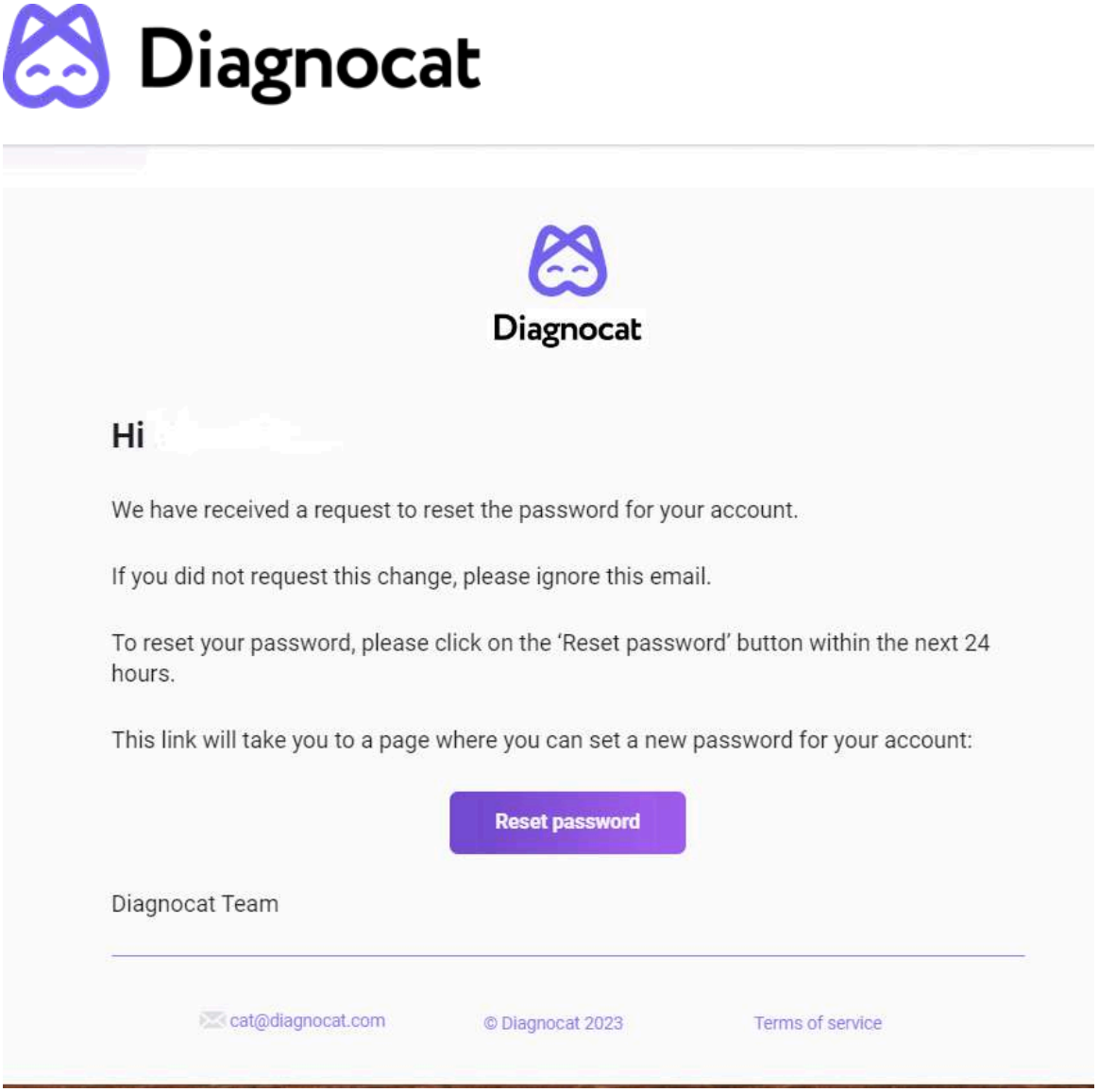


7.1.3. Reset password

If you need to reset your password, click the Forgot password link and enter your email address you used to register your Diagnocat account.

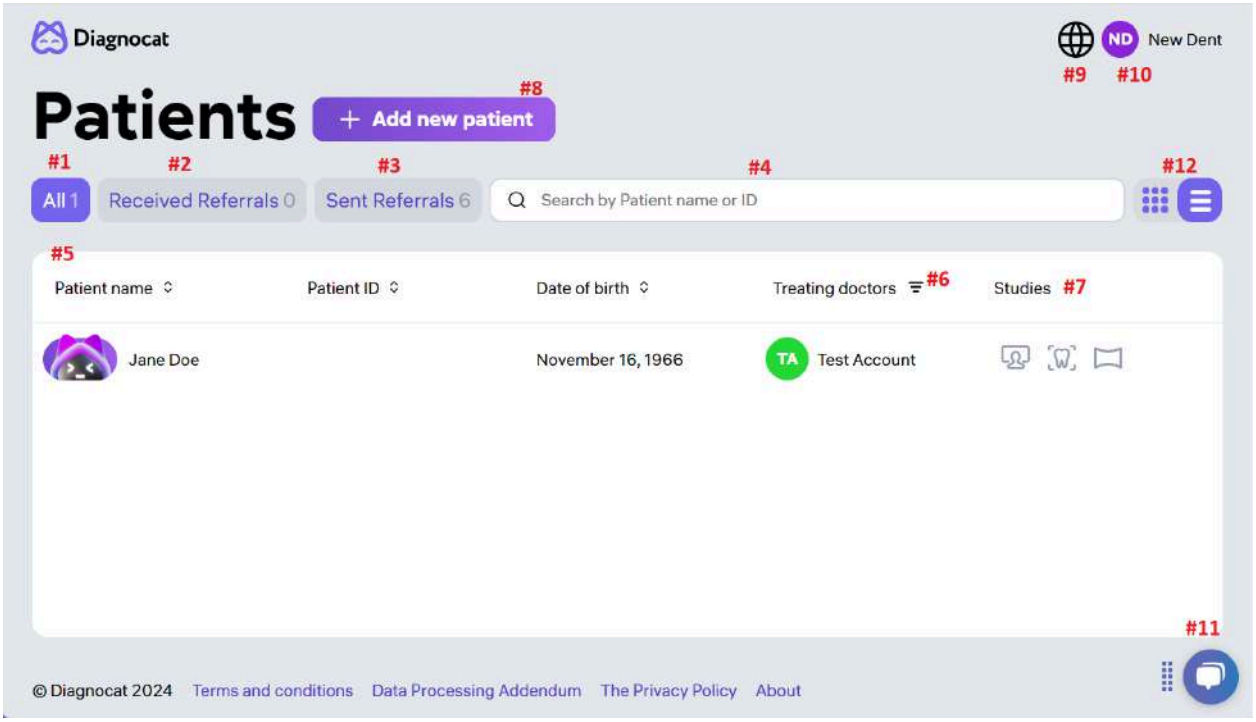


You will receive an email with instructions on how to reset your password.



Patients

Once you log in successfully, you will see the “Patients” screen.



#1: “All” gives you access to all your patients.

#2: “Received Referrals” gives you access to all studies shared with you by other users.

#3: “Sent Referrals” gives you access to all studies shared with other users by you.

#4: Using the “Search” field you can search for studies by patient name or ID.

#5: Shows you the list of all your patients.

#5: “Treating doctors” filter allows you to select a specific doctor/doctors.

#7: Shows existing studies.

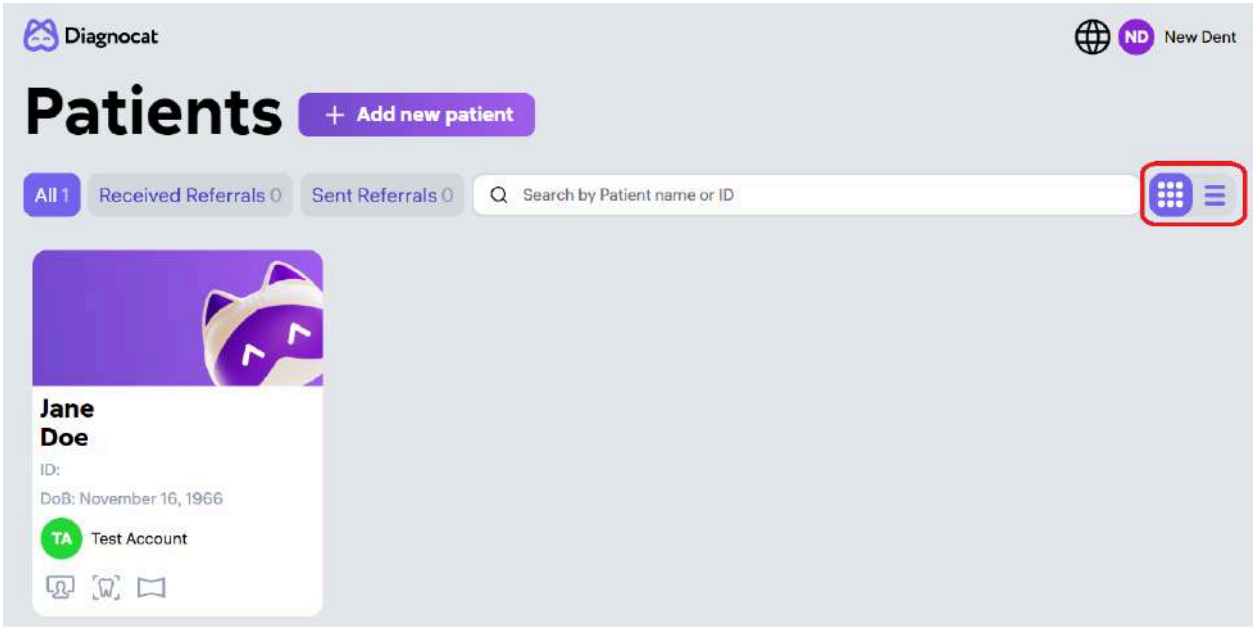
#8: “Add new patient” allows you to create a new patient.

#9: Allows you to change the interface language.

#10: Gives you access to your account and clinic settings.

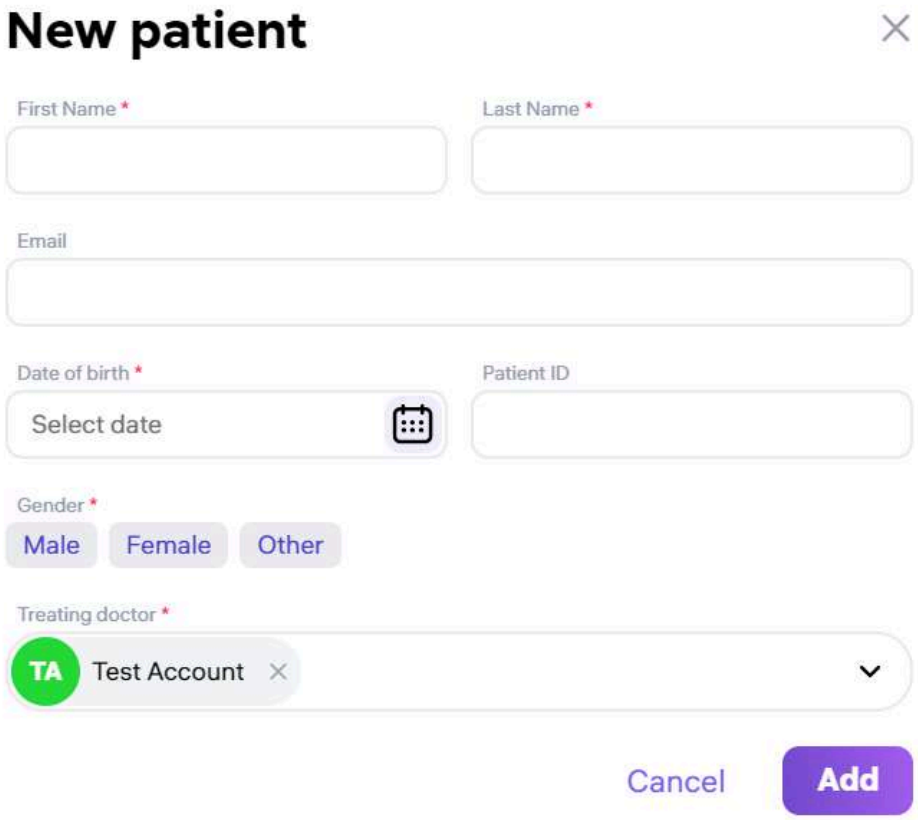
#11: Allows you to get access to the customer success team.

#12: The button allows you to change the visual design of the “Patient Card”. The visual design is shown below:



7.1.4. Create a new patient

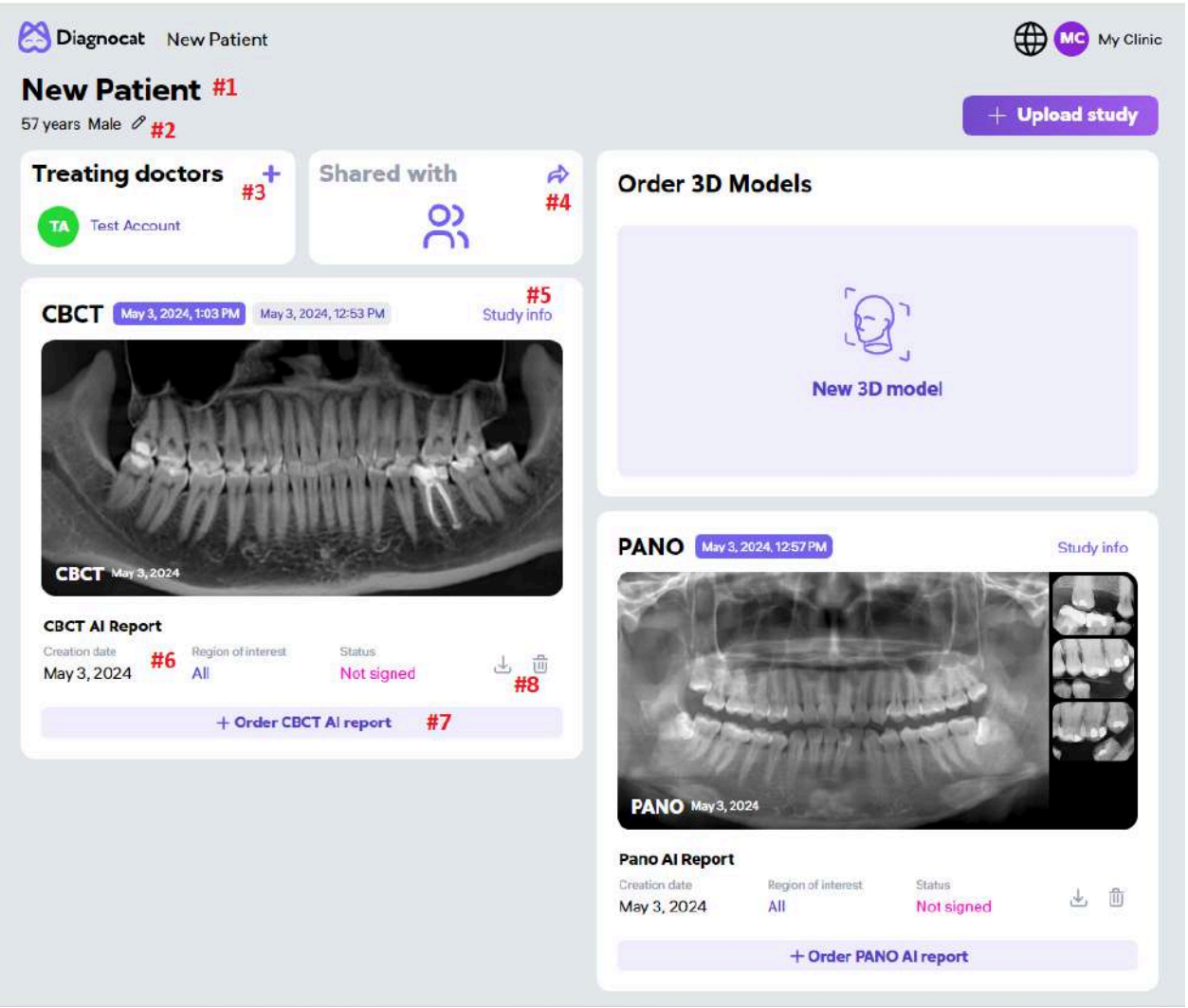
You can create a new patient by clicking “Add new patient” on the main screen.



Fill in a short form, it is necessary to fill in all required fields marked with an asterisk and click “Add”.

A new patient will appear in the patient list.

7.1.5. Patient Card



#1: Patient details.

#2: Edit patient details.

#3: Add a treating doctor.

#4: Share a patient with another doctor.

#5: Study details.

#6: Report details.

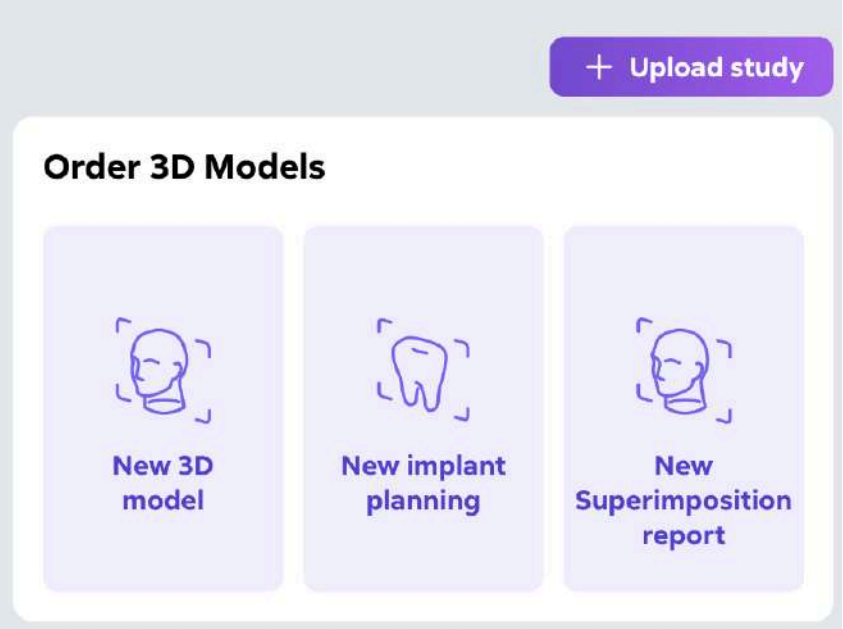
#7: Order a new analysis.

#8: Download (as PDF file) or Delete the report.

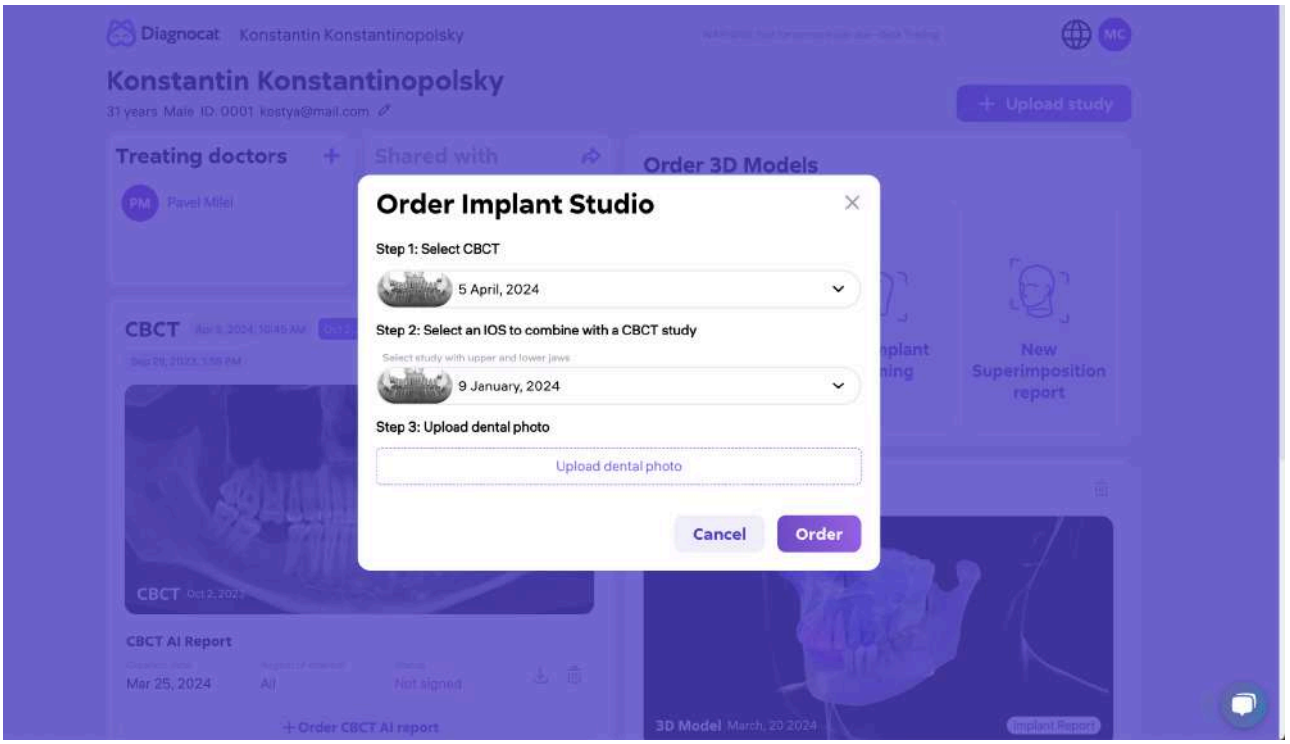
#9: Order 3D Model

7.2. ORDERING IMPLANT REPORT

Diagnocat allows you to create an Implant Report. Click the “New Implant Planing” button in the patient card, select CBCT and IOS to combine with a CBCT study and click “Order”.



To order an Implant Report, you need to upload a CBCT scan in DICOM (.dcm) format and two intraoral scan files of the upper and lower jaws in .stl format. No other files, such as bite registration or other scans, should be uploaded. To upload a CBCT scan, click Upload study on the patient’s details page, choose CBCT in the dropdown, browse for a DICOM file on your computer (you can choose between uploading a single .dcm file or a series of .dcm files as a folder), and click Upload. To upload intraoral scans, click Upload study, choose STL file in the dropdown menu, browse for the .stl files of the upper and lower jaw on your computer, and click Upload. As an optional step, you can also upload dental photos that will be superimposed with the 3D model from CBCT and STL.

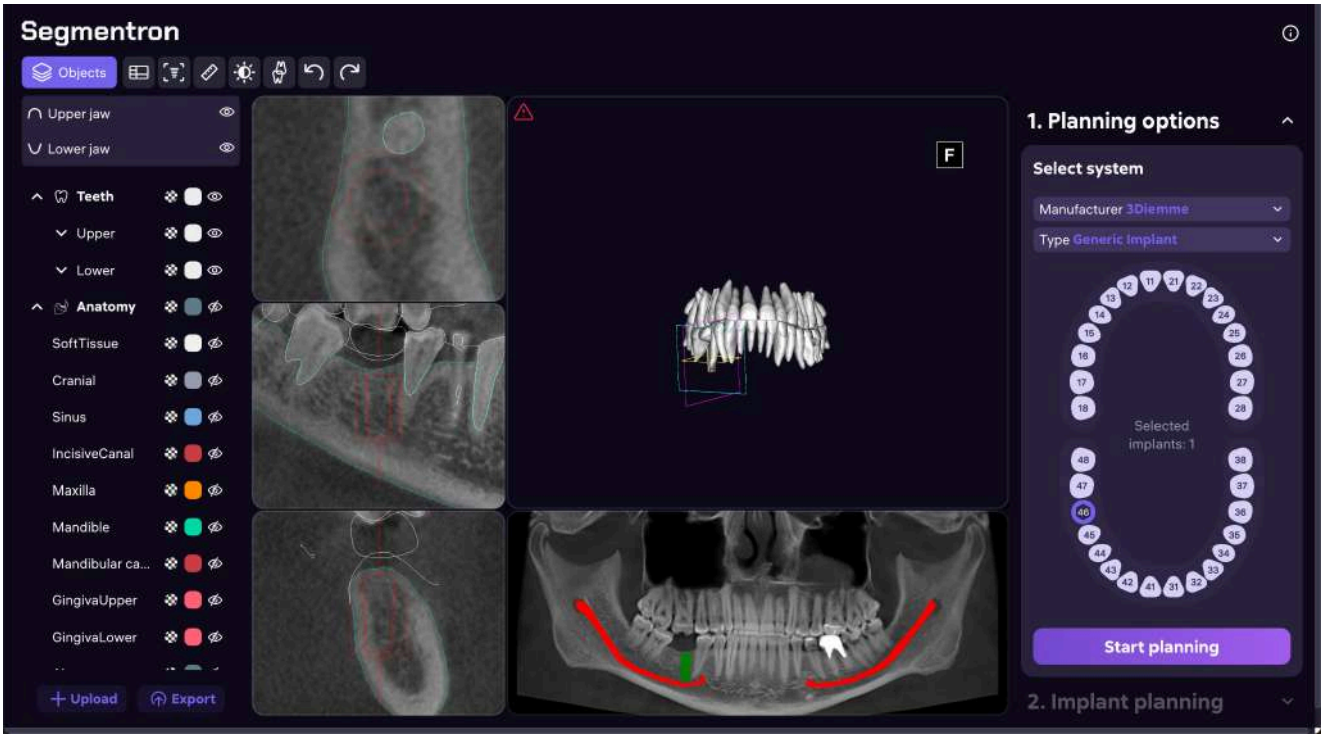


Please note that the uploaded CBCT and intraoral scans should reflect the same anatomical conditions of the patient, so that they can be matched for the implant planning purposes.

After you have uploaded the images on the "ORDERING IMPLANT REPORT" step, the report will start generating. After ordering, you can view the generated report by clicking on the report title and opening the Segmentron Implant Device.

7.3. ELEMENTS OF SEGMENTRON IMPLANT USER INTERFACE

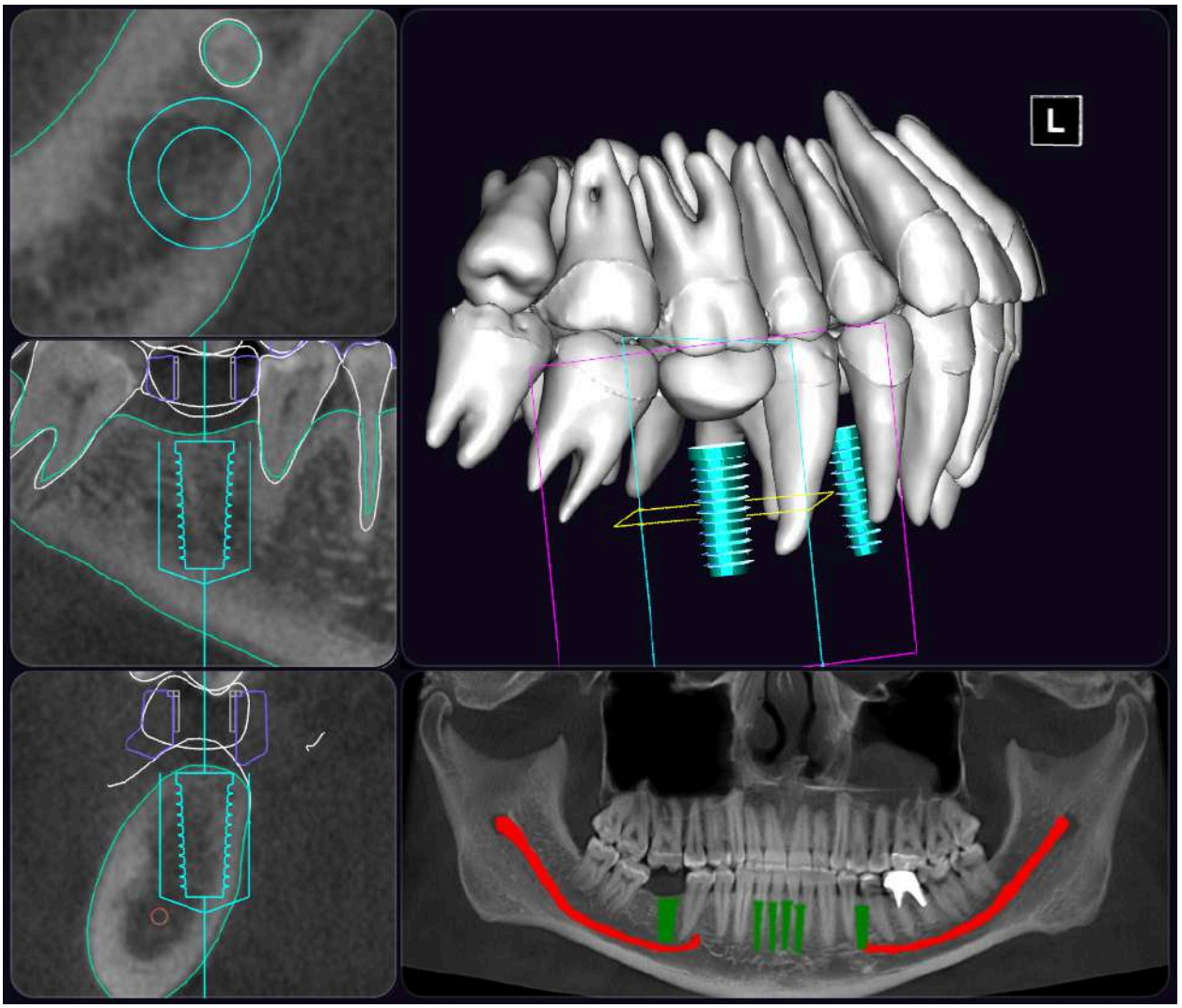
When you open the link, you will see the main interface of Segmentron Implant, including the 3D model on the 3D scene and 2D images on the MPR panels and Pano.



The main user interface of Segmentron Implant comprises the following distinct blocks:

- **Multiplanar reformation** viewports (**MPRs**) represent radiological images of CBCT scan in three projections: orthogonal view, tangential view, axial view
- **Panoramic** viewport (**Pano**) represents a section of CBCT scan, which visualizes the patient's dental scan in a flat panoramic image.
  Note! The panoramic view is provided only for informative purposes and may contain dimensional discrepancies.
- **3D scene** viewport represents the 3D model of the patient's head based on the selected display settings
- **Toolbar** allows to activate/deactivate different instruments
- **Objects panel** provides a representation of all anatomic and artificial objects in a tree structure and allows manually to switch on/off the visibility of these objects and adjust their color and transparency level
- **Planning panel** is the main section of the user interface, which is dedicated to implant planning.

Diagnocat



7.4. VIEWING VIRTUAL PATIENT'S MODEL

You can view the segmented virtual patient's model on the 3D scene, as well as see the contours of segmented objects on MPRs and in Pano. The visualization of different segmented objects (visibility, color, opacity) can be controlled via the Objects panel (see description below). In addition, it is possible to choose a predefined visual Style from the corresponding menu (see below).

7.5. PLANNING WORKFLOW

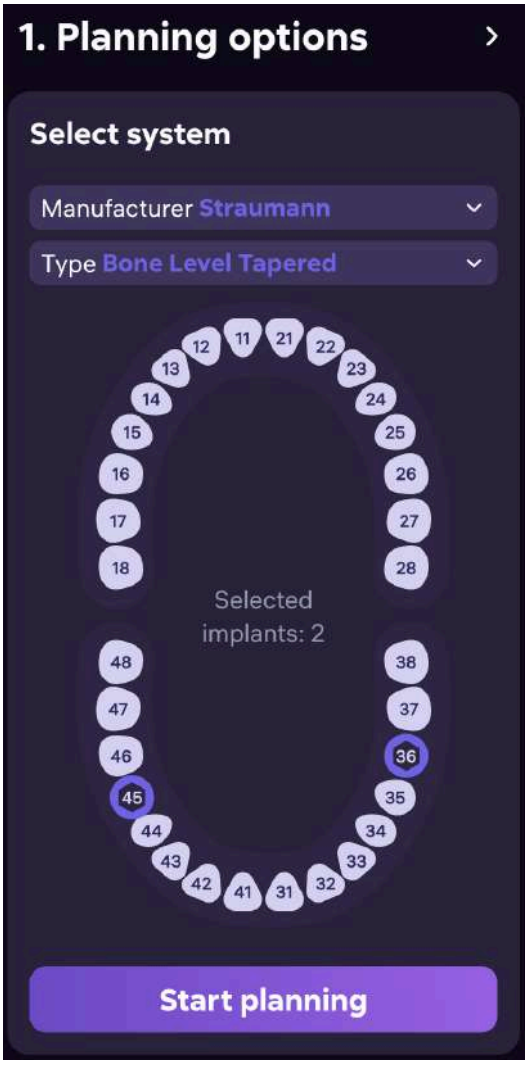
Use the Planning panel for planning implant treatment. The Planning panel covers 4 steps of the user flow:

- Planning options
- Implant planning
- Surgical guide

- Planning results

All steps of the planning flow represent expandable/collapsible cards that can be navigated through using the vertical scroll of the Planning panel.

STEP 1 – PLANNING OPTIONS



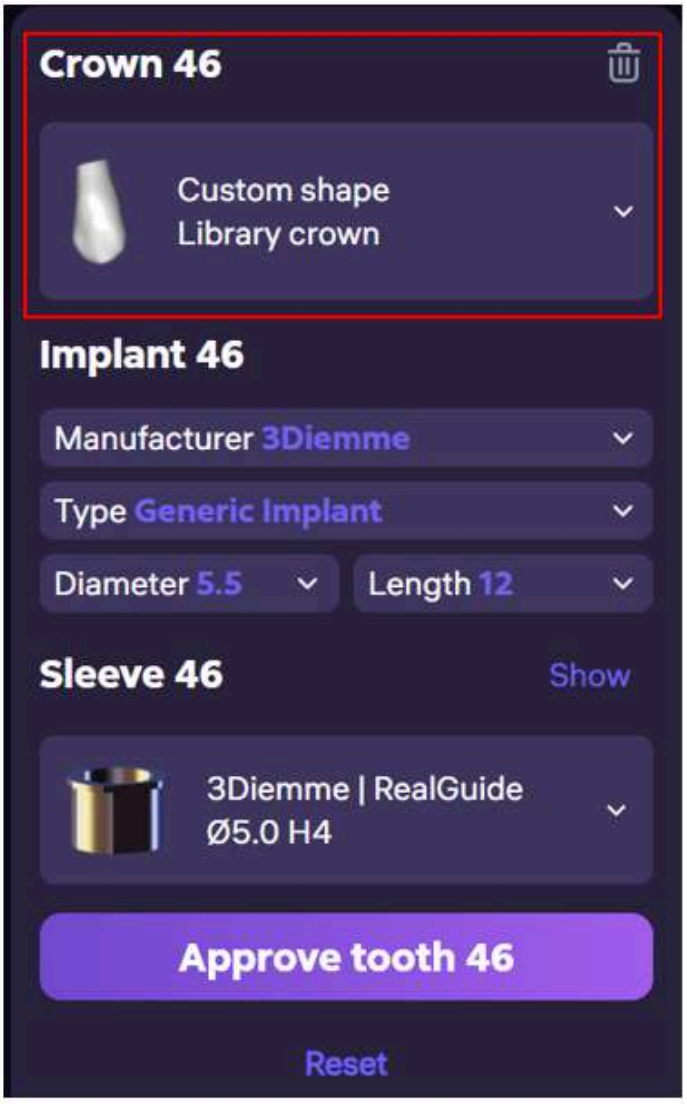
To start the planning, you need to choose the implant system and sites. Select a manufacturer and type of the implant system from the corresponding dropdown menus (they can also be changed later at the Implant Planning step). Next, choose the sites (teeth numbers) where you want to place an implant or multiple implants. To add an implant, click on the corresponding tooth number in the tooth chart. You can add an implant at the site of a missing or a present tooth. For the missing teeth, the implants are added automatically, by default. The added implants appear on the 3D scene along with the digital crowns (as dedicated 3D objects), and on MPRs and Pano (as contours). The initial position and dimensions of the implant, as well as the shape of the digital crown, are suggested by the AI and can be corrected in the subsequent

planning steps. To remove a placed implant, simply click on the corresponding tooth number in the tooth chart again. Click Start Planning to proceed to the next step.

STEP 2 – IMPLANT PLANNING

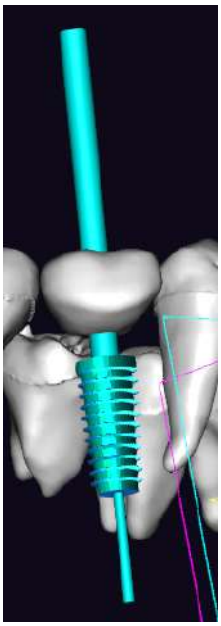
In the second step, you can adjust the properties of the crown, implant, and sleeve for each tooth number selected in the first step. You can change the manufacturer and type of the implant system selected in the first step.

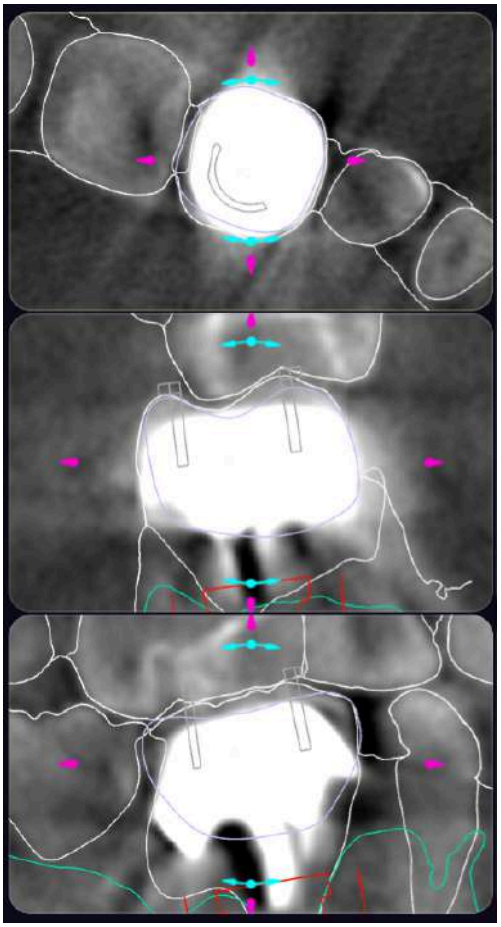
To change the shape of the crown, use the corresponding dropdown menu in the implant card and choose the appropriate shape from the library of crowns.



To adjust the shape or position of the digital crown, click on it on the 3D scene. Object controls will appear, the orientation of the controls is dependent on the camera angle.

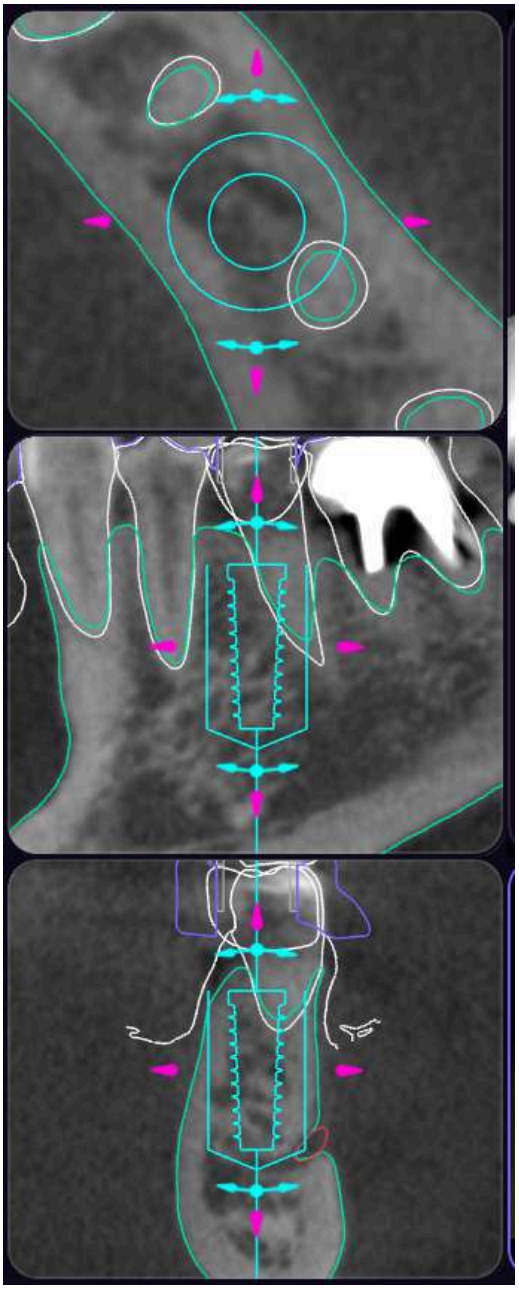
- To move the crown along one axis, click on the pink arrow and move the cursor in the desired direction.
- To rotate the crown around one axis, click on the blue error and move the cursor in the desired direction of rotation.
- To scale the crown along one axis, click on the yellow sphere and move the cursor to scale the crown up or down.



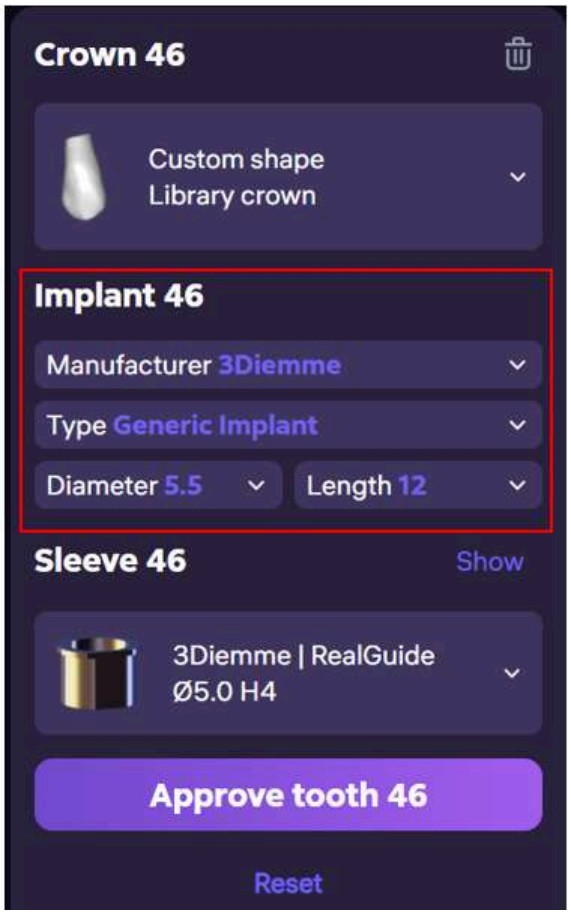


To adjust the position of the implant, use the Implant Mode controls on the MPRs. Implant Mode can be activated via the Toolbar. During the planning process, you can move and rotate the implant in the 2D planes (MPR) in the Orthogonal, Tangential and Axial views to position the implant correctly and view it.

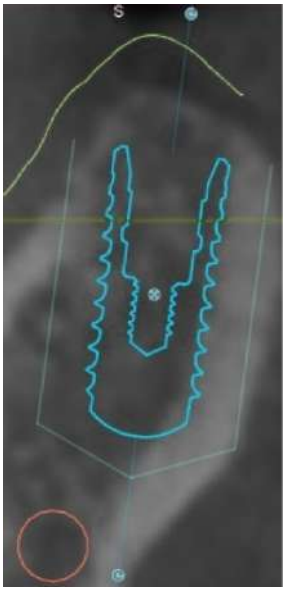
- To move an implant along one axis, click on the pink arrow and move the cursor in the desired direction.
- To drag an implant freely in one plane, click on the implant and move the cursor in the desired direction.
- To rotate an implant, click on the blue error above or below the implant and move the cursor in the desired direction of rotation; the rotation is performed around the opposite edge of the implant.



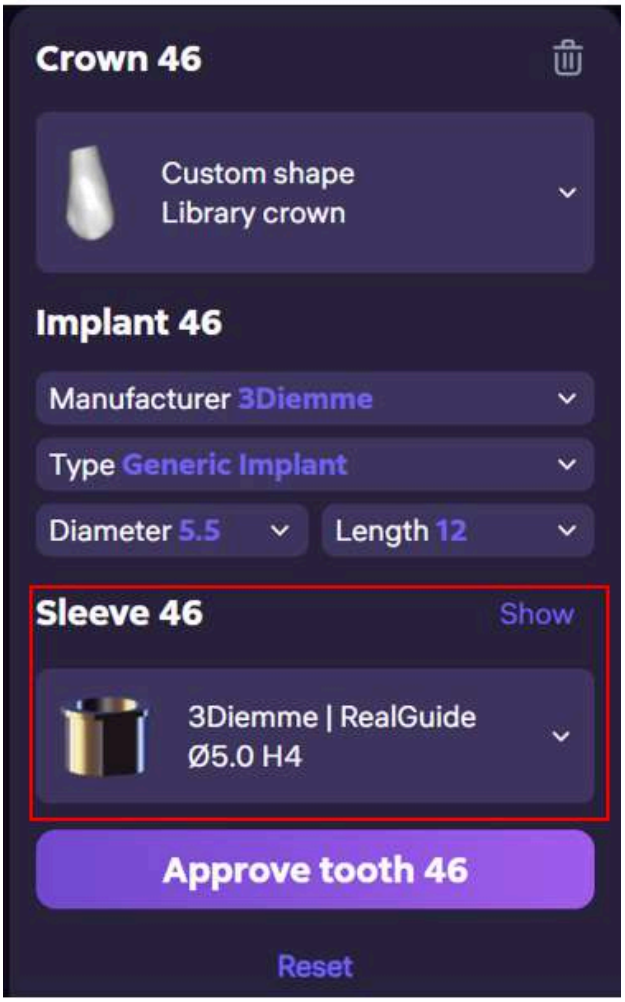
To change the diameter or length of the implant, use the corresponding dropdown menus in the Planning panel.



The safety zone contour around the implant indicates the safe positioning area to help you avoid collisions with anatomic structures and other implants. The offset of the safety zone is 1.5 mm from the bottom and lateral edges of the implant.



You can change the type of sleeve in the corresponding dropdown menu. The list of available sleeves depends on the selected Manufacturer of the implant system.



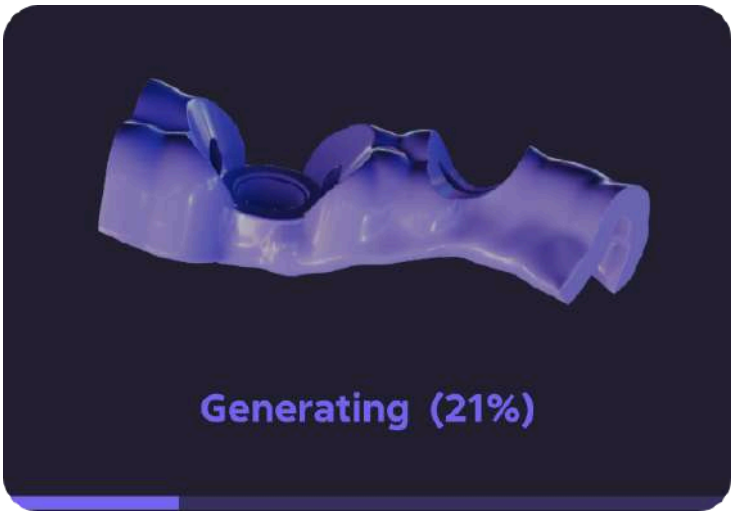
To confirm an implant plan, click Approve tooth in the corresponding card. To reset all planning properties to default values, click Reset.

To delete the implant (including the crown and sleeve) for a given tooth number, click on the Trash icon in the corresponding implant card. You can restore deleted implants by clicking Restore in the corresponding tooth card.

STEP 3 – SURGICAL GUIDE

Diagnocat

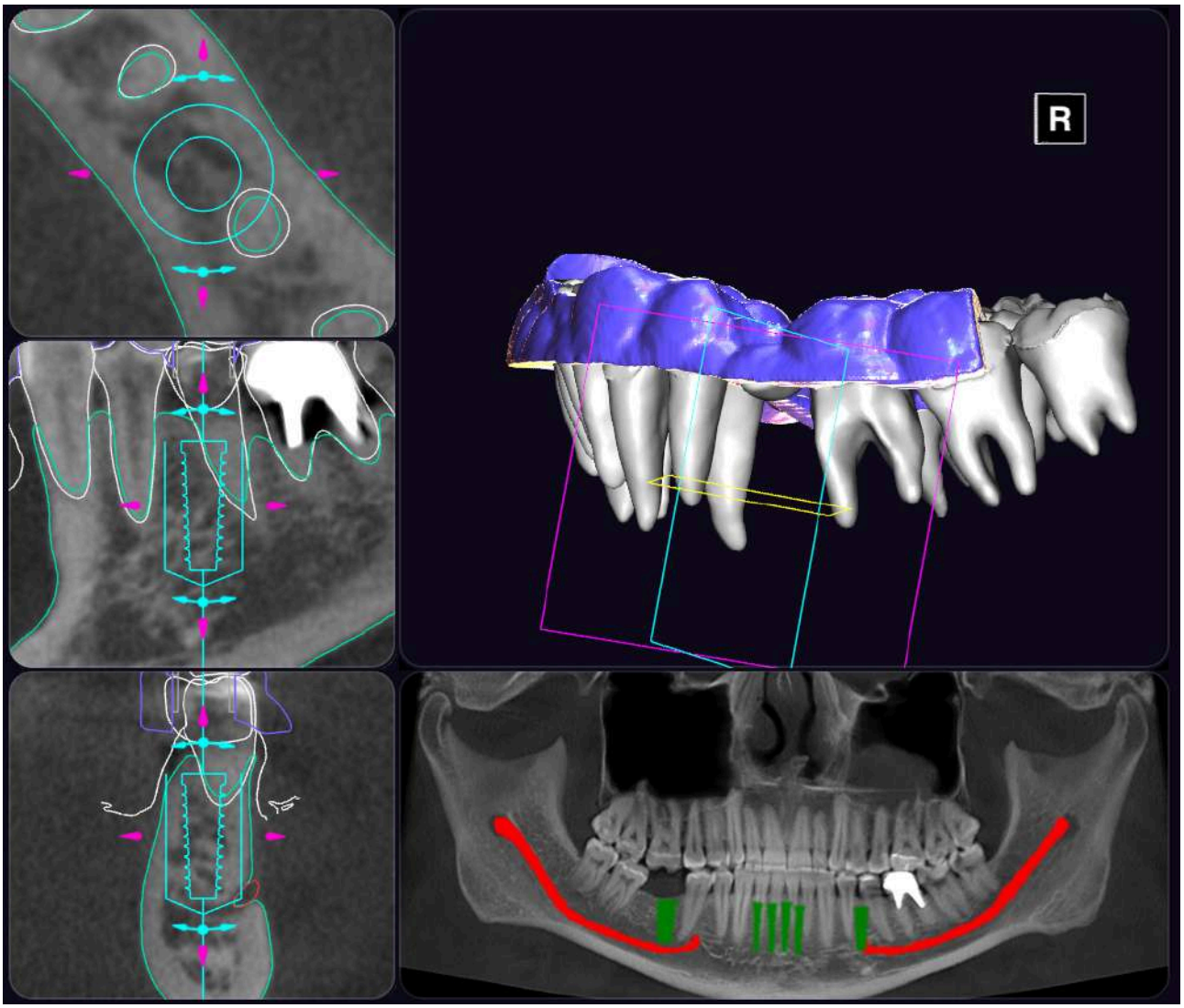
Click Generate surgical guide in the third planning step to initiate the generation of the surgical guide based on your choice and planning/ position that you have done.



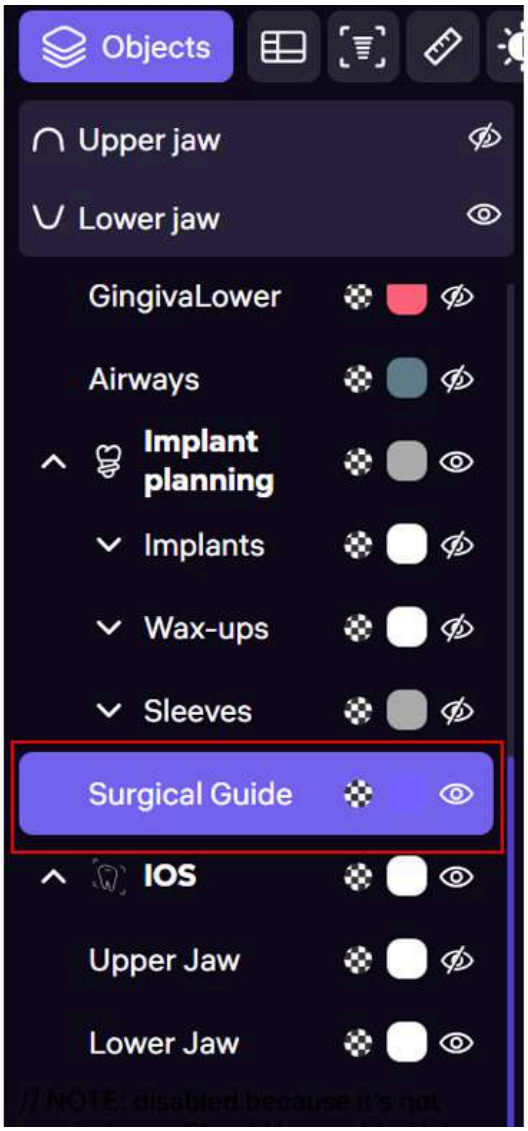
While the guide is generating, you will see a progress bar indicating the guide readiness percentage. The guide generation may take several minutes. Do not close this webpage until the generation has finished.

If guide generation runs into a problem, you will see an error message. Please contact Support support@diagnocat.com and let them know about your issue.

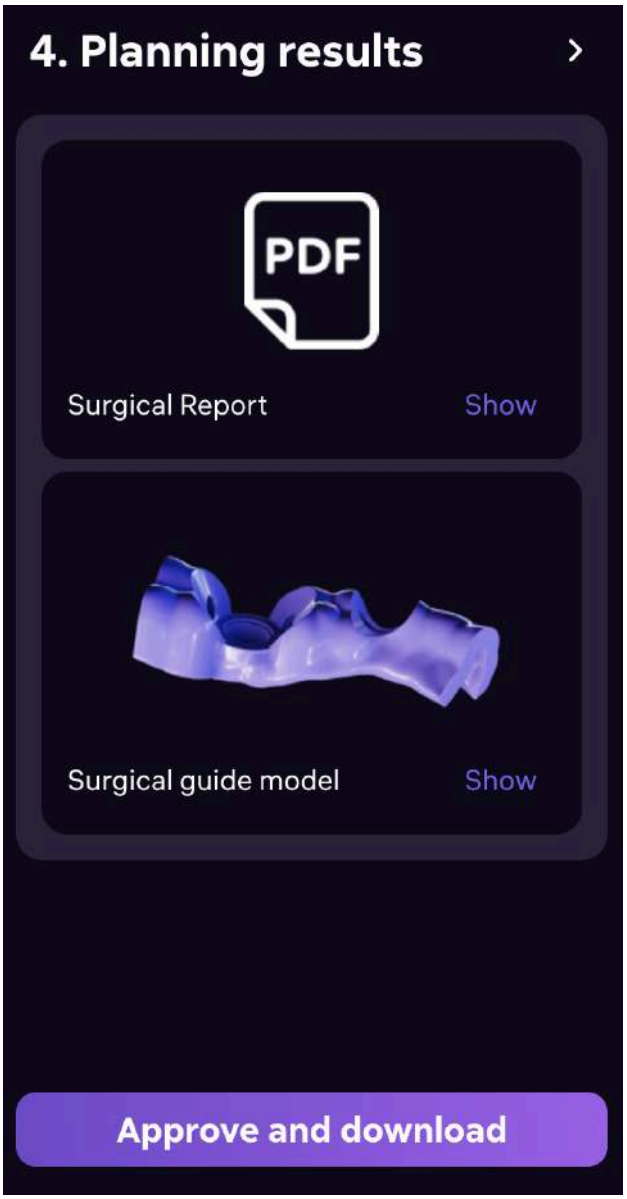
After the generation has completed, the surgical guide will appear on the 3D scene and MPR planes (the outline is colored purple).



The surgical guide will also appear in the Objects panel.



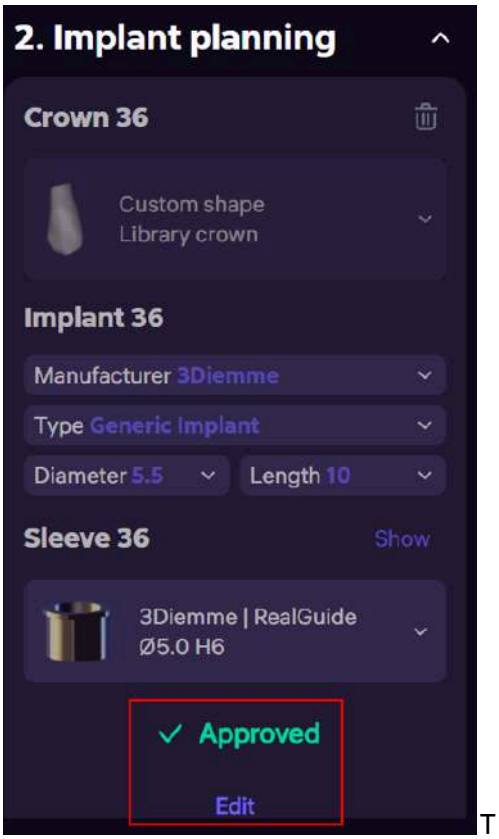
STEP 4 – PLANNING RESULTS



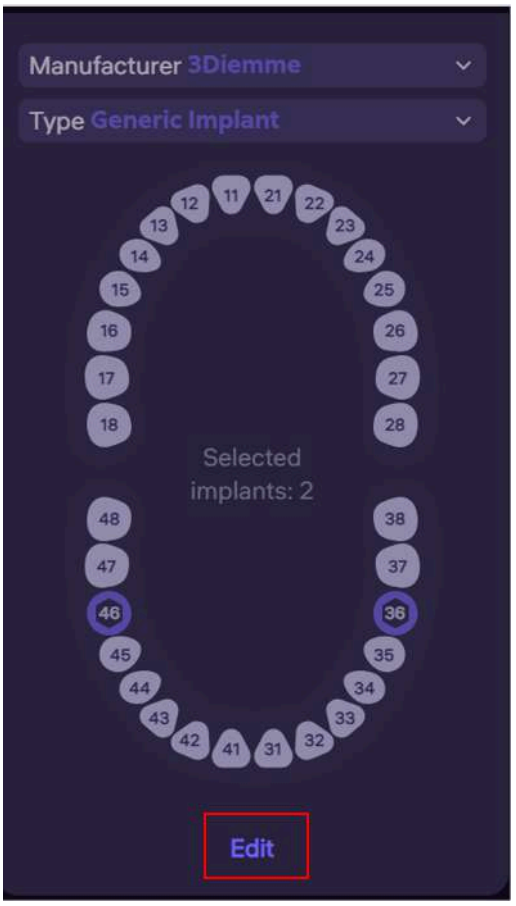
In the final step, you can preview and download the Planning results.

The generated model of the surgical guide appears on the 3D scene.

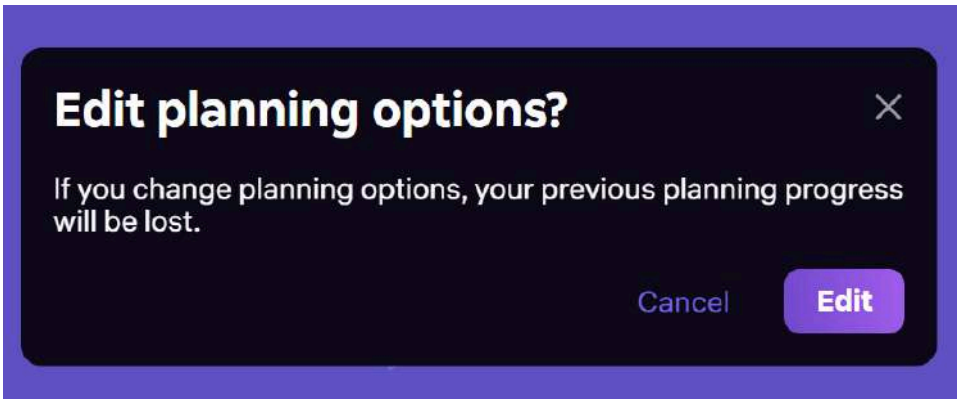
In case you need to make any adjustments to the planning, you can scroll back to the previous steps in the Planning panel and click Edit to adjust the Planning Options or Implant Planning properties for a specific implant.



T

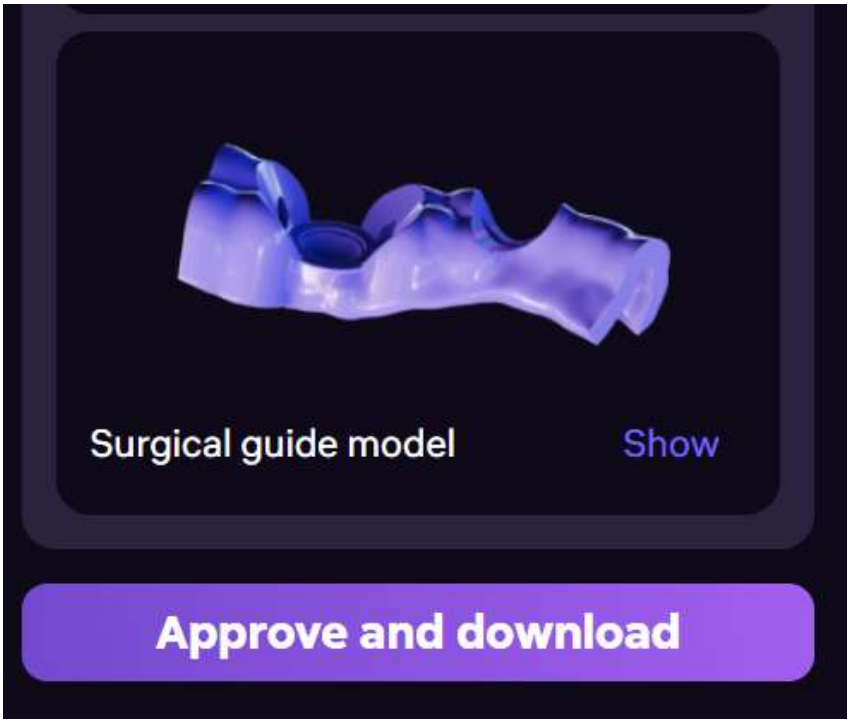


If you make changes in a step Planning options, then after clicking the "Edit" button you will see a window confirming the changes.



Please note that in case of any changes in the planning, the surgical guide model will need to be generated again.

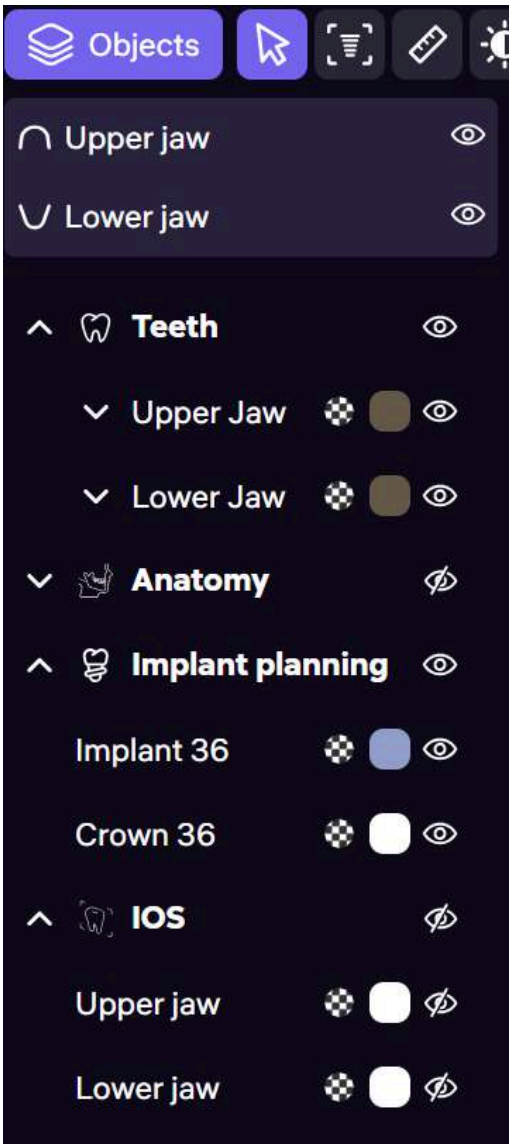
To complete the planning and download the results, click Approve and download. The Surgical guide model (in .stl format) will be downloaded on your computer. The planning will be marked as Approved.



By clicking “Approve and download”, you confirm that you have reviewedthe Surgical Guide model and you approve the medical and clinical aspects of the

planning. Printing the Surgical Guide model and conducting the implant surgery is not the responsibility of Segmentron Implant.

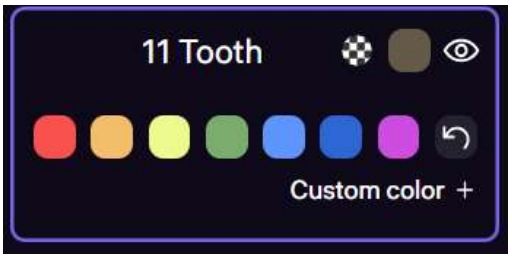
7.6. OBJECTS PANEL

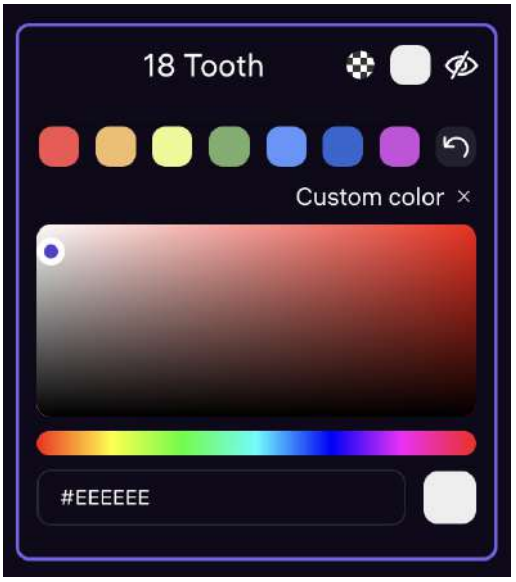


To open the Objects panel, click Objects in the Toolbar. The panel lists all anatomic objects in a tree structure.

You can control the visibility (switch on/off) of any anatomic or artificial object via the Eye icon  . To change the transparency of an object on the 3D scene, click the Transparency icon  and move the slider to the desired value.

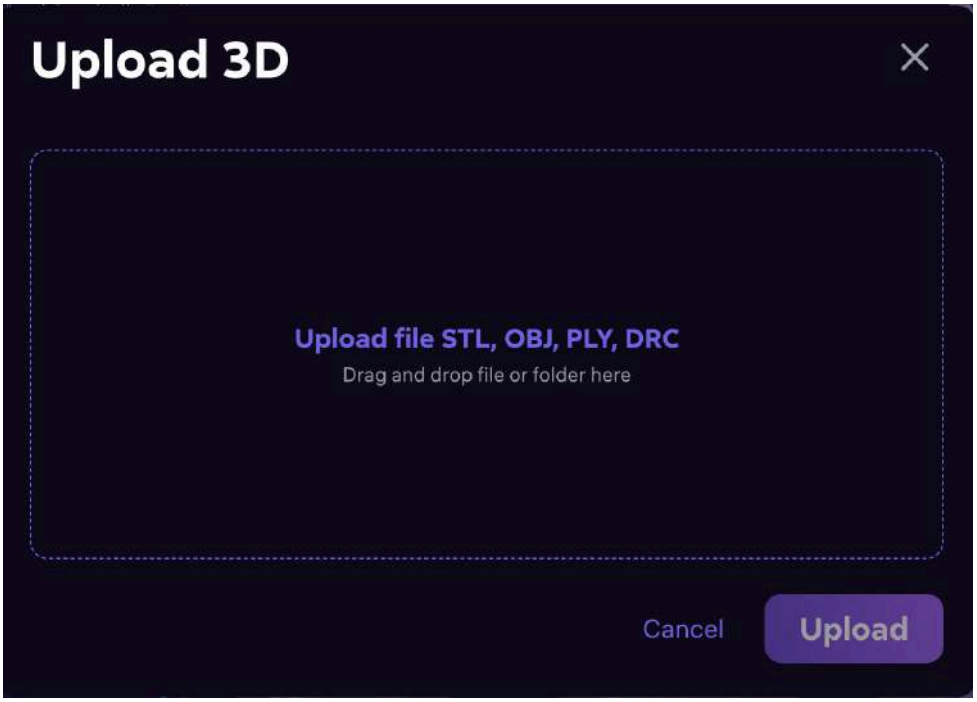
To change the color of an object on the 3D scene, click the Color icon  and click on the desired color from the palette. . There is also a possibility to configure a custom color, by clicking on the “+” icon and choosing the desired color in the color picker or typing its value in HEX format.

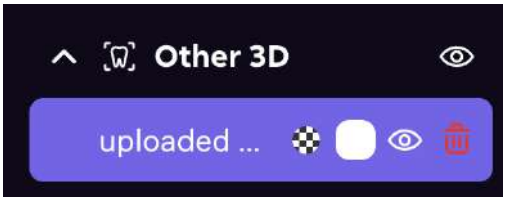




You can switch on/off the visibility of groups of objects corresponding to a specific jaw in the upper part of the panel, using the Eye icon next to Upper jaw or Lower jaw.

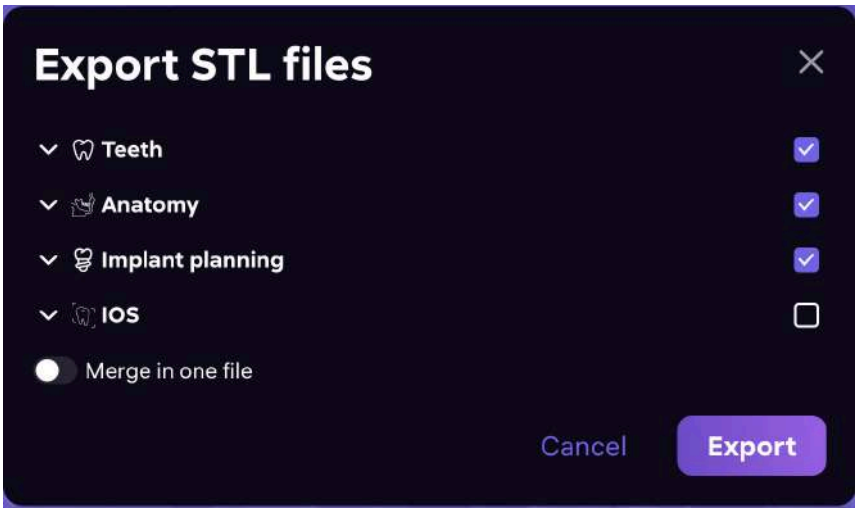
You can also upload your own 3D objects on the scene, by clicking the Upload button in the Objects panel. In the modal window, select (or drag & drop) the desired file(s) (in .stl format) from your computer and click Upload. The uploaded objects(s) will appear on the 3D scene, as well as in the Objects panel. You can move the uploaded objects on the 3D scene using object controls. To remove an uploaded object click the Delete icon in the Objects panel.





To export all anatomic and artificial objects listed in the Objects panel, click the Export button 

. You will be asked to select what objects will be included in the export and whether to merge them in one file. The objects will be exported as a .zip archive containing .stl files

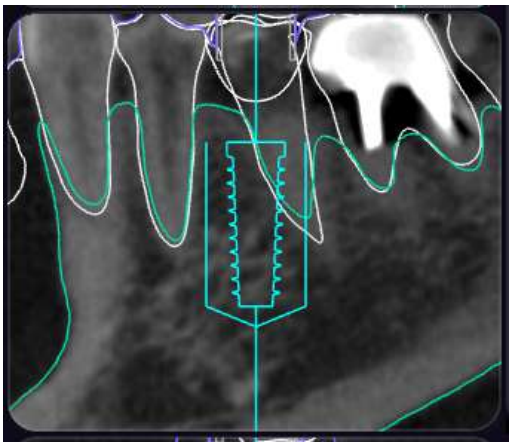


7.7. TOOLBAR

The Toolbar contains instruments supporting the implant planning. These include:

- Objects – opens/closes the Object panel (see above).
- Layouts  – allows to change the layout of the 3D scene, MPRs, and Pano.

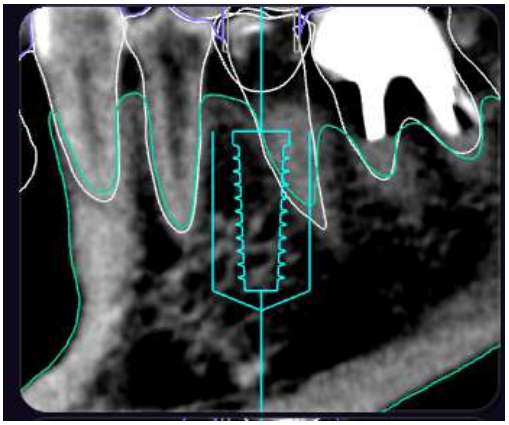
- Implant mode  – focuses the view in MPRs on the selected implant.



- Brightness-contrast – allows to change the brightness or contrast of radiological images on MPRs and Pano. To change the brightness, click the mouse on the MPRs or Pano and move it up/down; to change the contrast, click the mouse and move it left/right.

To change the brightness or contrast, the user moves the cursor with left-mouse down:

- left - decrease contrast
- right - increase contrast
- down - decrease brightness
- up - increase brightness



The change of brightness/ contrast applies to MPR planes and Pano.

- Ruler – activates the ruler instrument for measuring distances on MPRs. To measure an object on MPRs, click the mouse at the initial and final points of the object.

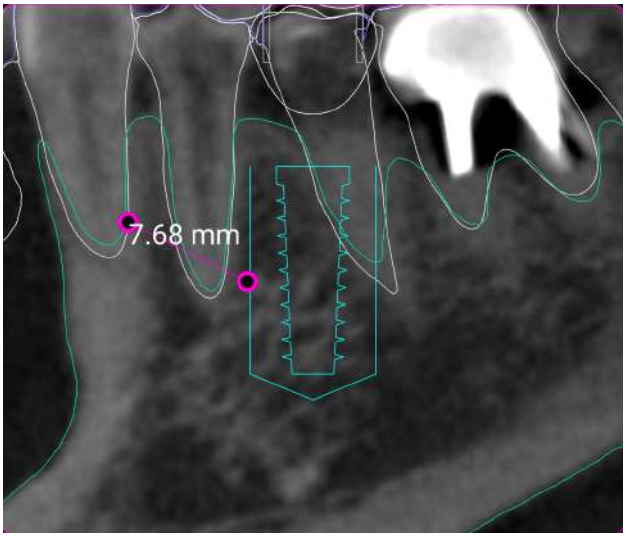
After the instrument has been activated, the following mechanics applies:

- user makes first left-click anywhere on MPR plane to mark the beginning of the ruler object
- user makes the second left-click to mark the end of the ruler object

- after the beginning is marked, the ruler object follows the mouse
- the ruler measurement (rounded to the 2nd decimal) appears at the end of the object

The user can delete the object by choosing it and clicking backspace or delete

Note: All the measurements in the software are presented in millimeters and accurate to two decimals (+/-0.01mm).

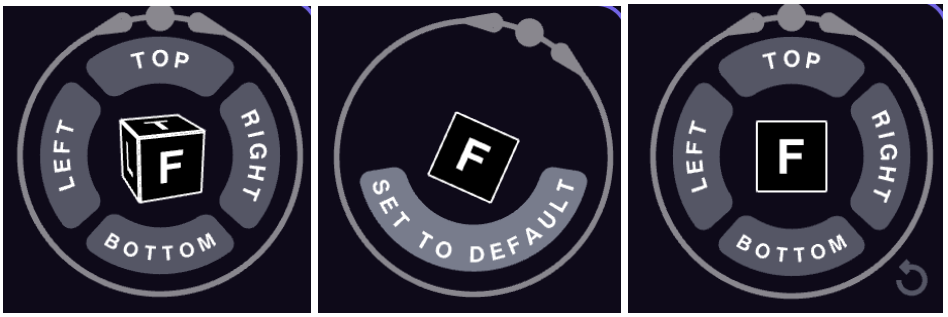


Undo/Redo instruments  – allows to undo/redo the last action related to implant planning from the Toolbar, including the changes to the implant's and crown's position and shape.

The user can use both the "Undo" button and Ctrl+Z buttons to undo the last action.

7.8. OTHER PLANNING INSTRUMENTS

Cube controls



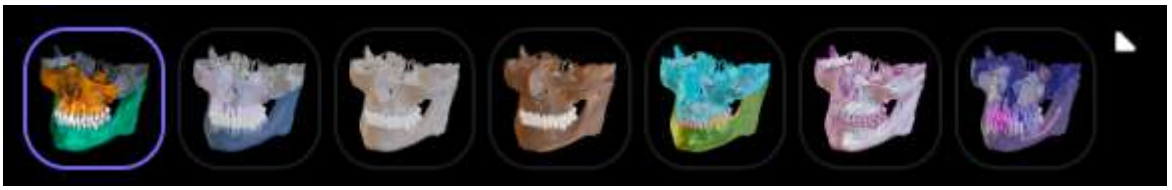
You can control the orientation of the 3D model on the 3D scene with the help of the Cube controls. The 3D cube figure indicates current orientation of the 3D model with the 6 faces (F - front, BA - back, L - left, R - right, T- top, BO - bottom). When hovering on the cube, the buttons corresponding to 4 faces appear around it. The displayed buttons depend on the current

orientation of the 3D model. A click on the button sets the orientation of the 3D model to the selected value.

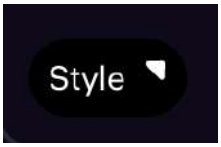
You can also click on the rotation circle (which appears on hover of the cube) and move the mouse right to rotate the 3D model clockwise or left to rotate it counterclockwise. The rotation happens relative to the current angle of the camera.

If you want to save the new orientation of the 3D model, click ‘Set to default’ button. To reset the orientation of the 3D model back to its initial value click on the reset icon.

Styles panel



The Styles panel allows to change the visual presets of the 3D model. To open the panel, click on the Styles icon on the 3D scene.



You can choose between 8 Styles presets, which differ in color, and transparency level.

Maximize viewport

You can maximize the size of any viewport (3D scene, MPRs, Pano) by hovering on the corresponding viewport and clicking the Maximize icon. Once the viewport is maximized, the icon changes to Minimize. Click it to return to the standard proportions of the viewport.

Saving planning progress

The system saves the progress of your planning in the cloud, so that you can proceed the planning from where you left after closing or reloading the app.

8. TROUBLESHOOTING

In the event of encountering any problems while using Segmentron Implant it is necessary to:

- Make sure that the inquiries sent to Segmentron Implant meet the requirements described in the medical product's technical documentation.
- Analyze the result (error) obtained and compare it to the technical documentation.
- If in spite of ensuring compliance with the technical documentation the issues keep occurring, please contact the manufacturer.

9. MAINTENANCE AND SERVICE

In case of noticing any malfunctions in the functioning of the medical device, contact the maintenance service at the e-mail address: support@diagnocat.com

10. FOR HELP AND ASSISTANCE

CONTACT INFORMATION

For general and product-related comments, questions, or concerns, please contact the local reseller.

MANUFACTURER

DGNCT LLC

333 Southeast 2nd Avenue

20th Floor#563

Miami,

Florida 33131,

USA

https://www.diagnocat.com/

Phone: + 1 519 619 4212

E-mail: support@diagnocat.com

Please report any serious incident that has occurred in relation to the device injury or adverse event to the local competent authority and to DGNCT LLC. Please refer to the manufacturer’s website for the updated contact info: https://www.diagnocat.com, if necessary.

Please report of any serious incident that has occurred in relation to the device injury or adverse event to the local competent authority and to sales@diagnocat.com