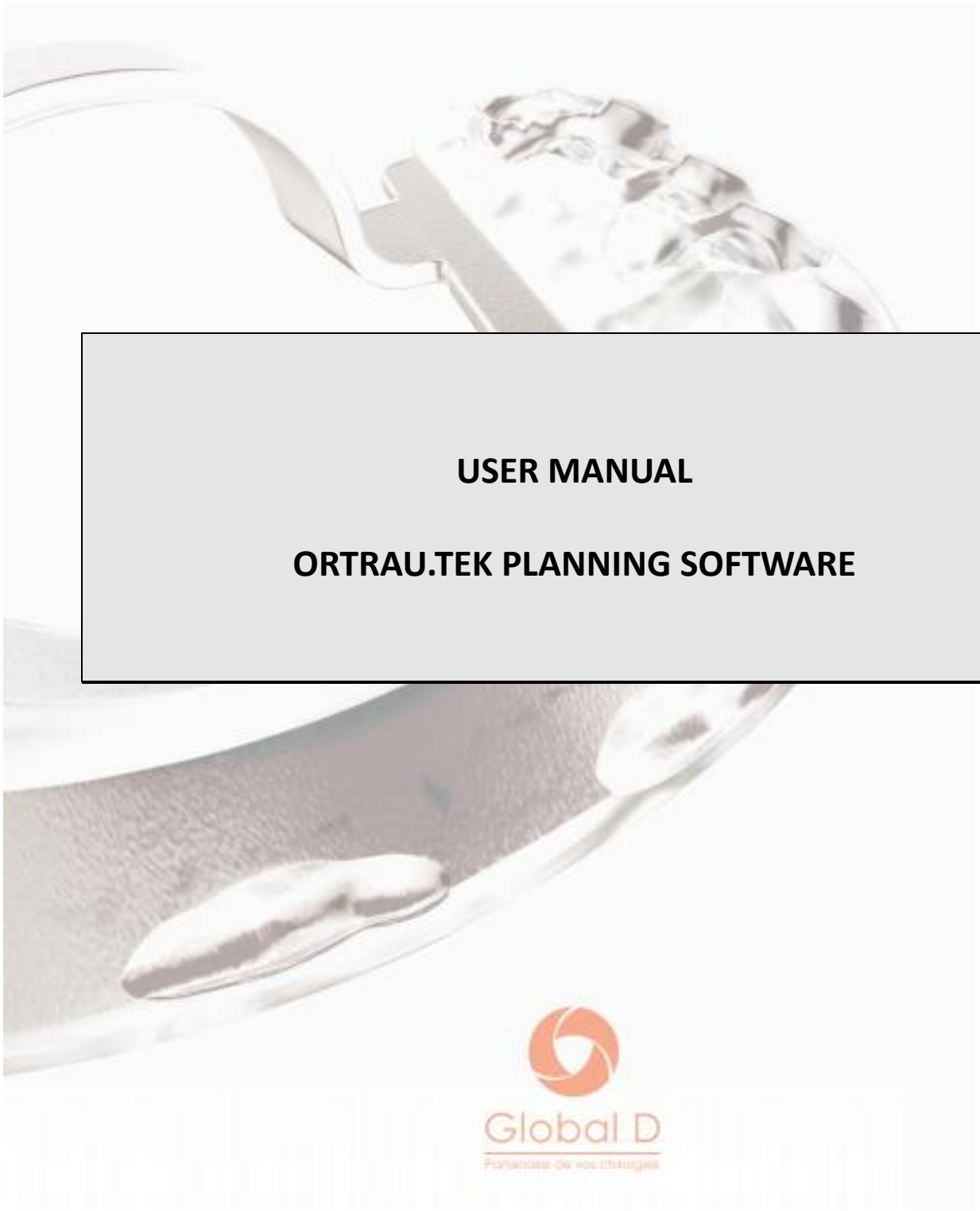
Manufactured by

Distributed by



USER MANUAL

ORTRAU.TEK PLANNING SOFTWARE

SUMMARY

List of tables

GENERAL INFORMATION

1- General information

NAME/COMMERCIAL NAME OF THE DEVICE:

The name of the device is “ORTRAU.TEK PLANNING SOFTWARE.”

INTENDED USE

ORTRAU.TEK PLANNING SOFTWARE is intended to inform clinical management by providing 3D visualization and planning tools for complete preoperative 3D bone planning in orthognathic surgery.

GENERAL DESCRIPTION:

ORTRAU.TEK PLANNING SOFTWARE is a web application designed for CMF (Cranio Maxillofacial) surgery planning, more particularly for complete 3D bone planning in orthognathic surgery.

"Orthognathic Surgery" is the name for jaw surgery, which means "Surgery that straightens the jaws". There are four main procedures for repositioning the jaws correctly:

- Surgery of the upper jaw = Maxillary osteotomy,
- Surgery of the lower jaw = Mandibular osteotomy,
- Surgery on 2 jaws at the same time = Bi-maxillary osteotomy,
- Chin surgery = Genioplasty

This software enables the 3D visualization and planning of the position of the occlusal* block (maxillary and mandibular) and the chin position to be carried out for maxillofacial surgery and, more particularly, in orthognathic surgery in order to correct occlusal and/or chin position anomalies. This software is intended to inform clinical management by providing 3D visualization and planning tools for complete preoperative 3D bone planning in orthognathic surgery. It does not directly modify the anatomy or treat the patient but rather informs the surgeon to help him to plan the surgery. The software does not make surgical decisions or propose them to the oral and maxillofacial surgeon, who remains fully responsible for the clinical drive and final decisions.
Output data of the software are used to design personalized gutters or custom-made guides and plates, reconstructed using the patient’s bone structure at the request of a surgeon via the “Workflow CMF platform”.
**Occlusal / Occlusion is defined as the way the teeth meet when the lower jaw (mandible) and upper jaw (maxilla) come together. It is how the teeth contact in any type of functional relationship.*

Using 3D items provided by GLOBAL D, this software enables display of the occlusal block positions and/or chin positions in the form of three preliminary plannings. Based on these three preliminary plannings, the surgeon can approve one as it is or create their own planning by editing one of the three preliminary plannings.

The technical data output generated by the software are as following:

- Data from .Json planning:

- Three translations for bimaxillary surgery:
  • Centering
  • Forward, backward movement
  • Impaction, expansion
- Five rotations:
  • One rotation, called “mandibular autorotation,” for bimaxillary surgery and Lefort I monomaxillary surgery
  • Four rotations for bimaxillary surgery with first maxilla and also for bimaxillary surgery with the first mandible
    - Impaction, expansion (posterior and anterior)
    - Horizontalization
    - Centering by rotation

- STL objects to export from the planner: the final bite block (maxilla + mandible)

The output data are sent to GLOBAL D to design the associated devices:

- Personalized gutters for occlusal positioning,
- Custom-made maxillary, mandibular or chin osteotomy guides, and custom-made maxillary, mandibular or genioplasty plates.

SOFTWARE VERSION:

The main version of the software considered in this file is **version 2.0**

GENERAL INFORMATION

Gutters:

The objects provided as input data are, for a standard occlusion:

	Standard occlusal			
	Bimaxillary surgery, 1st maxilla	Bimaxillary surgery, 1st mandible	OSBM	LeFort I
Initial maxilla	X	X	X	X
Initial mandible	X	X	X	X
Initial occlusal plane	X	X	X	X
Chin in initial position if associated genioplasty	X	X	X	X
Initial aligner	X	X	X	X
Intermediate aligner	X	X		
Intermediate mandible	X	X		
Final maxilla	X	X		X
Final mandible	X	X	X	X
Final occlusal plane	X	X	X	X
Chin in final position if associated genioplasty	X	X	X	X
Final aligner	X	X	X	X

and, in the case of 3D bone planning:

	3D bone plan			
	Bimaxillary surgery, 1st maxilla	Bimaxillary surgery, 1st mandible	OSBM	LeFort I
Facial mass	X	X	X	X
Initial right-hand ascending branch	X	X	X	X
Initial left-hand ascending branch	X	X	X	X
Initial maxilla	X	X	X	X
Initial mandible	X	X	X	X
Chin in initial position if associated genioplasty	X	X	X	X
Initial soft tissues	X	X	X	X
Initial occlusal plane	X	X	X	X
Initial aligner	X	X	X	X
Intermediate mandible	X	X		
Intermediate right-hand ascending branch	X	X		
Intermediate left-hand ascending branch	X	X		
Intermediate aligner	X	X		
Final right-hand ascending branch	X	X	X	X
Final left-hand ascending branch	X	X	X	X
Final maxilla	X	X		X
Final mandible	X	X	X	X
Final soft tissues	X	X	X	X
Final occlusal plane	X	X	X	X
Final aligner	X	X	X	X
Chin in final position if associated genioplasty	X	X	X	X
Interincisal point (I for maxilla, I for mandible)	X	X		X
Right-hand canine point (13 for maxilla, 43 for mandible)	X	X		
Left-hand canine point (23 for maxilla, 33 for mandible)	X	X		
Right-hand molar point (16 for maxilla, 47 for mandible)	X	X		
Left-hand molar point (26 for maxilla, 37 for mandible)	X	X		
Right-hand condyle	X	X		X
Left-hand condyle	X	X		X
Horizontalization rotational axis	X	X		
Centering rotational axis	X	X		

GENERAL INFORMATION

Guides and Plates:

The objects provided as input data are:

	3D bone plan				
	Bimaxillary surgery, 1st maxilla	Bimaxillary surgery, 1st mandible	OSBM	LeFort I	Genioplasty only
Initial facial mass	X	X	X	X	X
Initial right-hand ascending branch	X	X	X		
Initial left-hand ascending branch	X	X	X		
Initial maxilla	X	X		X	
Initial mandible	X	X	X	X	X
Initial right-hand nerve	X	X	X		X
Initial left-hand nerve	X	X	X		X
Initial maxilla teeth	X	X		X	
Initial mandible teeth	X	X	X		X
Initial chin	If associated genioplasty box checked	If associated genioplasty box checked	If associated genioplasty box checked	If associated genioplasty box checked	X
Initial soft tissues	X	X	X	X	X
Initial occlusal plane	X	X	X	X	

	Bimaxillary surgery, 1st maxilla	Bimaxillary surgery, 1st mandible	OSBM	LeFort I	Genioplasty only
Intermediate mandible	X	X			
Intermediate right-hand ascending branch	X	X			
Intermediate ascending branch	X	X			
Final facial mass	X	X		X	
Final right-hand ascending branch	X	X	X		
Final left-hand ascending branch	X	X	X		
Final maxilla	X	X		X	
Final mandible	X	X	X	X	
Final right-hand nerve	X	X	X	X	X
Final left-hand nerve	X	X	X	X	X
Final maxilla teeth	X	X		X	
Final mandible teeth	X	X	X		X
Final soft tissues	X	X	X	X	X
Final occlusal plane	X	X	X	X	
Final chin	If associated genioplasty box checked	If associated genioplasty box checked	If associated genioplasty box checked	If associated genioplasty box checked	X
Interincisal point (I for maxilla, i for mandible)	X	X		X	
Right-hand canine point (13 for maxilla, 43 for mandible)	X	X			
Left-hand canine point (23 for maxilla, 33 for mandible)	X	X			
Right-hand molar point (16 for maxilla, 47 for mandible)	X	X			
Left-hand molar point (26 for maxilla, 37 for mandible)	X	X			
Right-hand condyle	X	X		X	
Left-hand condyle	X	X		X	
Horizontalization rotational axis	X	X			
Centering rotational axis	X	X			

GENERAL INFORMATION

PRECAUTIONS / WARNINGS:

Information to be provided to the users: the residual risks, their associated recommendations and patient consequences are listed below:

Residual risks	Recommendations	Patient consequences
Access to the software by someone who should not have access rights.	Never transfer access rights to a third party; the login and password are strictly personal. Such behavior could make confidential data accessible to third parties.	No patient consequences.
Security flaw in software dependency.		
Data is compromised.	Make sure of the compliance of input data (bone model)	No patient consequences
Use of an outdated or unverified browser.	Always use a browser that complies with the manufacturer's requirements and ensure that it is not obsolete to avoid security breaches. There is a security risk if the browser is obsolete.	No patient consequences.
Security flaw due to using an outdated browser.		
Security flaw due to validating software on an outdated browser.		
Mixing data and causing confusion between multiple cases.	To avoid data related to planning output, ensure that the patient data is correct. There could be a risk that the data displayed by the software is incorrect.	No patient consequences.
Bugs not reported, non-compliance and/or material safety issues to ONE ORTHO.	Please don't hesitate to let us know about any bugs or anomalies (see §10 contact). Despite our utmost care during the development of the software, there is always a risk that it may contain a fault.	Longer operating times.
The "back button to the procedure tracking page does not work.		
The server containing the medical data is down.		
The website presenting the electronic instructions for use does not display correctly the e-IFU on the user's screen.	Comply with the minimum requirements regarding the characteristics of the material, including the definition of the screen, and the computer networks, as defined in the User Manual, in order to guarantee the correct display of the software interface and to avoid inconveniences and	No patient consequences.

	security problems. Indeed, there is a security risk in using a browser that is not approved by the manufacturer or in using the electronic User Manual un an environment that does not correspond to the requirements of the material and the computer network.	
The labeling information are not available on the software".	Ensure that the version of the User Manual used is the same as the version identified on the software label. There could be a risk that the labelling provides incorrect information about the software identification or that this User Manual accessible through the software corresponds to a different version of the software.	No patient consequences.
The information in the label is not correct (UDI / Date of production/…) before software production / use.		
Wrong User Manual version on the IFU website leading to software use error.		
The surgeon plans a case that may not be the best proposal for the case. (Usability risks)	Ensure that the data presented by the software is not interpreted. The oral and maxillofacial surgeon is responsible for the choice of planning.	Inadequate care and longer operating time.
Poor indication for case planning. (Usability risks)		
Poor casing planning. (Usability risks)	Before validating the planning, check that the expected outcome is correct.	Longer operating time, pain and recovery.
Incomprehensible translation of documents provided to the user.	Please do not hesitate to let us know of any element (see §10 Contact) for which the translation is not satisfactory. Despite the rigorous with which we prepare the translation of the software and its associated documentation, there is always a risk of providing a translation that is incomprehensible to the user.	Longer operating time.
Incomprehensible translation of the software.		

GENERAL INFORMATION

RESTRICTIONS OF USE:

Information to be provided to the users:

Non-compatible device combinations:

It is prohibited to use several web browsers or several tabs of a browser in parallel to simultaneously access several pages of the application.

Data storage:

All data is hosted on an HDS-certified (Health Data Hosting) server. No data is stored locally on the user's machine.

This restriction exists to avoid mixing data and causing confusion between multiple cases.

This software is designed for professionals (Oral and maxillofacial surgeons). It must in no way be used as the sole basis for making clinical decisions about the patient's diagnosis, care, or management.

The plausibility of the information obtained through the software must always be clinically verified before it is used for the treatment of patients. Any application of medical information from the program that does not fall within the original design or intended use of the program is discouraged and will be considered a misuse of the software.

GENERAL INFORMATION

INSTALLATION SPECIFICATIONS:

Operating systems:

- Windows,
- Mac OS.

Browser:

- Google Chrome V109 or more

Google Chrome can be downloaded under the following URL:
https://www.google.com/chrome/

The only browser to use, which is verified and guaranteed by the manufacturer, is “Chrome”.

The browser used must be compatible with WEBGL technology:
https://caniuse.com/?search=webgl

The access URL for the site is as follows: https://dotek.app

Screen definition:

The platform is fully responsive, meaning that it adapts to the size of the screen. However, devices such as smartphones do not fit the use of ORTRAU.TEK PLANNING SOFTWARE, in fact, on smartphone-type reduced formats, the adaptation may modify the layout of the user screen. A minimum of 1200px in 16:9 format is recommended to display all the application’s information.

The minimum scale of visualization is 100%.

Internet connection:

An internet connection is required to use the application. A minimum connection speed of 10 Mbps is recommended.

Material:

The hardware requirements for the client workstation required for a comfortable user experience are:

- **Processor:** The processor must be equivalent to an Intel Core i5 (sixth generation or newer)
- **Graphics card:** The graphics card must have a minimum video memory of 2048 MB.

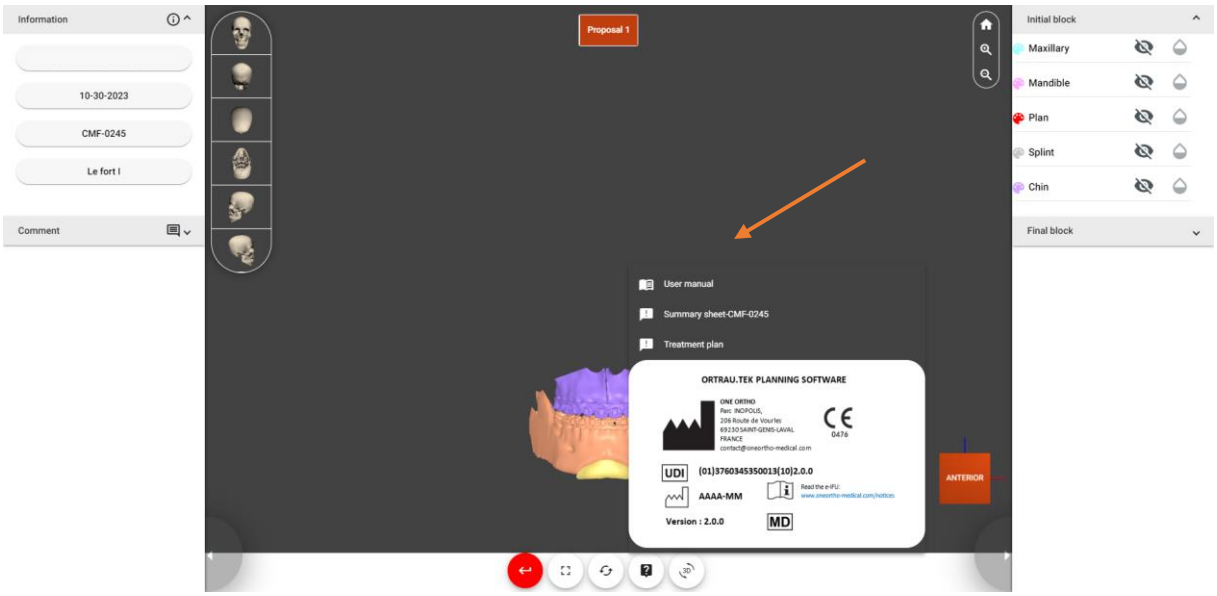
Intended conditions of use:

- **Environment**: Home office and office at the hospital or clinic.
- **Frequency**: Repeated use, the software is intended to be used once or more before each surgery for which the surgeon needs a plan.
- **Location**: User Home, hospital, clinic.
- **Mobility**: ORTRAU.TEK PLANNING SOFTWARE is a web application accessible via a computer complying with the installation specifications indicated above.

GENERAL INFORMATION

ACCESSIBILITY OF THE DOCUMENTATION:

This user manual can be accessed at any time from the lower menu by clicking on the icon. An “Info” menu then appears; this makes three documents available to download, including the user manual.



Regulatory information is also accessible at any time in the bottom menu by clicking on the same icon .

An "info" menu then appears, displaying the following regulatory information:

- Designation of the product,
- Name and address of the manufacturer,
- CE marking with the NB number,
- UDI code: (01)UDI-DI(10)version of the software,
- Manufacturing Date (YEAR-MONTH): This is the release date as defined on the “Release note”,
- Link to the notice website,
- Version of the software,
- MD logo for medical device.

Note 1: This label is a representation of the information available on the software label. This screenshot does not always reflect the actual information.

2- Terms of use

Indications

ORTRAU.TEK PLANNING SOFTWARE is indicated in various maxillofacial skeletal anomalies and more particularly in orthognathic surgery to correct the position of the maxilla (LeFort I), the mandible (sagittal split) and/or the chin (genioplasty).

Intended users

The intended users of the medical device are oral and maxillofacial surgeons with expertise in maxillofacial surgery and knowledge of anatomy, biomechanics, and reconstructive surgery of the musculoskeletal system, as well as of operative surgical techniques. The surgeon is responsible for approving the proposed plan in the medical device.
There is no required training for the use of the software.
(The technical instructions specific to this user and the parameters to be taken into account can be found in this user manual in §4 "Ortrau.Tek Planning").

Target population

ORTRAU.TEK PLANNING SOFTWARE is intended for use for male and female who have reached bone maturation with various maxillofacial skeletal anomalies (maxilla, mandible, chin).
Only the healthcare professional (the surgeon) can define if the patient has reached its bone maturation.
There is no "special population" / "vulnerable population" for this device (no pregnant woman, no pediatric, ...).

Claimed performances

- **Claims of non-clinical performance intended by the manufacturer**

The claims of non-clinical performance of ORTRAU.TEK PLANNING SOFTWARE are described in table 1:

Table 1: Claims of non-clinical performance of ORTRAU.TEK PLANNING SOFTWARE.

Claim of non-clinical performance	Criteria of the claim
Restitute the plan created by the surgeon on the 3D planning tool (which allow the 3D visualization of the craniomaxillofacial anatomy) using an STL export	Uncertainty of +/- 0.25 mm compared to the surgeon's plan
Enabling an increase in translations and rotations of the 3D planning tool	Increment of 0.5 mm in translations and rotations

- **Claims of clinical performance intended by the manufacturer**

According to EU MDR 2017/745, "clinical performance" is the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer.

The claims of clinical performance of ORTRAU.TEK PLANNING SOFTWARE are described in table 2:

Table 2: Claim of clinical performance of ORTRAU.TEK PLANNING SOFTWARE.

Claim of clinical performance	Criteria of the claim
Accuracy of surgery with virtual planning	Linear differences between pre-and post-operative CT scans ≤ 2 mm
	Angular differences between pre- and post-operative CT scans ≤ 4°

Claimed benefits

According to EU MDR 2017/745, "clinical benefit" is the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.

The manufacturer claims indirect patient benefit for the device under evaluation **ORTRAU.TEK PLANNING SOFTWARE.**

The claim of indirect clinical benefit of ORTRAU.TEK PLANNING SOFTWARE is described in table 3:

Table 3 : Claim of indirect clinical benefit of ORTRAU.TEK PLANNING SOFTWARE.

Claim of clinical benefit	Criteria of the claim
Time reduction regarding surgery time	Reduction ≥ 15% of the surgery time compared to conventional surgery

Contraindications

The planning software must not be used when using gutters, guides, and plates are contraindicated.

Adverse side effects

No adverse side effects have been recorded in association with the web application.

3- Lifetime

The software's lifetime is two years.
During this period, One Ortho guarantees the software's performance and undertakes to carry out updates to enable its optimal use.

4- Ortrau.tek planning

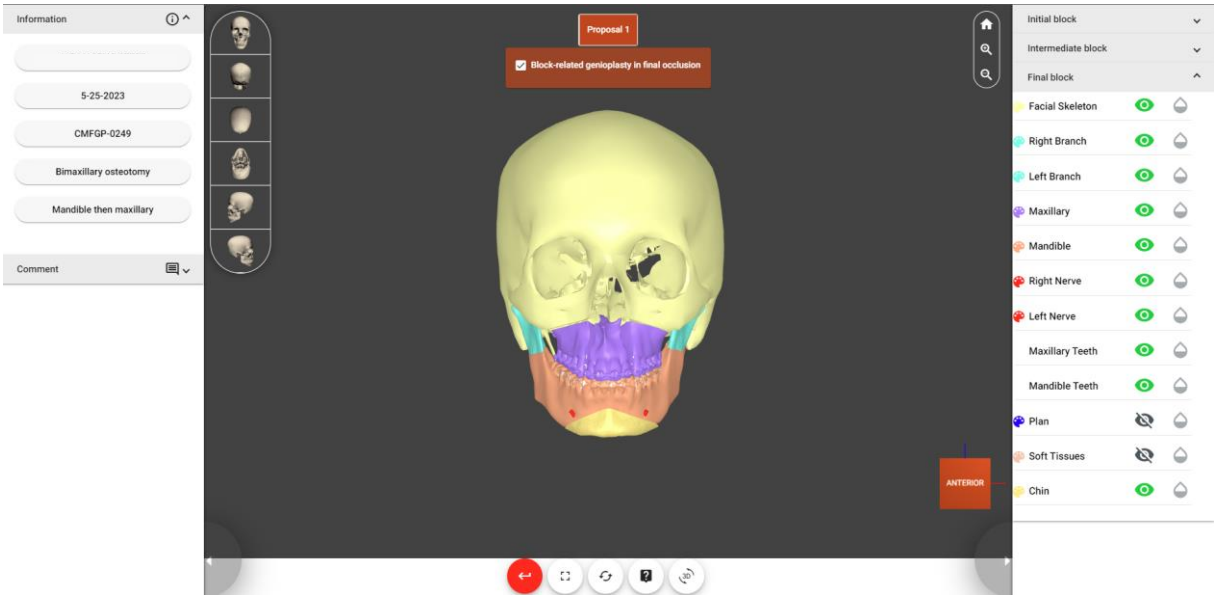
4.1 Planning visualization

Once the planning is put online by the technical team, the surgeon will receive an email indicating that they may log onto the platform in order to visualize the three suggested planning and approve one of them.

For a planning with an **STL PROVISION (ready-to-use STL files)** model, the surgeon will need to send their STL files and will only have access to the 3D visualization once these files have been approved by the technical team.
For all other procedure models, access to the 3D visualization is automatic once the planning is put online by the technical team.

To access the 3D visualization, click on the  icon in the “Planning” column of the procedure monitoring dashboard.

On a standard computer screen, the planning window is presented as follows:



In the 3D display area, to rotate its 3D models, the user must hold down the left mouse button and move their mouse.

To zoom in on the 3D models, the user must click on the mouse wheel, then scroll up with the mouse to zoom in and scroll down to zoom out.

To translate the bone models, the user must hold down the right mouse button and move the models by dragging the mouse.

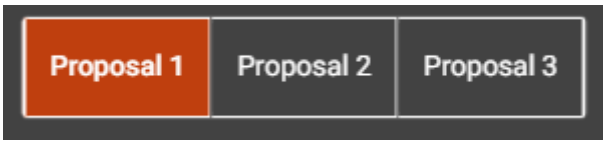
PLANNING VALIDATION

Various tools are available to the user to help them visualize their planning:

On the left of the visualization window, the user has access to six standard anatomical views of the bone models:

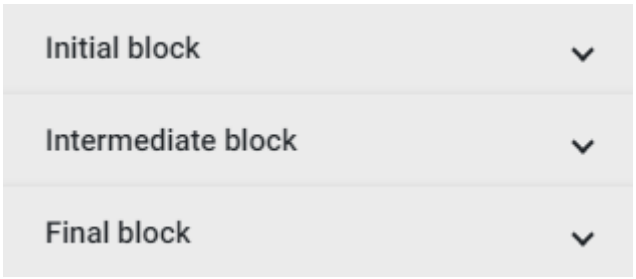
This enables the standardized positions to be displayed quickly, in order to make the 3D experience easier. Finally, after multiple movements, this tool allows you to return to a standard position.

At the top of the screen, the surgeon can switch from one planning suggestion (pre-planning) to another by selecting the button corresponding to the desired suggestion, between 1 and 3:

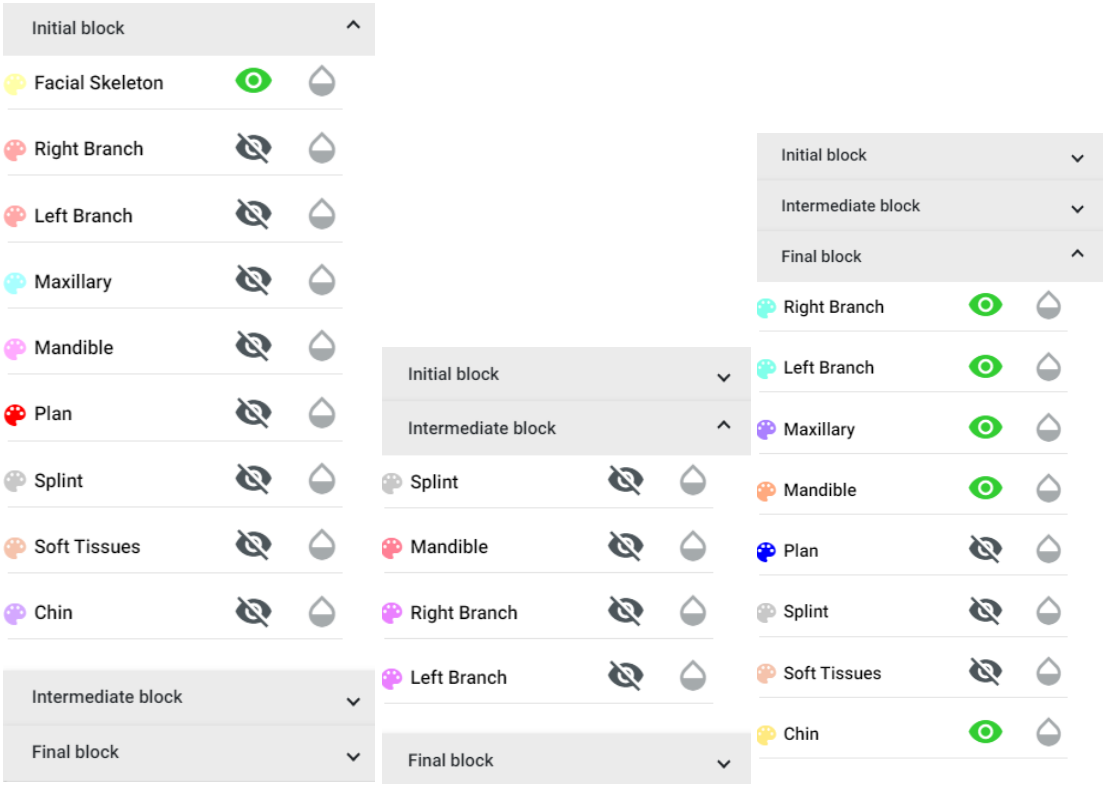


On the right-hand side of the web page, the user can access tools to display or hide the various elements of the 3D view:

PLANNING VALIDATION



- In the "**Initial block**" menu, the surgeon can display or hide the objects that appear there and apply transparency.
- In the "**Intermediate block**" menu, the surgeon can display or hide the objects that appear there and apply transparency.
- In the "**Final block**" menu, the surgeon can display or hide the objects that appear there and apply transparency.

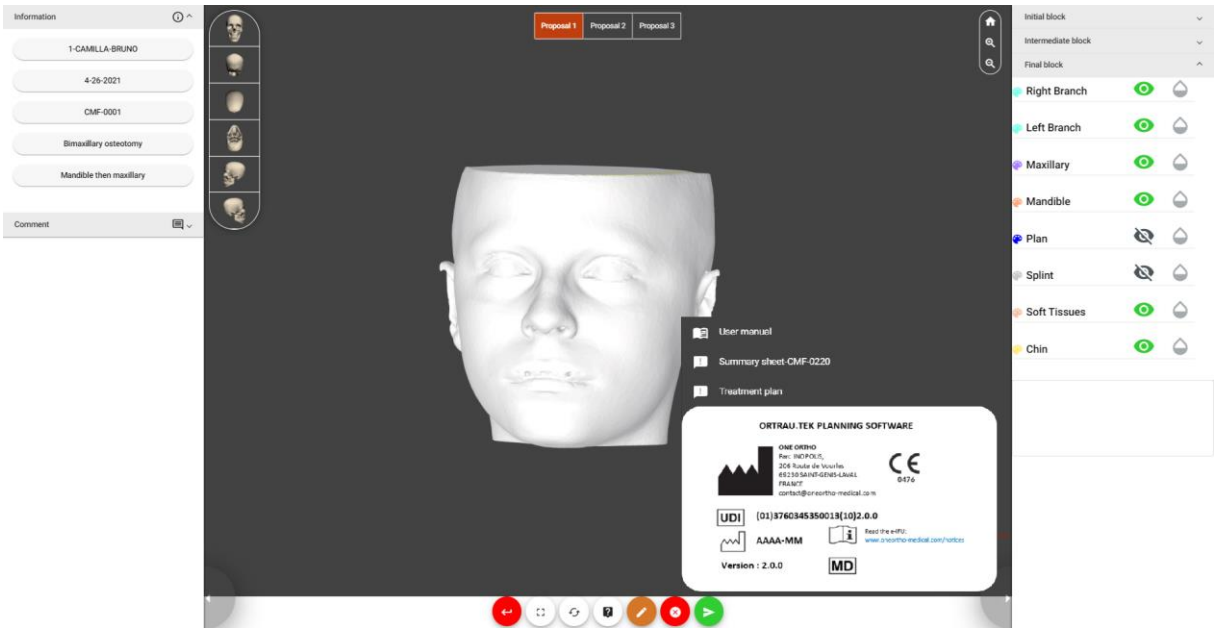


For each menu, the various display modes allow you to hide or display the bones, hide or display the gutters, display the soft tissues, and make the bones transparent.

<u>Soft tissue visualization (OPTIONAL):</u>

ORTRAU.TEK PLANNING SOFTWARE offers the possibility of visualizing the soft tissue in initial and final occlusion for proposed planning.

PLANNING VALIDATION

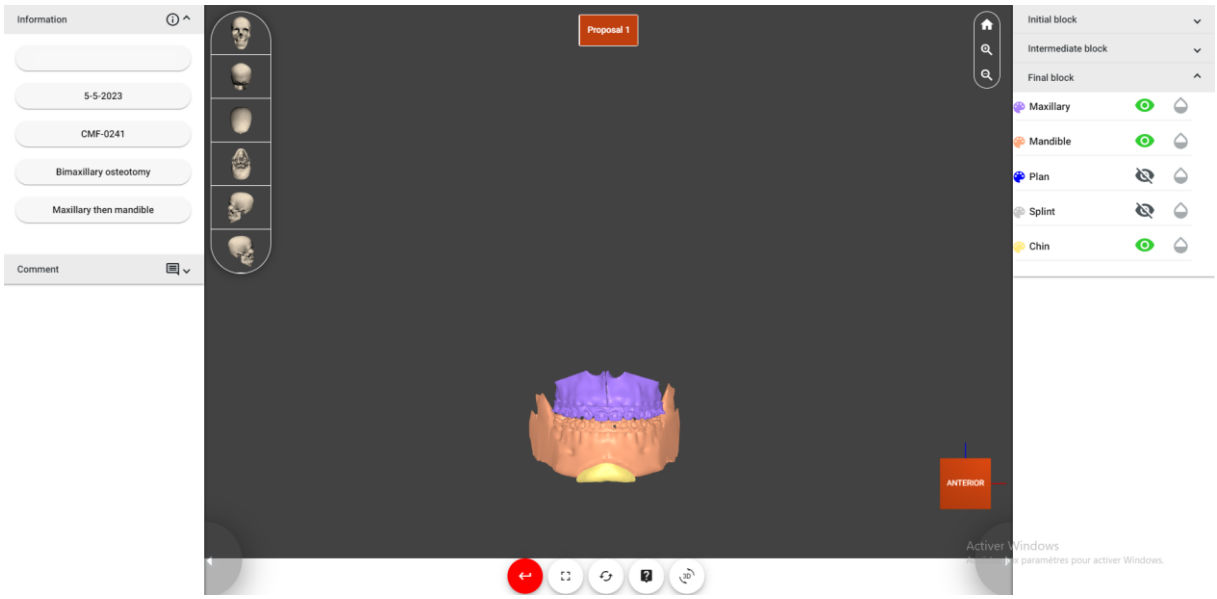


Example of soft tissue visualization

4.2 Planning validation

Once the various planning has been carefully examined by the surgeon, they will be able to decide whether to approve or refuse the individual plannings suggested.
Depending on the planning model chosen for the case under consideration, the surgeon will have several options:

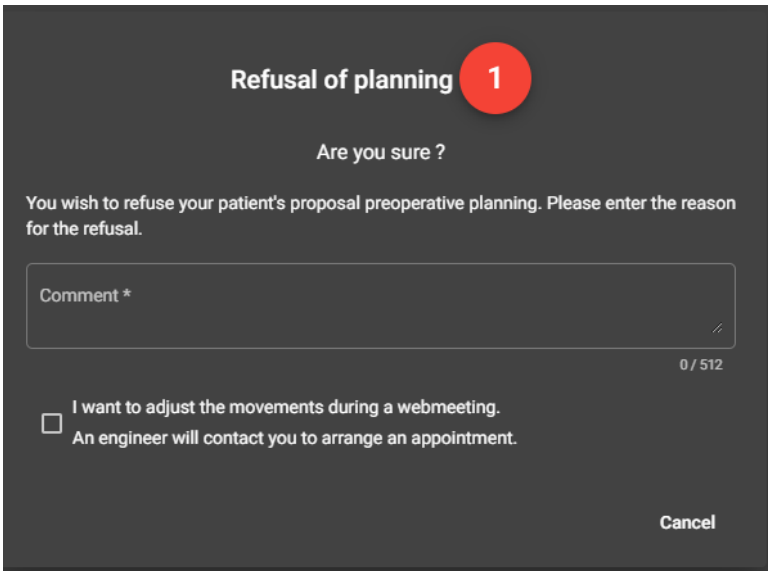
4.2.1 Standard occlusion type planning



Two buttons are available for the “Standard occlusion” type of planning:

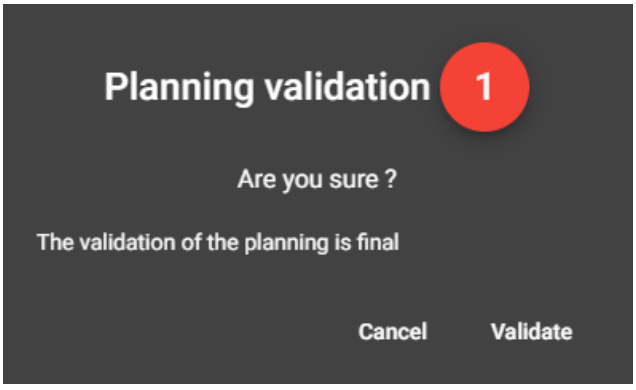
- The refusal button  . Once the surgeon clicks on this, a new window opens up for this suggestion :

PLANNING VALIDATION



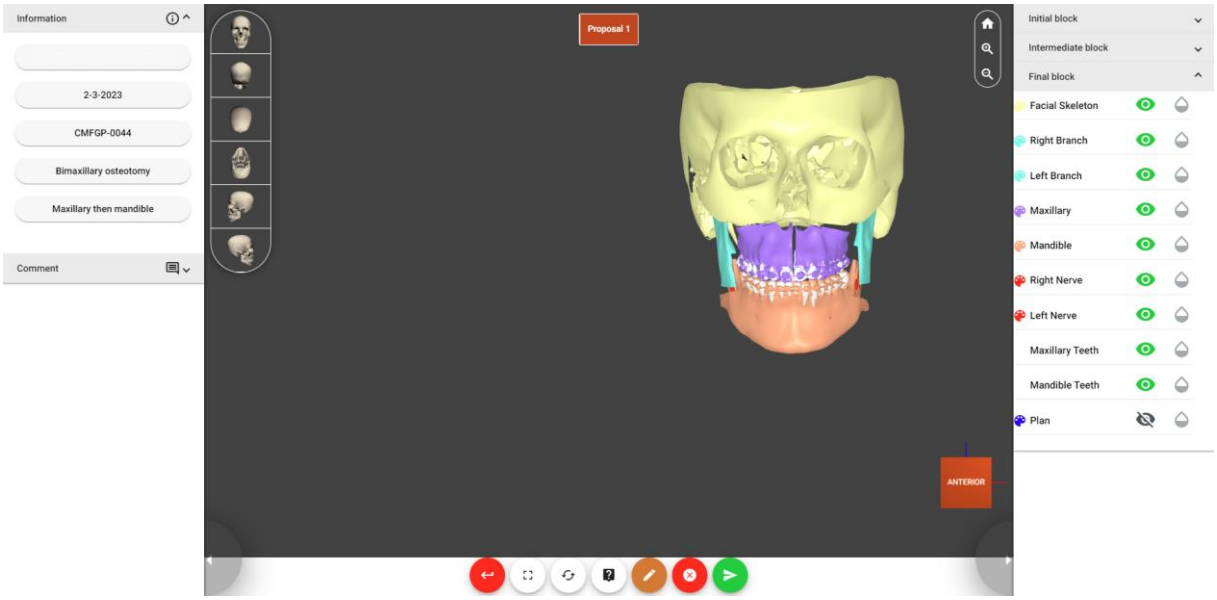
In this case, the surgeon must indicate in the comment section the reason for their refusal of the suggested planning . They also have the option of requesting a web meeting with a member of the technical team to design new planning suggestions together.
A member of the technical team will suggest a meeting. Once the new suggestion has been placed on the platform, the surgeon must log in again to approve it.

- The  button allows the surgeon to approve the suggested planning. This approval **is binding on the surgeon**:



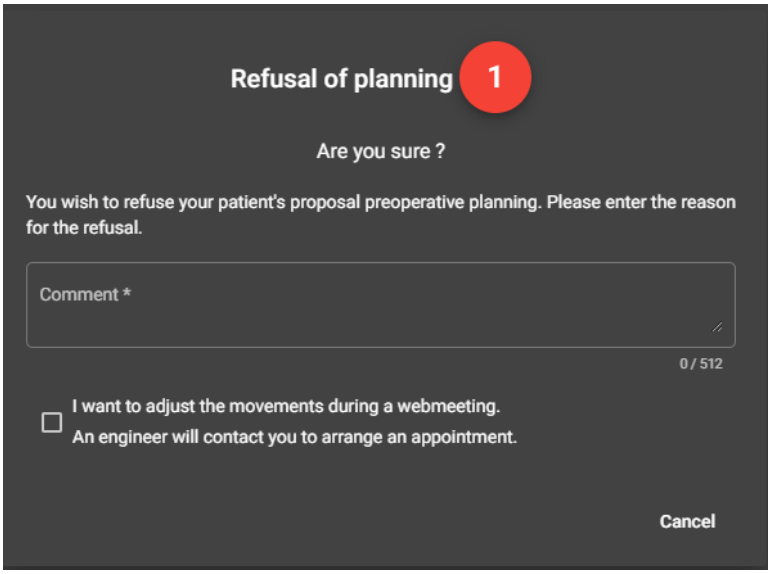
PLANNING VALIDATION

4.2.2 Planning type planning:



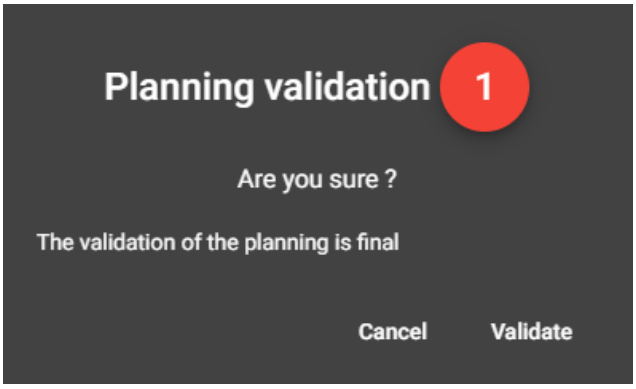
Three buttons are available for the "Planning" type of planning:

- The first is the edit button  . This allows the surgeon to modify the suggested and selected planning. **(Refer to the next section, 4.3 Planning modification)**
- The second is the refusal button  . Once the user clicks on this, a new window opens up:



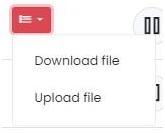
The surgeon must indicate in the dedicated comment section the reason for their refusal of the suggested planning. They also have the option of requesting a web meeting with a member of the technical team to design the new planning together. A member of the technical team will suggest a meeting. Once the new suggestion has been placed on the platform, the surgeon must log in again to approve it.

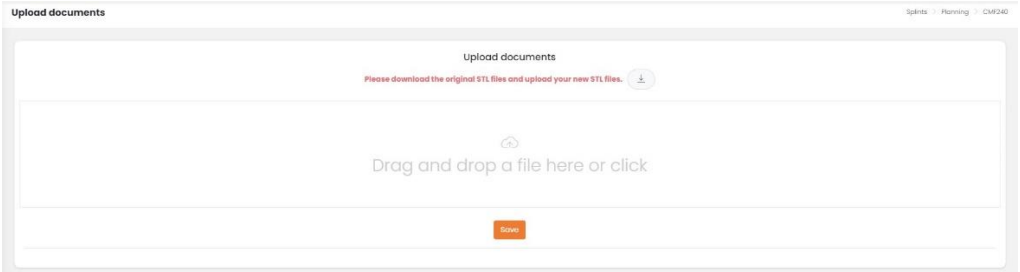
- The third is the approval button . This allows the surgeon to approve the suggested planning. This approval **is binding on the practitioner**:



4.2.3 STL file provision type of planning – "Ready-to-use"

For the surgeon, the first step for this type of planning is to **download the STL files** provided by the technical team. To do so, they must click on the "**Download data**" button available in the "**Planning**" column of the "CMF" module's case tracking. Once the STL files are in their possession, the surgeon can carry out any movements that they wish to using their own planning software. Once the results are satisfactory for the practitioner, they must upload them to the platform to make them available to the technical team by clicking on the "**Upload the file**" button available in the "**Planning**" column of the "CMF" module's case tracking. A new page is displayed on the screen:





The user still has the original files available for download via the button or from the case tracking.

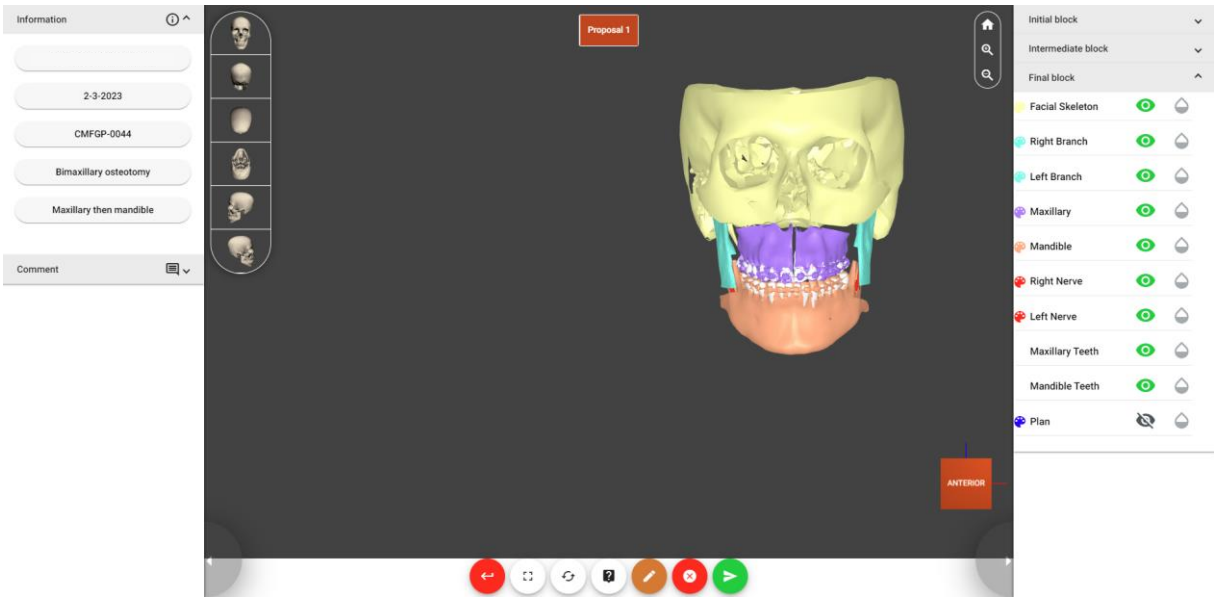
PLANNING VALIDATION

In the drop zone present on the screen, the user must select the compressed folder containing the new STL files.

Once the compressed folder is available, the user has the option of dragging it into the drop zone or clicking on it and retrieving the folder from their local directory.

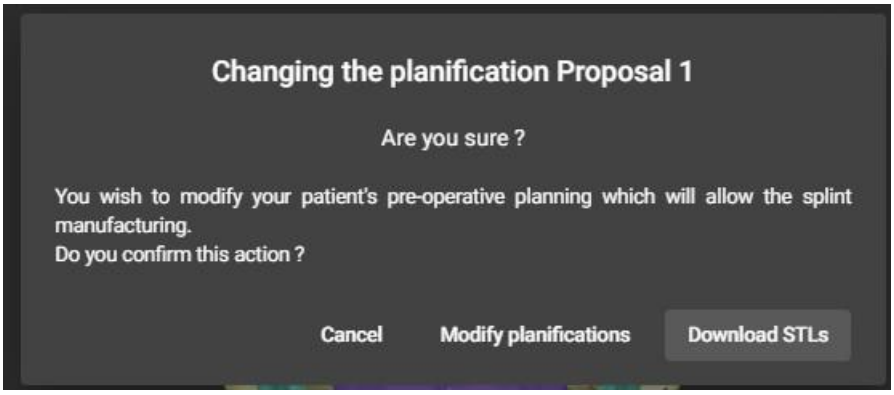
Clicking on the 

button allows the practitioner to approve the folder they have selected and thereby submit the new STL files to the technical team.
Once these files are approved and integrated into the platform, the surgeon will be advised by email that the planning is now available for visualization and approval:



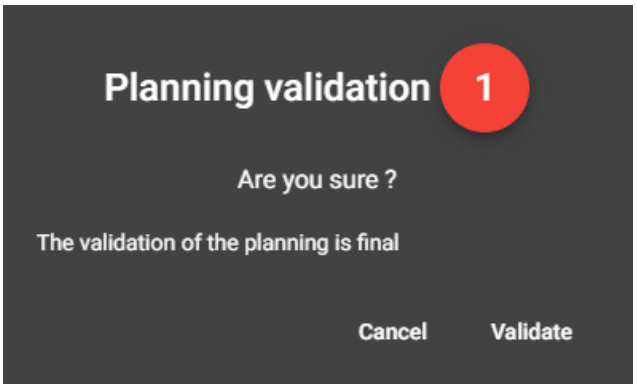
Two buttons are available for the “STL provision – STL files ‘Ready-to-use’”-type of planning:

- The first is the  button. This allows the surgeon to make changes to the suggested planning using the online planning tool. Once the button is clicked, a confirmation message is displayed:



(refer to the next section, 4.3 Planning modification)

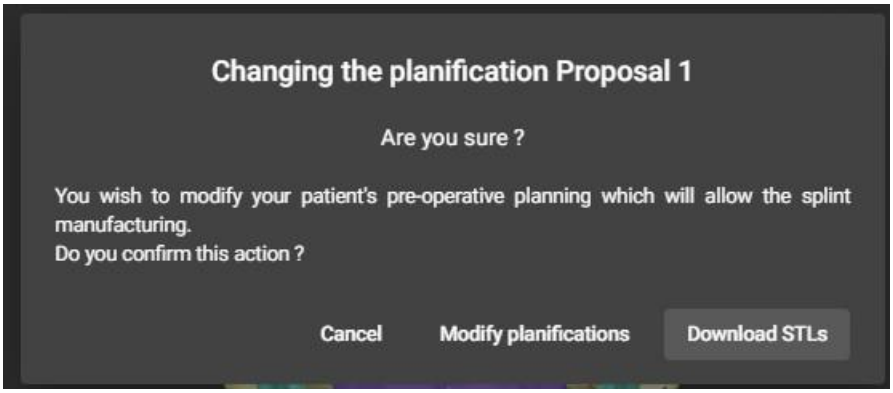
- The second one is the approve button . This allows the surgeon to approve the suggested planning. This approval **is binding on the practitioner**:



4.2.4 STL provision type of planning – 3D pre-planning

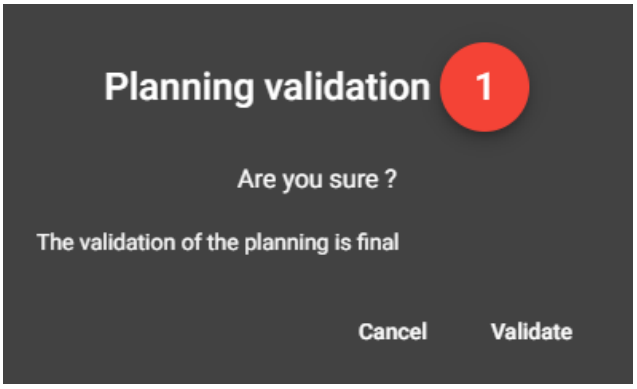
Two buttons are available for the "STL provision – pre-planning" type of planning :

- The first is the edit button . This allows the user to return to the case tracking.



(Refer to section 4.3 Planning modification)

- The second one is the approve button . This allows the surgeon to approve the suggested planning. This approval **is binding on the practitioner**:



4.3 Planning modification

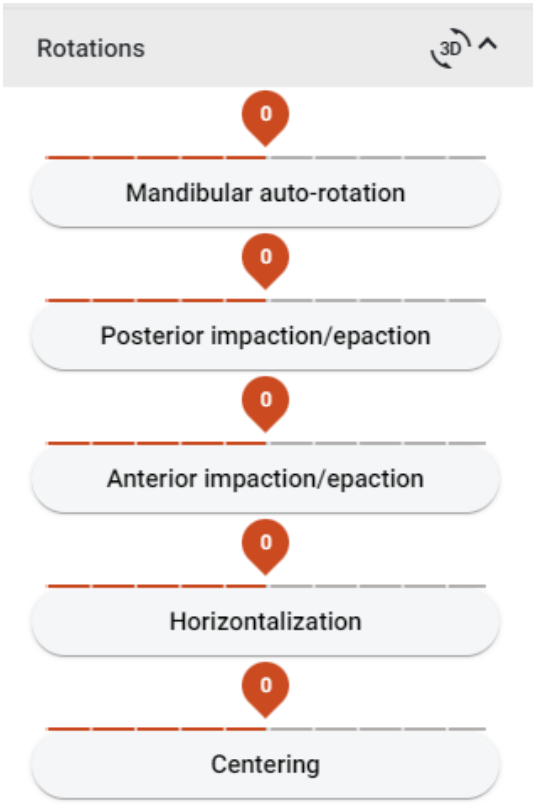
Modification is only available for procedures using the **Turnkey planning** or **STL provision** models.

To access the modification, click on the  button located in the lower menu: a dialog box will open up.

4.3.1 Turnkey planning

The dialog box is as follows:

The surgeon can click on  in order to modify the selected suggestion, by displaying the "**Rotations**" menu on the left, which groups together all of the rotational movement tools.

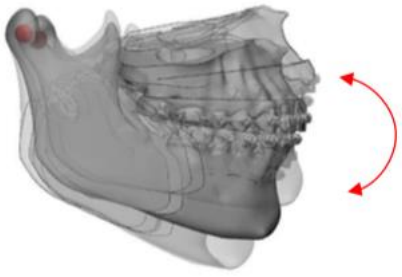


The surgeon can modify the rotation parameters by moving the red slider, selecting it by clicking and holding; the displayed value will then change in the red bubble.

For the “Monomaxillary surgery: LeFort I” procedure type, the only movement that can be modified is the **mandibular autorotation**, which corresponds to the rotation around the axis passing through the two mandibular condyles (left-hand and right-hand condyle of the mandible)

The rotation (**mandibular autorotation**) is defined as follows:

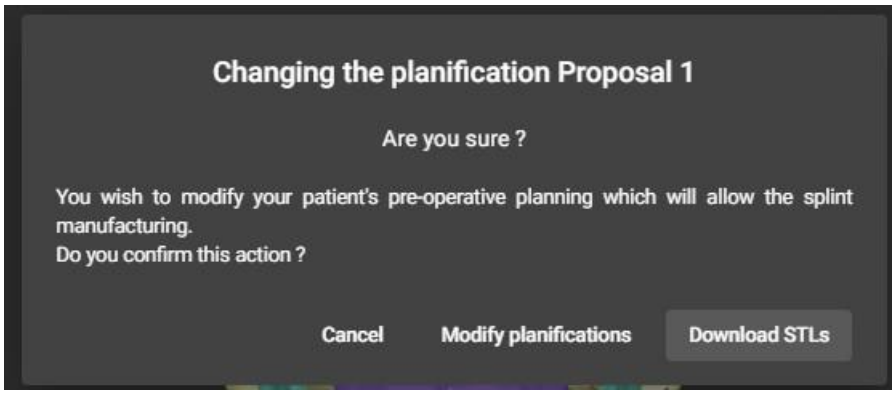
- Two fixed points: left-hand and right-hand condyle of the mandible
- One rotational axis corresponding to the axis passing through the two mandibular condyles
- Value range: +/-5 mm in increments of 0.5 mm (measurement of the movement of the interincisal point projected on the Z axis)



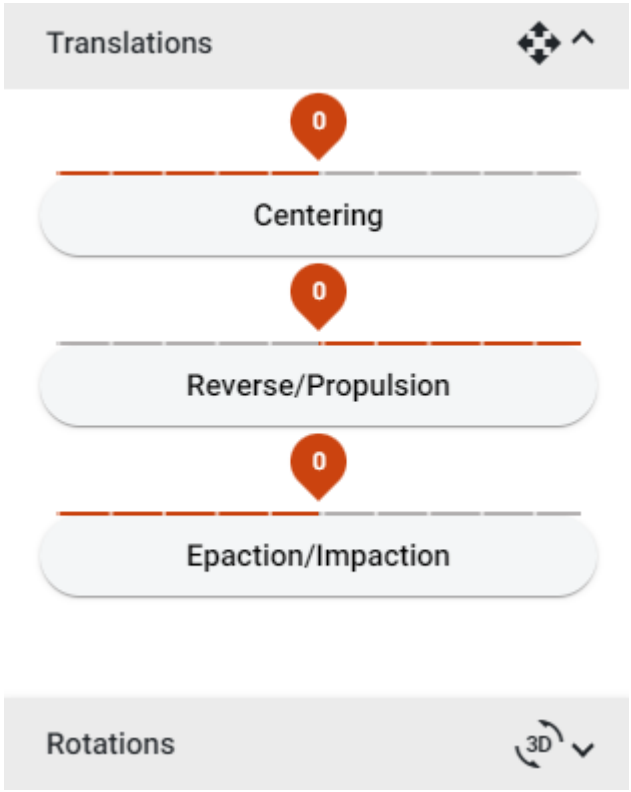
4.3.2 STL provision model planning

The dialog box is as follows:

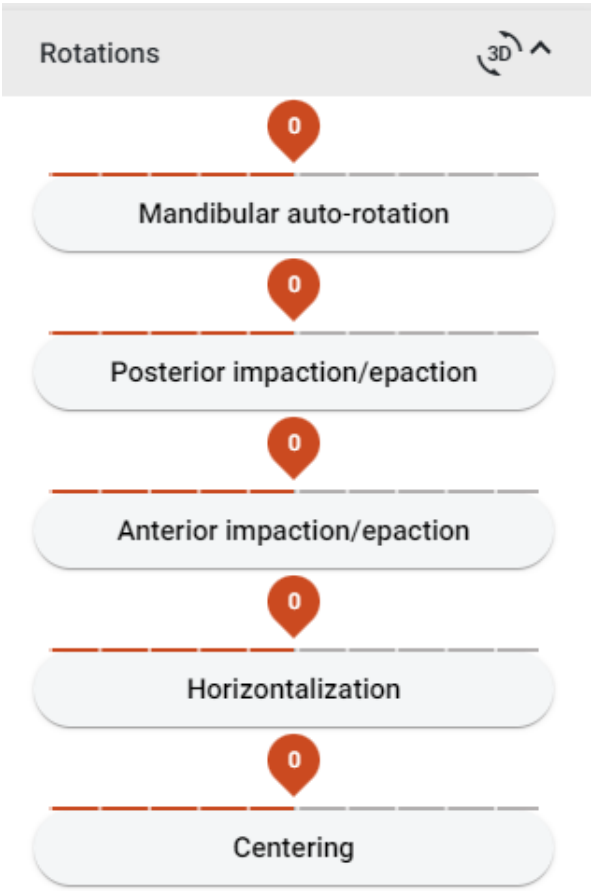
PLANNING VALIDATION



The surgeon can click on Modify planifications to display the "Translations" and "Rotations" menus on the left.



PLANNING VALIDATION

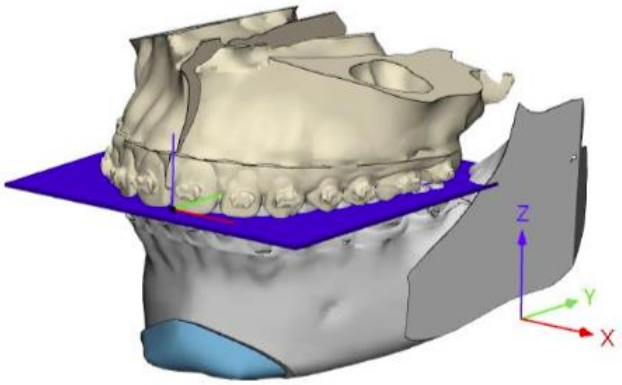


The surgeon can modify the translational and rotational parameters by changing values.
For this procedure model, three translational movements and five rotational movements can be modified.

Translational movements:

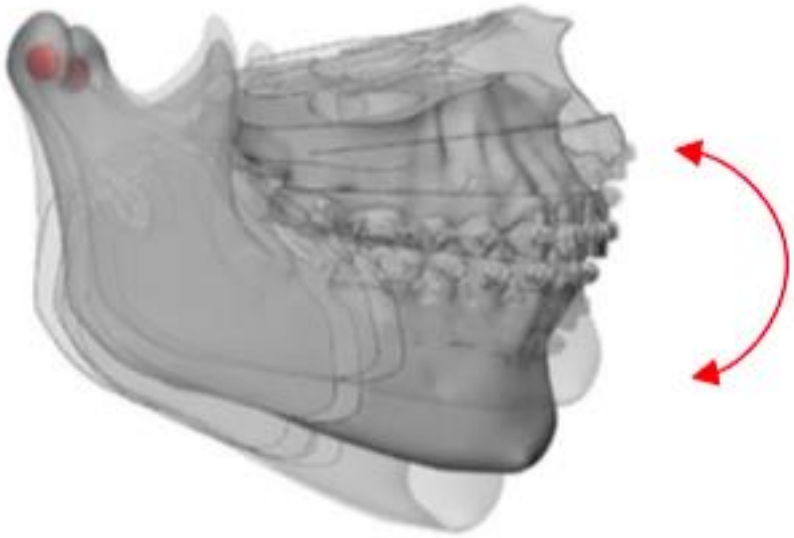
- **Centering movement**, corresponding to the translation of the occlusal block on the X axis of the coordinates system
- **Propulsion/backward movement**, corresponding to the translation of the occlusal block on the Y axis of the coordinates system
- **Impaction/epaction movement**, corresponding to the translation of the occlusal block on the Z axis of the coordinates system

PLANNING VALIDATION



Rotational movements:

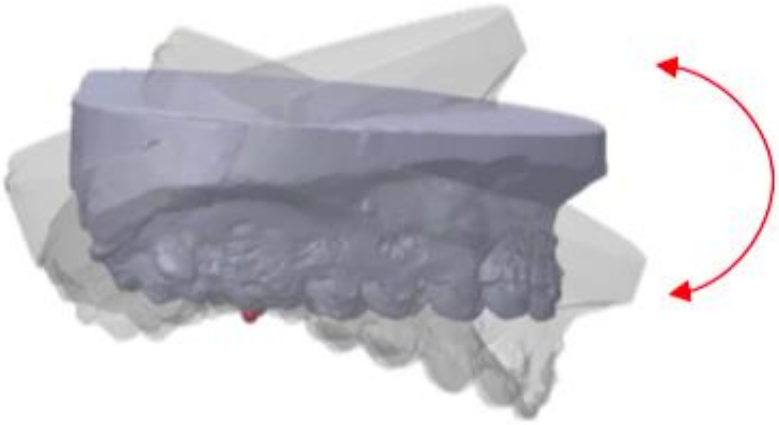
- **Mandibular autorotation movement**, corresponding to the rotation around the axis passing through the two mandibular condyles (left-hand and right-hand condyle of the mandible)



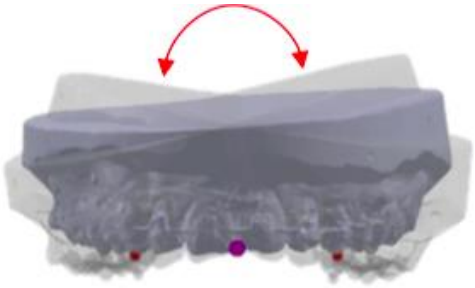
- **Posterior impaction/epaction movement**, corresponding to the rotation around the X axis of the coordinates system with the interincisal point as a fixed point, and points 16 and 26 as moving points.

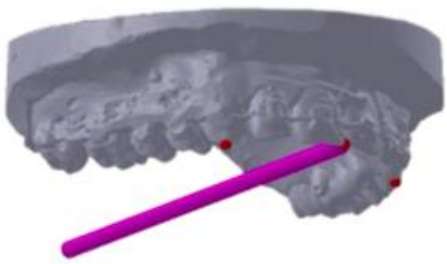
PLANNING VALIDATION

- **Anterior impaction/epaction movement**, corresponding to the rotation around the X axis of the coordinates system with two fixed points 16 and 26, and the interincisal point as a moving point.

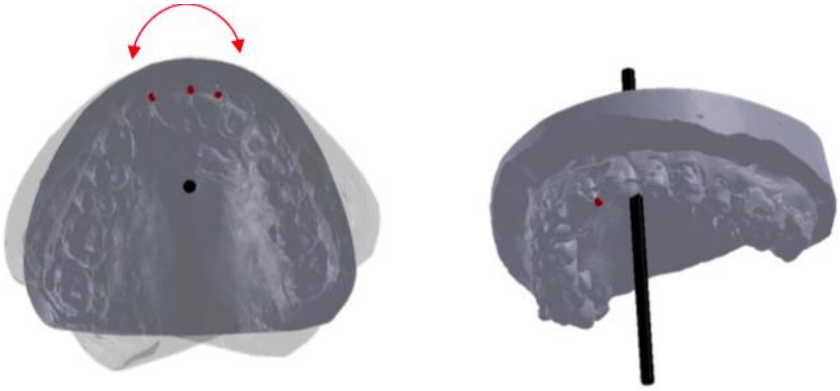


- **Horizontalization movement**, corresponding to the rotation around the central axis of the maxilla passing through the interincisal point, two moving points 13 and 23



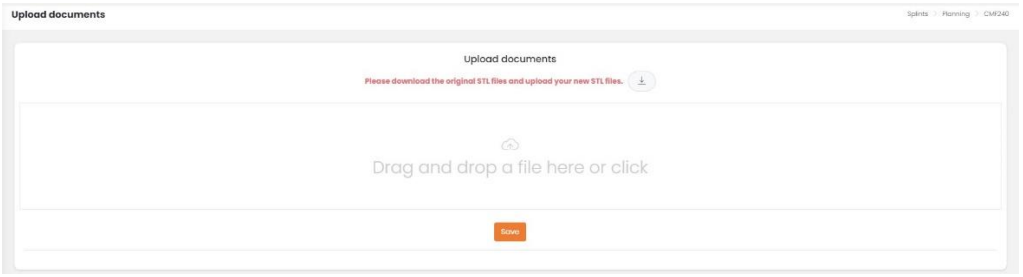


- **Centering movement**, corresponding to the rotation around the axis passing through the center of the maxilla, and normal to the initial occlusion planning, and the interincisal point as a moving point.



The surgeon can click on 

to upload these STL files and will be redirected to the following screen:

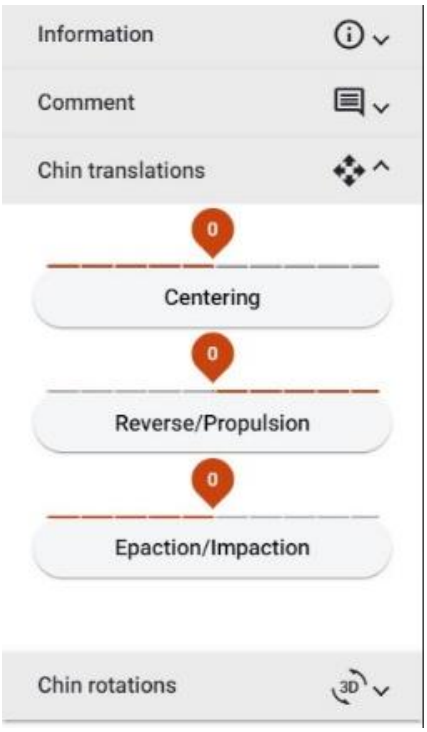


4.3.3 Genioplasty (simulation)

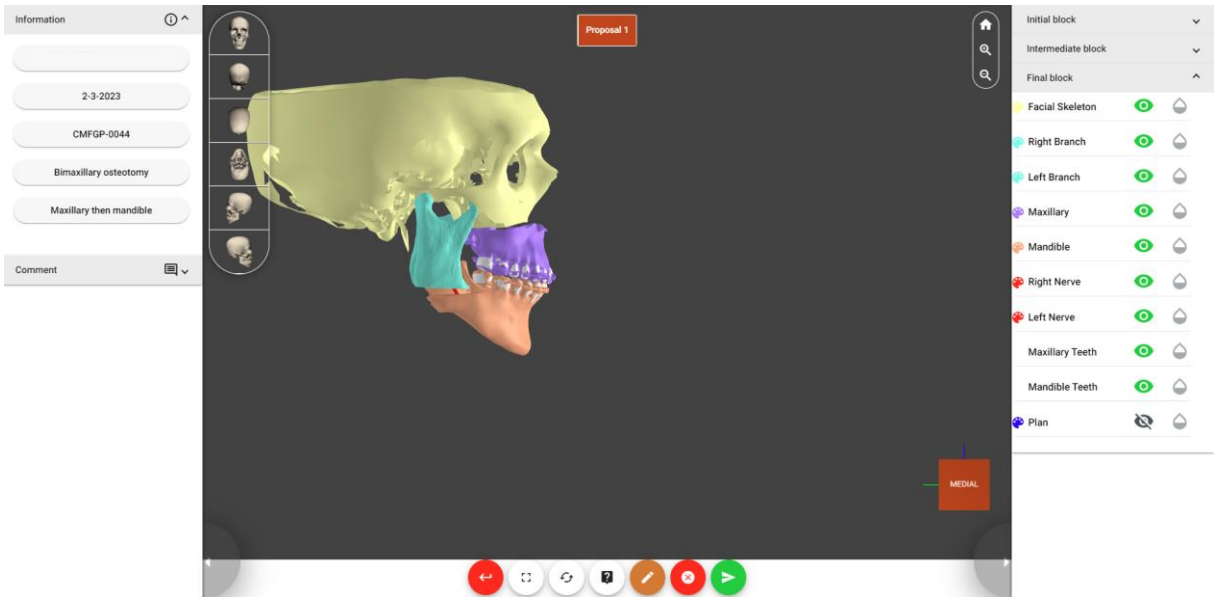
To access the genioplasty, the 

box located above the 3D view must be unchecked. Two additional menus appear in the left-hand menus:

PLANNING VALIDATION



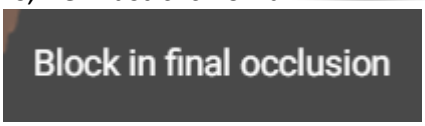
These two menus give access to functionalities for moving the chin in the XYZ axes of the view's orthonormal coordinate system.



5- Bone models extraction in .STL (Administrator GD)

Once the surgeon has validated the final occlusal position, the Global D administrator can access the planning to export the associated 3D models.

To do this, he must click on a 

, located at the bottom of the 3D scene, and then click on 

.

The mandible and maxilla in the final position are uploaded in STL format by the administrator GD.

INDEX OF SYMBOLS

6- Index of symbols

	Zoom in on the visualization
	Zoom out on the visualization
	Back to the procedure monitoring
	Genioplasty simulation
	To modify the movements or the planning
	Approve the planning
	Full-screen display
	Reset the planning
	Export the STL files
	Display the user manual or the case summary sheet
	Hide the object

INDEX OF SYMBOLS

	Display the object
	Apply transparency
	Go to suggestion 1
	Go to suggestion 2
	Go to suggestion 3

CONTACT US

7- Maintenance

An annual update is carried out to perform security maintenance. This is automatic and completely transparent for the user.

8- Cybersecurity

Our approach to cybersecurity control is based on risk management across each step of the software's life cycle, so that cybersecurity concepts are integrated from the design stage. Safety measures are applied to authenticate the user with the web application, which is managed using a login and password, this only gives a user access to their own cases and therefore restricts patient data access to authorized individuals only. As such, please be careful not to share your password and to log out when you have finished using the application.
All risks related to cybersecurity are integrated and controlled in the medical device's risk management file.

9- Incident / bug

Despite our rigorous development of this software, any serious incident that occurs connected with the device must be reported to the manufacturer and to the Competent Authority of the Member State within which the user and/or the patient is located.

A list of known bugs is available at the following link: https://github.com/oneorthomedical/planner-ortrautek-issues/issues

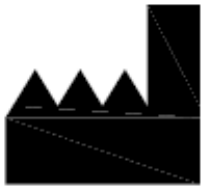
If a bug is not present in this list is detected, please send the information for ONE ORTHO's attention.

10- Contact

Contact:
For any questions about using the software, please contact the manufacturer: ONE ORTHO at the following email address: contact@oneortho-medical.com
or by telephone on 04 26 78 76 74.
The ONE ORTHO team is available to answer your questions from Monday to Friday from 9 a.m. to 6 p.m.

CONTACT US

11- Manufacturer



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contact@oneortho-medical.com

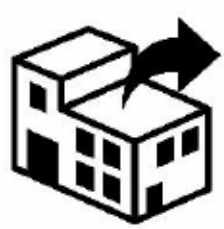
CE 0476

Class IIa medical device, manufactured by the company ONE ORTHO, complies with the requirements of the EU Regulation 2017 / 745.

Date first CE marking obtained: May 21st, 2021.

12- Distribution

This software is distributed by the company GLOBAL D:



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