Instruction For Use - Relu® Cloud 3.2, rev 10 (US)

AI-powered automation for dental CAD workflows

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1 Introduction

Dear valued user,

Thank you for choosing **Relu® Cloud** — our AI-powered software platform built to help dental professionals deliver faster, more scalable, and more consistent care. Your decision to use our technology marks an important step in the digital transformation of dentistry, where automation and precision work hand in hand.

At **Relu**, we are committed to reshaping dental workflows through intelligent software. Relu Cloud enables dental labs and clinicians to streamline their design processes using artificial intelligence and rule-based logic. The platform automatically processes intraoral scans, CBCT data, and facial scans to generate **pre-fabrication design aid** such as custom trays, mouthguards, and implant surgical guides.

Each design workflow is structured as a **modular service**, representing a specific task (e.g., segmentation, implant planning & surgical guide, custom trays). These services come with preset configurations that users can adapt to meet specific clinical or lab protocols, allowing for rapid, repeatable, and high-quality results.

Relu® **Cloud** is a **cloud-based solution**, meaning no software installation or special hardware is needed. The interface is accessible via a secure web portal, with role-based user permissions, audit trails, and state of the art cybersecurity remediations. Credits are only consumed upon case submission, and our refund policy ensures that you only pay for clinically valuable outcomes.

To further support performance and collaboration, the platform includes built-in quality control tools: an interactive 3D viewer, sculpting interface, model inspection features, and secure file-sharing capabilities.

Whether you're scaling your lab's output or adopting in-house 3D workflows in a clinic, Relu®**Cloud** adapts to your needs. We're proud to support your journey toward intelligent dental design — and we're here to be a trusted partner every step of the way.

Thank you for choosing Relu.

Sincerely,

The Relu Team

2 Device Description

MD	Relu® Cloud, version 3.2
	March 2026
	Relu BV, Kolonel Begaultlaan 1a/5, 3012 Leuven, Belgium
UDI	(01)05419980224521(8012)3.2.0
Customer Support	support@relu.ai
Website	www.relu.ai
	https://relu.ai/relu-cloud/us/3.2/IFU
Rx Only	This device is intended for use by qualified healthcare professionals.

The Relu® Cloud software bill of materials can be made available on request. Please contact customer support for more information.

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The Relu® Cloud is a software application that allows trained health care professionals to use medical images for:

1. Visualization
2. Collaboration
3. Measurements & annotations
4. Image Processing (segmentation, registration, fusion, modelling)
5. Treatment planning
6. Export (images, measurements, annotations, models, 3D files)

The web application can be further used for measurements, diagnosis, monitoring, treatment planning, design, modeling, and reporting

2.1 Intended Use

Relu® Cloud is a software system intended to assist dental professionals in:

(1) generating digital three-dimensional models of a patient's teeth and jaws from dental or medical imaging data;

(2) supporting user-driven planning activities related to dental implant procedures;

(3) supporting digital workflows for the design of patient-specific endosseous dental implant surgical guides; and

(4) supporting digital modeling and editing workflows for the design of protective occlusal mouthguards, without therapeutic, diagnostic, or mandibular repositioning claims.

The software enables the export of digital designs in industry-standard file formats (e.g., STL) for fabrication according to user-defined workflows.

Relu® Cloud is intended for use by qualified dental professionals in clinical or laboratory environments.

Relu® Cloud does not perform patient-specific fabrication of physical devices and does not generate automated diagnostic or therapeutic decisions.

2.2 Indications for use

Relu® Cloud is a software program for the management, transfer, and analysis of oral and maxillofacial image information, and can be used to provide design input for dental solutions. It displays and enhances digital images from various sources to support the diagnostic process and treatment planning. It stores and provides these images within the system or across computer systems at different locations.

2.3 Contraindications

If the digital model of the patient or treatment planning on the model does not correspond to clinical findings and physical examination, it shall not be used for further purposes.

Use is contraindicated where input data quality prevents accurate anatomical representation, where significant patient motion artifacts are present, or where anatomical correspondence between modalities cannot be verified.

IOS–CBCT registration requires dentate regions to be present. Fully edentulous cases are not supported.

2.4 Target Population

The patient population is including, but not limited to the following:

Parameter	**Scope**
Age	Age 21 and older. For Implant treatments, patients with fully developed permanent teeth.
Gender	All
Ethnicity	All
Treatment needs	Dentistry and Implantology

2.5 Intended user

The Relu® Cloud can be used by the following user groups after required training. The web app must be used in conjunction with expert clinical judgment.

1. Technical profiles: dental technicians, clinical engineers, design engineers.
2. Clinical profiles: dentists, dental assistants, dental specialists, orthodontists and implantology.

Users fabricating patient-specific devices based on Relu® Cloud generated and exported 3D designs are responsible to ensure they operate under applicable regulatory clearance.

> **Caution**
>
> US Federal law restricts this device to sale by or on the order of a Dental technician or Dental clinician.

2.6 Intended environment

The Relu® Cloud is a software and requires a recent computer. The application is intended to be used in dental practice, dental lab or equivalent.

2.7 Device lifetime

Relu® Cloud is classified as Software as a Medical Device (SaMD). Relu defines the expected lifetime of Relu® Cloud as the period during which it will be actively maintained to ensure continued performance, safety, and compliance. During this period, Relu commits to delivering timely security patches, performance updates, and regulatory compliance updates as needed, and at a minimum, every two years or sooner based on emerging risks or vulnerabilities.

3 Performance specification and constraints

For performance, the medical device allows to accurately visualize, model and measure objects and geometries up to the resolution of the raw input data. No higher accuracy than the input data can be achieved.

For measurements, the device is able to measure up to the voxel resolution for volume data (e.g., CBCT, CT) and up to the triangle resolution for mesh data (e.g., STL, PLY). The degree of accuracy of the measurement function is therefore the same as the degree of accuracy of the raw input data.

For safety, the results of the application are always subject to the decision of the clinician, therefore being inherently safe.

Algorithm performance has been verified and validated and is documented in the device's verification and validation records. Performance is dependent on input data quality and adherence to the validated acquisition parameter ranges described in Section 6.5.

3.1 CBCT Segmentation

- Input: CBCT Scan (3D Volume)
- Output: A mask indicating where each structure is present in the image (3D Volume).
- Limitations: The structure must be present in the provided image to generate a proposal. Performance depends on input data quality (see Section 6.5 for validated acquisition parameter ranges). The masks must be reviewed before use.

Information presented to the user:

Users are presented with the information in a highlighted format on a scan viewer. The segmentation area is highlighted for the user's review and adjustment. There are no applicable units in this process.

Level of User Interaction:

The required interaction for the user is at the final step, the user must review whether the anatomy is correctly indicated.

3.2 IOS Segmentation

- Input: Intra Oral Scan (3D Mesh)
- Output: A Mask on the faces of the mesh indicating which tooth is present where on the Mesh. The mask on the teeth is according to the FDI number, all non-teeth elements (gingiva, base) are classified as background.
- Limitations: Masks must be reviewed before use. Performance depends on input data quality.

Information presented to the user:

Users are presented with the information in a highlighted format on a scan viewer. The segmentation area is highlighted for the user's review and adjustment. There are no applicable units in this process.

Level of user interaction:

The required interaction for the user is at the final step, the user must review whether the anatomy is correctly indicated.

3.3 Registration

- Input: Intra Oral Scan (3D Mesh) & CBCT (3D Volume) or Facial Scan (3D Mesh) & CBCT (3D Volume)
- Output: A transformation matrix that transforms the mesh to the coordinate system of the CBCT
- Limitations:
  - For Intra Oral Scan and CBCT: The algorithm relies on teeth being present in the CBCT and IOS to perform the registration; edentulous cases are not supported. The algorithm is designed for registering data from the same patient at similar times, and does not accommodate changes such as newly added bridges, crowns, or recently extracted/moved teeth. Performance depends on input data quality (see Section 6.5).
  - For Facial Scan and CBCT: The algorithm relies on the face being visible in the CBCT; this implies that only large FOVs are supported by the algorithm. Performance depends on input data quality.

Information presented to the user:

Users are presented with the information in a highlighted format on a scan viewer. They can review the overlay of the mesh on the CBCT.

Level of user interaction:

The required interaction for the user is at the final step, the user must review whether the anatomy is correctly indicated.

3.4 Implant planning

- Input: CBCT (3D Volume) & Intra Oral Scan (3D Mesh, optional), treatment parameters (implant libraries to use, teeth to extract, guide options, etc.)
- Output:
  1. Information about all placed implants: position, size, as well as implant object library ID
  2. Information about all placed wax-ups: position, size, as well as implant object library ID
  3. Information about all placed sleeves: position, size, as well as implant object library ID
  4. Guide meshes (one per IOS)
  5. Base models (one per IOS): original IOS with base
  6. Emergent profile models (one per jaw): original IOS with any crown that belongs to "teethToExtract" virtually extracted

Limitations & scope:

Performance depends on input data quality (see Section 6.5).

The scope for the automatic implant & crown planning algorithm is:

1. Single units and maximum 4 singles side by side
2. Bridges maximum of 4 elements: 1 or 2 pontics and 2 pilar implants
3. Second molars will be proposed if opposing is present or proposed

4. Sinus lifting and bone grafting cases for the above implants (implants will be shown in the final proposed position):
    1. Sinus Lift (Smaller Augmentation) of maximum 4 mm
    2. Bone grafting needed:
        1. Lateral Grafting (Horizontal Deficiency): maximum of 6 mm total width (to fit a minimum 3 mm diameter)
        2. Vertical Grafting (Apical Deficiency): maximum 4 mm total height (to fit a minimum 8 mm length).

The quality of the implant & crown proposal for cases outside of this scope is not guaranteed.

The scope for the automatic guide design algorithm is:

1. We currently only support tooth-supported guides. One side of the implant can be edentulous, in this case the guide will rest on the gingiva.
2. Scan quality: the IOS scan shall be of good quality, with no holes or missing data, artefacts or other issues.
3. The scan must represent the situation of the patient at the time of the surgery. If any changes occurred or will occur to the dentition of the patient before the surgery (teeth movement, loss, or other), a newer scan shall be taken and used.
4. The adjacent teeth of the implant site shall not be mobile
5. Minimum arch coverage:
    1. For single implant cases, the IOS shall capture at least 2 adjacent teeth on either side of the implant side (or equivalent amount of gingiva). 3 adjacent teeth is recommended for better stability.
    2. For multiple implants, it is recommended to include a full arch scan for better stability.

The quality of the guide proposal for cases outside of this scope is not guaranteed.

A model of the IOS is provided together with the guide when exporting it. The user shall use this model to verify the correctness of the model (fit with the teeth, etc.)

Information presented to the user:

Users are presented with the planned implants & waxups in the viewer, on top of the 2D CBCT views, and in a 3D view with all segmented structures.

Level of user interaction:

The required interaction for the user is at the final step, the user must review whether the implant planning is correct, and adapt where necessary.

4 Installation and maintenance updates

The device does not require installation, as it operates entirely through a web-based interface. Updates are deployed automatically to ensure the user always accesses the latest validated version of the software. The updated version will be made available directly through the user's web browser upon accessing the medical device.

Information regarding version updates, including release notes and relevant instructions, will be communicated to the user via **Intercom** on the Relu Cloud platform.

5 Warnings and precautions

Input data formats

The device is meant to be used with CBCT scans and/or Intra Oral and/or Facial Scans. Scanning protocols are left to the discretion of the user; however, we recommend that industry standards are referenced and followed and are selected to be appropriate for the intended use.

Input data quality

Relu® Cloud must be used with high quality input data. Poor quality input data (motion artifacts, metal artifacts, truncated field of view, low resolution) can result in inaccurate results generated by Relu® Cloud. See Section 6.5 for validated acquisition parameter ranges.

Image orientation

The 3D and 2D visualization must always be verified by a trained user on left–right orientation before any further use, to see that the images are not mirrored.

Review proposals before use

Automatic results and design proposals provided by Relu®, including segmentations, alignments, implant planning, implant libraries (including implant-sleeve offset, drill lengths, related parameters), surgical guides, mouthguards, crowns and other AI-based dental designs, must always be independently verified by the trained user prior to export, production, or clinical use. Where available, third party surgical protocols, catalogs, and user manuals must be consulted. The automatic proposals are generated using parameters set by the user. The scope of options & editing given enable the user to shape the design freely; thus, responsibility for the final result lies with the user.

Adhere to IT system requirements

Relu® Cloud must be used on computer equipment that adheres to the specified system requirements. Inferior computer hardware can result in slow response and failure.

Cybersecurity precautions

Relu® Cloud must be accessed with individual user accounts. Shared logins are prohibited. Users are expected to take adequate measures to mitigate cybersecurity risks on local hardware and data, including installation of security updates, two-factor authentication, and appropriate user access management.

For trained professionals only

Relu® Cloud shall only be used by trained dental professionals. We recommend that all users participate in digital training offered by Relu and read the user manual section thoroughly. The AI proposals must always be verified by the trained user before any further use.

Exports verification

Any exports made with the applications must be verified for accuracy with the images visualized in the web application or another trusted software before any further use. The user is responsible for ensuring that the designs (e.g. mouthguard, implant surgical guide) are correct and adapted for the patient & his treatment. The user is also responsible for choosing the parameters of the design (thickness, design offset, etc.) that are adapted for his fabrication workflow. The user is responsible for ensuring that the produced devices are robust, safe, and clinically fit.

Object recomputation

Any modification to implant planning invalidates an existing surgical guide. The guide must be recomputed and re-verified before export or clinical use. Any modification to the mouthguard outline invalidates an existing mouthguard. The mouthguard must be recomputed and re-verified before export or clinical use.

Caution when images are edited simultaneously

Relu® Cloud supports multiple users editing imported images. However, the software does not support simultaneous modifications of the same case. Users must review their results carefully before exporting to ensure they are not overwritten by others.

Generic implant libraries

Users are responsible for ensuring that any generic implant, i.e. a generic cylinder for which the dimensions can be fully defined by the user, used within the software is clinically appropriate. Relu is not responsible for the accuracy, suitability, or safety of any user-defined or generic implant.

Implant library compatibility

The software allows flexible treatment planning, including the use of different implant libraries for implants, surgical kits, sleeves, and abutments. The software displays recommended OEM combinations, along with the corresponding sleeve offsets, drill lengths, and other parameters. If you select non-recommended combinations, the software will not make assumptions about compatibility, sleeve offsets, or drill lengths.
You are solely responsible for verifying: the validity of any non-recommended kit–sleeve combination, the correct drill lengths, sleeves, spoons, and offsets, and the consistency of all planning parameters with the manufacturer's official library and surgical protocols.
You must always review and confirm the software's proposals, including sleeve-implant combinations, sleeve offsets, drill lengths, and drill offsets, against the manufacturer's official data before clinical use.

In-app warnings

The software automatically performs safety and consistency checks and displays in-app warnings for detected issues. Always review and understand all warnings before using the results in a clinical context. Proceed with caution and verify all relevant parameters as appropriate.

⚠ Fabricating patient-specific devices

In the US, the physical surgical guide for endosseous dental implant placement is a medical device. Please contact a third-party medical device manufacturer registered and listed in compliance with FDA regulatory requirements to manufacture the physical surgical guide for endosseous dental implant placement or to purchase a validated milling/printing system to create the physical implant surgical guide at an on-site location. For more information, please contact your local regulatory agency for information regarding the regulatory status and requirements related to the manufacture of implant surgical guides and other patient specific devices designed by Relu® Cloud.
More specific, FDA considers these devices being medical devices classified under 21 CFR 872.3980, which have regulatory requirements for Device Establishment Registration and Listing (see 21 CFR Part 807) and following Quality Systems regulations (see 21 CFR Part 820).

6 Technical requirements & operating conditions

Recommended Requirements for Relu® Cloud:

6.1 Internet

Type	Requirements
Internet Speed	>50 Mbit/s upload / download (Relu® Solutions requires a stable internet connection. Interruptions during upload may result in errors.)

6.2 Hardware

Type	Requirements
Device	Desktop, laptop
CPU	8 Cores: Intel i7, Ryzen 7, Apple M chips
GPU	8 GB VRAM
RAM	16 GB
Memory type	SSD
Free Disk Space	10 GB
Display	1920 x 1080 pixels (Full HD)

6.3 Software

Type	Requirements
Operating System	Windows 11, MacOS 15, Ubuntu 24.04 (or later)
Browser	Chrome v138 (or later)

6.4 Data

Type	Requirements
CBCT	Size: < 1 GB. Format: .dcm (DICOM), .nii, .vti, .nrrd
Digital Impression	Size: < 200 MB. Format: .stl, .ply, .obj, .drc, .dcm (3Shape format). No fully edentulous cases
Facial Scanner	Size: < 200 MB. Format: .stl, .ply, .obj. Facial scan should include nose and mouth

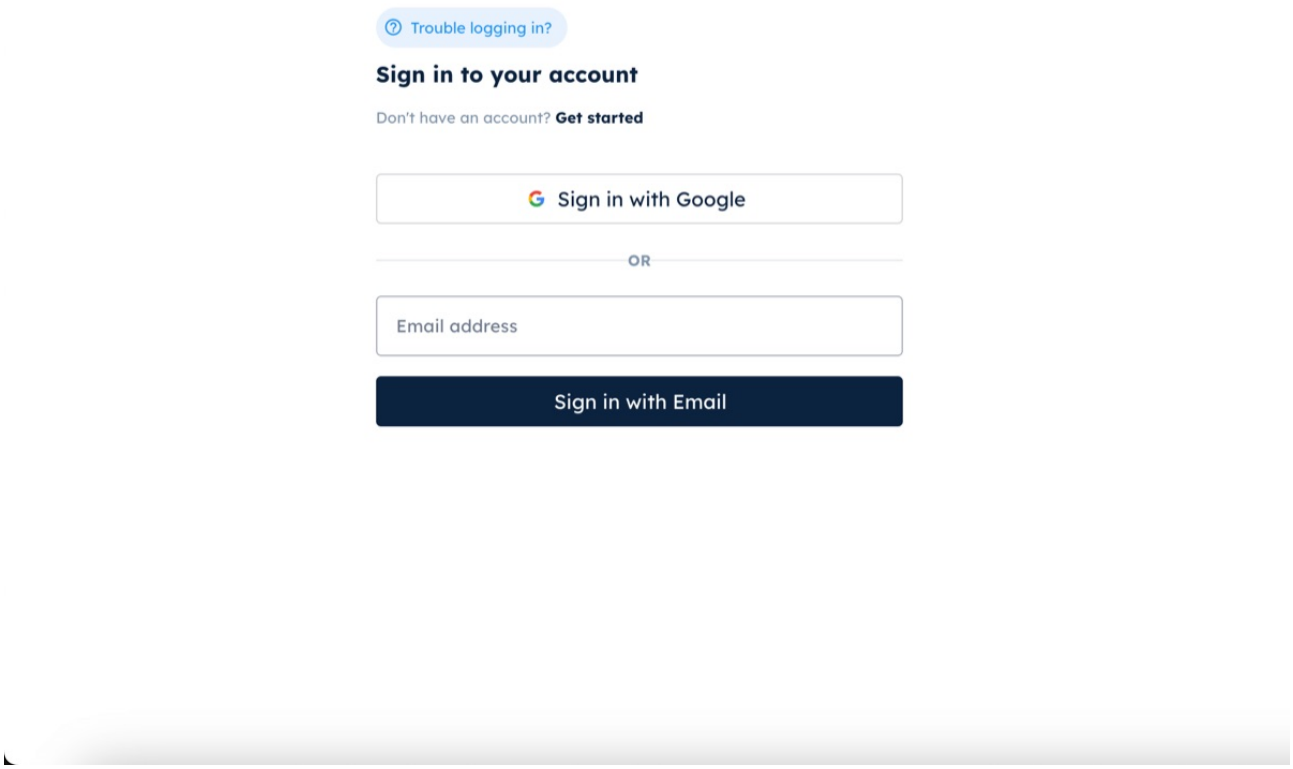
6.5 CBCT Acquisition Parameter Ranges used in verification and validation

Parameter	Validated Range
Field of View (FOV)	>= 4 x 8 x 8
Voxel Size	0.1 – 0.5mm
Scanner Manufacturers Represented	Multiple vendors including but not limited to Planmeca, Morita, NewTom, Ray, Carestream, LargeV
Tube Voltage (kVp)	70 - 150
Tube Current (mA)	1-175

The CBCT datasets used during verification and validation included the acquisition parameter ranges listed above. Use of scans acquired with substantially different acquisition settings may affect the quality of automated proposals and may require additional user review and refinement.

7 Relu Account

7.1 Creating an Account / Sign up



This is where your journey with Relu begins. To use any of our AI-powered design services, you need to create an account:

- Visit cloud.relu.ai
- Click **Sign up**

> **Note**
>
> The sign-up and login pages look nearly identical. Always double-check the button labels before proceeding.

Each user must register using their **personal email address** and verify their account upon sign-up. **Shared or team logins are not permitted**, as they violate cybersecurity standards and compromise traceability within the platform. A Team can use the Organizations functionality to collaborate.

We strongly recommend using:

- A **strong, unique password**
- A secure password manager to safely store and manage your login credentials.

7.2 Log In

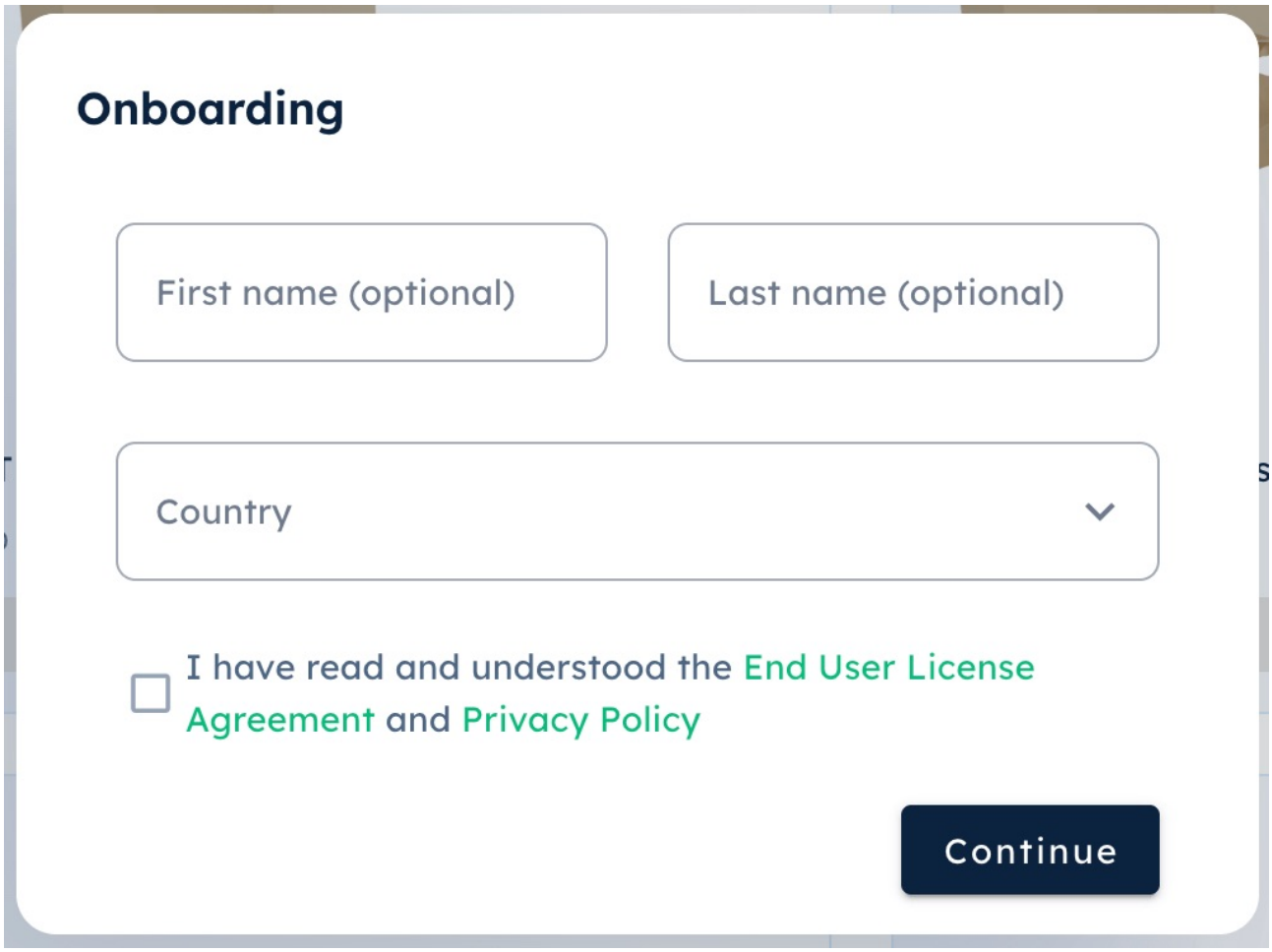
After registering:

- Enter your **email** and **password** to log in
- If your browser or password manager suggests autofilling credentials, ensure that the correct personal account is selected

> **Note**
>
> Do not use shared credentials. Every user should log in with their individual account to ensure secure and traceable access.

Upon first login, you will be prompted to accept the End-User License Agreement (EULA) and privacy policy, with links to each of them.

Additionally, you are required to specify your **country**. This is a regulatory requirement.



7.3 EULA Consent

Before accessing the Relu platform, all users are required to review and accept the **End-User License Agreement (EULA)**. This ensures clarity around usage rights, data handling, and responsibilities.

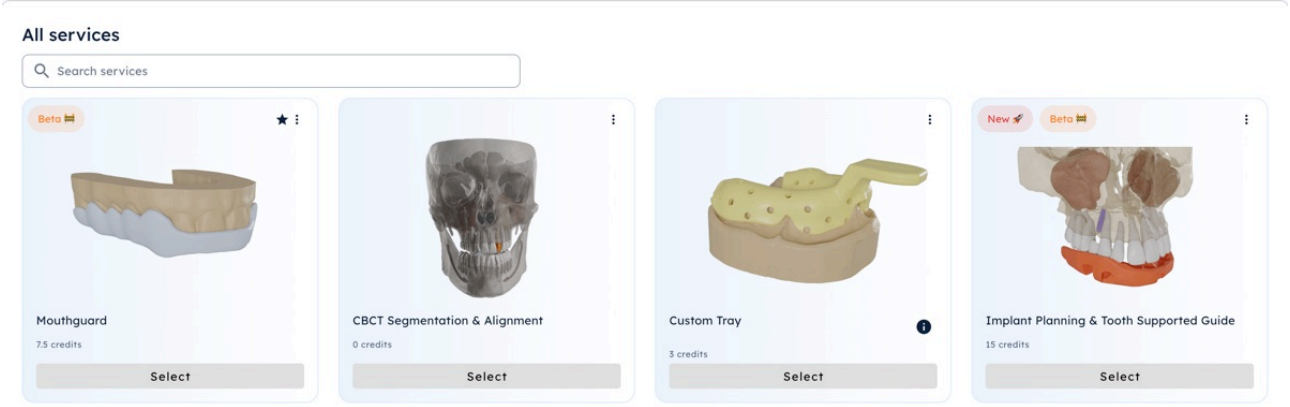
- The EULA prompt appears immediately after your first login
- You must **accept** the terms to proceed and use the platform
- The acceptance is logged and linked to your personal account

You can review the full EULA at any time here: https://relu.ai/end-user-terms-and-conditions

8 Working with services

8.1 Services dashboard & modules

Once logged in, you'll land on the **Services dashboard**. Here, you'll find an overview of all the automation services available on the Relu platform. Each service is a tool that performs a specific dental design task automatically, like segmenting scans, or generating custom trays.



- You can scroll through the list or use the **search bar** to find what you need.
- Each service card shows a preview image, name, credit cost, and availability:
  - **Select**: Double clicking the service card also opens up the recipe
  - **Beta Test**: Available only to certain selected users for testing
  - **Coming Soon**: Not yet active but listed for awareness

The credit cost is shown at the bottom of each card, helping you manage your usage according to your available credits.

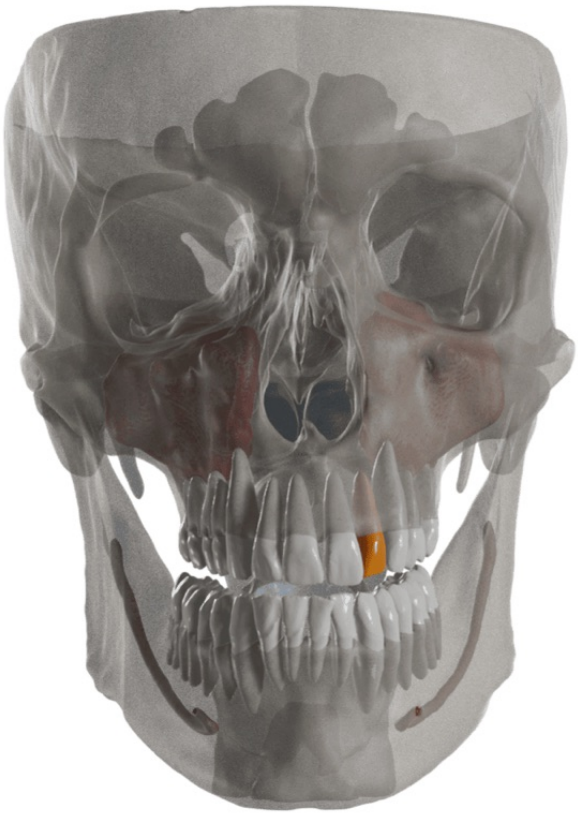
8.2 Understanding services

- Services are individual automation modules
- Each card represents a recipe.
- You can **search**, **filter**, and **favorite** recipes for easier access.
- You can favorite a service by clicking the star icon in the upper right corner of the recipe card. Favorited services will appear first in your recipe overview for quicker access.

8.3 Available services

The following services are available on the Relu platform. Each service is described below, including its inputs, outputs, and configurable parameters.

8.3.1 CBCT Segmentation & Alignment Service



> **Warning**
>
> Cases must remain within the validated clinical scope (see Section 3 - Performance specification and constraints). Cases exceeding this scope are not guaranteed.

8.3.1.1 Description

The **Segmentation & Alignment Service** is a medical service that automatically generates **anatomical segmentations** from patient scans and aligns data from **multiple modalities** (such as CBCT, intra-oral, and facial scans).

The generated results can then be **reviewed, adjusted, and exported** in the **Medical Editor** before being used for further planning or exported for downstream workflows.

8.3.1.2 Inputs

- **CBCT (3D Volume, DICOM)** – required for full segmentation functionality.
- **Intra-oral scans (3D Mesh, STL/PLY/OBJ)** – optional, can be aligned to CBCT.
- **Facial scan (3D Mesh)** – optional, only one facial scan can be provided per order. Supported format is **OBJ**, optionally with associated texture files (.MTL and .PNG). A **ZIP archive** containing these files is accepted.

8.3.1.3 Outputs

Depending on the uploaded input scans, the following outputs can be generated:

- Segmentation of dental and maxillofacial structures: maxilla, mandible, teeth (crowns and roots), mandibular canals, maxillary sinuses, and airway
- Gingiva segmentation from intra-oral scan
- Fused teeth combining crown data from intra-oral with root data from CBCT
- Closed intra-oral crowns
- Aligned intra-oral scans
- Aligned facial scan
- Panoramic arches for panoramic projection

8.3.1.4 Parameters

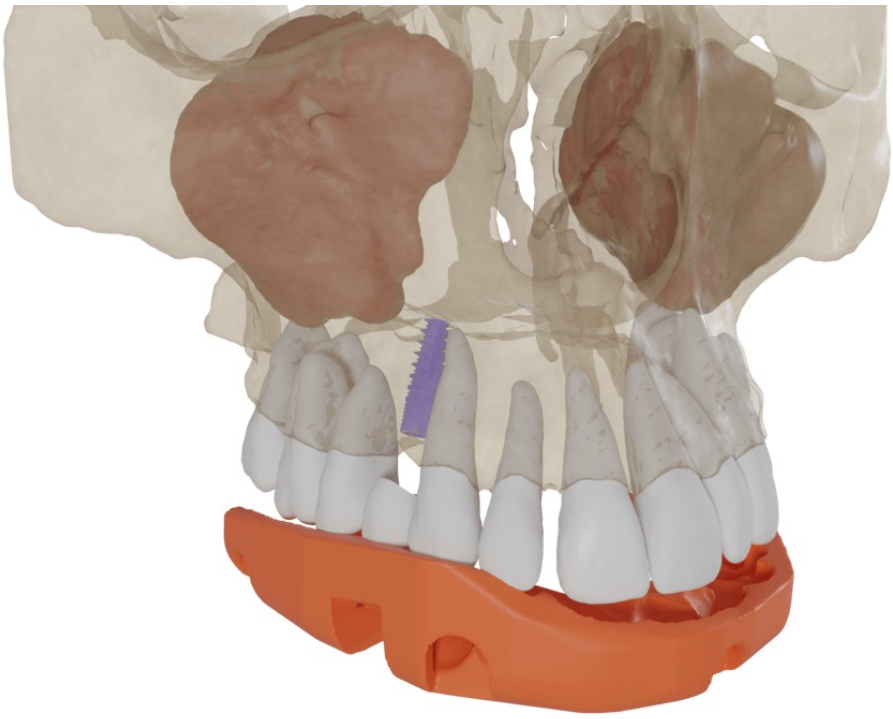
None

8.3.1.5 Review & Manual Editing

The outputs of the service are initial proposals; users shall review the results, and manually adapt them with the given tools to achieve the desired result.

You can find more information about the review & editing functionalities in Section .

8.3.2 Implant Planning & Tooth Supported Guide Service



> ⚠ Warning
>
> Cases must remain within the validated clinical scope (see Section 3 - Performance specification and constraints). Cases exceeding this scope are not guaranteed.

8.3.2.1 Description

The **Implant Planning & Tooth-Supported Guide Service** builds directly on the **Segmentation & Alignment Service**, which provides the anatomical segmentation of the CBCT and the alignment of the intra-oral scan (IOS).

This service automatically generates a **proposed implant treatment plan** for the patient based on the provided input parameters.

The proposal includes **implants**, **virtual wax-ups**, **temporary crowns, abutments** and **sleeves**, as well as a **tooth-supported surgical guide** generated from these components.

The complete treatment plan and surgical guide can be **reviewed, refined, and exported** using the **Medical Editor**.

> ⚠ Warning
>
> All automatic results are proposals only. They must always be reviewed and verified by a qualified professional before any clinical use.

8.3.2.2 Inputs

- **CBCT (3D Volume, DICOM)** – required.
- **Intra-oral scans (3D Mesh, STL/PLY/OBJ)** – optional, but required to generate a surgical guide model. Will be automatically aligned to the CBCT.
- **Facial scan (3D Mesh)** – optional, only one facial scan can be provided per order. Supported format is **OBJ**, optionally with associated texture files (.MTL and .PNG). A **ZIP archive** containing these files is accepted.

8.3.2.3 Outputs

The generated outputs include all the outputs from the CBCT Segmentation & Alignment service. Additionally, depending on the uploaded input data, the following results may be automatically generated:

- **Implant treatment proposal:** Includes automatic placement of **implants**, **sleeves**, **abutments**, **wax-ups**, and other implant-related objects.
- **Surgical guide and base models:** Automatic generation of a **tooth-supported surgical guide** and corresponding **base models**, enabling verification of the guide's fit on the dentition.
- **Emergence-profile models:** One model per jaw, representing the original intra-oral scan with the relevant teeth virtually extracted to define the emergence profile.
- **Temporary crowns:** Automatically generated based on the wax-ups, abutments, and defined margin lines.
- **Surgical report and patient passport:** Automatically generated documentation containing implant details, component information, and traceability data.

8.3.2.4 Parameters

As with other services, these parameters can be **saved as a preset** for easy reuse in future orders.

Please note that **treatment-specific parameters** are not saved in presets, as they are unique to each patient.

Treatment Details

You can define several **treatment parameters** that the AI will take into account when planning the implant treatment.

Automatic Implant & Crown Proposal

You can choose to let the AI **automatically propose implants and crowns in edentulous areas**.

When this option is enabled, the AI will detect edentulous sites and propose appropriate implants and crowns automatically—no need to manually define each position.

> **Note**
>
> Implant placement in areas where teeth must first be extracted always needs to be explicitly specified.

Visual Tooth Selector

Use the **visual tooth selector** to define where the AI should plan implants and/or crowns:

1. Select the **restoration type**: *Implant & Crown*, or *Pontic* (crown without implant)
2. Click the **tooth numbers** that correspond to the desired restoration sites.
3. To remove an implant or crown, click the **"X" icon** next to it or click the same tooth number again.

Implant System

Here you can define the **implant system**, **surgical kit**, and **sleeves** that will be used for planning and guide generation.

The AI will only select components from the specified libraries, though you can modify them later in the **Medical Editor**.

You must specify the following parameters:

- **Implant manufacturer**
- **Implant product line**
- **Surgical kit**
- **Sleeve product line**

If your preferred system is not available, you can select the **Generic** system.

Some libraries are marked as:

- **Non-mesh** – placeholder geometry is used (not manufacturer-validated).

> **Warning**
>
> Use *generic* and *non-mesh* libraries with care. It is your responsibility to verify that these components are compatible with your clinical instruments and workflow.

Advanced Parameters

You can configure advanced guide design parameters that influence how the **surgical guide prefabrication design aid** is generated, such as:

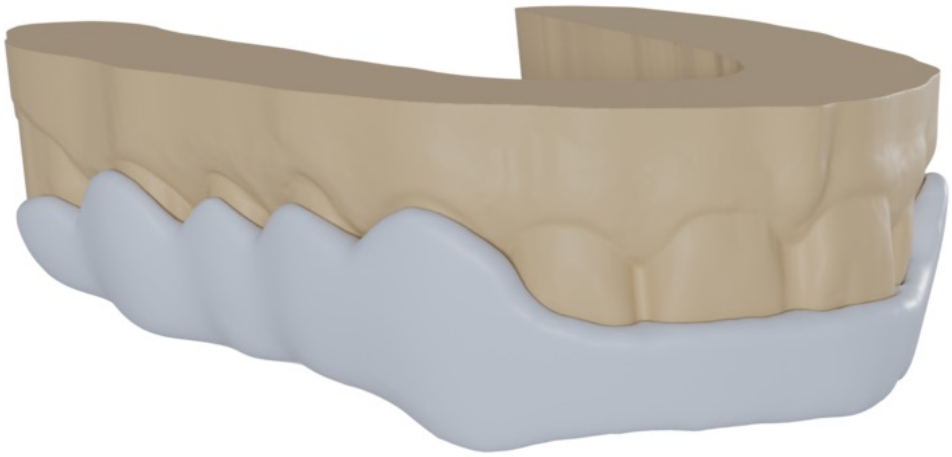
1. **Mesh thickness** (mm): defines the wall thickness of the mesh. Thicker meshes are more rigid.
2. **Design offset** (mm): compensates for dimensional tolerances in downstream fabrication. A small positive offset slightly enlarges internal dimensions to improve fit.

8.3.2.5 Review & Manual Editing

The outputs of the service are initial proposals; users shall review the results, and manually adapt them with the given tools to achieve the desired result.

You can find more information about the review & editing functionalities in Section .

8.3.3 Mouthguard Service



8.3.3.1 Description

The Mouthguard Design Service within Relu® Cloud supports the digital design of protective occlusal mouthguards based on dental surface models derived from intraoral scan (IOS) data. The service assists dental professionals and dental laboratories in preparing digital mouthguard designs for downstream fabrication.

The service is limited to protective occlusal coverage and is **not** intended for therapeutic treatment, orthodontic applications, mandibular repositioning, or clinical diagnosis.

8.3.3.2 Inputs

- **Intra-oral scans (3D Mesh, STL/PLY/OBJ)** – required to provide the scans of both the lower & upper jaws, representing dental arches with erupted teeth suitable for occlusal coverage.

8.3.3.3 Outputs

- **Mouthguard**
- **Mouthguard outline**
- **Waxed jaw**

8.3.3.4 Parameters

Parameters include:

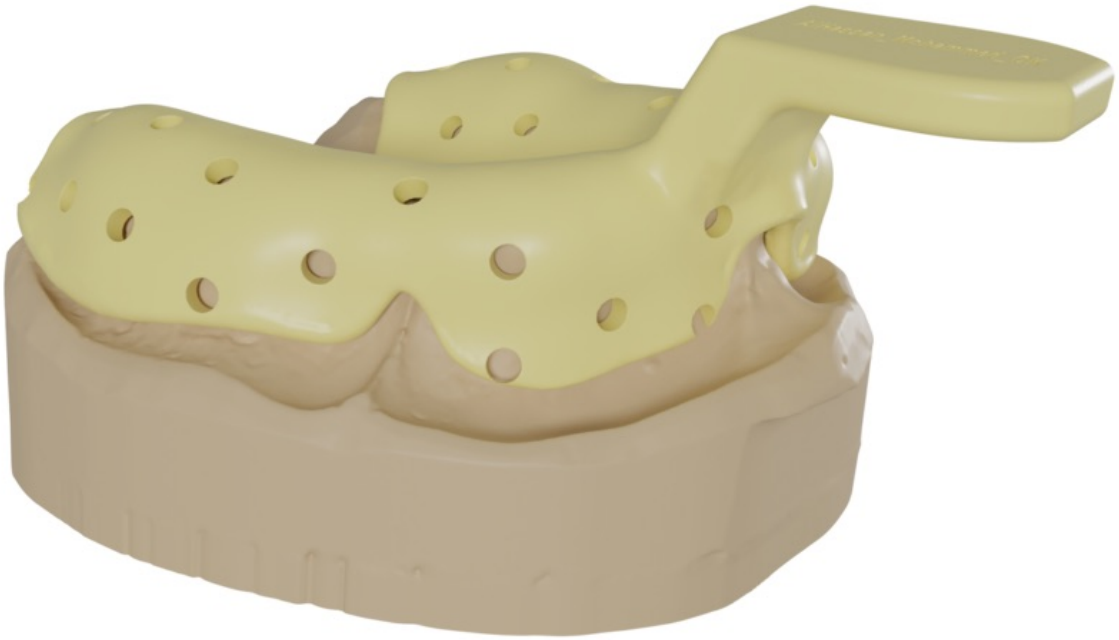
1. **Minimum mesh thickness** (mm): defines the minimum wall thickness of the mesh. Thicker meshes are more rigid.
2. **Design offset** (mm): compensates for dimensional tolerances in downstream fabrication. A small positive offset slightly enlarges internal dimensions to improve fit.
3. **Guidance Angles & Ranges:** controls how the software simulates jaw movements to shape the occlusal guidance surfaces of the mouthguard.

8.3.3.5 Review & Manual Editing

The outputs of the service are initial proposals; users shall review the results, and manually adapt them with the given tools to achieve the desired result.

You can find more information about the review & editing functionalities in Section .

8.3.4 Custom Tray Service



8.3.4.1 Description

The Custom Tray Design Service within Relu® Cloud supports the digital design of custom trays intended for use as impression or fabrication aids within dental laboratory and clinical workflows. The service assists users in preparing digital tray designs for downstream fabrication.

The service is limited to the design of digital tray geometries and is **not** intended for diagnosis, treatment planning, or clinical decision-making.

8.3.4.2 Inputs

- **Intra-oral scan (3D Mesh, STL/PLY/OBJ)** – required. Scan of either the lower or upper jaw.

8.3.4.3 Outputs

- **Custom tray**
- **Custom tray outline**
- **Model**

8.3.4.4 Parameters

Parameters include:

1. **Minimum mesh thickness** (mm): defines the minimum wall thickness of the mesh. Thicker meshes are more rigid.
2. **Design offset** (mm): compensates for dimensional tolerances in downstream fabrication. A small positive offset slightly enlarges internal dimensions to improve fit.

8.3.4.5 Review & Manual Editing

The outputs of the service are initial proposals; users shall review the results, and manually adapt them with the given tools to achieve the desired result.

You can find more information about the review & editing functionalities in Section .

8.4 Opening a service

- Click **Select** or double-click a service card to open it.
- The service interface will load, allowing you to proceed with case setup.

8.5 Presets

Each services includes:

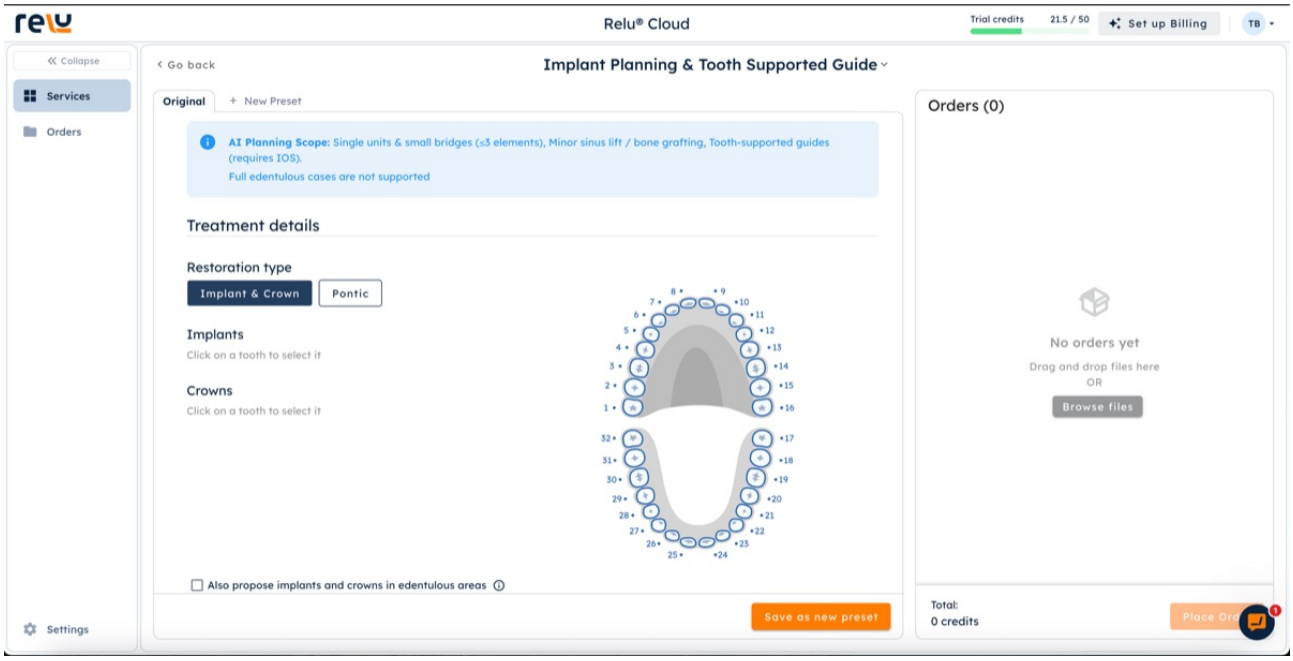
- A **preset summary** that displays default values tailored to the selected workflow
- A full list of **adjustable parameters** that can be edited to match your specific needs

You can:

- Modify parameter values directly within the interface
- Save your configuration as a **custom preset** for future use
- Easily switch between saved presets when placing new orders

Custom presets are stored at the user or organization level, depending on your permissions.

9 File upload & case creation



Before uploading: Please check our Data Requirements for accepted file formats, naming conventions, and scan quality guidelines.

9.1 File Upload Area

- Drag and drop your scan files into the designated area or click **“Browse Files”** to upload manually.
- Supported file types and sizes depend on the selected service. Relu® can process a wide range of 3D and imaging formats, including but not limited to **.stl, .ply, .obj, .dcm (DICOM), .drc, .nii, .vti, and .nrrd**. Specific requirements may vary per service and are detailed in the corresponding workflow instructions.
- Supported input: The system auto-detects upper and lower jaws based on file naming.
- You can manually move files between the upper and lower sections if needed.

9.2 Preset Selector

- Use the **“Select a preset”** dropdown to apply predefined model settings.
- If no preset is selected, default settings (“Original values”) are applied.
- Click **“Save”** to store custom settings for future use.

9.3 Orders Panel

- Each entry represents a file you’ve uploaded for processing
- To **remove a single item**, click the **“X”** next to its name
- To **remove all items**, click **“Clear”**
- The **total price (in credits)** of your order is shown at the bottom

> **i** Jaw Selection
>
> Relu automatically detects whether a file belongs to the **upper** or **lower jaw** by scanning for keywords such as `"upper"`, `"lower"`, `"maxillary"`, or `"mandibular"` in the filename. Make sure your files are named clearly to avoid misclassification. You can manually correct the jaw selection if needed by dragging the file to the correct box.

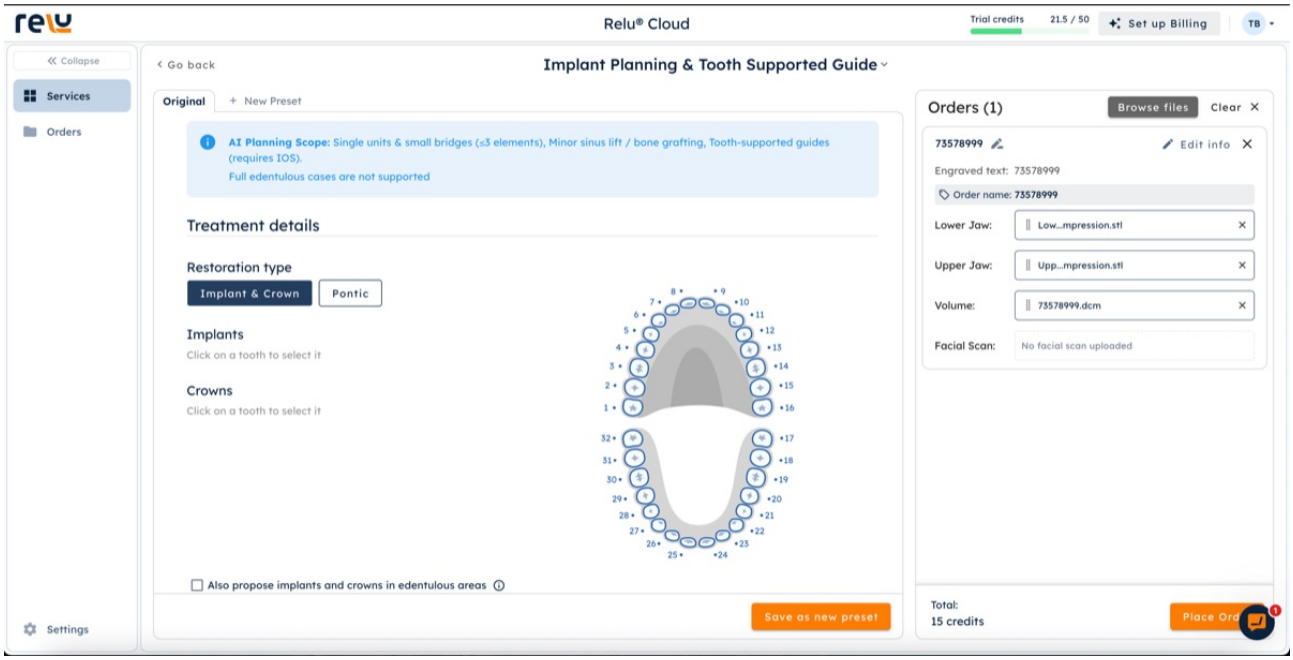
- Once everything is correctly assigned and reviewed, click **“Place Order”** to confirm
- Click **“Clear”** to remove all items.
- When ready, click **“Place Order”** to confirm.
- The price (in credits) of your total order is shown at the bottom.

10 Setting the Parameters for Services

Each service in Relu Cloud comes with its own set of adjustable parameters, tailored to the specific clinical indication. For full parameter details, refer to the corresponding service description in Section 8.3:

- **Segmentation & Alignment Service** — Section
- **Implant Planning & Tooth Supported Guide** — Section
- **Mouthguard** — Section
- **Custom Tray** — Section

11 Confirming the order



After you click **Place Order**, your files are submitted to the system. Within a few seconds, you'll be automatically returned to the Service **Overview** screen.

At this point:

1. A green banner will appear in the bottom-right corner of your screen saying: **"Order submitted successfully"**
2. Your case will be automatically added to the **Orders** section (accessible from the left-hand navigation bar).
   - You can monitor its progress from there.
   - Cases are listed with timestamps and service names, so you can easily track your work.

> **Note**
>
> Tip: If you don't see the confirmation message or your case in the Orders tab, refresh the page or double-check your internet connection.

> **Note**
>
> Before placing your order, you can view the total price (in credits) at the bottom right of the screen, just below the Place Order button.

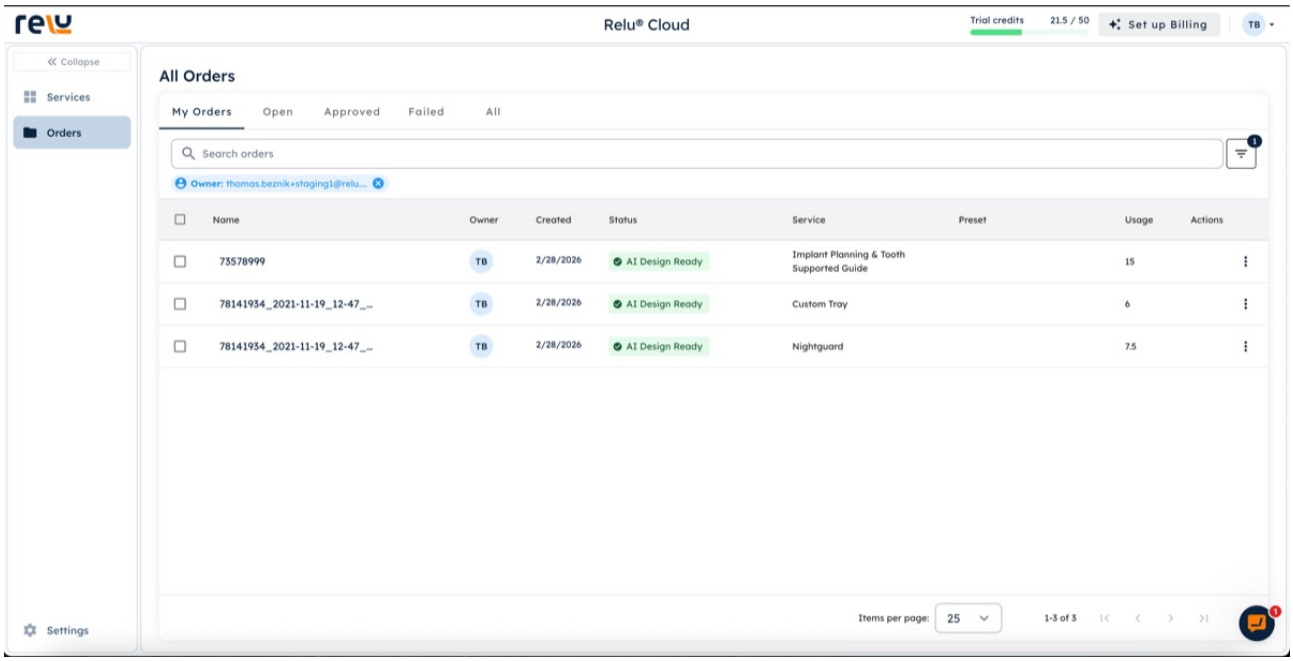
12 Managing orders

This section explains how to track, inspect, download, share, and manage orders created within the Relu platform.

12.1 Order overview

The **Order Overview** section provides a comprehensive list of all processing and completed orders made within the platform. It allows users to track their submissions, view order details, and monitor

credit usage.



Main Features:

The **Order Overview** provides a complete list of all orders—both processing and completed.

Search & Filter

- Search orders by name
- Filter by owner email

Custom Columns

- Click **"COLUMNS"** to choose which fields (e.g., Name, Status, Recipe, Usage) appear in the table.

Table Details

Each row includes:

- **Name**: Filename or scan name
- **Owner**: User email
- **Created**: Submission date
- **Status**: Processing state (check = completed)
- **Service**: Automation module used
- **Preset**: Settings applied during submission
- **Usage**: Credits consumed

Pagination

- Use the **Items per page** dropdown and navigation arrows to manage result display.

More Options (menu)

- Open contextual menu for actions like downloading, sharing, viewing in 3D, or deleting an order.

12.2 Available Actions (menu)

From the Order Overview, clicking the menu provides access to:

In the **Order Overview**, each row representing a submitted case includes a **menu** on the far right. Clicking this opens a contextual menu with several useful actions for managing your order:

Available Actions:

- **Order Info**: View detailed metadata about the order, including creation time, selected service, preset used, credit consumption, and file history.
- **View in 3D**: Opens the selected case in the **Order Viewer,** a 3D inspection environment where you can rotate, zoom, sculpt, or inspect your model. Ideal for reviewing accuracy before download or printing.
- **Download Inputs**: Allows you to download the **original files** (e.g. intraoral scans, DICOM, PLY) that were uploaded for this order. Useful for backup or further offline processing.
- **Download Outputs** *(grayed out if not ready)*: Once processing is complete, this button lets you download the **AI-generated output files** such as STL models, segmentations, or plan results.

  Note: If greyed out, it means the output is still being generated.
- **Delete**: Permanently removes the order from your dashboard.

  Warning: This action cannot be undone and should only be used when you're certain the data is no longer needed.
- **Share Order**: Generates a secure sharing link so you can collaborate with colleagues or external partners.
  - Recipients may need a Relu account to access shared orders.
  - Ideal for cross-team validation, case review, or lab-to-clinic coordination.

13 Order Editor – Review & Adjust Orders

You can open processed orders directly in our Editor application, in order to review the results, and adjust them with editing tools if necessary.

Depending on the service used to create the order, you will see different tools. The available editor modes are described in the sections below.

13.1 Review & Adjust Segmentation and Implant Planning & Surgical Guide Results

13.1.1 Overview

13.1.1.1 Purpose

You can visualise, edit, and validate results such as anatomical segmentations, implant positions, and surgical guides.

The editor app combines automation and manual control — automatically generating clinical proposals while allowing you to inspect, refine, and approve them with powerful visual and editing tools.

The steps, tools, and data you'll see depend on the **service** used to create the order (e.g. *CBCT Segmentation & Alignment* or *Implant Planning*) and on the **input scans** you uploaded.

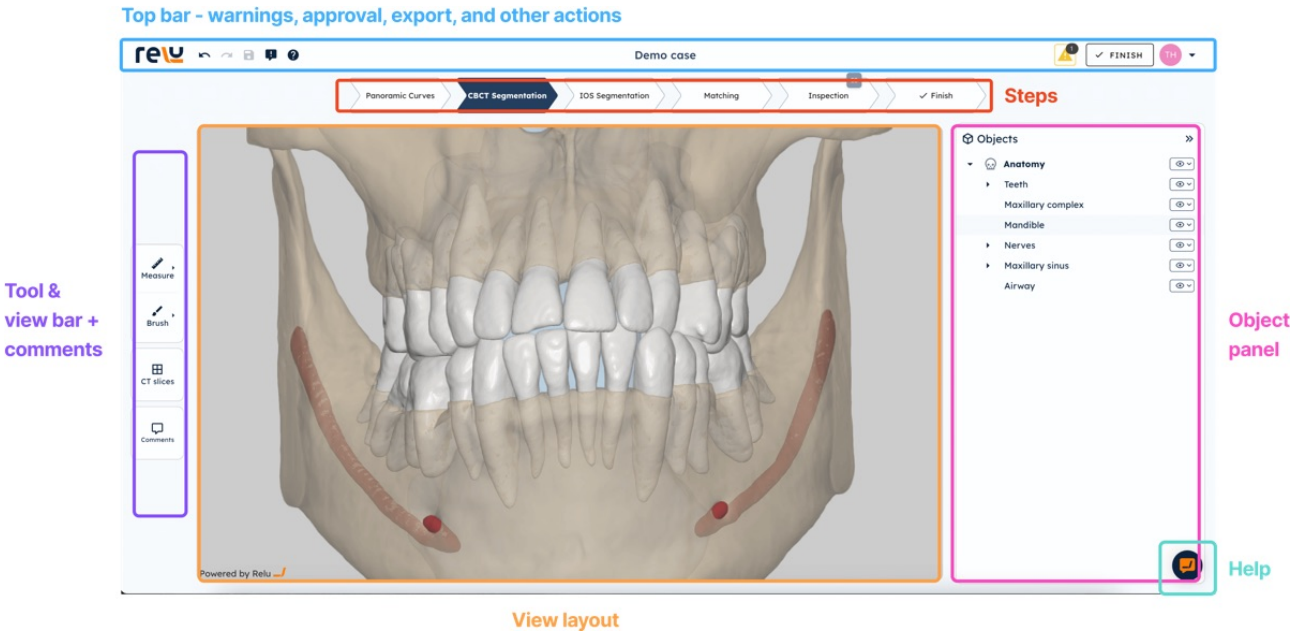
The **Implant Planning & Surgical Guide Service** builds directly on top of the **CBCT Segmentation & Alignment Service**. That means all tools and data available in the latter are also available in Implant Planning.

13.1.1.2 Structure

Modes

The editor can operate in two modes:

- **Review & Adjustment Mode:** used for verifying and refining proposals without altering base anatomical data. This is the default mode in which the Editor is opened.
- **Advanced Edit Mode:** enables detailed, step-by-step editing of the workflow stages that led to the final result (e.g. segmentation, matching, panoramic projection). All manual edits are saved. To open this mode, click **Advanced Edit** in the top bar.



The image above shows the general structure of the user interface. It can be divided into 6 main areas:

Top bar - Main Application Actions

The top bar contains the main actions of the application, along with any active warnings. Available actions include:

- Undo / Redo
- Save
- Report Issue
- Help
- Approve Treatment (for implant workflows)
- Switch to Advanced Edit Mode
- Profile actions such as Logout

> **Warning**
>
> Always review warnings before exporting or using results in any way.

Steps

Accessible only in **Advanced Edit Mode**, the Steps panel allows you to navigate between the different workflow stages (e.g. *IOS–CBCT Matching*).

Each step focuses on one task — for example, alignment, segmentation, or inspection — and displays only the tools, data, and views relevant to that task.

The number and type of steps depend on the selected service and the data you uploaded.

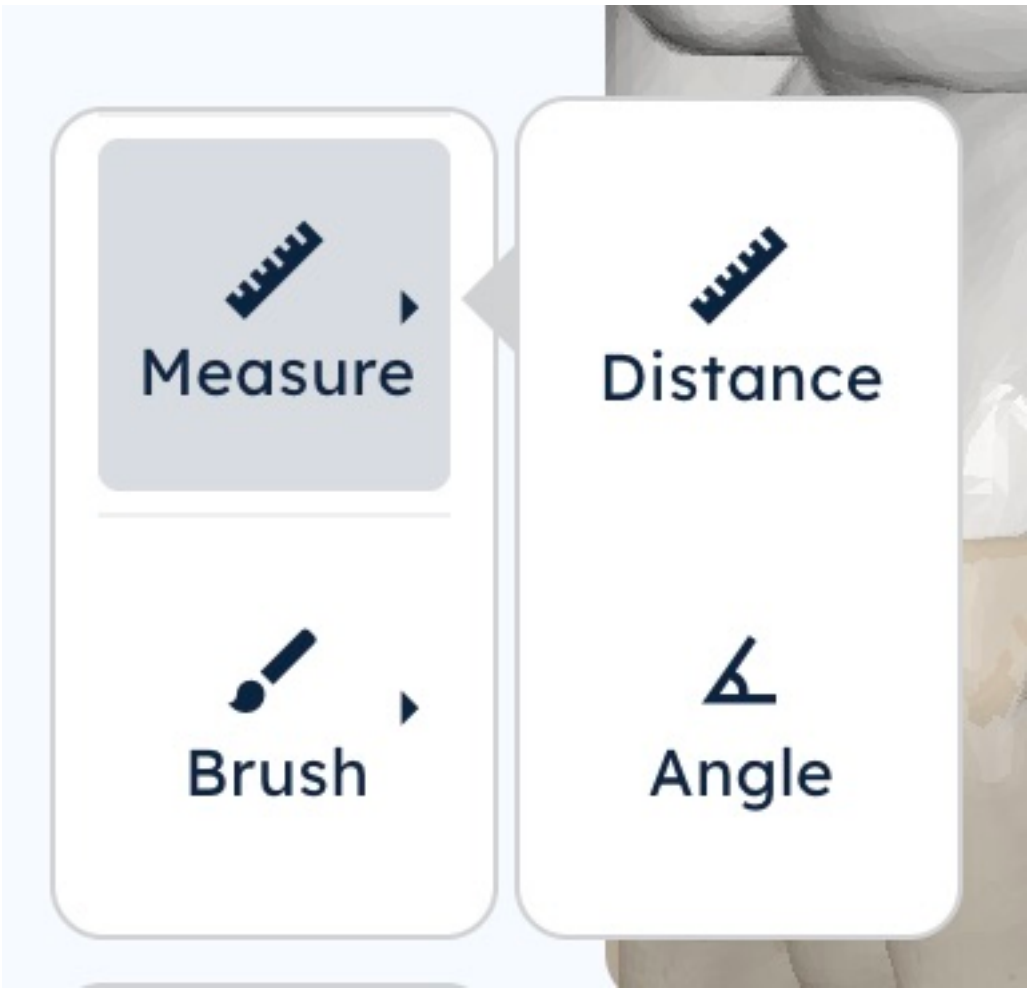
Tool & View bar

This bar includes three sections: **Tools**, **Views**, and **Comments**.

Tools

Tools are used to inspect and modify results. Some tools have multiple options (indicated by a small arrow).

Hover over the icon to see the list, then click to activate a tool — only one tool can be active at a time.



Views

Views determine what you see in the **View Layout**.

Only one type of view can be active at a time, but each may have multiple configuration options.

Comments

Toggle the comments panel to collaborate directly within an order. Comments are visible to all users who have access to that order.

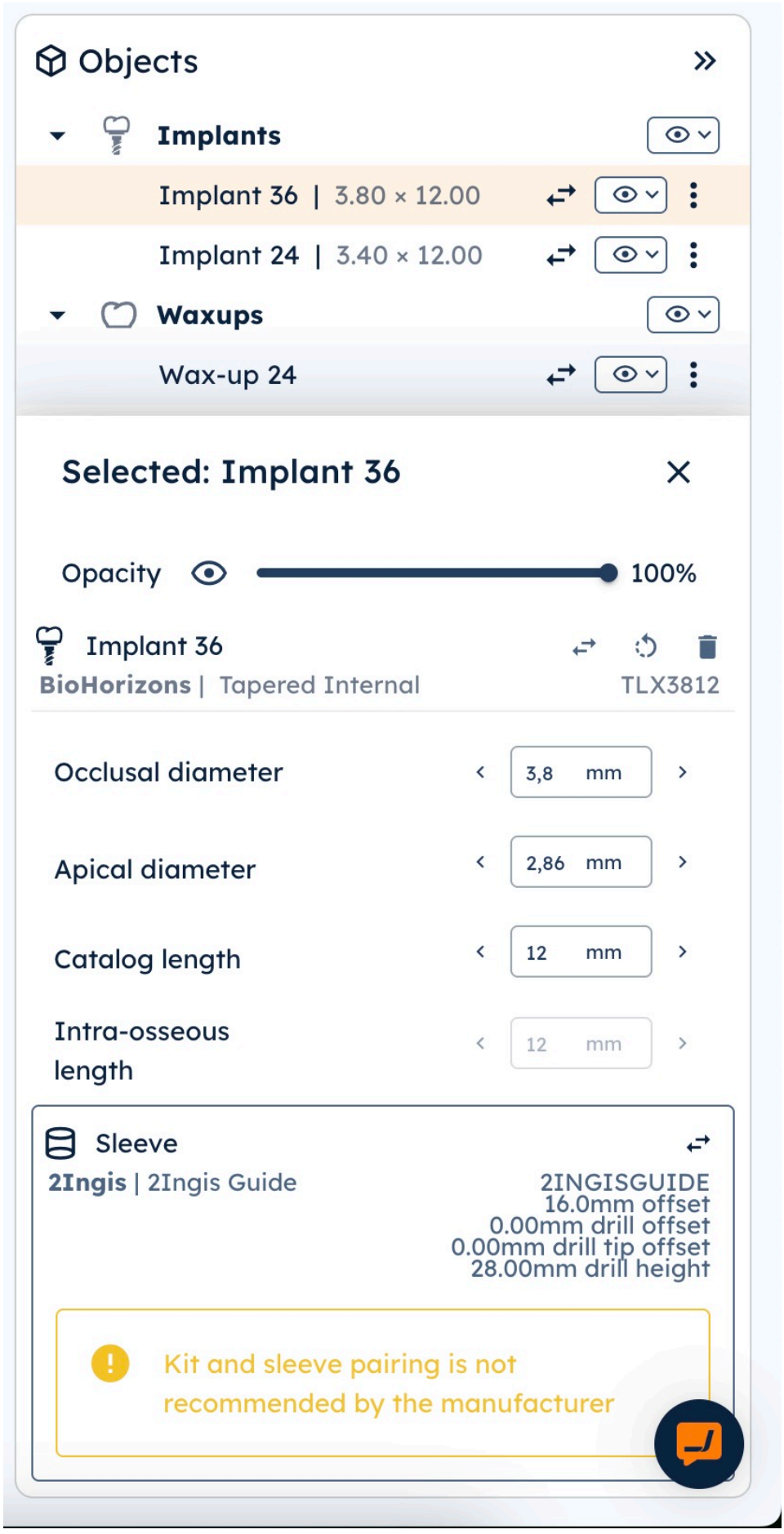
Object List

The **Object List** lists all data used in the active step:

- **Input Files:** Original CBCT, intra-oral, or facial scans uploaded by the user.

- **Outputs:** AI-generated or user-edited results such as segmentations, implants, abutments, crowns, and guides.

Objects are grouped by category (e.g. all implants), allowing you to change the visibility or opacity of the entire group. Clicking an object selects it and opens a panel with details and context-specific actions.


Objects
Implants
Implant 36 | 3.80 × 12.00
Implant 24 | 3.40 × 12.00
Waxups
Wax-up 24
Selected: Implant 36
Opacity
100%
Implant 36
BioHorizons | Tapered Internal
TLX3812
Occlusal diameter
3,8 mm
Apical diameter
2,86 mm
Catalog length
12 mm
Intra-osseous length
12 mm
Sleeve
2Ingis | 2Ingis Guide
2INGISGUIDE
16.0mm offset
0.00mm drill offset
0.00mm drill tip offset
28.00mm drill height
Kit and sleeve pairing is not recommended by the manufacturer

You can hide or show objects using the **eye icon**, and adjust transparency by hovering over it.

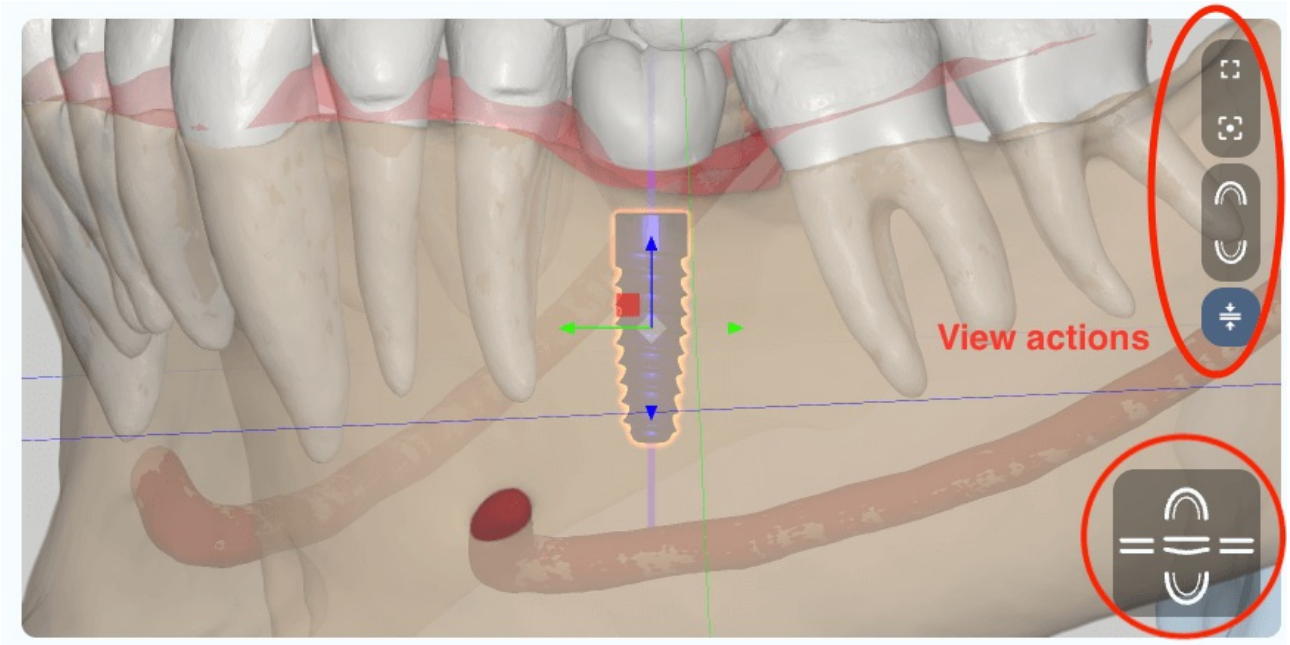
Minimise the Object List sidebar by clicking the arrow at its top left to give more space to the View Layout.

View Layout

This is where you explore your scans and planning results.

Multiple views can be opened at once or switched to fullscreen mode.

The available views will depend on the uploaded input data, selected service, and current step.



When hovering over a view, you'll see view-specific actions. All views share the following:

1. **Fullscreen / Exit fullscreen** – expand or restore the view.
2. **Reset view** – resets the camera to its default position.

3D View

Displays 3D objects such as segmentations, implants, and input scans.

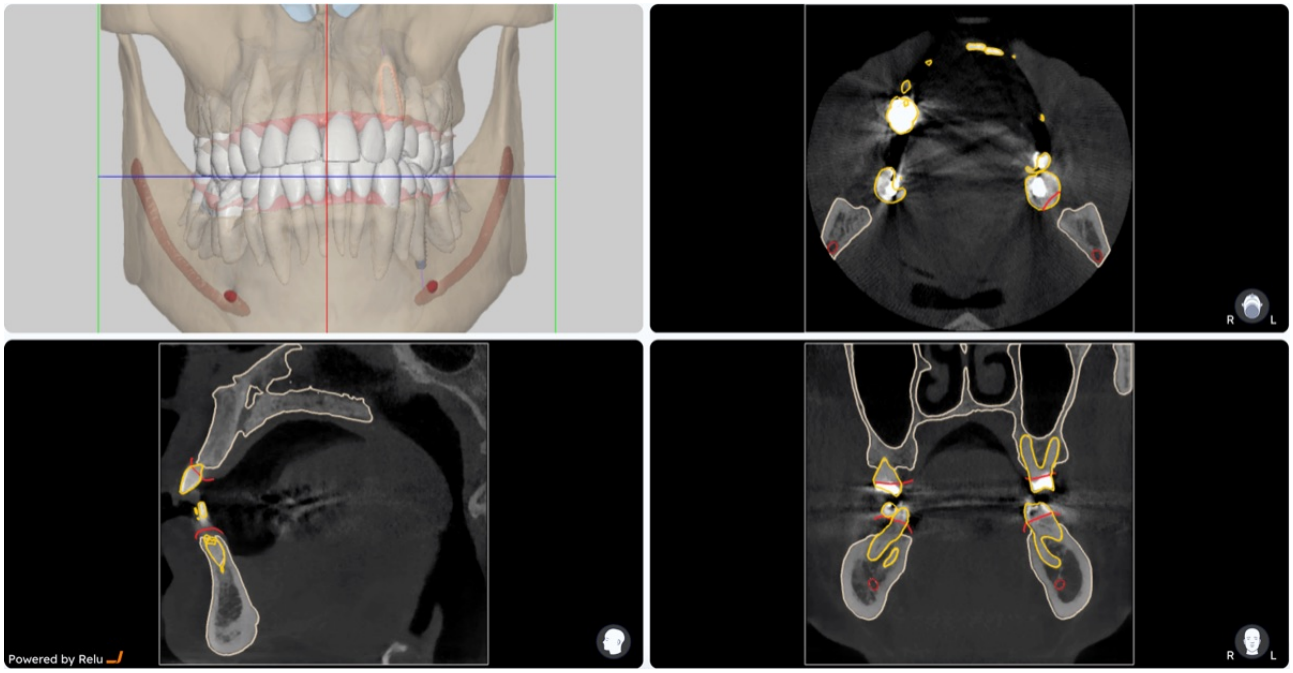
Controls:

- Drag → rotate
- Ctrl + drag → pan
- Click object → select
- Click empty space → deselect

Additional actions:

- Hide either the upper or lower jaw.
- Jump to a predefined viewpoint (Top, Front, Left, Right, or Bottom).
- Toggle **Occlusion / Open Mouth** (only if both IOS scans are available).

2D CBCT Views



Visualise the CBCT volume through **axial**, **sagittal**, and **coronal** slices.

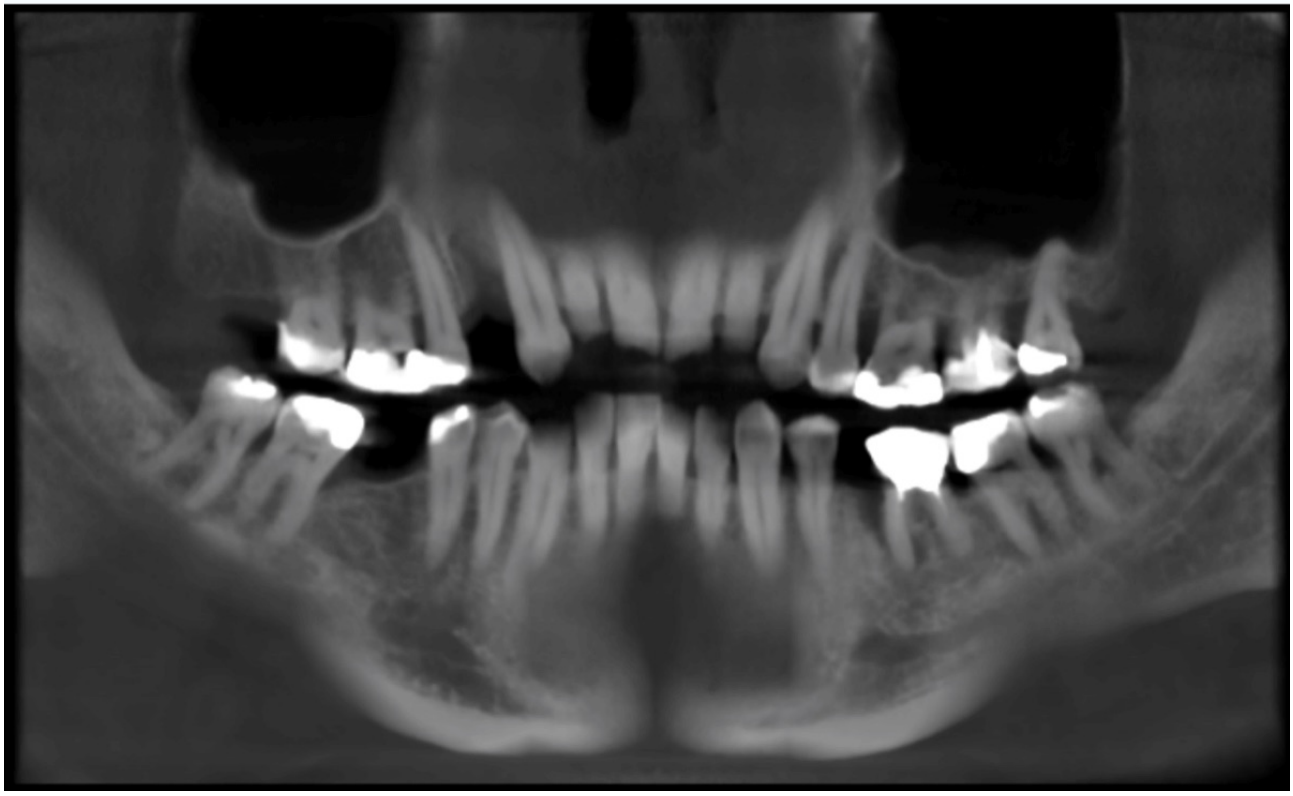
Controls:

- Ctrl + drag → pan
- Ctrl + scroll → zoom
- Click → move crosshairs in other views
- Scroll → navigate through slices

Additional options:

- **Snap to Object** – centres views on the selected item.
- Adjust **Brightness** and **Contrast**.

Panoramic projection view



Shows a 2D projection of CBCT slices along the panoramic arch.

You can edit this arch in **Advanced Edit → Panoramic Arches**.

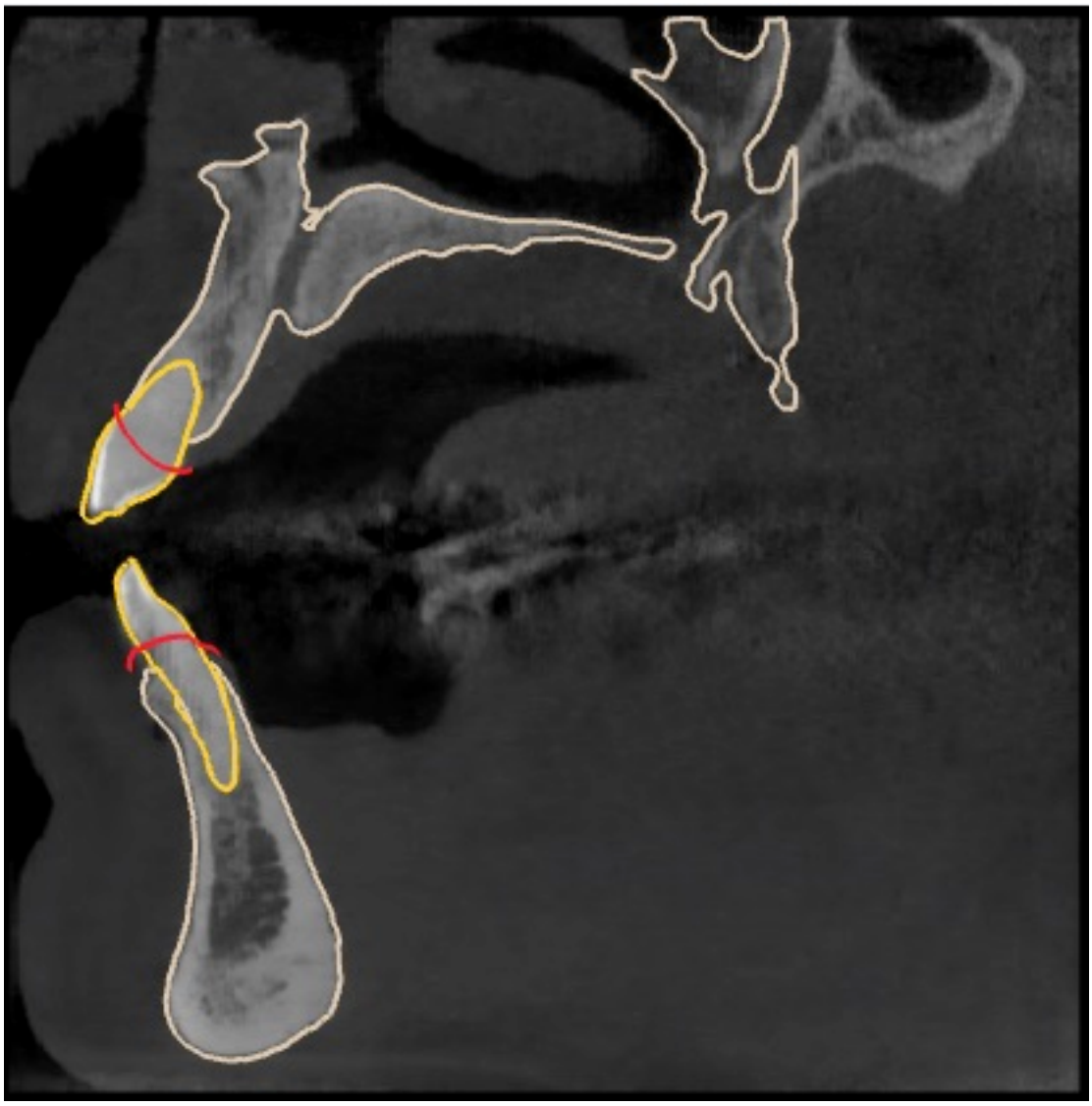
Controls:

- Ctrl + drag → pan
- Ctrl + scroll → zoom
- Scroll → expand the arch

Options:

- Choose **Upper** or **Lower** arch.
- Adjust **Brightness / Contrast**.
- Control the **number of slices** used for the projection.

Panoramic reslice view



Displays a cross-section that follows the panoramic arch.

Controls:

- Ctrl + drag → pan
- Ctrl + scroll → zoom
- Scroll → move along the arch

Options:

- Adjust **Brightness / Contrast**.

Help

Click the **Help** bubble to contact Relu's customer support team directly from within the application.

Feedback & Refunds

At Relu, we value your feedback. It helps us continuously improve our AI and software.

Click the **feedback** icon in the top bar.

You can choose between:

- Submitting general feedback, or

- Requesting a refund (if no clinical value could be extracted from the order).

Refund requests are subject to review by a Relu Administrator. For details, refer to the **End-User License Agreement (EULA)**.

Dependent Objects & Re-computation

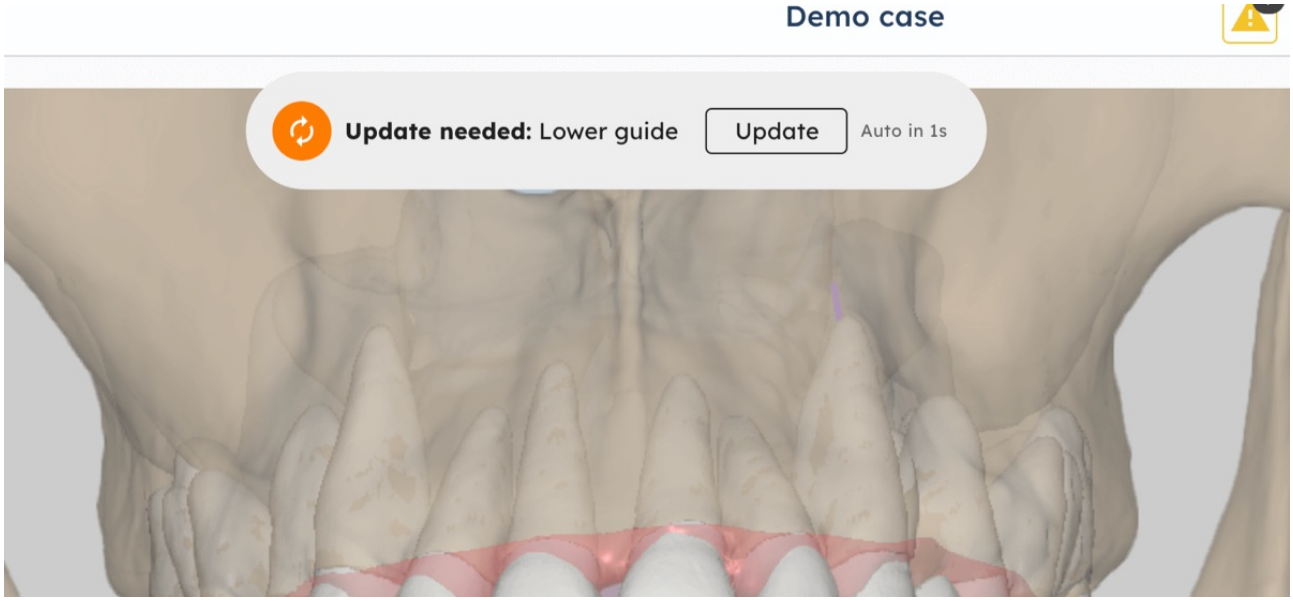
Certain objects depend on others (for example, a surgical guide depends on sleeves, or a segmentation mask on its mesh surface). When one object changes, the related object must be **recomputed**.

The software continuously tracks these dependencies and automatically triggers re-computation when needed. You can also do this manually.

A **sync icon** next to each object in the list shows its current computation status:

- Orange: re-computation needed
- Rotating blue: in progress
- Green: up to date
- Red: failed

If the object is visible in the current view, a popup will appear allowing you to manually trigger the re-computation.



During re-computation, **exports are temporarily disabled** to ensure only up-to-date data is used.

13.1.2 Segmentation & Alignment

13.1.2.1 Purpose

The **Segmentation & Alignment** steps form the foundation of all workflows.

These steps:

- Provide **AI-assisted anatomical segmentation** of CBCT data
- Allow **alignment** of intra-oral and facial scans

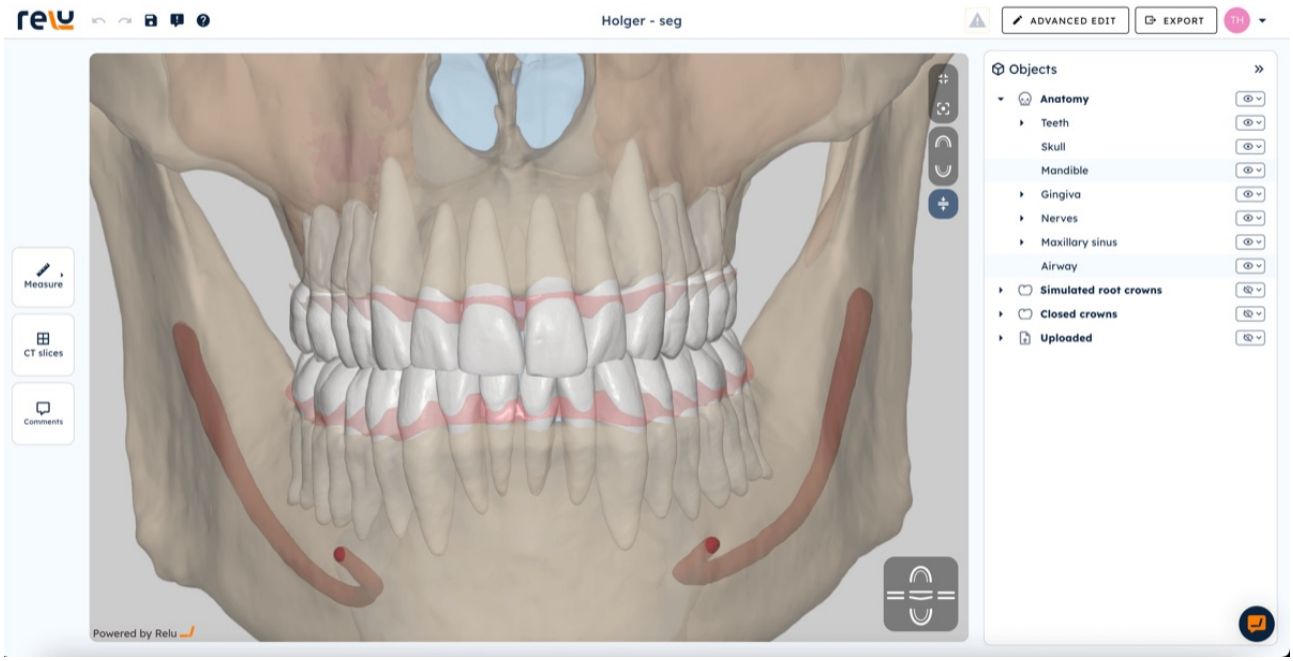
They appear in both:

- **Segmentation Service**, and
- **Implant Planning Service**, since implant planning builds directly upon these results.

You can export the results to use in other software or as part of larger clinical workflows.

For details, see Section .

13.1.2.2 Review & Adjustment Mode



When you open an order of the **Segmentation & Alignment** service, the application starts in the **Inspection Step**.

Depending on the uploaded scans, the following data are displayed:

- **Fused teeth** (if available): intra-oral crowns merged with CBCT roots
- If no fused teeth: **CBCT teeth** or **IOS closed crowns**
- **CBCT segmentations** (maxillary complex, mandible, nerves, etc.)
- **Gingiva** from the intra-oral scan
- All **uploaded input scans**

The goal of this step is to **review all automatic results** and decide whether they are ready for export or need manual correction.

If something looks incorrect, click **Advanced Edit** in the top bar to open the editing workflow.

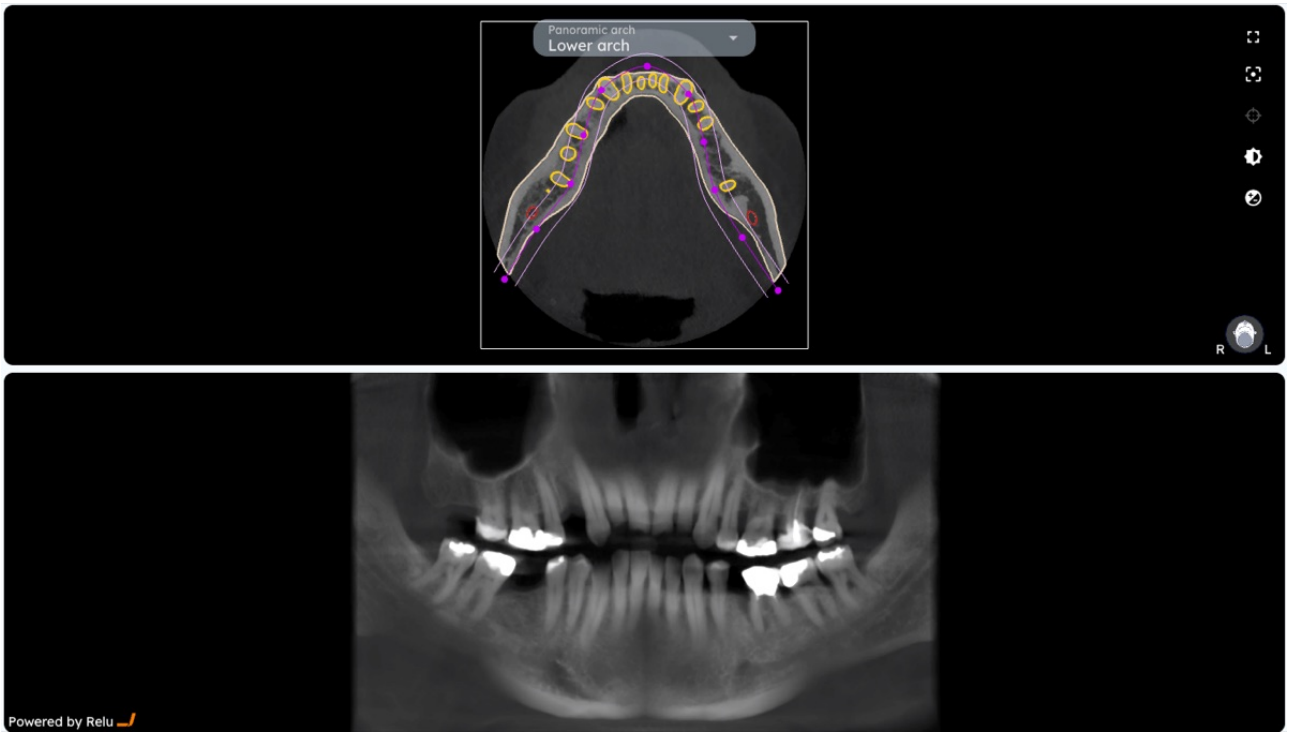
If everything looks good, click **Export** to proceed.

13.1.2.3 Advanced Edit Mode

When you switch to **Advanced Edit Mode**, additional steps appear depending on your uploaded data.

These steps allow you to manually adjust or refine the automatic AI results.

Panoramic Curves Step



The **Panoramic Curves Step** lets you **view and adjust** the dental arch trajectory proposed by the AI.

This curve defines how panoramic projections and reslice views are generated. Two curves are automatically proposed:

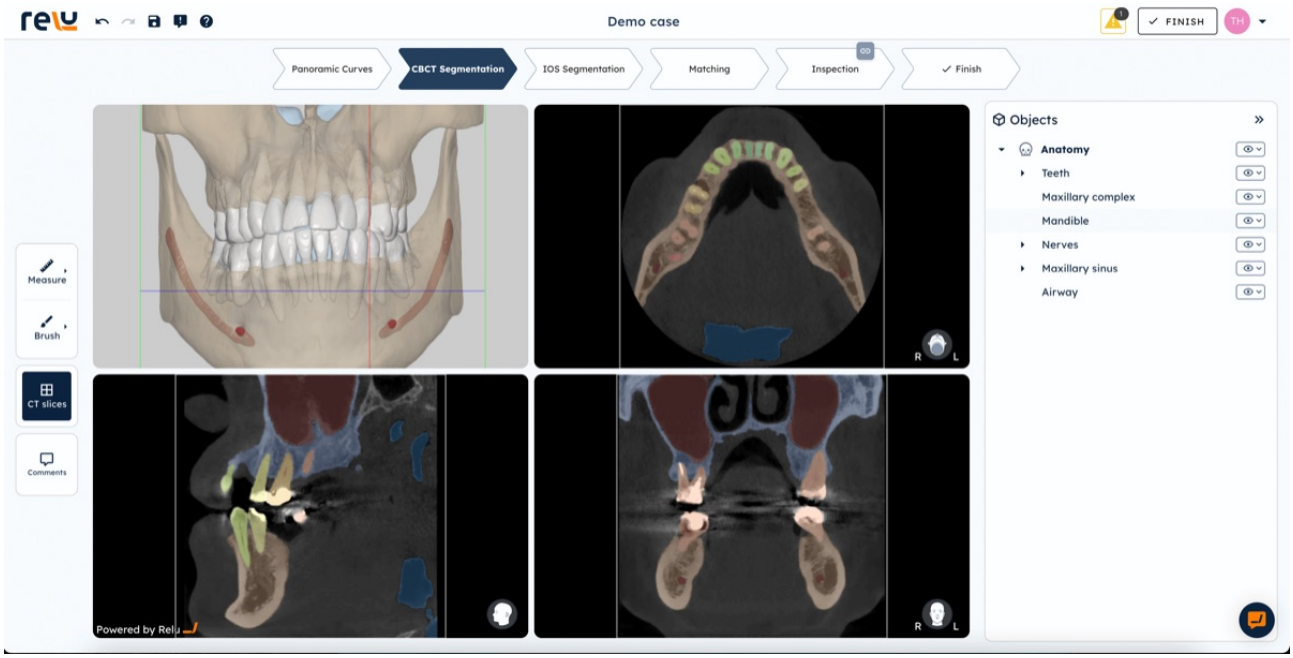
- One for the **upper** jaw
- One for the **lower** jaw

You can:

- Edit both curves by dragging their **purple control points** directly in the top view (overlaid on the CBCT axial slice)
- Adjust the **thickness** of the curve
- Switch between **upper** and **lower** curves
- Immediately see changes in the **panoramic projection view**

> ⚠ Warning
>
> Accurate panoramic curves are essential for correct implant visualisation and treatment-planning accuracy.

CBCT Segmentation Step



The **CBCT Segmentation Step** displays and allows refinement of **AI-generated anatomical segmentations** (e.g. bone, teeth, nerves).

Segmentations appear as **colored masks** over the 2D CBCT slices. You can use the **Brush Editing Tool** to modify these masks. **To edit:**

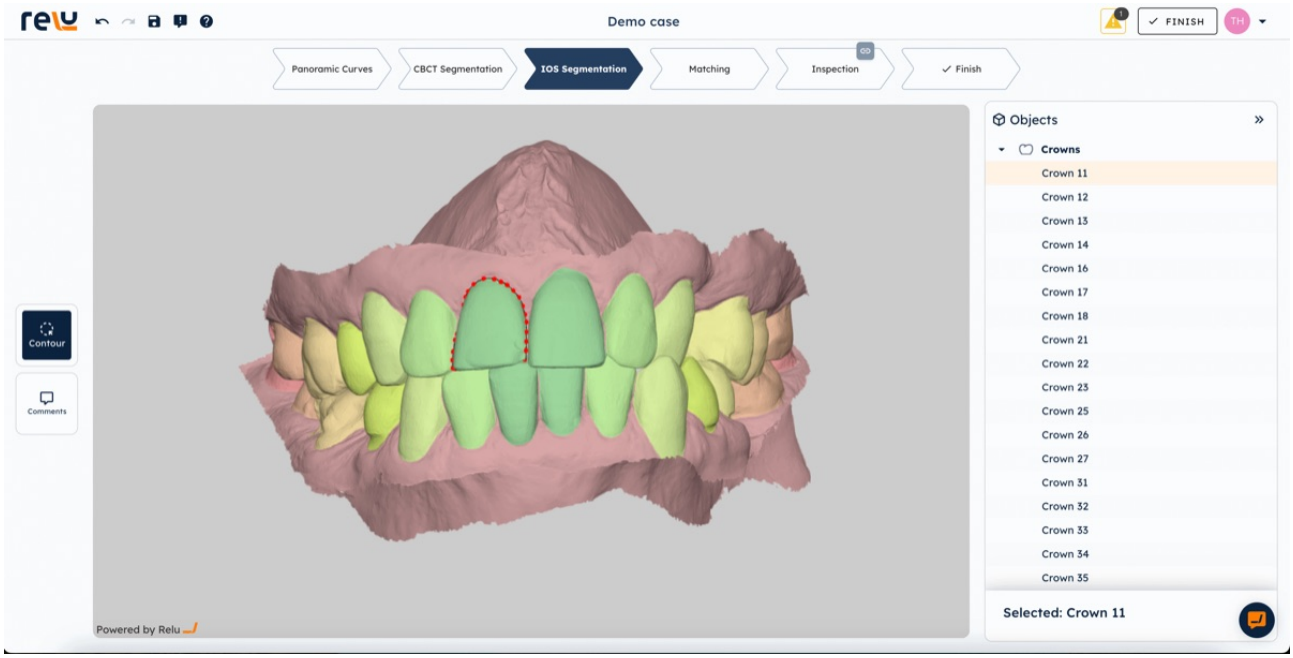
1. Select the **Brush Tool** in the toolbar.
2. Select the object to edit from the **Object List**.
3. Adjust the brush settings:
   - **Mode** – Add or Remove
   - **Size** – Brush diameter
   - **Depth** – Slice depth (how many slices are affected)

When you edit a segmentation mask:

- Its **3D mesh (surface representation)** will need to be **recomputed** (done automatically after a short delay or triggered manually).
- If you edit **teeth segmentation** in an order containing an IOS, the **fused teeth** will also be recomputed.

> **Note**
>
> Before proceeding, validate that: segmentation boundaries match CBCT anatomy, mandibular canal and sinus contours are accurate, and bony structures are continuous and free of artefacts.

IOS Segmentation Step



The **IOS Segmentation Step** lets you review and edit the segmentation of **teeth crowns** in intra-oral scans.

Segmented teeth are displayed in color on the IOS surface. To edit a crown:

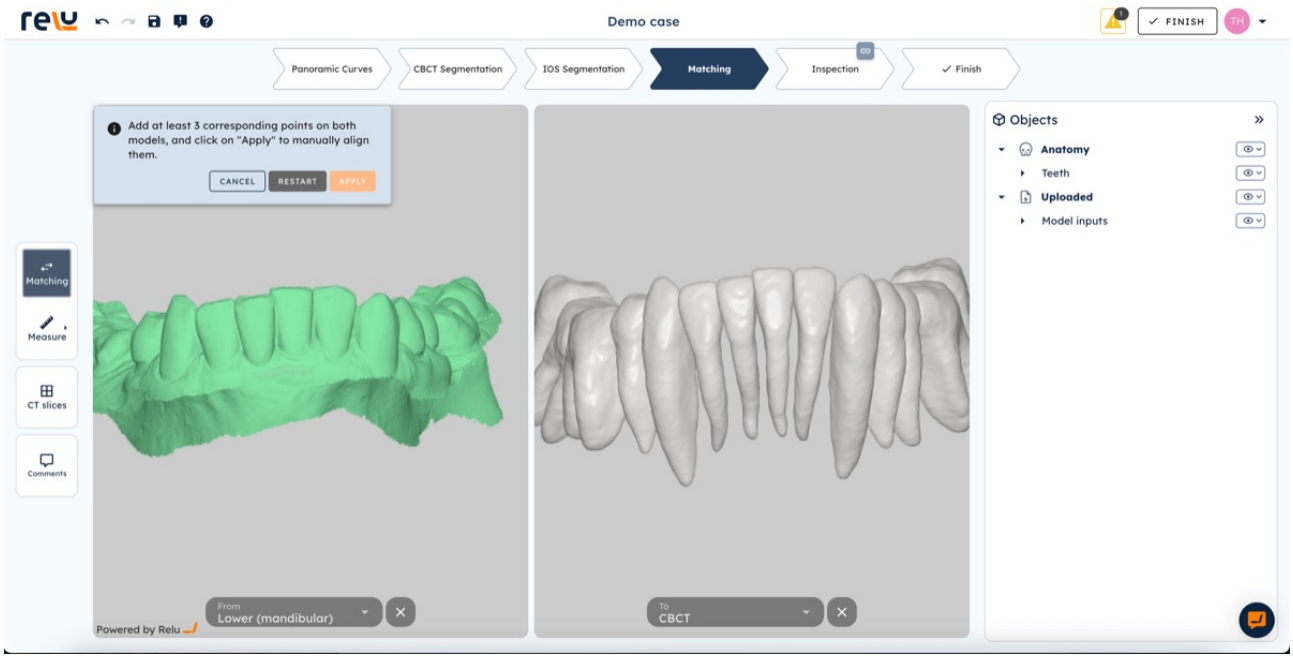
1. Activate the **3D Contour Tool**.
2. Select the crown from the **Object List**.
3. Adjust its outline by moving the **control points** of the contour.

When you edit a crown segmentation:

- The associated **closed crown** and **fused tooth** will automatically require re-computation.

> **Note**
>
> Before proceeding, validate that: gingiva and teeth margins are accurately segmented, and there are no holes, missing data, or overlaps between surfaces.

IOS-CBCT Matching Step



The **Matching Step** allows you to refine the **automatic registration** of the intra-oral and/or facial scans with the CBCT dataset.

To edit:

1. Activate the **Matching Tool**.
   - The 3D view will split into two windows: one showing the **source** object, one showing the **target**.
2. Use the selection panel at the bottom of the views to choose which objects are used for registration.
3. Refine the alignment with **Point-Based Matching**:
   - Select **at least three corresponding points** on both the source and target datasets.
   - Click **Apply** in the blue top-left panel to compute the optimal alignment.

For the CBCT, the software uses the **segmented teeth** as reference points.

Use the 2D CT slices to evaluate alignment — intra-oral and facial scan cross-sections are shown directly on top.

Changing this alignment will affect the **fused teeth** and **surgical guide**, both of which will need re-computation.

> **Warning**
>
> Accurate alignment is critical for precise implant positioning and surgical-guide design.

13.1.3 Implant Planning & Surgical Guide

13.1.3.1 Purpose

The **Implant Planning Service** extends the segmentation workflow with **AI-assisted implant planning** and **surgical guide generation**.

When you open an order, the system provides an automatic proposal of:

- **Anatomy segmentation**: bone, teeth, nerves, etc.
- **Wax-up / crown** position and size

- **Dental implant** positions and size from the requested implant library
- **Sleeve** positions and catalogue numbers from the requested sleeve library
- **Tooth-supported surgical guide** model, based on the sleeves

Just like in the **Segmentation & Alignment** service, you can further refine segmentation and alignment via **Advanced Edit Mode**. For details, see the Segmentation & Alignment section above.

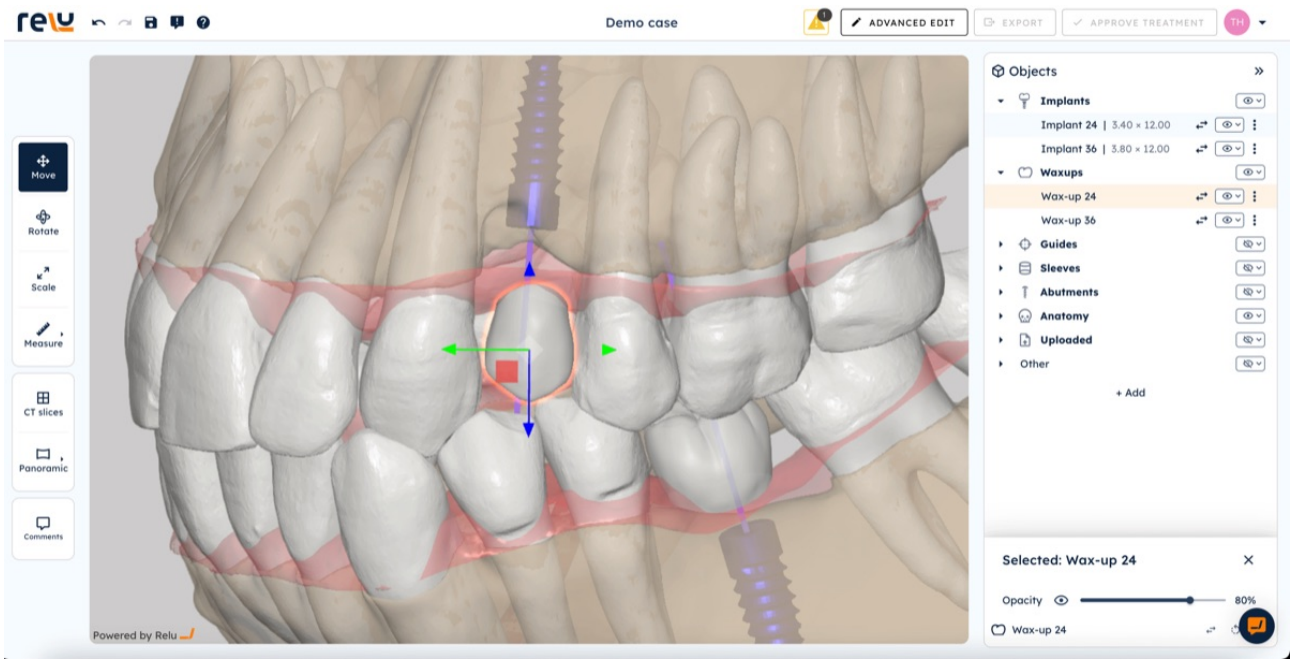
This service blends **automatic proposals** with **full manual control** over implant parameters, libraries, wax-ups, sleeves, and guide settings.

All automatic results must be **reviewed and approved by a trained dental professional** before export or clinical use.

You can export results for use in other software or as part of larger clinical workflows. See Section for more information.

13.1.3.2 Planning

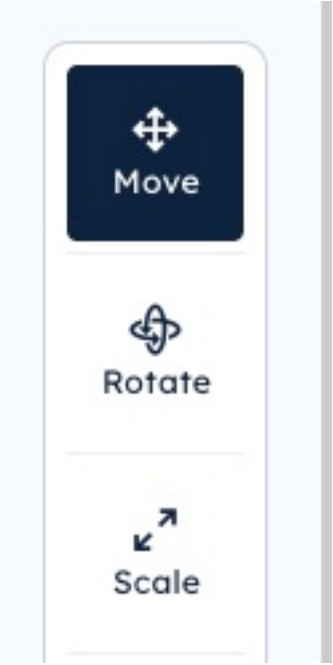
Virtual Wax-ups



Use **virtual wax-ups** to plan implants in a **top-down** manner, taking the intended restoration into account. The AI automatically places and scales a wax-up for each implant, based on neighbouring teeth.

You can edit **position**, **orientation**, and **size** of any wax-up in both **2D** and **3D** views:

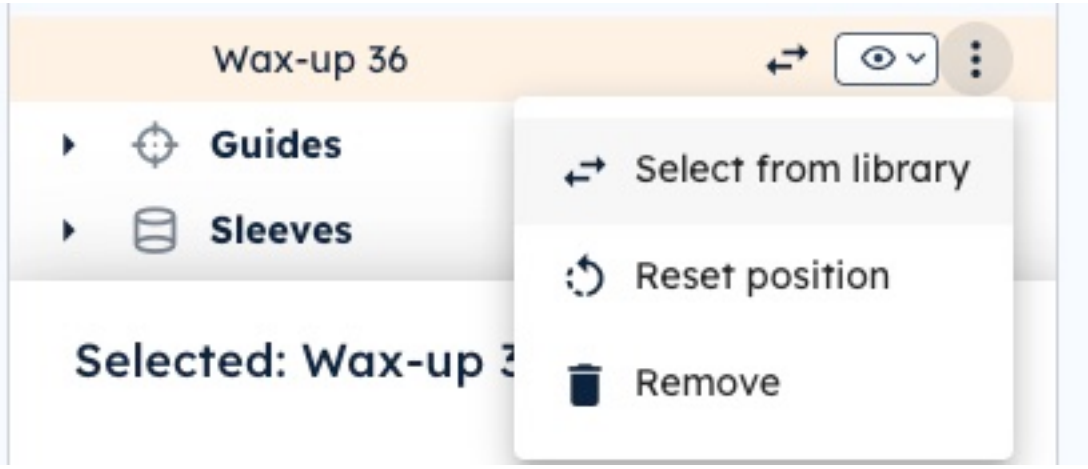
- **3D View**: use the **Move**, **Rotate**, or **Scale** tools.



- **2D Views**: use handles — **green squares** (scale), **red circles** (rotate), or drag to move.

Additional actions are available from the **menu** in the Object List:

- Delete the wax-up
- Change the **crown type** (e.g., incisor)
- **Reset** to the original AI position



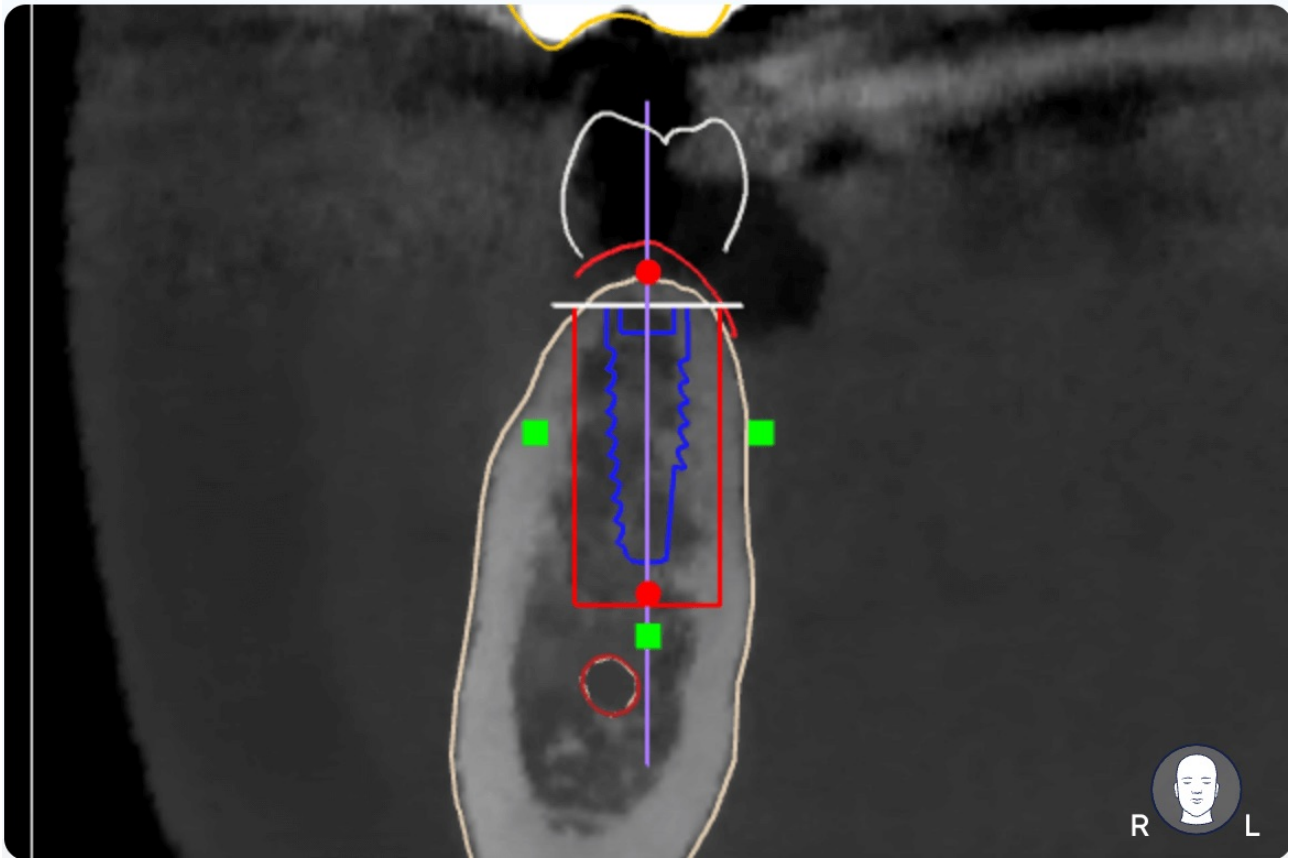
Implants

The AI proposes **implant positions** and selects **sizes** from the requested library, considering the associated crown, available space, nerves/sinuses, and other safety constraints.

You can edit implants in 2D & 3D using the same tools as for crowns. In the 2D view, choose whether rotations are around the **apex** or the **implant top**.

When you **resize**, the software picks a size from the **same product line** as the current implant.

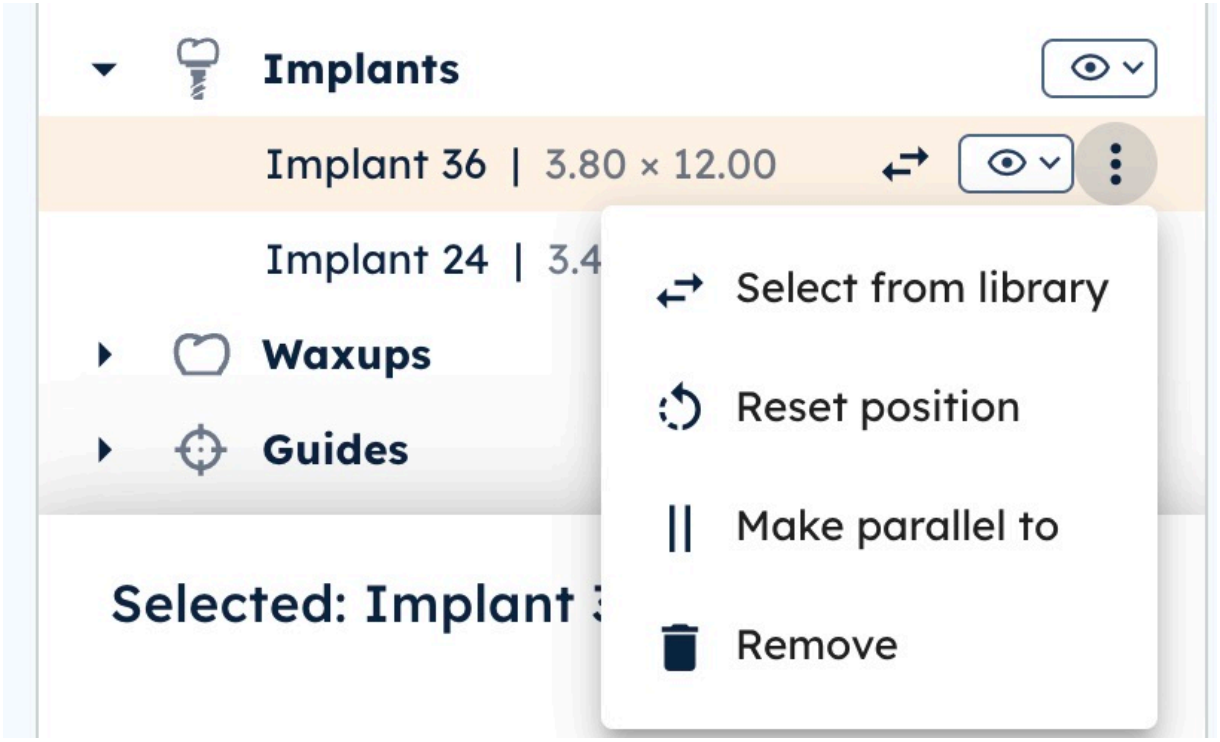
Safety visualisation in 2D views

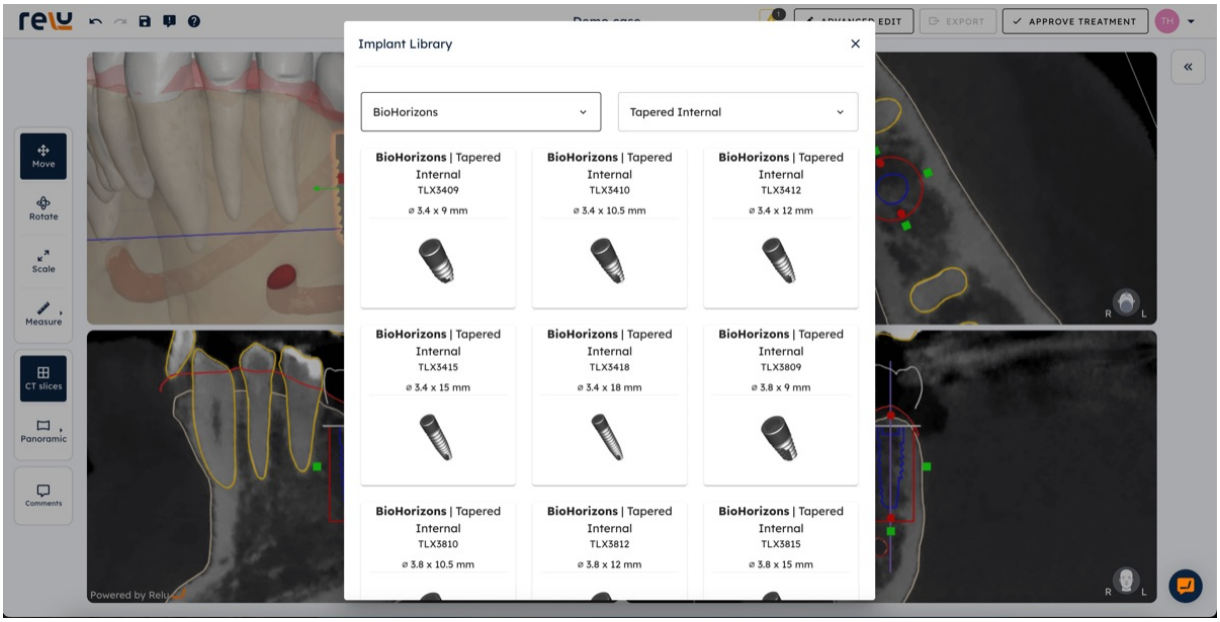


- The **safety zone** around the implant is shown in **red** (default: **1.5 mm** lateral, **2.0 mm** apical). You can increase these margins in **Settings**.
- A **white line** indicates the **bone level**, useful for positioning **tissue-level** implants.

Libraries & info

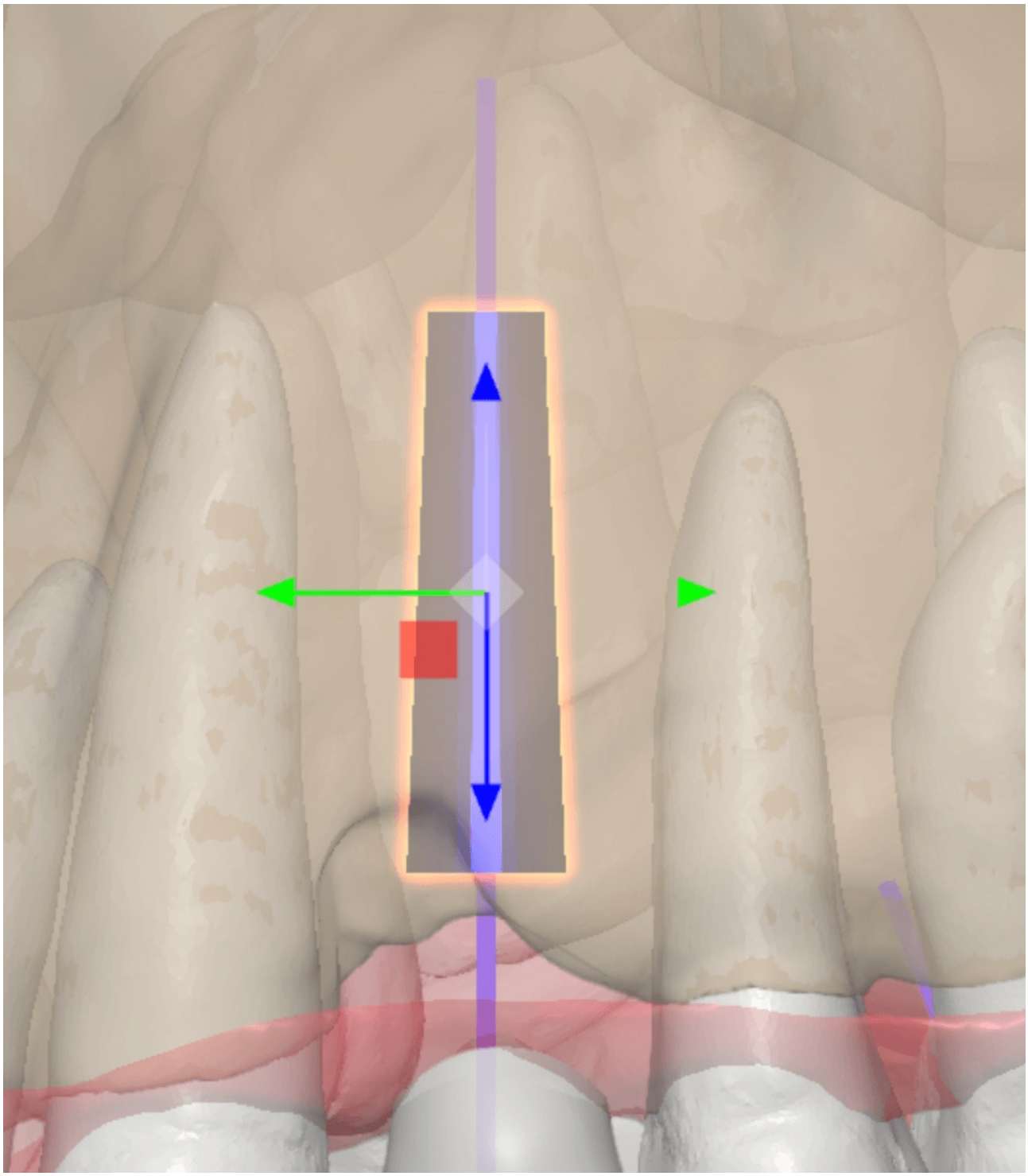
- Switch the **implant library** from the **menu** in the Object List (filter by manufacturer and product line).





- Select an implant to view details like **catalogue length**, **intra-osseous length**, etc.
- For multi-unit restorations, use **Make parallel** to align selected implants.

Generic Implant Libraries



You can also use **generic implants** (you define all dimensions) when a specific implant is not in our standard library.

> **Warning**
>
> You are responsible for confirming that any generic implant is clinically appropriate and compliant with applicable regulations. Relu is not responsible for the suitability, accuracy, or safety of user-defined implants.

Abutments

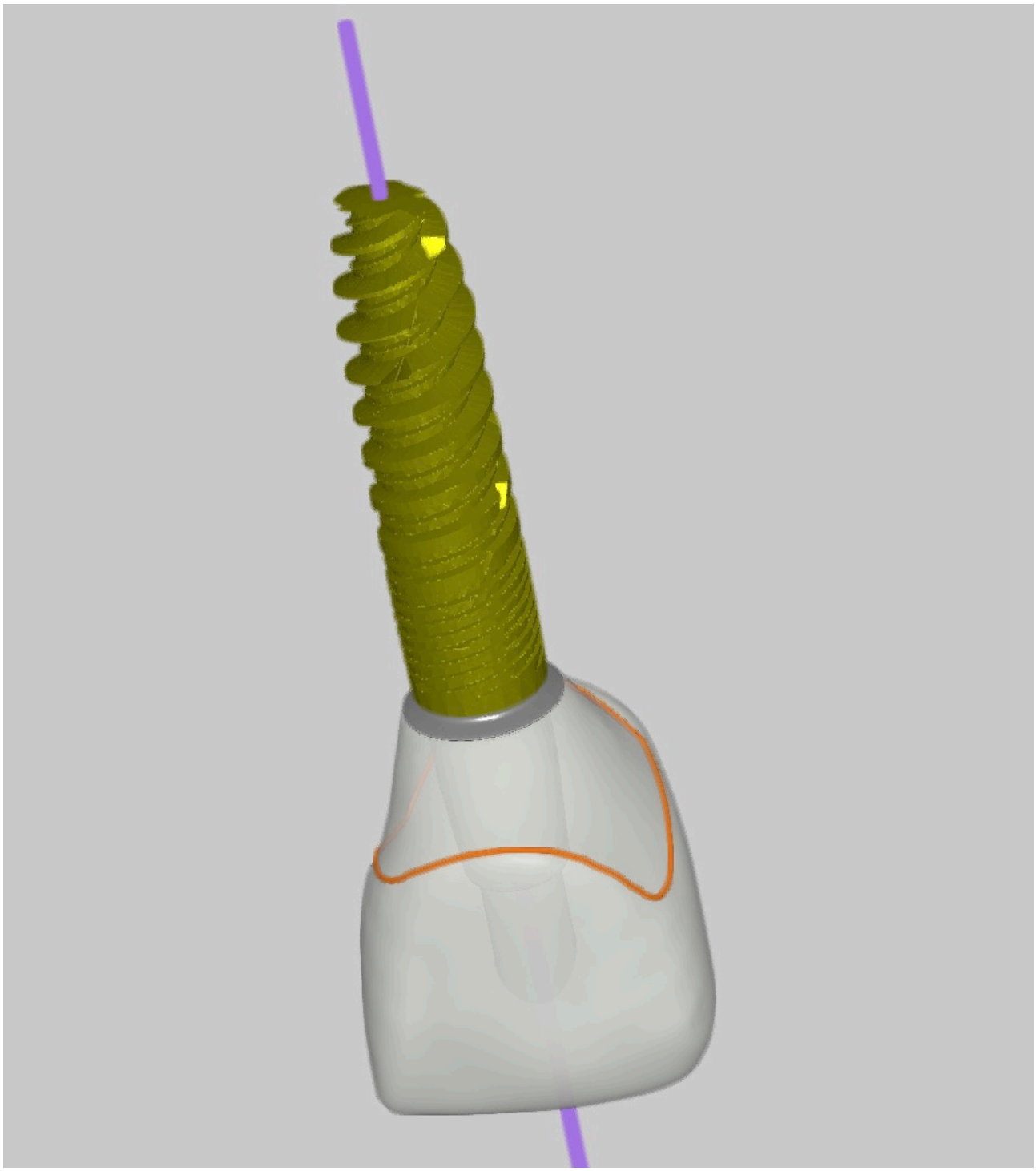
You can add different **abutment** types to implants (e.g., **scanbodies**, **Ti-base**, **temporary**).

Use the **Add** button at the bottom of the Object List (see Adding Implant Objects Manually below).

The software automatically selects a **compatible abutment** for the chosen implant. You can switch it via **Select from Library** in the Object List (filter by manufacturer and product line).

If you later **switch implants**, compatibility is **re-checked** automatically and the abutment is **updated** if needed.

Temporary Crowns

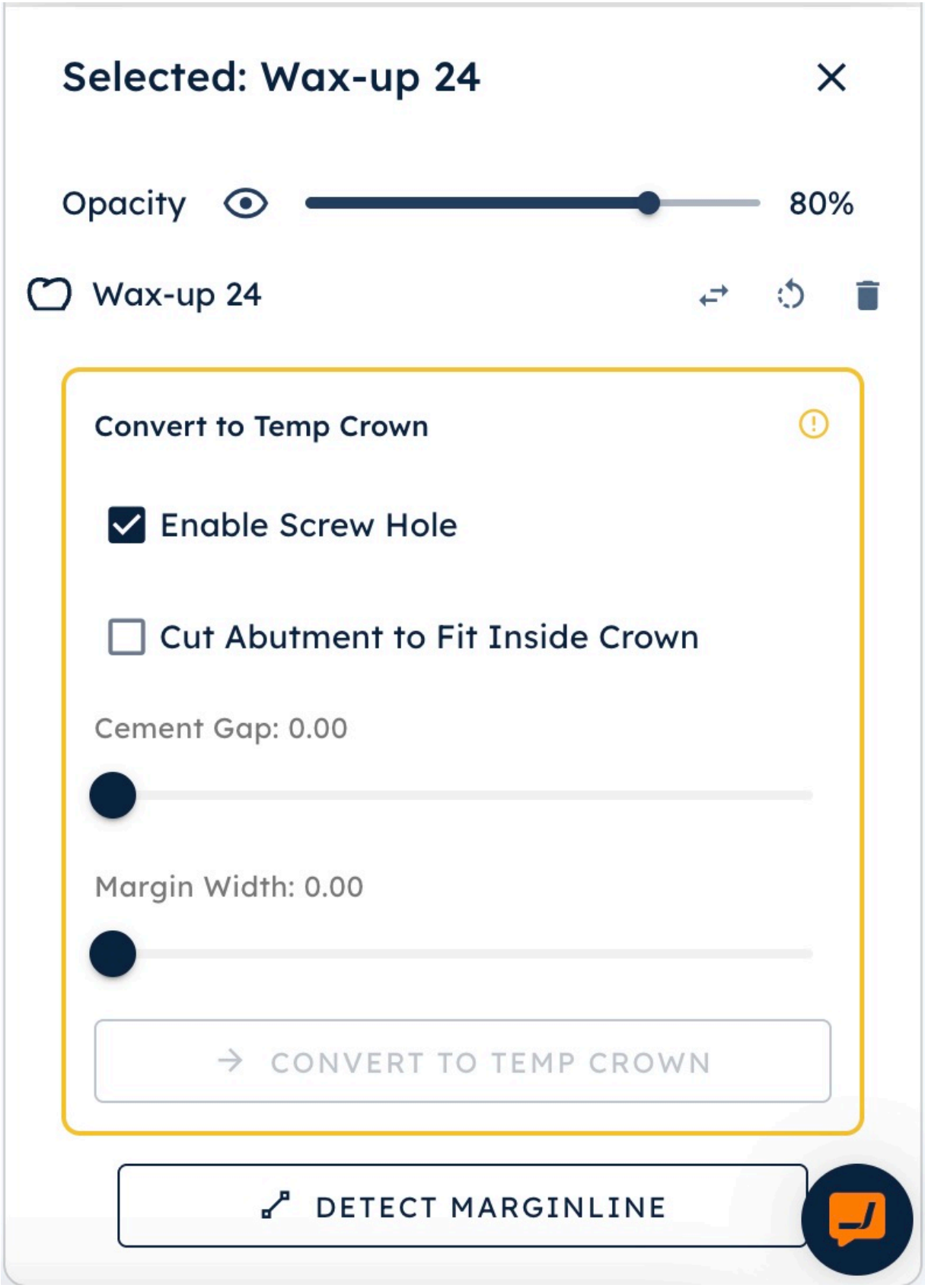


You can generate **temporary crowns** based on:

- the **virtual crown** (wax-up),
- the **abutment**, and
- a **margin line** defined on the IOS (required).

First, enable the feature in **Settings**. Then, when a wax-up is selected, additional tools and options appear:

- **Margin Line Tool** – edit the margin line by **moving, adding, or removing** control points.
- **Temporary Crown Generation Settings** (Object List):



- **Screw hole** – enable for screw-retained crowns
- **Cut abutment to fit inside crown**
- **Cement gap** – clearance between abutment and crown interior

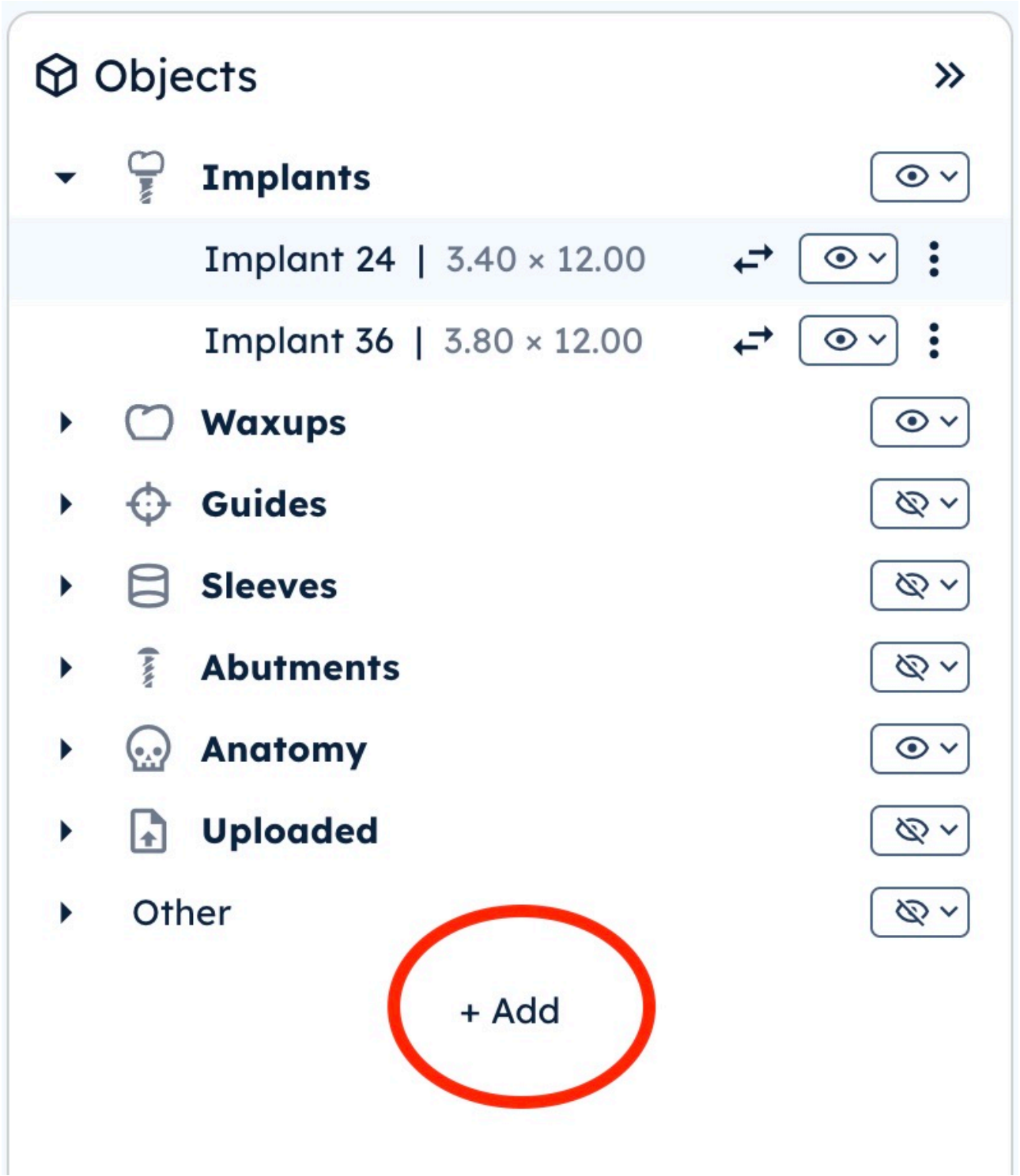
- **Margin width** – distance between the margin line and crown start

When ready, click **Convert to temp crown** to generate.

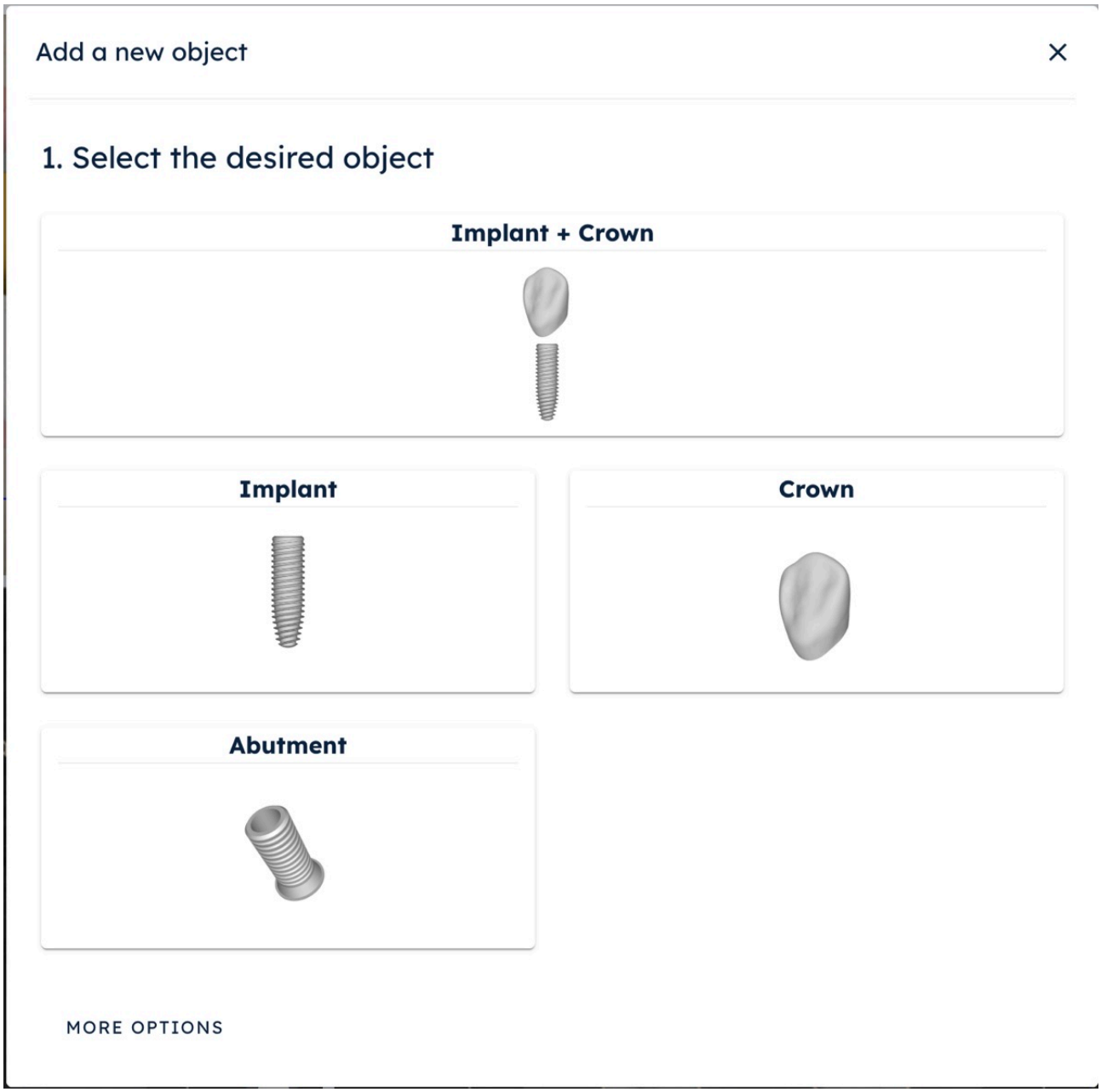
> **Note**
>
> Temporary crown generation isn't supported for all library abutments. If unsupported for your current abutment, a warning will appear.

Adding Implant Objects Manually

You can manually add implant objects using **Add** in the Object List.



Choose the **object type** (implant, crown, abutment, etc.):



Then select the **location** where you want to place it.

> **Note**
>
> You can't add an implant or crown where one already exists. Abutments can only be added where an implant already exists.

13.1.3.3 Surgical Guides

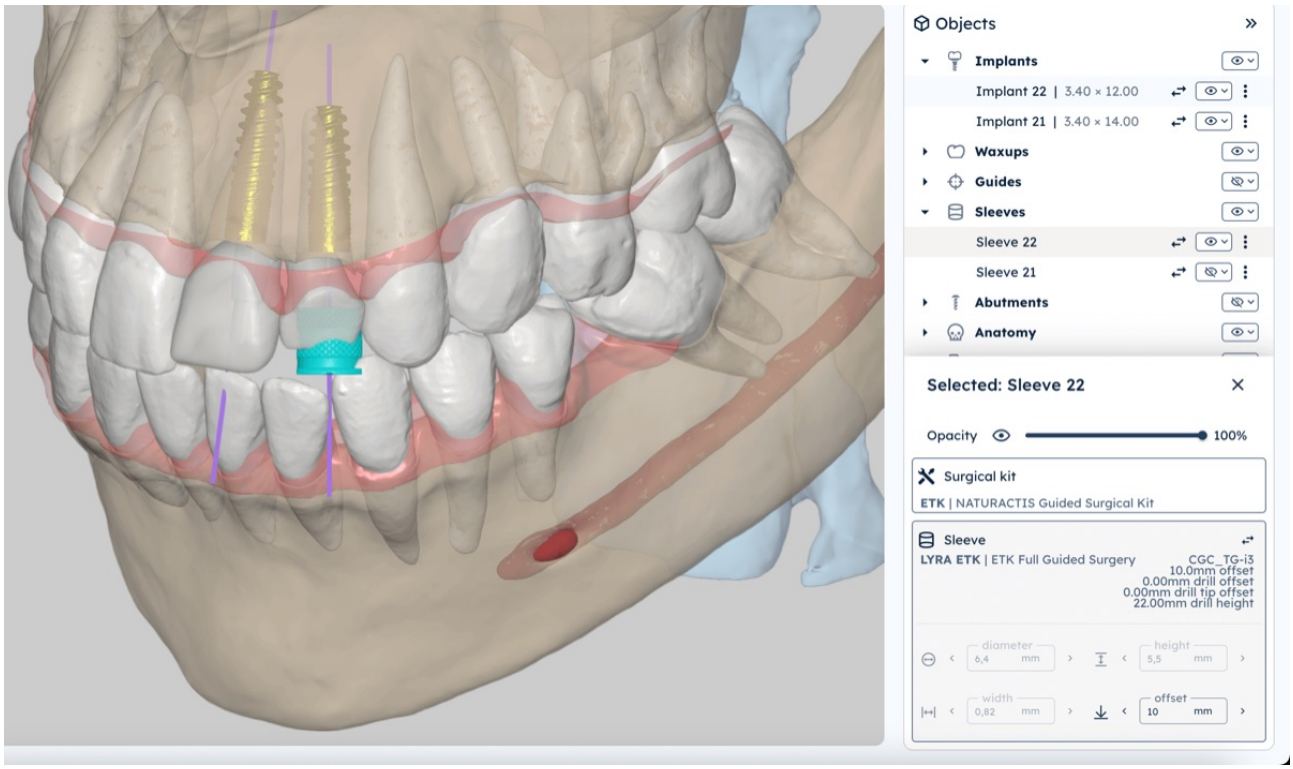
Surgical guides are generated directly from your implant plan.

They support both **automatic** and **manual** creation of **tooth-supported guides**, ensuring sleeves are precisely positioned relative to planned implants.

Guides are automatically **re-computed** when sleeve changes, maintaining consistency across the workflow.

You can configure guide design parameters — e.g., **guide thickness**, **design offset**.

Sleeves & Surgical Kits



The surgical guide is designed to position the **drilling sleeves** accurately relative to each implant. This positioning depends on three main factors: **the implant**, **the surgical kit**, and **the sleeve**.

Relu supports both **fully guided** and **pilot drilling** workflows.

The AI automatically proposes and positions the sleeves according to the parameters defined during order creation. You can manually modify the **sleeve type** and its **offset**.

Each sleeve remains linked to its corresponding implant; if the implant moves, the sleeve position updates automatically to maintain the correct offset.

When switching implants, the software verifies that the selected sleeve and offset are compatible with the new implant.

If they are not, the system will automatically replace them with a valid combination.

i Key terminology

- **Sleeve offset:** Distance between the top of the sleeve and the implant's bone level.
- **Drill offset:** Fixed offset added on top of the sleeve during surgery (e.g., due to a drill spoon).
- **Drill tip offset:** Additional drilling depth below the implant apex (distance between implant tip and osteotomy bottom).
- **Implant intra-osseous length:** Portion of the implant within the bone. This may differ from the total implant length (e.g., for tissue-level implants).
- **Drill length:** Total drill length = drill offset (if using a recommended kit–sleeve combination) + sleeve offset + implant intra-osseous length + drill tip offset (if applicable).

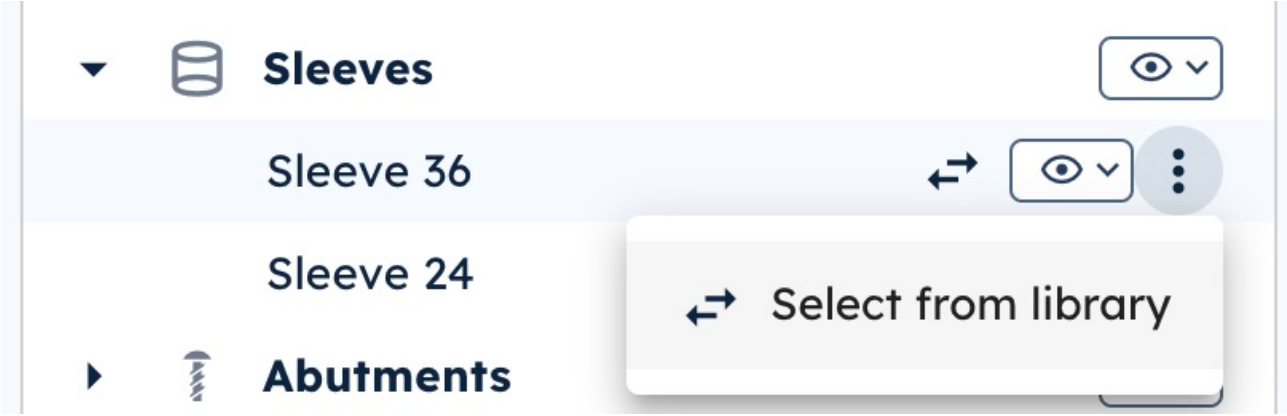
We recommend using **only manufacturer-approved surgical kit–sleeve combinations**. How-

ever, to provide flexibility in treatment planning, Relu allows you to select **non-recommended combinations**.

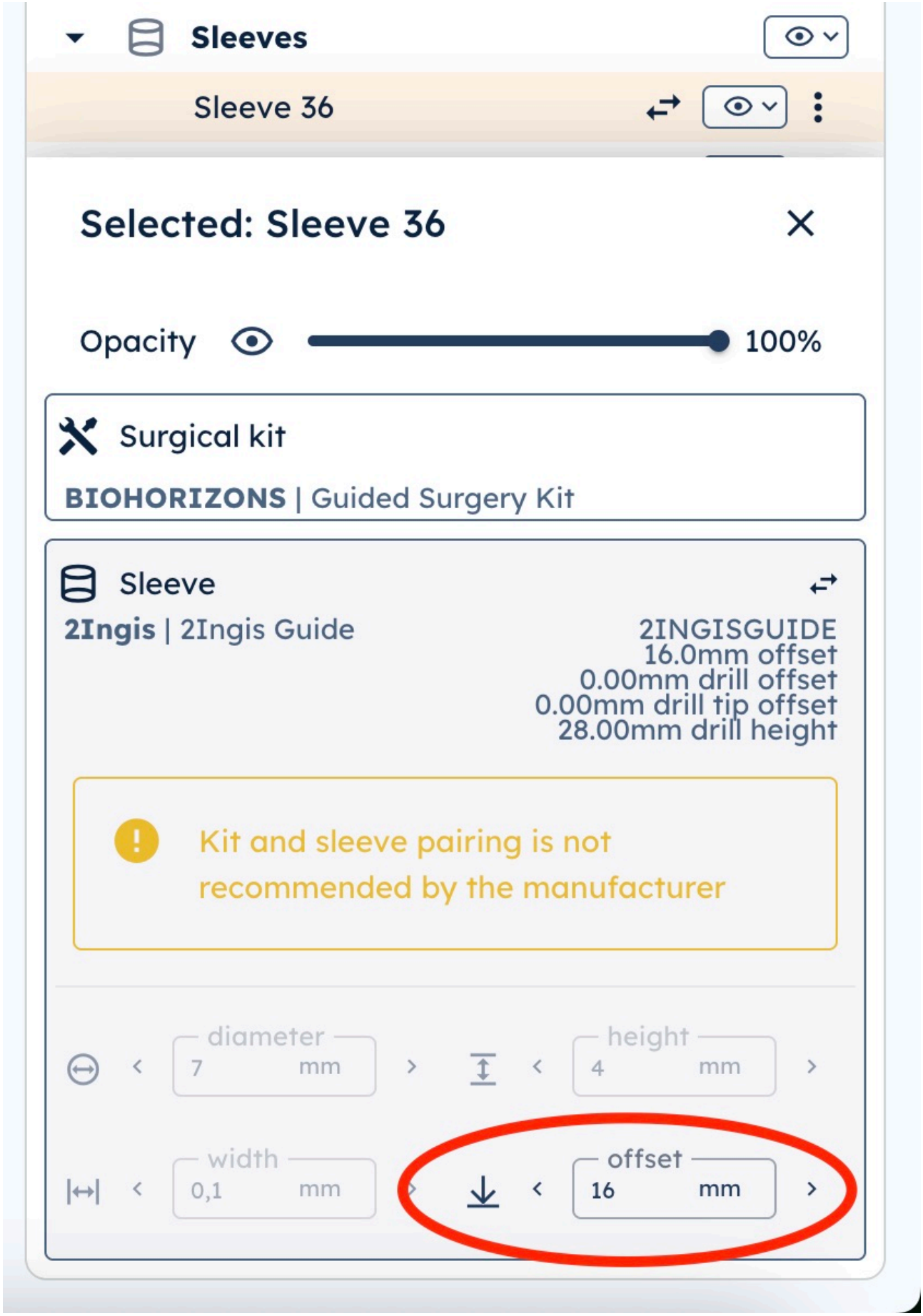
> **Warning**
>
> You are responsible for verifying the validity of any non-recommended kit–sleeve combinations, including the correct drill lengths, spoons, and offsets. Relu does **not** make assumptions for non-recommended combinations. For non-recommended combinations, the **drill offset** and **drill tip offset** are considered **0 mm**. Use non-recommended combinations **at your own risk**.

The software restricts sleeve offsets to the valid range defined by the selected kit–sleeve combination. You can exceed this range if desired; however, doing so may mean that the **longest drill in the kit will not reach full depth**, requiring part of the osteotomy to be performed **free-hand**.

You can change the sleeve library by selecting **"Select from Library"** in the **Object List**. In the selection dialog, you will see which sleeves are **recommended** for the chosen surgical kit and implant.



You can modify the sleeve offset by selecting the sleeve in the **Object List** and using the arrows next to the offset parameter. Detailed information about **drill length** and **surgical kit compatibility** is also displayed here.


Sleeves
Sleeve 36
Selected: Sleeve 36
Opacity
100%
Surgical kit
BIOHORIZONS | Guided Surgery Kit
Sleeve
2Ingis | 2Ingis Guide
2INGISGUIDE
16.0mm offset
0.00mm drill offset
0.00mm drill tip offset
28.00mm drill height
Kit and sleeve pairing is not recommended by the manufacturer
diameter
7
mm
height
4
mm
width
0,1
mm
offset
16
mm

Generic Surgical Kit & Sleeves

If your preferred surgical kit or sleeve library is not yet integrated in Relu, you can use **generic** kits and sleeves. The generic surgical kit defines drills ranging from **6.0 mm to 30.0 mm**, in **0.1 mm increments**. The generic sleeve allows **manual definition** of all sleeve parameters.

> ⚠ Warning
>
> You are responsible for confirming that any **generic surgical kit** or **user-defined sleeve** is **clinically appropriate** and **compliant with applicable regulations**. Relu is **not responsible** for the suitability, accuracy, or safety of user-defined or generic components.

Recommended vs Non-recommended Kit-Sleeve Combinations

- **Recommended combinations:** The software restricts sleeve offsets to those for which the **drill length** matches a valid drill from the kit and corresponds to a valid sleeve offset.
- **Non-recommended combinations:** The software calculates allowable offsets based on the drill lengths in the selected kit. **Drill offset** and **drill tip offset** are not considered, as the use of spoons or other accessories cannot be assumed. You are solely responsible for confirming that all computed offsets and drill lengths are appropriate for the clinical situation.

> ⚠ Warning
>
> Proper sleeve positioning relative to the implant is **critical to patient safety**. Incorrect sleeve height or offset can result in improper drilling depth or implant placement.

Surgical Guides (design)

An **initial surgical guide proposal** is automatically generated when opening the order. The guide is created based on the **sleeve types and positions**, as well as the **guide design parameters** (e.g., thickness, design offset) defined during order creation.

Guides are **hidden by default**; click the **eye icon** in the **Object List** to display them.

Relu surgical guides may look different from typical guides available on the market. Developed in collaboration with **key opinion leaders** and **dental laboratories**, these next-generation guides are engineered for improved **robustness and precision**. They have been **clinically validated** to ensure reliable performance. Each guide includes **viewing windows** to verify proper fit on the patient's dentition during surgery.

Whenever changes are made to sleeves — whether by moving an implant, adjusting the offset, or switching the sleeve library — the software automatically marks the corresponding guide as **requiring re-computation**. After a short delay without further modifications, the guide is **automatically regenerated**.

You can also manually adjust guide design parameters by selecting the guide in the **Object List** and triggering a **re-computation**. See Section for which parameters can be set.

By default, these values are taken from the **parameters set during order creation**.

> **Note**
>
> Guide re-computation runs in the cloud and can take a few minutes. You can safely close or navigate away from the page — the computation will continue in the background.

> **Note**
>
> Manual editing of guide windows, coverage areas, or the addition/removal of guide material is **not yet supported**. This functionality will be available in a future release. In the meantime, you may modify the guide externally by downloading the guide mesh, or design it in another CAD software using the **"Guide Design Kit"** export bundle.

> **Warning**
>
> The provided guide serves as a **pre-fabrication design aid.** The optimal parameters depend on multiple factors, including your **fabrication workflow & environment**, and **clinical preferences**. Always **validate and refine** these parameters for your specific workflow. Before surgery, verify the guide fit on the provided **intra-oral model**.

13.1.3.4 Validation & Approval

Before any outputs (such as surgical guides or exported STL files) can be generated, the **treatment plan must be approved** by an authorized user. Click **Approve Treatment** (top-right) and confirm authorization.

Once approved, the plan becomes **locked for editing**. Approval can be **reverted** if modifications are required.

Prior to approval, the user must review all aspects of the treatment plan, including:

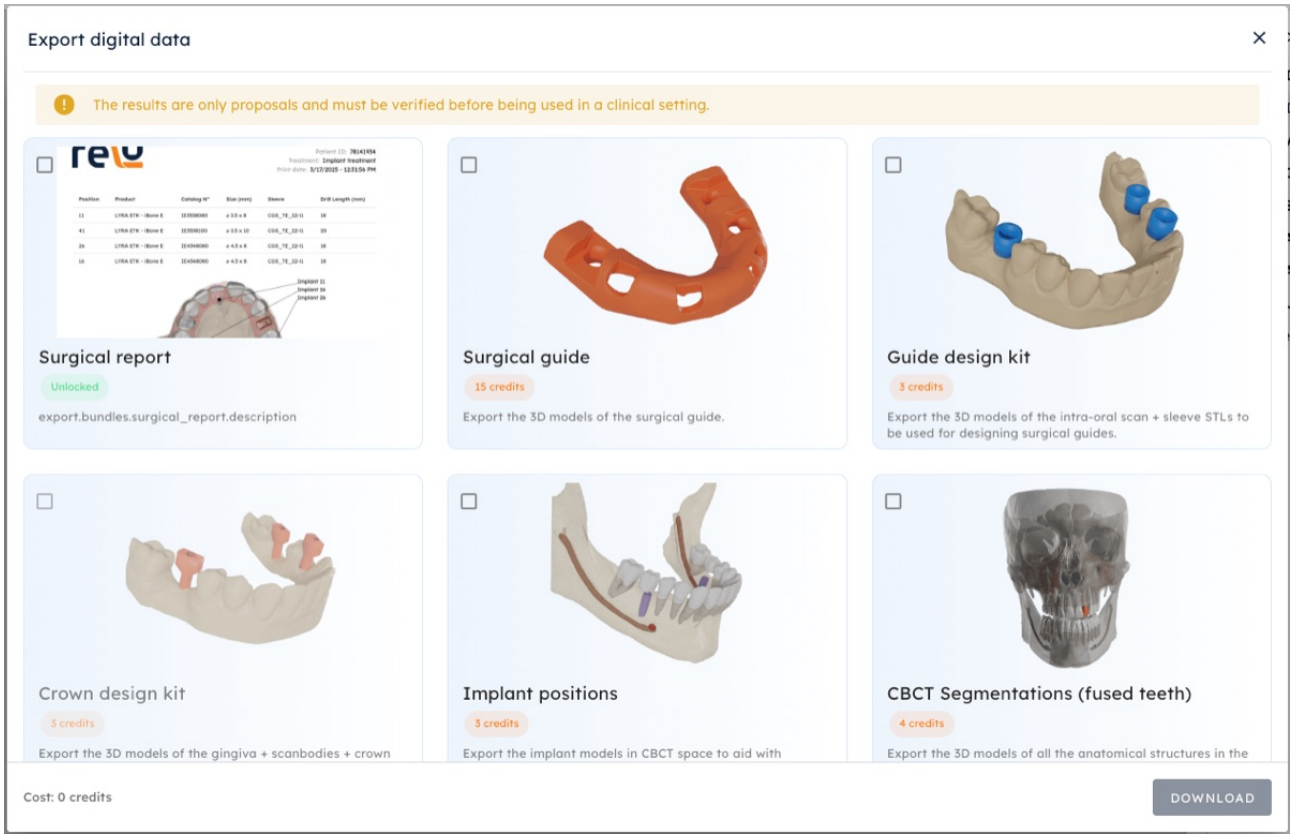
- Implant positions and angulations
- Sleeve–implant relationships
- Surgical guide design and fit
- Any other anatomical or mechanical constraints

In addition, all **software-generated warnings** must be reviewed. These warnings are automatically triggered by internal safety checks designed to help identify potential clinical or mechanical risks:

- **Distance to nerve canal**: alerts when the planned implant breaches or approaches the minimum safety margin to the mandibular nerve canal. The user must ensure compliance with clinical guidelines and patient-specific anatomy.
- **Distance between planned implants**: alerts when two planned implants are positioned closer than the minimum recommended inter-implant distance, which may compromise bone integrity or prosthetic design.
- **Non-recommended sleeve–implant combination**: Triggered when a sleeve is used with an implant for which the manufacturer does not provide official compatibility data. The system will allow planning flexibility, but the user must confirm that the combination is mechanically and clinically suitable.
- **Non-recommended surgical kit–sleeve combination**: alerts when a sleeve is paired with a surgical kit that does not match the manufacturer's recommended configuration. The user must verify the drill diameters, sleeve inner diameter, and physical compatibility before surgery.
- **Generic libraries**: alerts when **generic components** (implant, sleeve, or surgical kit) are used. Generic libraries allow custom-defined dimensions and are not linked to a real manufacturer. The user is responsible for confirming that these dimensions and mechanical characteristics correspond to the actual components used clinically.

13.1.4 Export

> **Warning**
>
> The trained professional is responsible for final validation of **fit, stability, and accuracy** of all exported outputs.



13.1.4.1 Prerequisites

- **Approval required:** To export an implant treatment plan, the plan must first be **approved**

by an authorized user. Click **Approve treatment** (top-right) and confirm authorization.
  - After approval, the plan is locked for editing. Approval can be **reverted** if changes are required.
- **Recomputation status:** If any change affects implant position/orientation/size, sleeve parameters, or guide design, the software **automatically recomputes** dependent elements (sleeves, guides, models).
  - While recomputation is active, **exports are disabled** and the UI indicates *Recomputation in progress*. Exports re-enable when status is **Up to date**.
- **Object availability:** Export options are only available when the **necessary objects exist** (e.g., the *Surgical guides* export appears only if at least one guide is present).

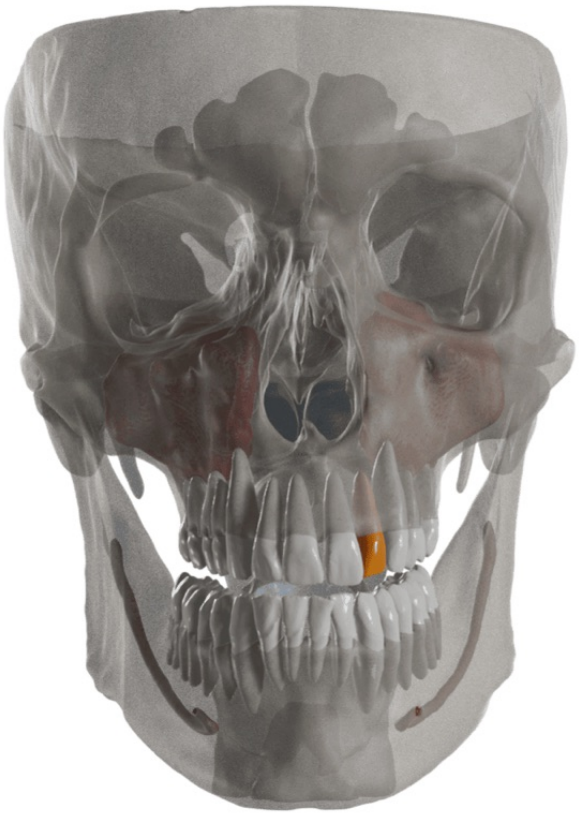
13.1.4.2 Export Bundles

> **Note**
>
> Unless otherwise noted, files are provided in STL format. Reports are provided as PDF.

As noted above, certain bundles might not be available depending on the objects that are present in the editor. For CBCT Segmentation & Alignment orders, only the Segmentations bundle is available.

Some exports require **credits** to unlock. You pay **once per export type per case**; after unlocking you may re-download the same export type as often as needed.

Segmentations

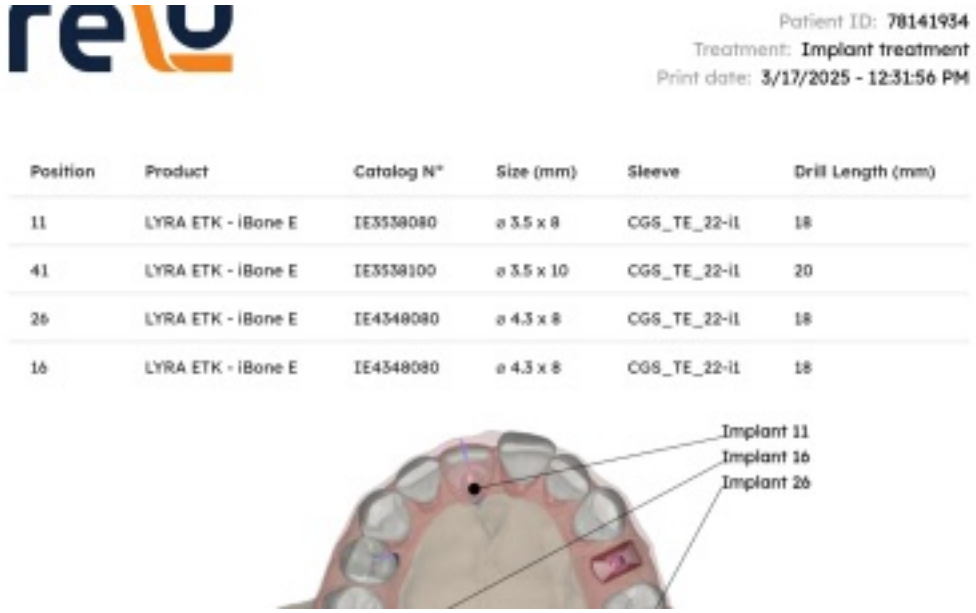


Includes STLs of automatically segmented anatomical structures:

- **Teeth**
- **Bone** (skull & maxillary complex)

- **Mandibular canals (nerves)**
- **Maxillary sinuses**
- ...

Surgical reports



Exports **two PDFs**:

1. **Surgical report:** Images of the surgical plan plus detailed descriptions of all implants (library, size, position) to support surgery and parts ordering.
2. **Patient passport:** Implant identifiers and space to attach manufacturer stickers for long-term traceability.

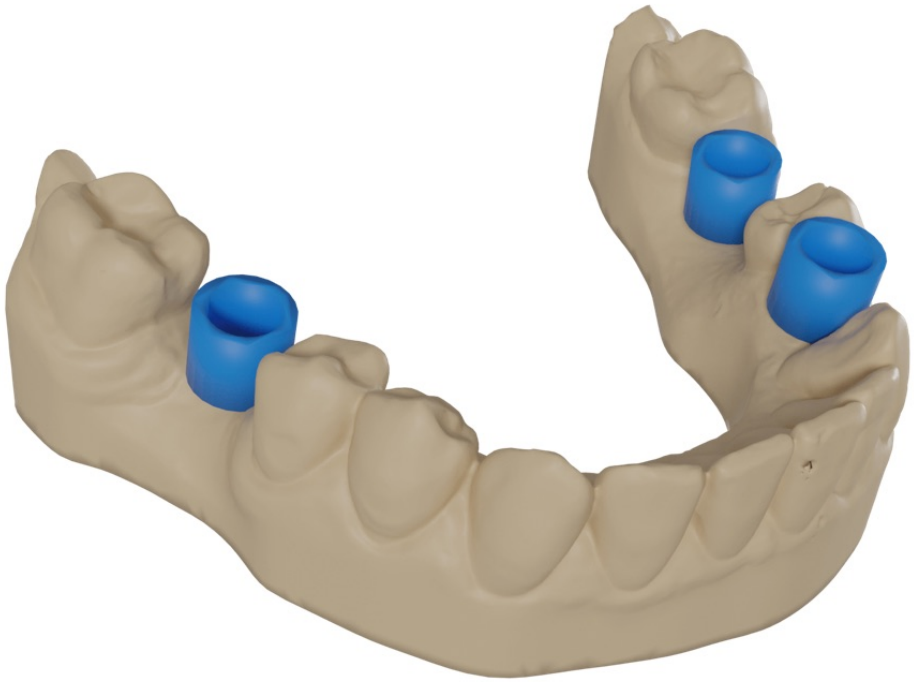
Surgical guides

Exports 3D design STLs of:

1. **Wax-ups**
2. **Surgical guides** (tooth-supported)
3. **Guide models** (IOS with base; relevant teeth virtually extracted) for **fit verification** of the guide

> **Note**
>
> Surgical guide exports are only available when the guide is Up to date. If re-computation is required, the export is blocked until completed.

Guide design kit



For users who wish to design their own guide in third-party software while preserving planned geometry. Exports:

1. **Sleeve placeholders** (cylinders matching sleeve dimensions; originals are not distributed for IP reasons)
2. **Guide models** (IOS with base; relevant teeth virtually extracted)

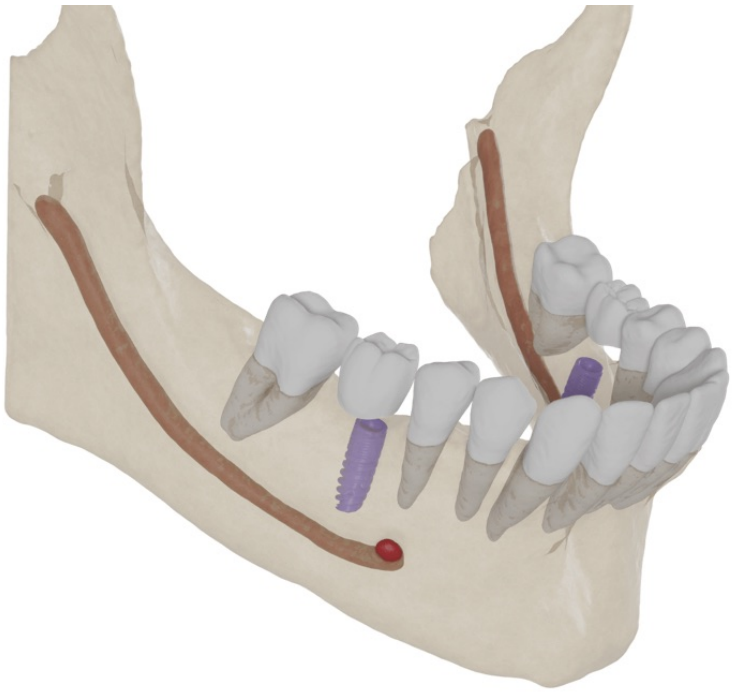
Crown design kit

For temporary/final restoration design in third-party software. Exports:

1. **Wax-ups**
2. **Scanbodies**
3. **Emergence profile models** (IOS with relevant teeth virtually extracted, preserving emergence profiles)
4. **Guide models** (IOS with base; relevant teeth virtually extracted)

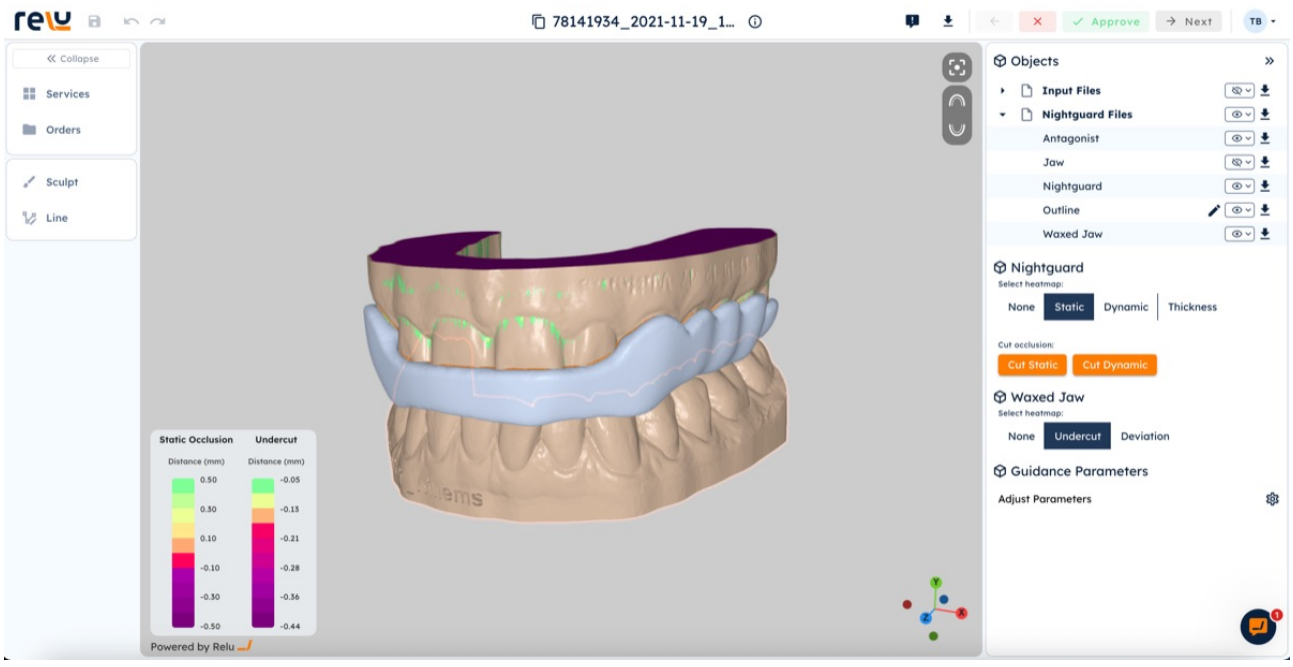
> **Note**
>
> Availability depends on implant libraries with integrated scanbodies manufacturers.

Implant positions



Exports **implant geometries in CBCT space** as STLs (cylindrical placeholders with the same key dimensions, not OEM models).

13.2 Review & Adjust Mouthguard Results



13.2.1 Overview

After the mouthguard design is generated, the user reviews and refines the result in the Relu® Medical Editor. This page covers the **mouthguard-specific** review and editing tools. For general viewer controls (navigation, hiding/showing objects, downloading files, etc.), see Section .

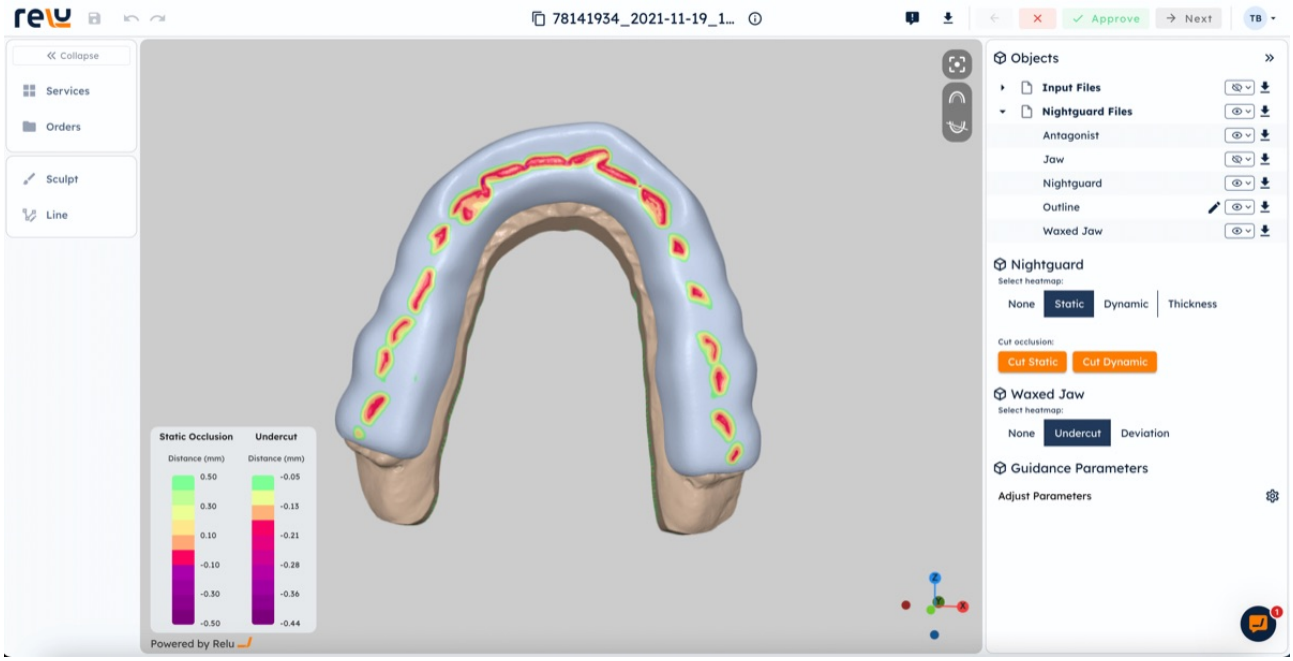
13.2.2 Objects Panel — Mouthguard Layers

The Objects panel (right side) lists the following layers under **mouthguard Files**:

Layer	Description
Antagonist	The opposing jaw geometry used for occlusion analysis.
Jaw	The jaw scan on which the mouthguard is designed.
Outline	The boundary line defining the extent of mouthguard coverage. Editable via the Line tool.
Mouthguard	The generated mouthguard geometry.
Waxed Jaw	The waxed-up jaw model used as the basis for mouthguard generation.

Each layer can be toggled visible/hidden and downloaded individually using the eye and download icons.

13.2.3 Heatmap Visualizations



The viewer provides color-coded heatmap overlays to help assess design quality. Heatmaps are available for two objects: the **Mouthguard** and the **Waxed Jaw**.

Mouthguard Heatmaps

Select a heatmap under the **Mouthguard** section in the right panel:

Heatmap	What it shows
None	No heatmap — shows the plain mouthguard geometry.

Heatmap	What it shows
Static	Distance between the mouthguard surface and the opposing jaw in static occlusion. Warm/red colors indicate areas closer than the target; green indicates areas at or above the target distance.
Dynamic	Distance map based on simulated dynamic jaw movements (protrusion, laterotrusion).
Thickness	Material thickness of the mouthguard.

Waxed Jaw Heatmaps

Select a heatmap under the **Waxed Jaw** section:

Heatmap	What it shows
None	No heatmap — shows the plain waxed jaw geometry.
Undercut	Visualizes undercut depth relative to the insertion direction. Helps assess retention characteristics.
Deviation	Shows deviation between the waxed jaw and the original scan geometry.

Reading the Color Legend

The color legend is displayed in the bottom-left corner of the viewer. It shows two scales:

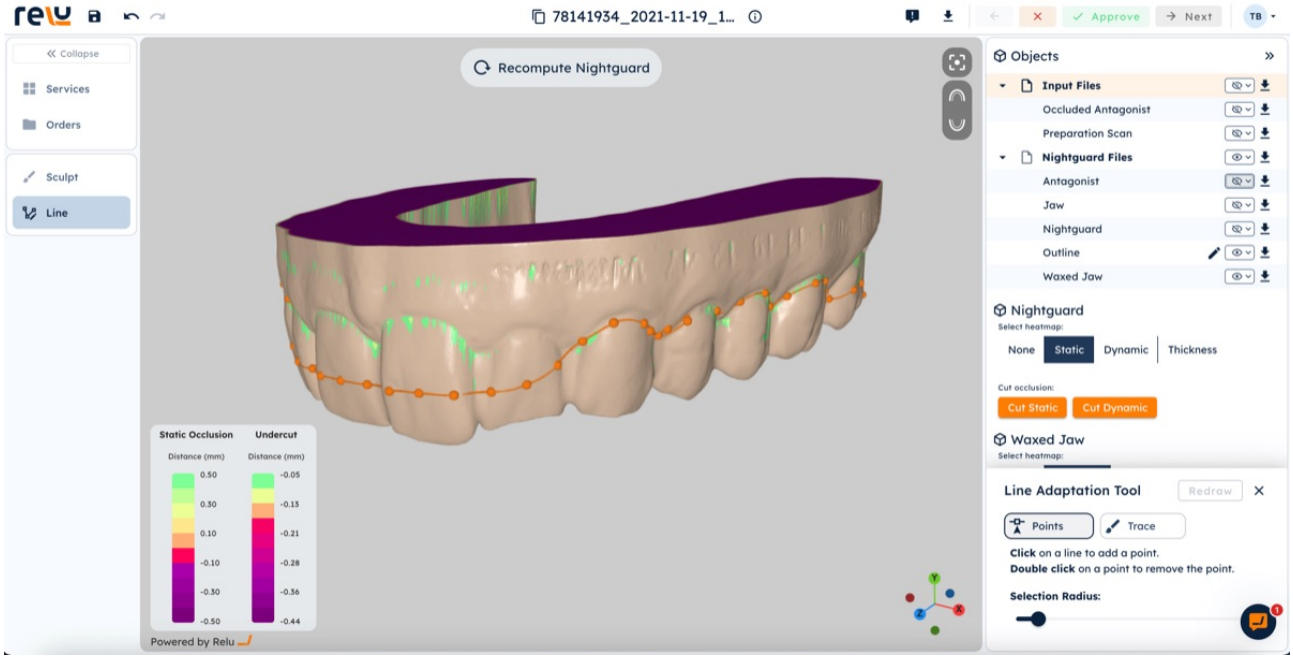
- **Static Occlusion**
- **Undercut**

13.2.4 Cut Occlusion

Two buttons in the mouthguard section allow automated removal of occlusal interferences:

Action	Description
Cut Static	Removes mouthguard material that interferes with the opposing jaw in static occlusion.
Cut Dynamic	Removes mouthguard material that interferes during simulated dynamic jaw movements.

13.2.5 Outline Editing — Line Adaptation Tool



The **Line** tool (left sidebar) opens the **Line Adaptation Tool**, which allows editing of the mouthguard outline — the boundary that defines where the mouthguard covers the teeth.

Points Mode

The default mode. The outline is displayed with orange control points along its path.

- **Click** on the outline to add a new control point.
- **Double-click** on an existing point to remove it.
- **Drag** a point to reposition it and reshape the outline.
- **Selection Radius** — adjusts how close your click needs to be to the line to register.

Trace Mode

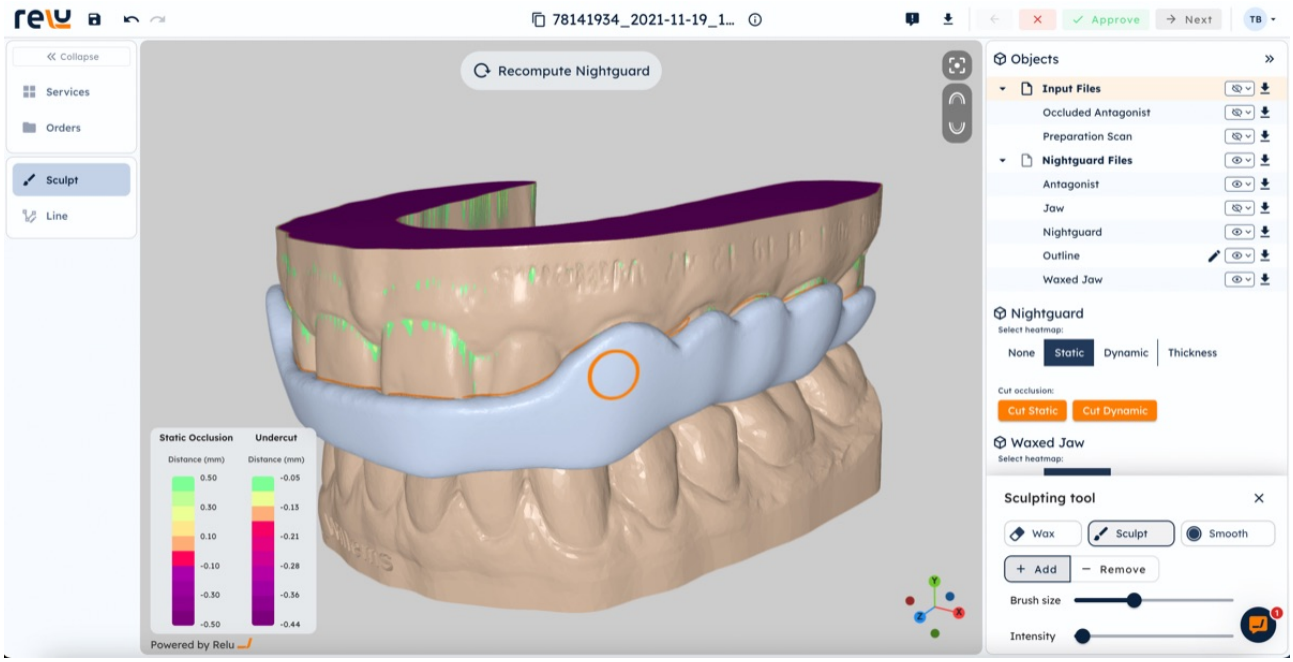
Allows freehand redrawing of a section of the outline by tracing a new path directly on the model.

Redraw

The **Redraw** button allows you to start from scratch to draw the outline.

> **Note**
>
> Once you're done with adapting the outline of the mouthguard, you need to trigger a recomputation of the mesh by using the "Recompute" button.

13.2.6 Sculpting Tool



The **Sculpt** tool (left sidebar) opens the **Sculpting Tool**, which allows direct manipulation of the mouthguard surface geometry.

Modes

Mode	Description
Wax	Adds or removes material using a wax-like deposition behavior. Suitable for building up or trimming areas.
Sculpt	Pushes or pulls the surface along its normal direction. Useful for targeted adjustments.
Smooth	Smooths the surface under the brush, reducing irregularities.

Direction

- **Add** — applies the tool in the additive direction (builds up / pushes outward).
- **Remove** — applies the tool in the subtractive direction (removes material / pushes inward).

Brush Settings

- **Brush size** — controls the diameter of the sculpting brush.
- **Intensity** — controls the strength of each stroke.

The sculpting cursor is shown as an orange circle on the model surface. Adjust brush size and intensity to achieve fine or broad modifications.

13.2.7 Guidance Parameters

The **Guidance Parameters** section (visible in the right panel when scrolled down) allows adjustment of occlusal guidance settings directly in the review view. Click **Adjust Parameters** to modify guidance angles and ranges.

13.2.8 Approval & Export

Once review and adjustments are complete:

1. Verify the design using the available heatmaps (static occlusion, thickness, undercut).
2. Click **Approve** (green button, top-right) to confirm the design.
3. The approved mouthguard design is exported as a digital file (e.g., STL) for downstream fabrication.

If the design is not satisfactory, click the **X** button to reject and return to the order. You can ask for a refund.

13.3 Review & Adjust Custom Tray Results

13.3.1 Overview

After the custom tray design is generated, the user reviews and refines the result in the Relu® Medical Editor. This page covers the **custom tray-specific** review and editing tools. For general viewer controls (navigation, hiding/showing objects, downloading files, etc.), see Section . For details on the **Sculpting Tool** and **Line Adaptation Tool**, which work the same way across services, see Section .

13.3.2 Objects Panel — Custom Tray Layers

The Objects panel (right side) lists the following layers under **Output Files**:

Layer	Description
Upper Custom Tray	The generated custom tray for the upper jaw (if uploaded).
Lower Custom Tray	The generated custom tray for the lower jaw (if uploaded).

Each layer can be toggled visible/hidden and downloaded individually using the eye and download icons.

13.3.3 Editing Tools

The custom tray editor provides three tools in the left sidebar:

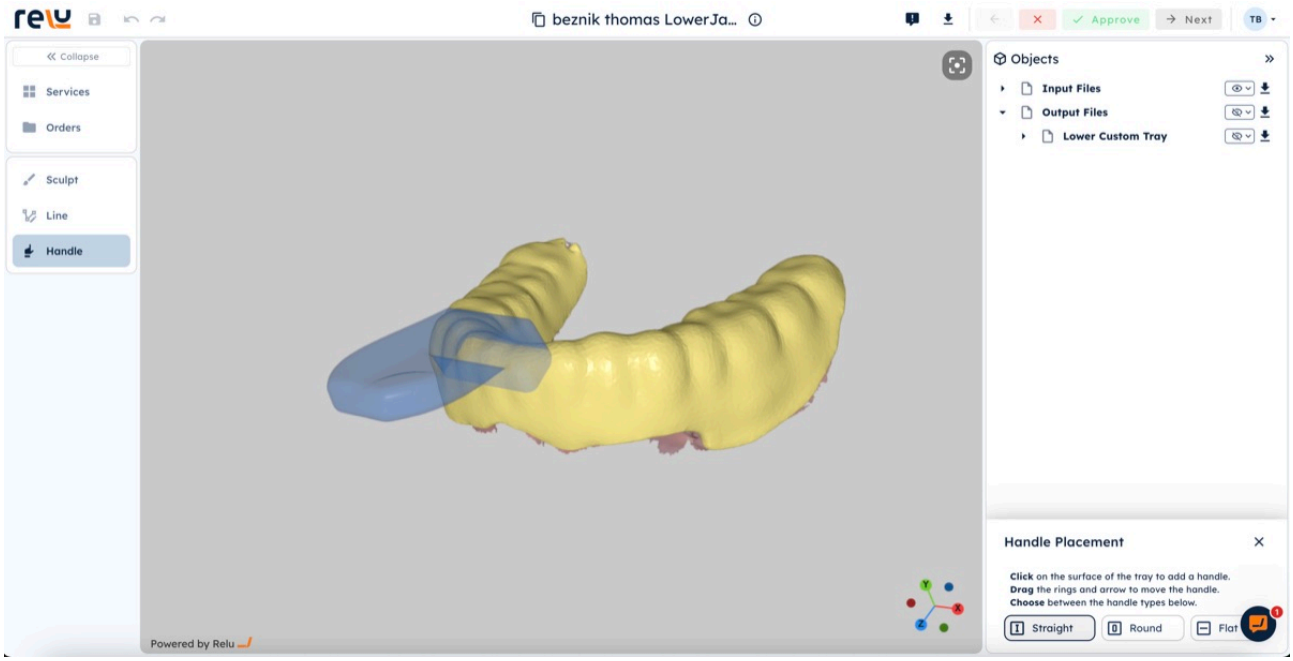
Sculpt

Opens the **Sculpting Tool** for direct manipulation of the tray surface. Works identically to the mouthguard sculpting tool — see Section for details on modes (Wax, Sculpt, Smooth), direction (Add/Remove), and brush settings.

Line

Opens the **Line Adaptation Tool** for editing the tray outline — the boundary that defines the extent of tray coverage. Works identically to the mouthguard line tool — see Section for details on Points mode, Trace mode, and Redraw.

Handle



Opens the **Handle Placement** tool, which is specific to the custom tray service. This tool allows the user to position and configure the tray handle directly on the 3D model.

- **Click** on the surface of the tray to place a handle.
- **Drag** the rings and arrow to reposition and reorient the handle.
- **Choose** between handle types:

Type	Description
Straight	A straight handle extending from the tray surface.
Round	A rounded handle shape.
Flat	A flat handle shape.

13.3.4 Approval & Export

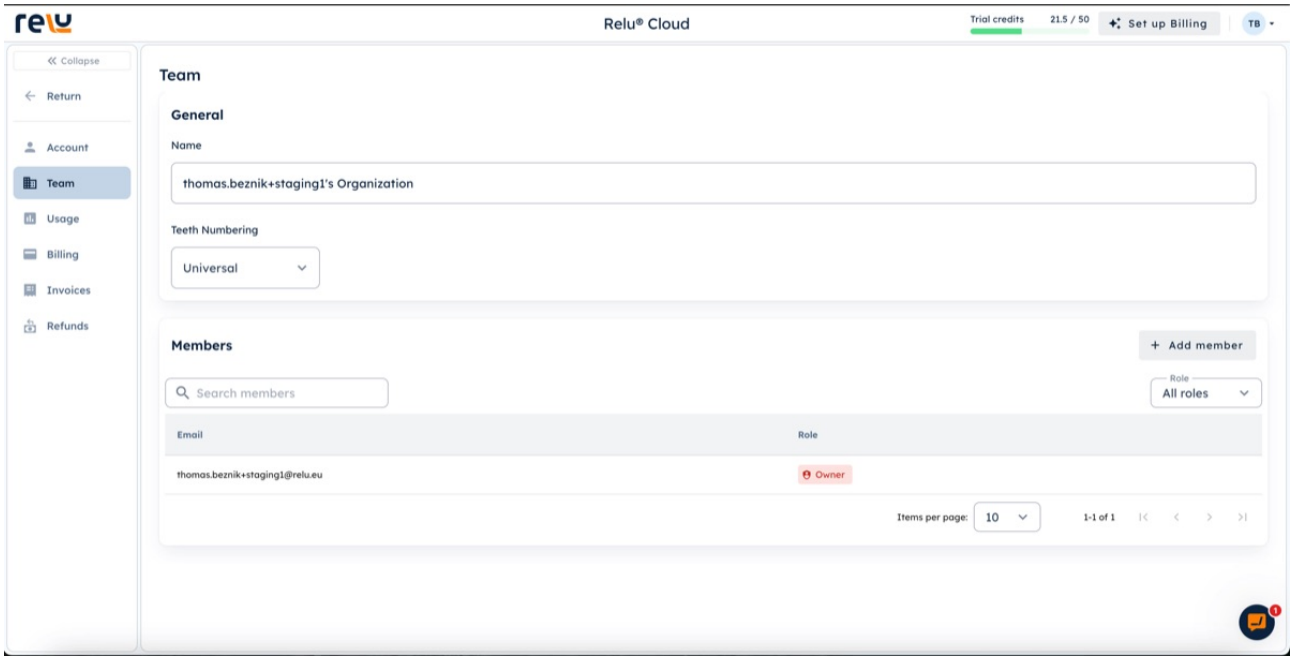
Once review and adjustments are complete:

1. Click **Approve** (green button, top-right) to confirm the design.
2. The approved custom tray design is exported as a digital file (e.g., STL) for downstream fabrication.

If the design is not satisfactory, click the **X** button to reject and return to the order.

14 Admins, Team & billing management

The **Team** settings page allows the team owner to manage company details, and team access. The **Billing** page allows the team owner to manage the billing information. This section is especially useful for labs or clinics working collaboratively under one account.



14.1 Team overview

- **Team Name**: View or edit the team/company name using the pencil icon.
- **Members**: View all current users. Click **+ ADD MEMBER** to invite new team members by email. Members can submit cases, view shared orders, and collaborate in real-time.

> **Note**
>
> The Team Owner is responsible for payment of all usage generated by members within the team.

14.2 Billing overview

- **Subscription details**: Shows if a subscription is active or not, with some information
- **Payment information**: Show the current payment method, and allows to change it
- **Billing information**: Complete your company details for invoicing:
  - Company name
  - Tax/VAT number
  - Address (street, postal code, city, region, country)

  Note: Required for legal and tax compliance.
- **Billing Contacts**: Optional: add dedicated billing personnel for payment communications.

14.3 Admin access

Admins have full control and can:

- View all team orders
- Manage user roles and permissions
- Enable/disable billing options
- Use **"Assume User"** to support colleagues within the platform

14.4 Access mechanisms

Relu offers multiple ways to access and interact with its platform, depending on your workflow and technical setup.

14.4.1 Web Application (Standard access – recommended for most users)

The majority of users interact with Relu via the secure, browser-based web app at cloud.relu.ai

- No installation required
- Access full design workflows, case management, and 3D viewer
- Compatible with modern desktop browsers

This is the preferred method for clinicians, labs, and teams looking for fast onboarding and easy cloud-based collaboration.

14.4.2 API Access (Advanced – For system integrations)

API access is available for advanced users and teams who wish to integrate Relu's automation modules into their own digital workflows or local applications. This enables seamless automation of tasks such as file submission, result retrieval, and credit tracking directly within proprietary systems.

To get started:

- Retrieve your **API token** from your **Connection** settings once access has been enabled
- Each automation module ("service") is identified by a unique **SERVICE ID**, available in the service menu
- Supports secure, automated communication between your system and Relu

> **Note**
>
> API access and local application integrations must first be enabled by a Relu Administrator. Please contact the Relu sales or support team to request activation and discuss integration options.

You can view the technical documentation here: https://api.automate.relu.ai/redoc

15 Payments & billing

Relu operates on a transparent **pay-per-use credit system**, with all billing handled securely via **Paddle**.

15.1 Credit system overview

Credits are the unit used to trigger and export actions on the Relu platform. You are **only charged when a case is submitted** for processing.

If the output is not clinically usable, you may request a refund.

> **Note**
>
> For full pricing details, including how many credits are required per recipe, please refer to our Pricing List https://relu.ai/pricing-list. See **17.4 Feedback & Improvements** for how to request a refund for any case that lacks clinical value.

15.2 Monthly billing & invoicing

There is **no need to purchase credits in advance**. Instead, Relu uses **monthly post-paid billing**:

1. Your team uses credits throughout the month.
2. At the beginning of the following month, you'll receive an invoice summarizing your usage.
3. Payments are processed securely through **Paddle**, our payment provider.

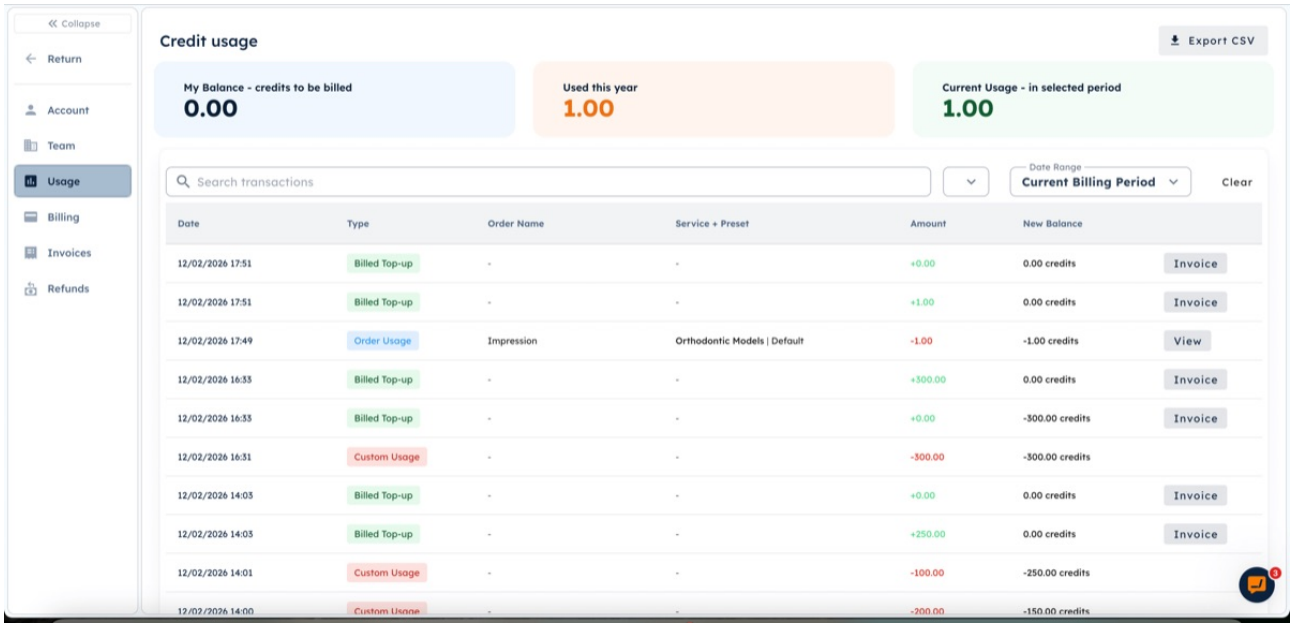
Relu supports a variety of payment methods including credit cards, bank transfer on request or apple pay. Once payment is completed, Paddle will automatically send a confirmation and a downloadable invoice for your records.

> **Note**
>
> You can track usage and credit consumption at any time by clicking your account name in the upper right corner and navigating to the **Usage** settings tab.

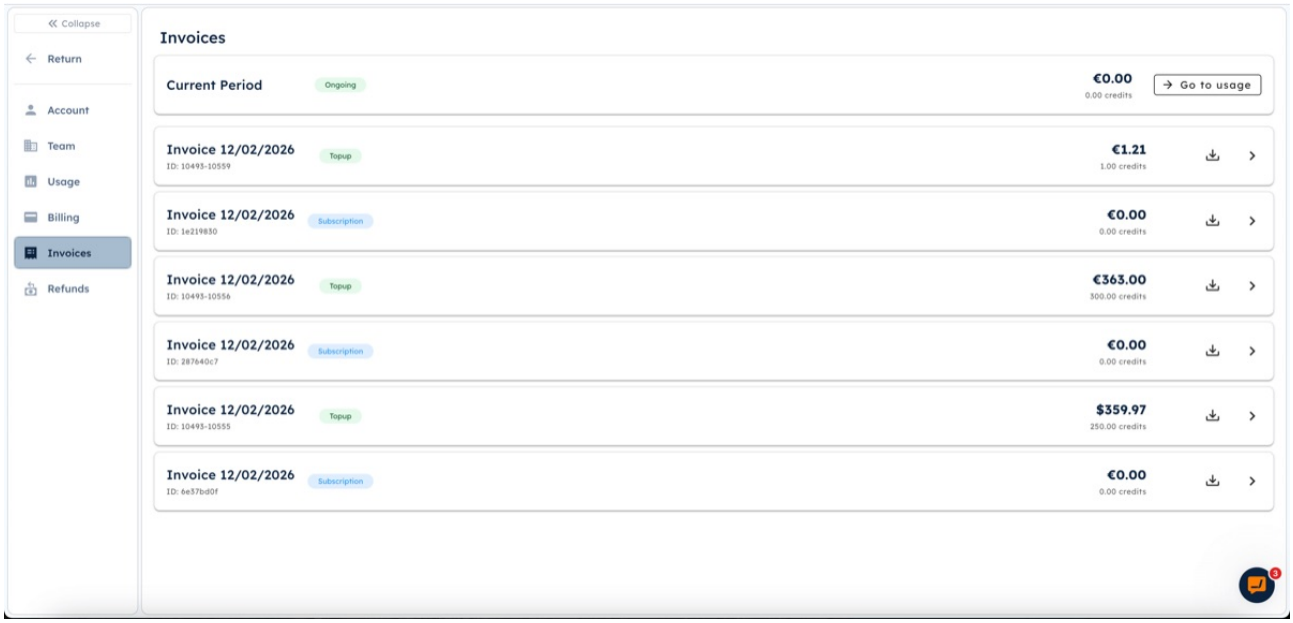
15.3 Billing setup & invoicing

To ensure accurate invoicing and streamlined payment processing, you can update your billing details and VAT number directly within the **Billing Settings** section of the platform. You also have the option to designate a specific **billing contact** to handle payment-related communications. For larger B2B accounts or organizations that require alternative payment arrangements, **invoice-based payments** can be requested by reaching out to sales.

15.4 Usage & invoices



To review your credit usage, navigate to the **Usage** settings page: you will find the cost incurred by each order, refunds, and credit settlements at the end of each month.



In the **Invoices** settings page, you can access a complete history of past transactions along with detailed payment summaries and downloadable invoices.

16 Logging out & session security

Relu uses **Auth0** to ensure secure authentication and user session management.

16.1 Logging Out

To log out of your account, simply click your **profile icon** in the top-right corner of the platform and select **"Log out"** from the dropdown menu. This ensures your session is securely closed, especially when using shared or public devices.

16.2 Session Timeout

To help protect your account, Relu sessions automatically expire after **24 hours** of inactivity. If you return to the platform after a prolonged pause, you may be prompted to log in again to continue working. For added security, especially when using shared or public devices, it is recommended to **log out manually** at the end of each session.

16.3 Cybersecurity Recommendations for the User

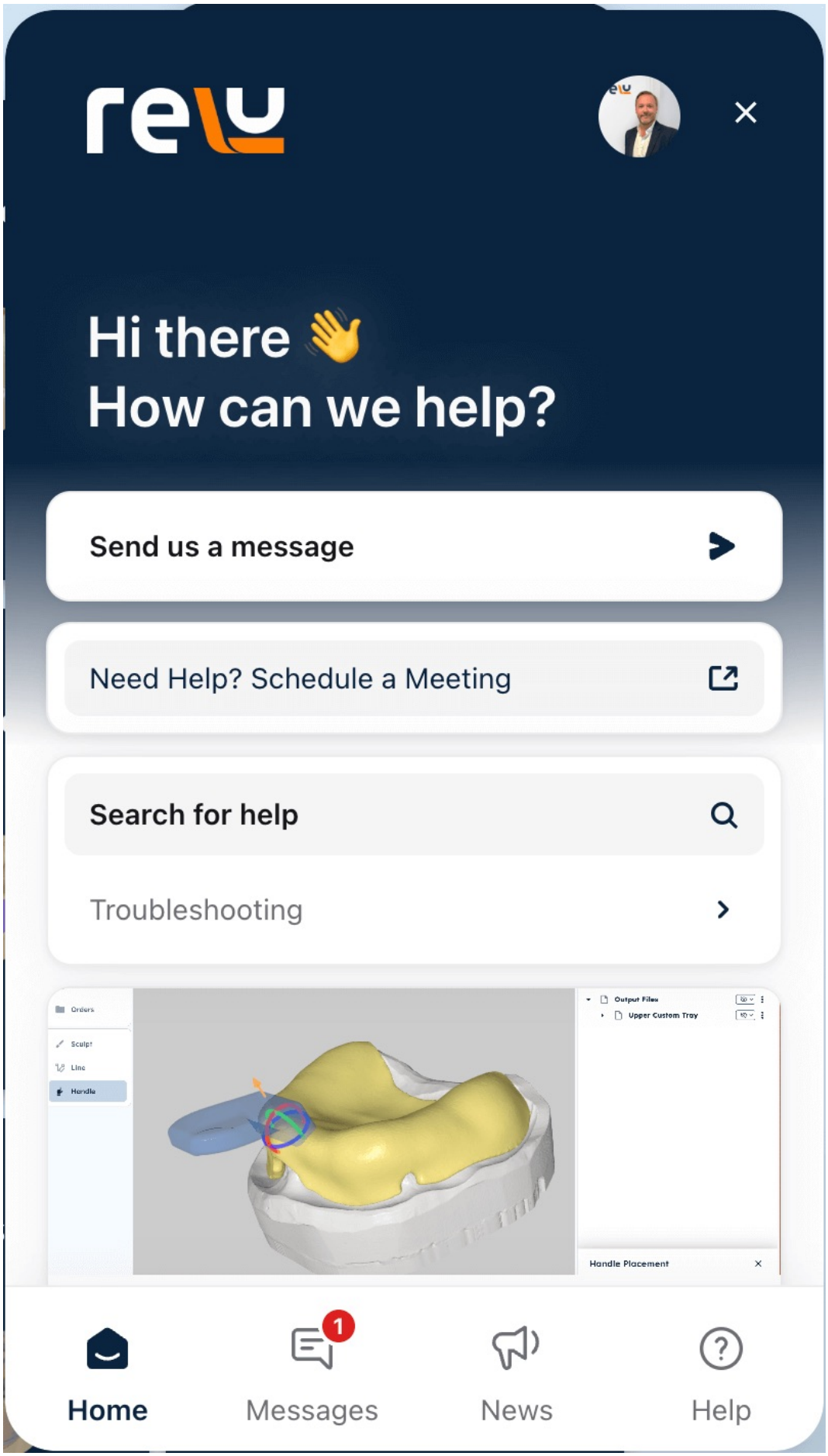
To maintain the highest level of security for your sensitive medical data, it is crucial to follow several cybersecurity best practices.

Create a strong, unique password for your account by combining letters, numbers, and special characters, and regularly update this password to prevent unauthorized access. Additionally, it is advisable to avoid using the application over public Wi-Fi networks, as they may lack sufficient security, posing a risk to your personal information. Also, remain alert to phishing attempts: never share your login credentials via email or over the phone, and ensure that you are always logging in through the official website of our medical application.

17 Help & Customer Support

Need help? Relu provides multiple support channels to assist you effectively.

17.1 Live chat via Intercom



For immediate assistance, you can use the live chat feature available within the Relu platform. Simply click the **chat icon** located in the bottom-right corner of your screen. Relu's virtual assistant will guide you through common questions or issues, and if needed, you can request to be connected to a human support agent during regular business hours.

17.2 Knowledge base

Browse articles, how-to guides, and troubleshooting steps at:

- help.relu.ai
- Also accessible through the platform's chat widget

17.3 Direct Email Support

If you are unable to resolve your issue through the chat widget or the online documentation, you can contact our support team directly via email at **support@relu.ai**. Be sure to include the email address associated with your Relu account, the case ID (if applicable), and a brief description of the problem you're experiencing. This will help our team respond more quickly and accurately to your request.

17.4 Feedback & Improvements

Your feedback plays a vital role in improving the Relu platform. If an output does not meet your expectations, you can use the **"Feedback"** option directly within the 3D Viewer to flag the issue and request a refund if needed. Alternatively, you're welcome to share suggestions or ideas for improvement via the chat widget or by emailing our support team through support@relu.ai.

17.5 Patient Data Storage

The Relu® Cloud software follows the HIPAA and GDPR guidelines for data protection. Patient data is anonymised, and encrypted both at rest and in-transit.

You can find more information about our privacy & security controls in our Trust Center, and more information about the protection of your privacy and personal data in our Privacy Policy.

17.6 Disposal

If the company decides the Relu® Cloud product is discontinued, this will be announced via e-mail 6 months in advance. The user must migrate all of its data from the Relu® Cloud.

All data is retained for a period of 10 years after the product is withdrawn from the market. After this date, all data is deleted according to industry standards/ privacy regulations.

17.7 Incident Reporting

If you become aware of an information security event or incident, possible incident, imminent incident, unauthorized access, policy violation, security weakness, or suspicious activity, then please immediately report the information using one of the following communication channels:

- Email privacy@relu.eu information or reports about the event or incident

Reporters shall act as a good witness and behave as if they are reporting a crime. Reports must include specific details about what has been observed or discovered.

Any serious incident related to the software must be reported without undue delay to Relu BV and to the competent authority of the Member State in which the incident occurred. The contact details of the

competent authority can be found via the following URL: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human.

17.8 Explanation of Symbols

Symbol	Meaning
	Indicates the item is a medical device
	Indicates the date when the medical device was manufactured
	Indicates a carrier that contains unique device identifier information
	Indicates the medical device manufacturer
	Indicates the need for the user to consult the electronic instructions for use
	Symbol indicating that the product is conform the requirements of this European Regulation. The number 1912 indicates the reference code assigned to the notified body that issues the CE certificate for this product.

The following table lists ISO 15223-1 compliant symbols that are used in information provided with the Relu® Cloud device and their meaning.