Splints

ME-UG-702C
Revision 5 (2026.07)
SW version 1.1.5

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Medit Splints

Workflow

Appendix

Symbols

No.	Symbol	Definition
1		Consult instructions for use on the website*
2		Consult instructions for use or consult electronic instruction for use
3		Caution
4		Warning
5		Prescription only (USA)
6		Date of manufacture
7		Manufacturer
8		Tips
9		Authorized representative in the European Community/European Union
10		Medical device
11		Serial number

No.	Symbol	Definition
12	CE 2797	This system complies with the regulatory requirements of Medical Device Regulation 2017/745 regarding medical device.
13	CH REP	Authorized representative in Switzerland
14	KR	Country of manufacture: Republic of Korea
15		Importer

**If a printed paper version of the user manual is required, it will be provided free of charge upon request to the manufacturer's contact information listed on the last page. The user manual in paper form will be supplied within a maximum of 7 days after receiving the user's request.*

Overview and General Information

Overview

Medit Splints provides an efficient and streamlined workflow for the design and creation of splints. Users can accelerate the process with Auto Creation, which uses previously defined parameters to generate splints quickly. Following automatic generation, a comprehensive suite of editing tools is available for precise adjustments and refinements, ensuring clinical and anatomical accuracy.

For scenarios requiring full user control, Manual Creation mode offers a guided, stepwise process for splint design, enabling meticulous customization at each stage.

Product Name	CAD/CAM Software
Trade Name	Medit Splints
Model Name	MA-ASP
UDI DI	(01)08800026700173
UDI PI	(10)1.1.5
Basic UDI-DI	88000267MA-ASPA8

Intended Use

Medit Splints is a software that creates dental splints that protect teeth, temporomandibular joints, and muscles, and stabilize occlusion. It enables users to perform tasks such as aligning scan data, adjusting occlusal relationships between jaw data, creating inner surfaces, defining splint outlines, designing outer surfaces, editing scan data, and adding labels to splints.

The program should be used according to the diagnosis and treatment plan set by the dental professional, and its use in specific treatment cases should be confirmed through consultation with a dental professional. The program must not be used for purposes other than those described in its intended use.

Indications for Use

The software is indicated for use by dental professionals to design dental appliances. The resulting dental appliances may be used, at the discretion of the dental professional, for patients requiring management of conditions such as bruxism or temporomandibular joint disorders. The software itself does not diagnose, treat, or directly manage any medical condition.

Contraindications

The software cannot be used for purposes other than to create dental splints.

Intended User Profile

The software is designed for use by dental professionals who have a basic understanding of dental procedures and terminology to operate it effectively and interpret its outputs. This includes but is not limited to dentists, dental hygienists, and dental technicians.

Intended Patient Population

The software can be used to design dental appliances for orthodontic patients, individuals with sleep apnea, athletes, and patients with temporomandibular joint disorder or bruxism.

Patient Safety Advisory

Poorly designed or tight splints can harm a patient's dental health by causing tooth damage, cavities, and root issues. They may also result in discomfort and difficulties when speaking and eating, especially in the early stages of wearing them.

Consequently, though the software can facilitate diagnostic and treatment planning processes, all decisions must be made by a skilled dental professional with a comprehensive understanding of the software's functionality and data interpretation. There are ample opportunities at each stage of the splint design process to identify and rectify any inaccuracies or errors that may lead to severe injuries. The dental professional must closely monitor the processes of designing and decision-making.

The final prosthesis is always reviewed and adjusted by a qualified clinician before being applied to the patient, thus lowering the actual clinical risk.

Security Risk Management and Error Handling

After the issue has been improved, if it is necessary to update the program, such as releasing a new installation file or applying some patch files, it is officially distributed through the head office sales/SE personnel, along with the application guide, to the person in charge of the corporation or the issue site.

Responses to security issues may be further announced on the website if necessary.

During the issue handling and recovery process, temporary operational restrictions may occur to ensure system stability and data integrity:

- Patient data may be temporarily inaccessible until the recovery process is completed.
- Clinical workflows may be interrupted; normal operations will resume once administrative actions have been completed. Patient data will not be automatically deleted during this process.
- A warning message will be displayed, and additional data entry will be restricted until the issue is resolved.
- User sessions may be automatically logged out to prevent unauthorized access.

Security Response Procedure

1. Reporting security issues
2. Share initial analysis results and progress
3. Issue delivery
4. Issue response plan / delivery
5. Issue response plan / share results

System Requirements

Windows

CPU	Intel Core i5 2.6 GHz or higher
RAM	16 GB or higher
Graphics Card	NVIDIA GeForce GT 1060(2 GB) or higher
OS	Windows 10 64-bit, Windows 11 64-bit

macOS

CPU	8-core or higher

RAM	16 GB or higher
Chip	M1/M2 or higher
OS	Sonoma 14 or later

Network Requirements

1. Network Type: wired LAN or Wi-Fi (WPA2 or higher)
2. Bandwidth: minimum 100 Mbps (1Gbps recommended)
3. Protocol: IPv4
4. Port: TCP 443
5. Latency: average below 50ms

Security Requirements

1. Authentication: Password must be 8-16 characters long, including a combination of at least three of the following: letters, numbers, and special characters. Passwords are accepted in English only.
2. Encryption: TLS 1.2 or higher, HTTPS transmission
3. Antivirus & Patches: keep the operating system and antivirus up to date

This software continuously monitors for security events such as unauthorized access, tampering attempts, and data integrity errors.

Unauthorized Access Prevention:

Only individuals who have been granted Admin account privileges in Medit Link can access patient information and internal servers. During the registration process, each user is assigned account permissions to manage and prevent unauthorized access.

Cybersecurity Information

Medit Splints does not access any patient PII/PHI from Medit Link. In this system, the communication and API exchanges use scan data files identified only by the patient's Case ID rather than any PII/PHI.

Preparations and Handling Before/During Device Use

- Product installation procedure: managed via the Cloud
- Mandatory user validation when creating Medit Link Account:

    - Create a user account in Medit Link
    - Send a user validation email
    - User confirms the validation
    - User logs in
- Troubleshooting guide: https://support.medit.com/hc/en-us

Required Facilities, Training, and User Qualifications

- Local network administrators/operators must have IT expertise (network, server, OS security configuration).
- Cloud services are managed on AWS by Medit administrators (AWS certified).

Information to Verify Proper Installation and Safe Operation

- Medit Splints Updates
    - Update through the App Box in Medit Link. (The latest Medit Splints installer file will be downloaded and installed.)
    - Run Medit Splints to check the installed version.
    - If security-related updates are required, install the updated Medit Splints version in the same way.
- Cloud Services: Managed and monitored through AWS Trusted Advisor with regular updates to apply required security measures.
- Data and Settings Backup/Restore
    - Data is managed locally via Medit Link and backed up to the Cloud.
    - Backups/restores can be performed by downloading data as needed.
    - Original IOSC files are retained for up to 6 months only.
    - User logs are retained for 3 months and can be manually deleted.
    - Stored data can be deleted from the Case Box in Medit Link, and the responsibility for such deletion rests with the user who performs it.
    - Cases can be transferred using the Case Converting Tool in the Settings menu of Medit Link.
    - When a user account is deleted, all user data (e.g., personal information, usage logs such as log-in and feature usage) and database data are permanently removed and cannot be restored.
- Integrity and Verification of Software Security Patches
    - The executable file of Medit Splints is automatically digitally signed during installation and verification, so users do not need to take any additional action.

IT Network Precautions

Guidelines

Execution of the health software on an IT-network could result in previously unidentified risks to patients, users, or third parties. The responsible organization is advised to identify, analyze, evaluate, and control these risks.

Hazard Situations

- Always ensure that your system is protected by the latest version of antivirus software and an active firewall.
- Connecting the network to any device other than Medit Splints may result in potential virus infections or data tampering. Verify that the network is operating under appropriate administrative control before proceeding.
- Even if automatic backup is configured, no backup will be performed if the software is not running or if the designated backup location is unavailable.

Subsequent changes to the IT network could introduce new risks and may require additional analysis. Such changes include:

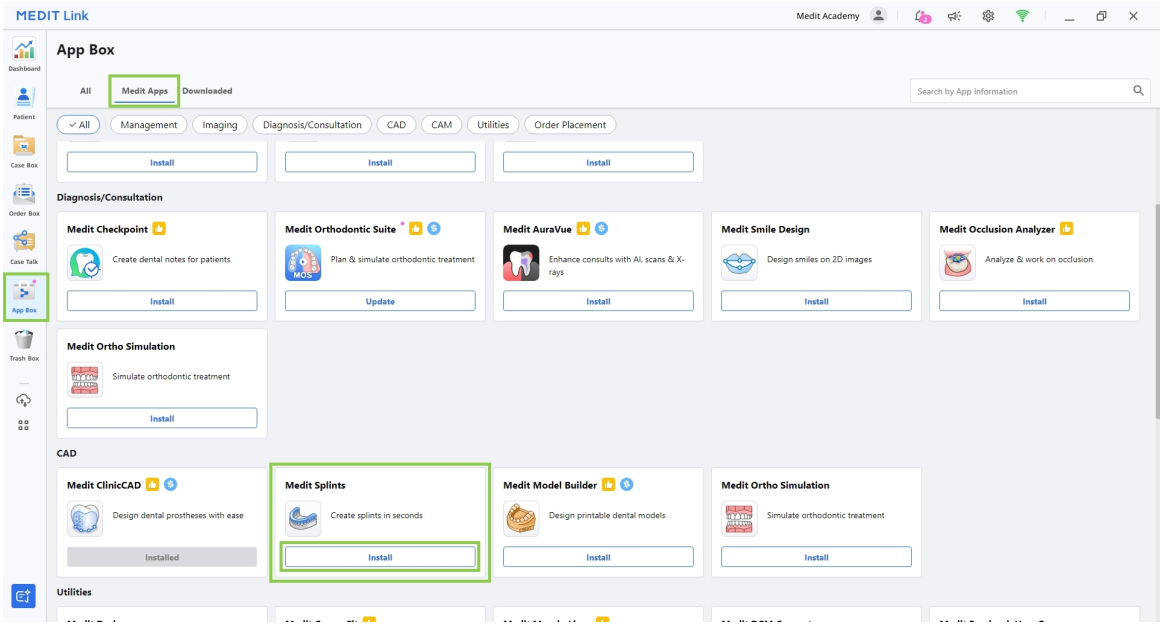
1. Modifications to the IT network configuration.
2. Adding items (hardware, software platforms, or software applications) to the IT network.
3. Removing items from the IT network.
4. Updating software applications on the IT network.
5. Upgrading software platforms or software applications on the IT network

In the event of a cybersecurity incident, if the cybersecurity detection software identifies a threat, the user must report it to the manufacturer and to the competent authority of the Member State.

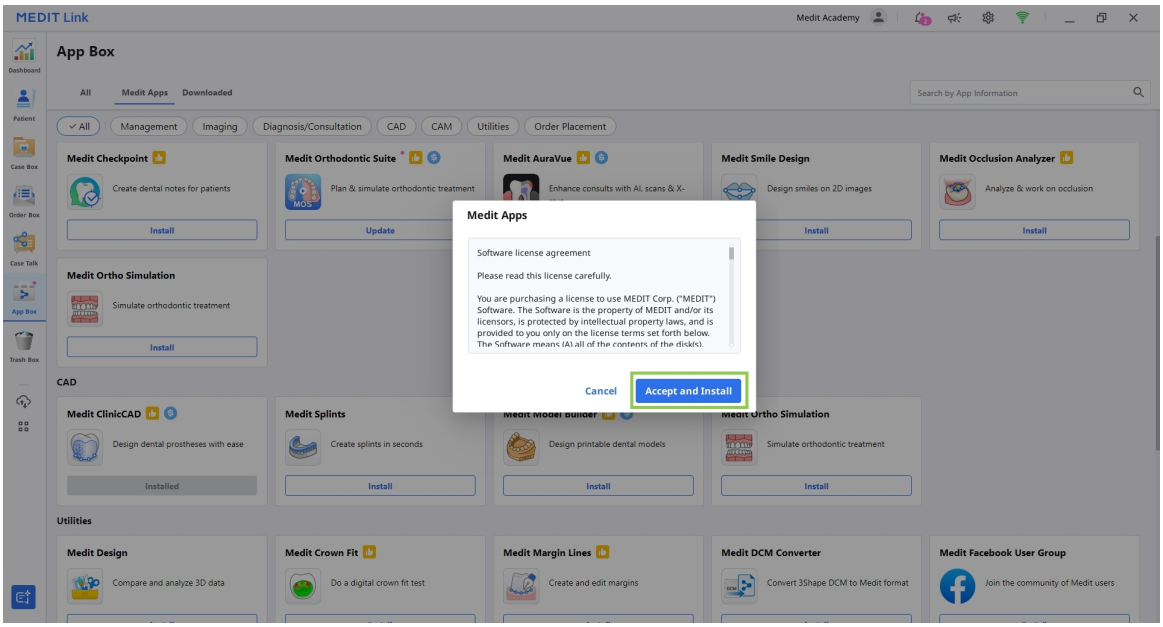
Installation Guide

1. Log in to your Medit Link account and go to the App Box on the left-hand menu.

2. In the Medit Apps tab, find the Medit Splints app and click "Install."



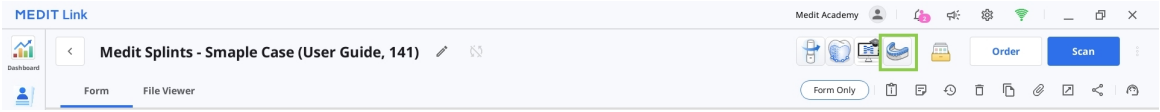
3. Read the Software License Agreement and confirm app installation by clicking "Accept and Install."



4. The app will be downloaded and installed automatically. It may take several minutes to finish the installation process.

> **⚠ Caution**
>
> Do not turn off the PC or close Medit Link during the installation process.

5. Once the app is installed, you can run it from any case in Medit Link by clicking the app icon in the top right corner of the Case Detail window.



6. To uninstall the program, open App Box and locate the Medit Splints app. Select the app card to open its details page, then click “Uninstall.”

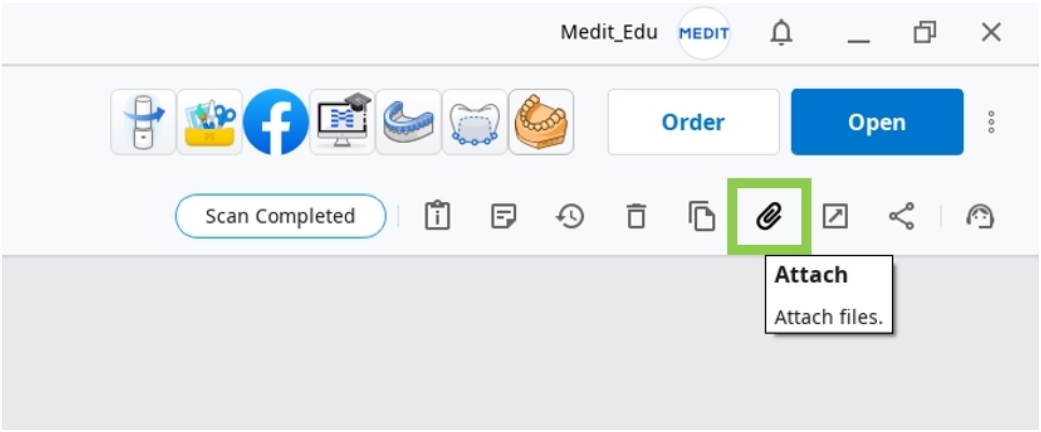
Data Management

Preparing Data

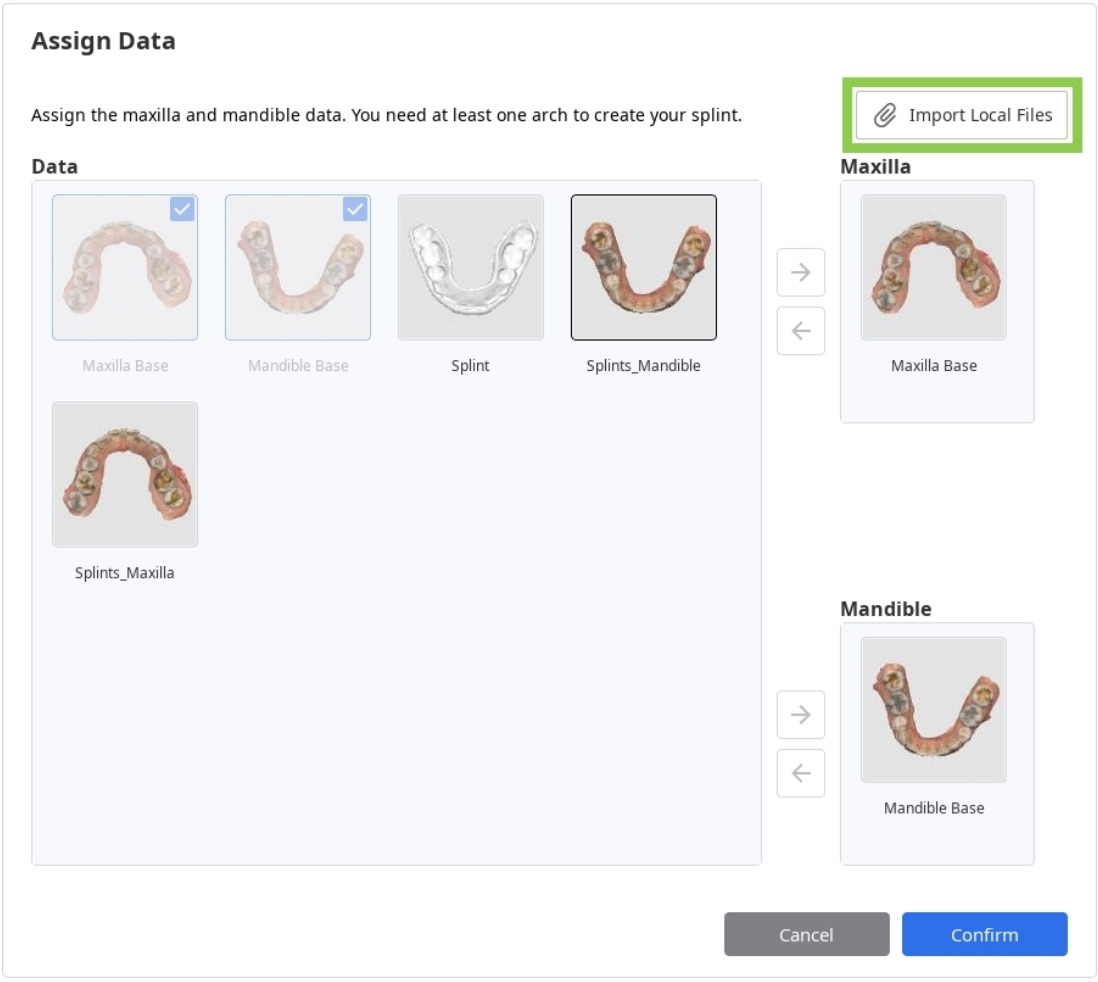
User must prepare scan data for at least one arch in a supported file format, such as meditMesh, OBJ, PLY, or STL. The data is either automatically imported from a Medit Link case or manually loaded when the application is launched.

Scan data can be loaded into the project using one of the following methods.

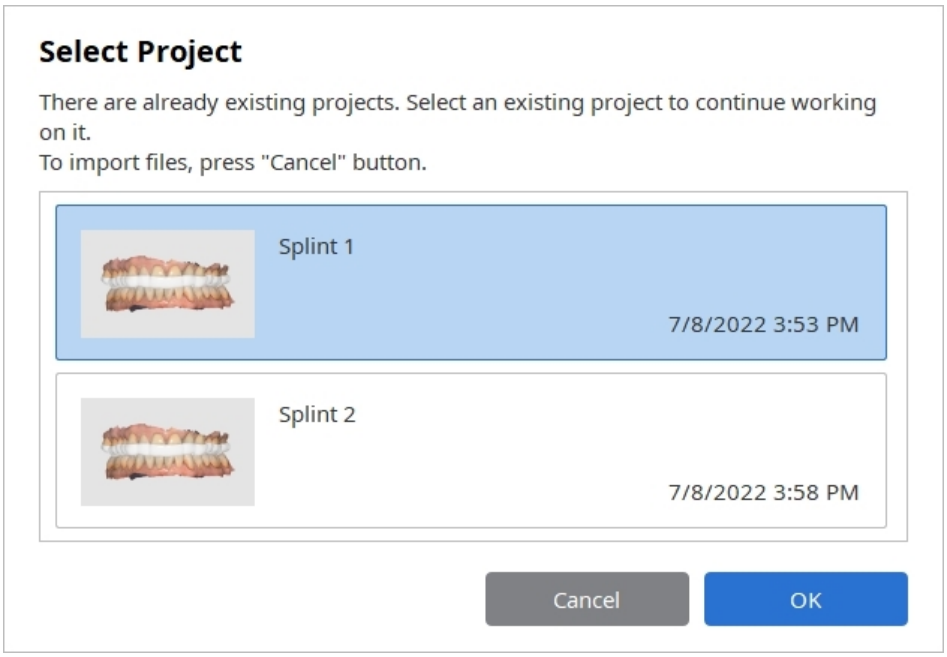
1. Automatic import from a Medit Link case
   Complete scanning in Medit Scan for Clinics or Labs, or import local data using the “Attach” feature in the Case Detail window. All data available in the case is automatically imported into Medit Splints when the application is launched.



2. Manual import upon launch
   If required scan data is not available in the case, it can be imported from local files after launching the application. Use the “Import Local Files” option in the Assign Data dialog window.



If the application is opened again from the same Medit Link case, the previously saved project can be loaded and continued.



3D Data Control

Users can control the 3D data using a mouse alone or both mouse and keyboard.

3D data control using a mouse

Zoom	Scroll the mouse wheel.	
Zoom Focus	Double-click on the data.	
Zoom Fit	Double-click on the background.	
Rotate	Right-click and drag.	
Pan	Hold both buttons (or wheel) and drag.	

3D data control using a mouse and keyboard

	Windows	macOS
Zoom		
Rotate		
Pan		

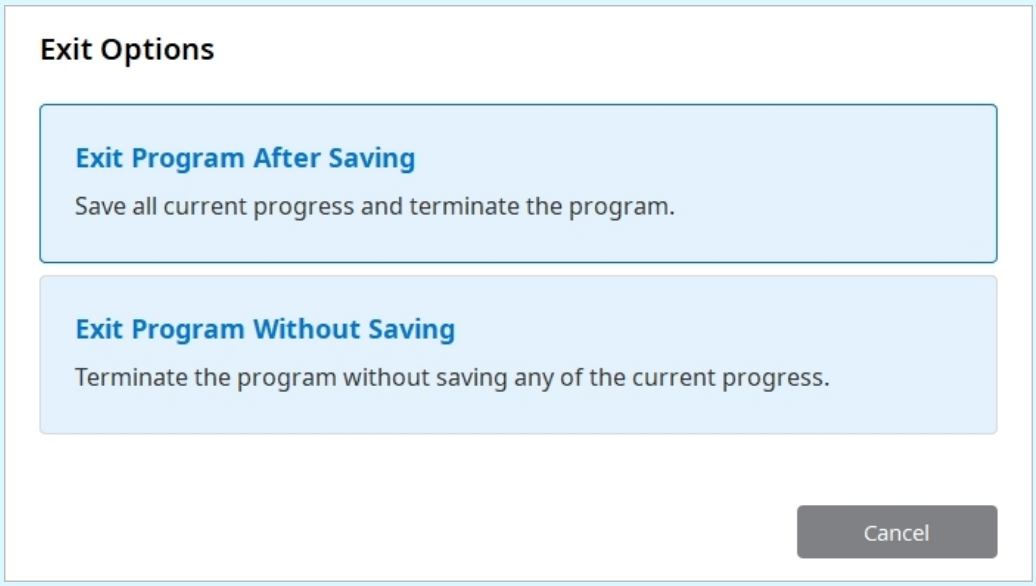
Saving Data

There are several ways to save the project data.

1. Click “Complete” at the top of the screen to finalize the project and splint design and save them to the Medit Link case.
2. Click “Next” in Label Mode to finalize the project and splint design and save them to the Medit Link case.
3. Click “Menu” in the Title Bar and select “Save As” to save the current project progress.

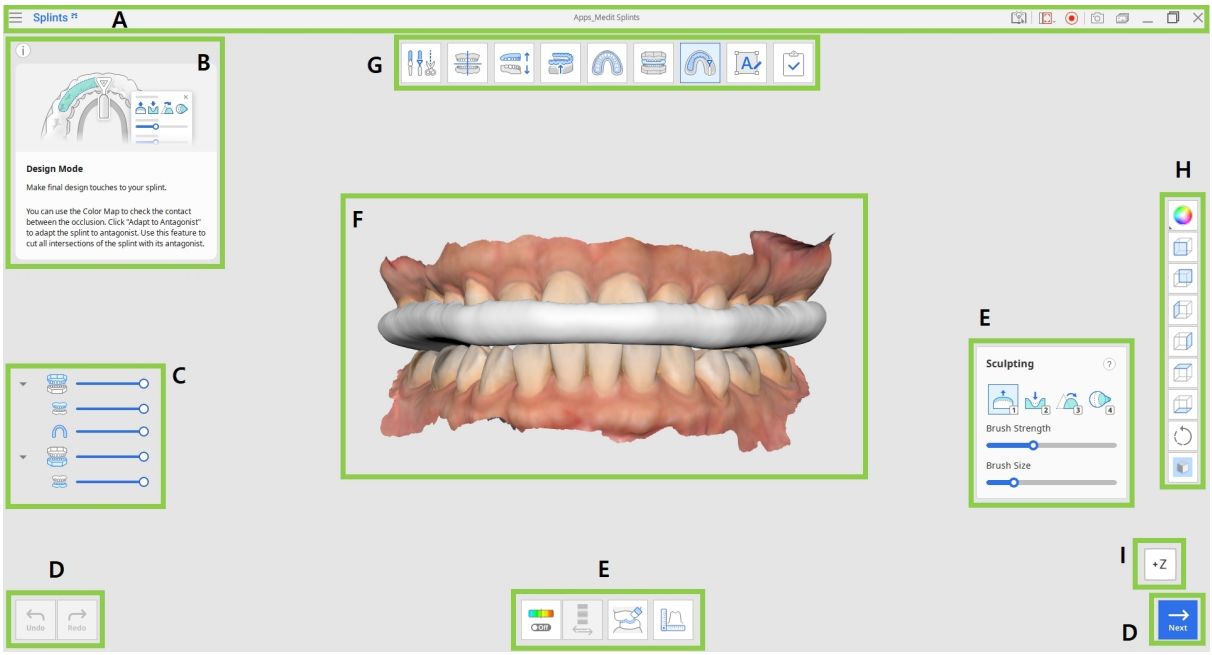
Note

Users can save their work progress for an unfinished project even if they terminate the program before reaching the final workflow step.



User Interface

User Interface at a Glance



A	Title Bar
B	Info Box
C	Data Tree
D	Action Control Buttons
E	Toolboxes
F	3D Data
G	Workflow
H	Side Toolbar
I	View Cube

Note

Please note that this is a general overview of the main elements. Some interface elements may vary slightly depending on the goal of each workflow step.

Title Bar

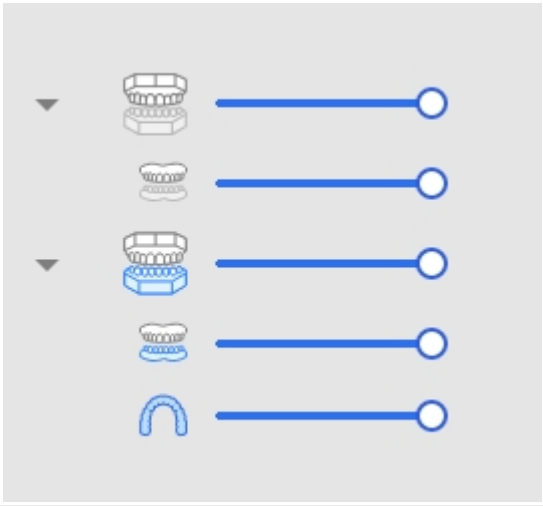
The Title Bar is the ribbon at the top of the application window that contains basic controls on the right and the program menu on the left. It also shows the app name and the opened case name.

	Menu	Manage the opened project, access available assistance resources, and check app details.
	Help Center	Go to the Medit Help Center page dedicated to this app.
	Select Video Record Area	Specify which area shall be captured for video recording.
	Start Video Recording	Start and stop the video recording of the screen.
	Screenshot	Take a screenshot. Capture the app with or without the title bar using automatic selection, or click and drag to capture only the desired area.
	Screenshot Manager	View, export, or delete the screenshots. Upon completion, all captured images will be saved to the case automatically.
	Minimize	Minimize the application window.

	Restore	Maximize or restore the application window.
	Exit	Close the application.

Data Tree

The Data Tree is located on the left side of the screen and shows a list of the project data organized into groups. Users can control each data visibility by clicking its icon in the tree or changing its transparency by moving its slider. The structure may vary slightly depending on the objectives of a specific step or tool.

	**Maxilla Group** • Maxilla **Mandible Group** • Mandible • Splint

Action Control Buttons

There are three buttons that control the overall work process. They are located in both bottom corners of the application window.

The “Complete” button will appear at the final step only.

Undo	Undo the previous action.

Redo	Redo the previous action.
Next	Apply changes and move to the next step.

Side Toolbar

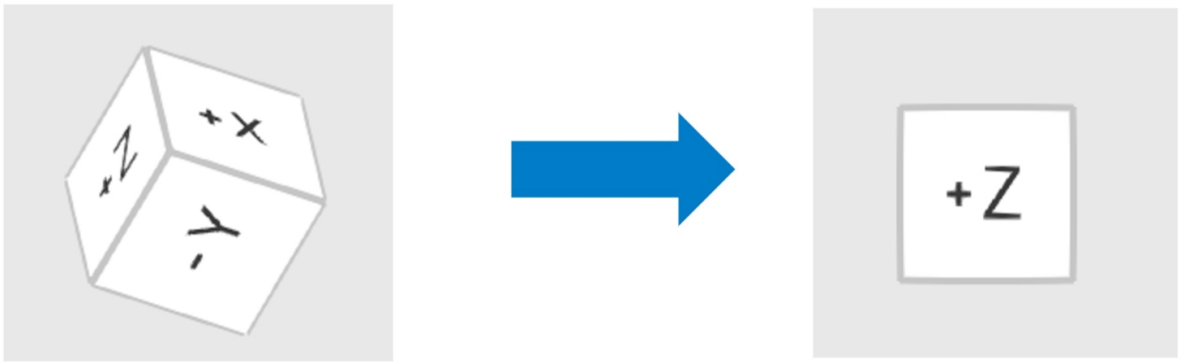
The Side Toolbar is located on the right side of the screen; it offers a number of tools for data visualization and control.

	Change Data Display Mode	Change between different data display options. (Textured/Textured with Edges/Monochrome/Monochrome with Edges/Wire-Frame)
	+Z Axis View	See the front view.
	-Z Axis View	See the back view.
	-X Axis View	See the left view.
	+X Axis View	See the right view.
	+Y Axis View	See the top view.
	-Y Axis View	See the bottom view.

	Rotate	Rotate data by click-and-drag.
	Grid Settings	Show or hide the grid (overlay on/off). Click multiple times to control overlay options.

View Cube

The View Cube shows the 3D view orientation; it rotates simultaneously with the 3D data to help understand data positioning within a three-dimensional space. You can click on the visible faces of the cube to rotate data and see it from a specific viewpoint.



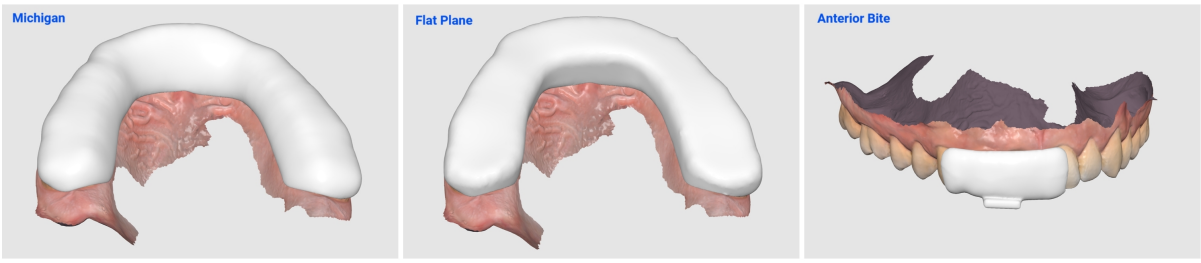
Workflow

On Splint Creation

After the scan data has been assigned, two key aspects of splint creation are confirmed with the user.

First, the target arch and splint type are defined. Three splint types are available, and depending on the selected type, specific modifications are applied to the splint outline and outer surface.

Splint Type	Description
Michigan	A full-coverage splint for all general cases.
Flat Plane	A full-coverage splint with a flat, smooth outer surface that enables unhindered mandible movement.
Anterior Bite	A splint that covers only a portion of the front teeth and prevents contact between the back and canine teeth.



Second, the design method is selected—either automatic or manual. The subsequent workflow varies depending on the selected method.

Auto Creation

Auto Creation is an automated splint design process that uses preset parameters. The workflow consists of three steps: Overview Mode → Design Mode → Labeling Mode.

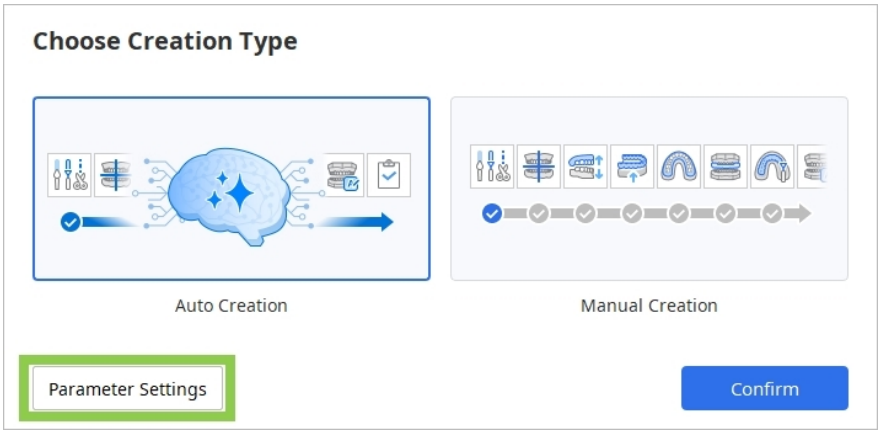
> **Note**
>
> Learn more about modes later in this chapter.

Upon first selecting Auto Creation after installation, the default parameters are used to automatically create a splint. The default preset parameters are as follows:

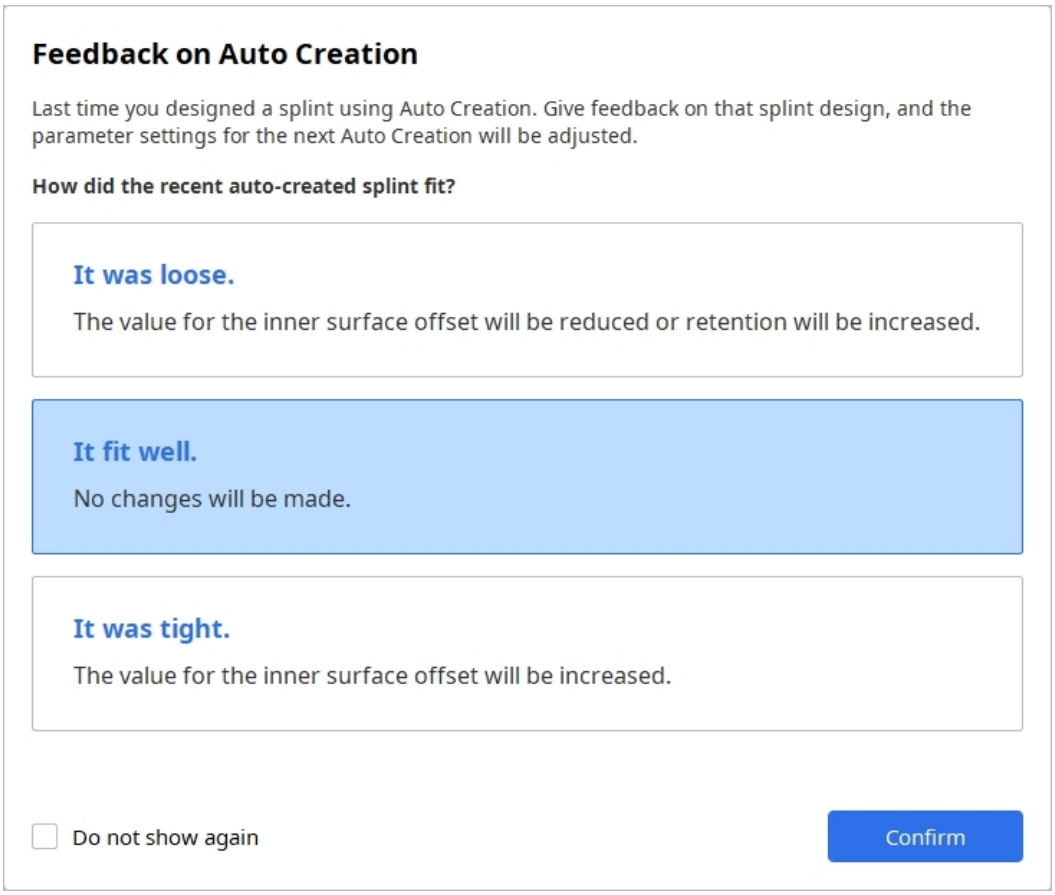
Mode	Parameter	Default Value
Occlusal Adjustment Mode	Distance to Antagonist	1.5 mm
Inner Surface Creation Mode	Inner Surface Offset	0.10 mm
	Smooth Surface	4/5
	Angle	0.1°
	Retention	0 mm
Outline Designation Mode	Buccal Side	half the teeth height
	Lingual Side	half the teeth height
Outer Surface Creation Mode	Lingual & Buccal Thickness	1.50 mm
	Smooth Surface	5/5
	Dual Layer Splint	Off

After the initial use, the most recently applied parameters are automatically saved and used for subsequent Auto Creation processes.

The parameters can be reviewed and modified by selecting “Parameter Settings” before creating the splint.



The next time Medit Splints is launched after using Auto Creation, feedback on the most recently auto-created splint will be requested. Based on the user's response, the application will learn and automatically adjust the parameters to improve the fit of future splint designs. Providing feedback is optional.



Manual Creation

Manual Creation is a step-by-step splint creation process that provides greater flexibility for making fine adjustments to the splint. The workflow for Manual Creation is as follows:

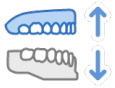
Overview Mode → Edit Mode → Alignment Mode* → Occlusal Adjustment Mode* → Inner Surface Creation Mode* → Outline Designation Mode* → Outer Surface Creation Mode* → Design Mode → Labeling Mode

Modes marked with an asterisk (*) include automatic analysis of the anterior and posterior teeth. Based on this analysis, suggested results are generated when the step is entered. The suggested results can be reviewed and modified if necessary before proceeding by clicking "Next."

Modes

The complete workflow consists of 8 modes, each representing a specific step in the design process. These steps must be completed in the sequence in which they appear at the top.

If the occlusion was scanned in an open state or if only one arch is present, the Occlusal Adjustment Mode step may be skipped. After completion of the Design Mode step, the process may proceed directly to the final Complete step, and the results can be saved to Medit Link.

	Overview Mode	Check your scan data
	Edit Mode	Edit and trim data using the wide array of functions provided.
	Alignment Mode	Align the data to the occlusal plane.
	Occlusal Adjustment Mode	Adjust the occlusal relationship.
	Inner Surface Creation Mode	Create the splint's inner surface.
	Outline Designation Mode	Designate the splint area.
	Outer Surface Creation Mode	Create the splint's outer surface.
	Design Mode	Design the splint using the tools provided.

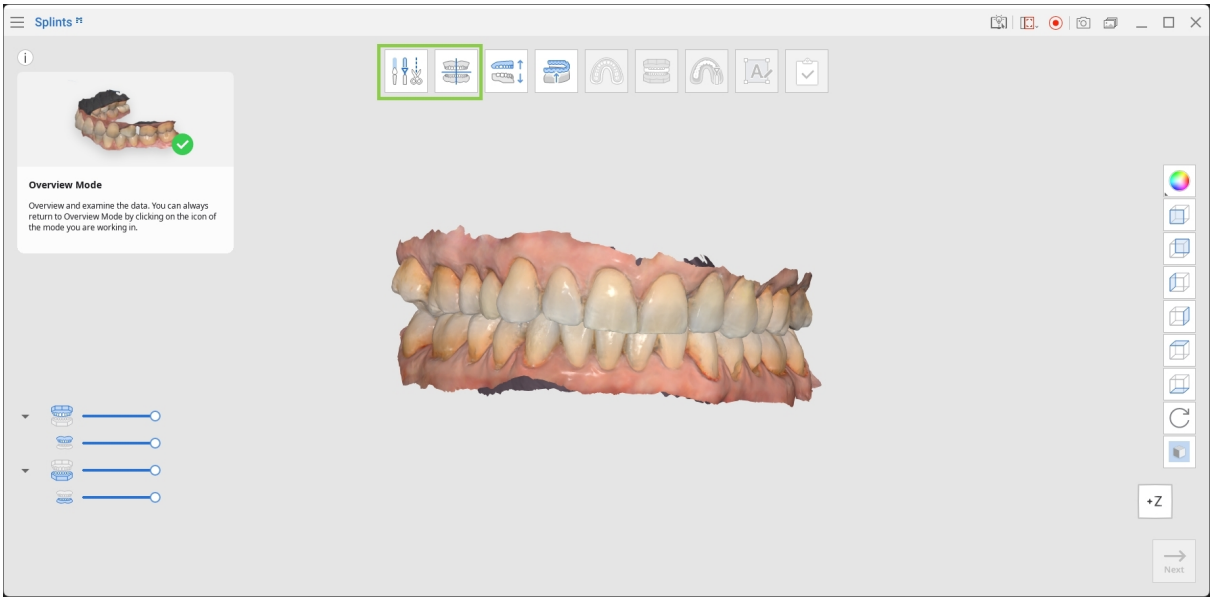
	Labeling Mode	Label the splint by engraving or embossing the text.
	Complete	Finish creating the splint and save the results to Medit Link.

The Edit Mode, Design Mode, and Labeling Mode are optional and can be skipped.

Overview Mode

Overview Mode is the landing page of Medit Splints, where imported data is initially displayed.

Review the data, and if editing is required, click the Edit Mode icon at the top of the screen. If no editing is required, you may skip Edit Mode and proceed to Alignment Mode.



Edit Mode

Edit Mode allows users to modify the scan data before creating the splint. Unnecessary data can be trimmed, holes can be filled, and surfaces can be sculpted as needed.

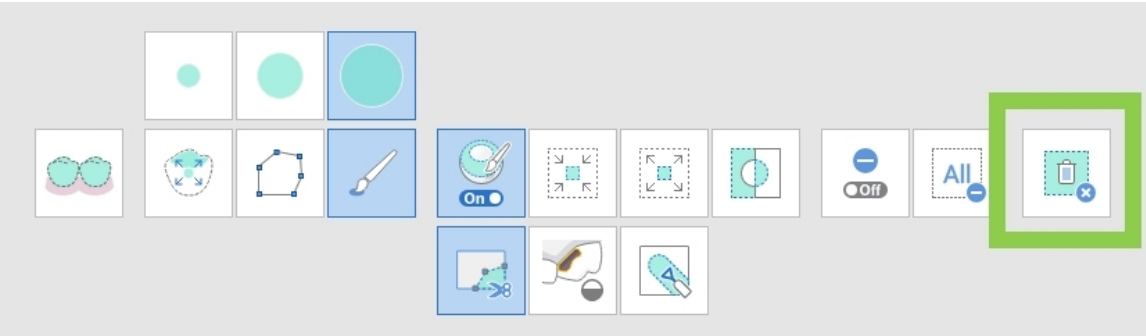
Toolbox

	Trimming Tool	Use various selection tools to remove unnecessary data.
	Fill Holes	Fill empty spaces in the 3D mesh data.
	Sculpting	Sculpt data by adding, removing, smoothing, or morphing.

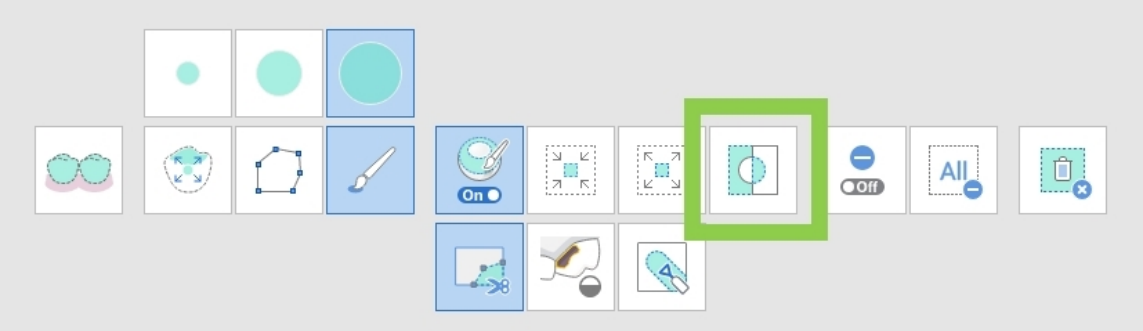
How to Trim Data

Use Smart Selection Tools to automatically select the teeth data, or choose “Polyline Selection” or “Brush Selection” to manually designate the trimming area.

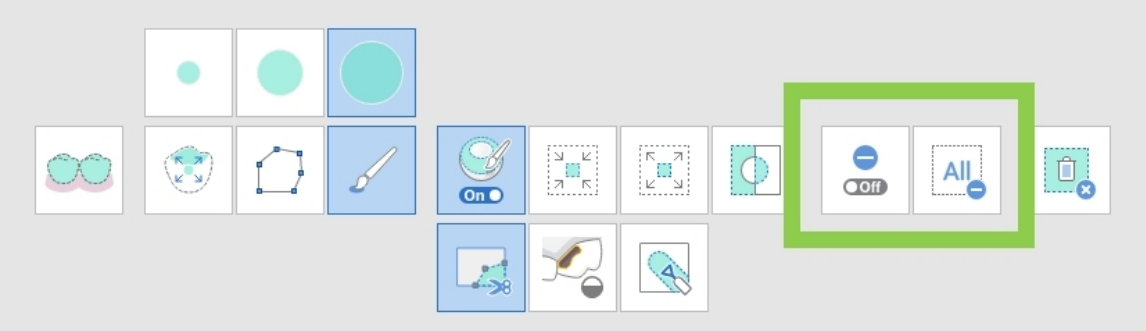
To delete the selected area, click “Delete Selected Area.”



You can revert the selection by clicking “Invert Selected Area.”



You can switch the selection tool to deselection mode by clicking “Deselection Mode,” or use “Clear All Selection” to remove all selections.



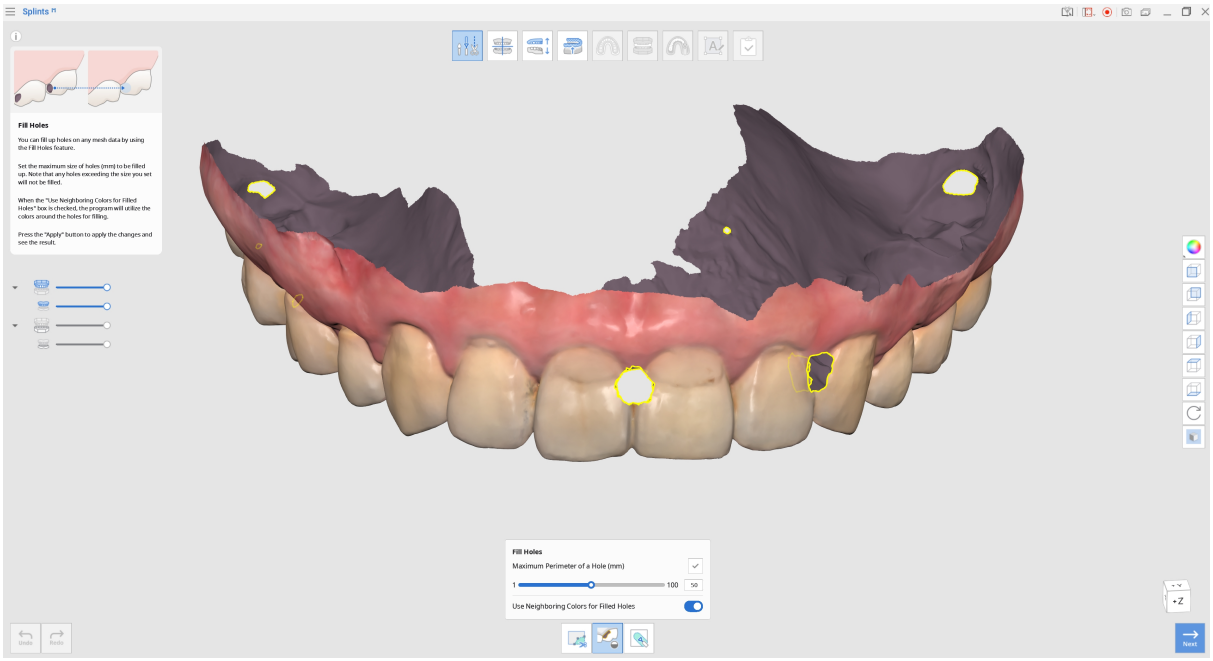
Toolbox: Trimming Tool

	Smart Teeth Selection	Automatically select all teeth of the arch, leaving out gingiva parts.
	Smart Single Tooth Selection	Automatically select the area of a single tooth, leaving out gingiva parts. Click, press, and drag the mouse on the tooth.

	Polyline Selection	Select all entities within a polyline shape drawn on the screen.
	Brush Selection	Select all entities along a freehand-drawn path on the screen. The brush comes in three sizes.
	Autofill Selected Area	Automatically fill in entities of the selected area.
	Shrink Selected Area	Reduce the selected area each time you press the button.
	Expand Selected Area	Expand the selected area each time you press the button.
	Invert Selected Area	Invert the selection.
	Deselection Mode	When on, this function deselects the area using various tools.
	Clear All Selection	Clear all selected areas.
	Delete Selected Area	Delete the data from the selected area.

How to Fill Holes

Use “Fill Holes” to fill in any holes left from scanning or fill in deleted areas.



1. Maximum Perimeter of a Hole (mm)

   Set the maximum hole size (in mm) to be filled. Holes larger than the specified size will not be filled.

2. Use Neighboring Colors for Filled Holes

   When this option is enabled, the program uses surrounding colors to fill the holes. Otherwise, filled areas will appear gray.

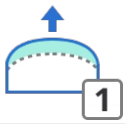
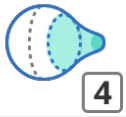
3. Apply

   Click the “Apply” button to apply the changes.

How to Sculpt Data

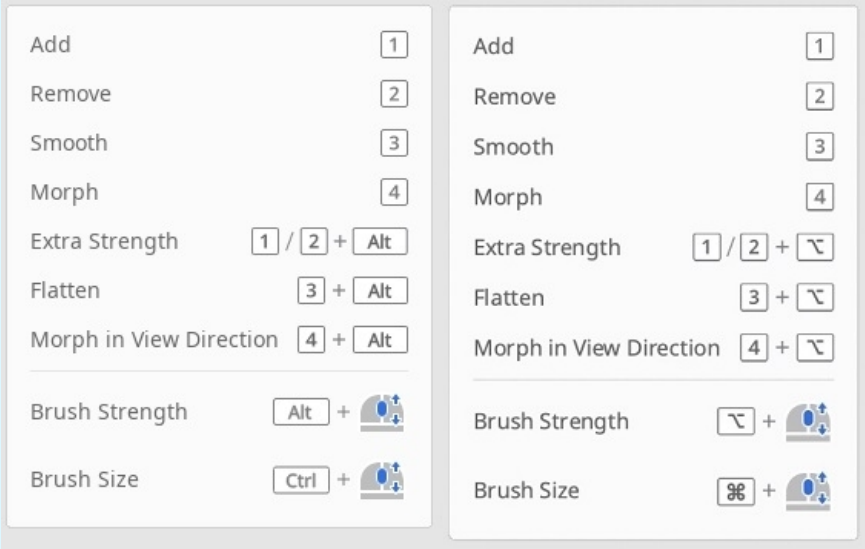
Select the “Sculpting” tool to modify the data. The sculpting tools allow you to add, remove, smooth, or morph parts of the data.

Toolbox: Sculpting

	Add	Use the mouse to add data on the surface.
	Remove	Use the mouse to remove parts of the data.
	Smooth	Use the mouse to smooth parts of the data.
	Morph	Use the mouse to morph parts of the data.

Tip

To make sculpting easier, use shortcuts.



Click “Next“ when done editing.

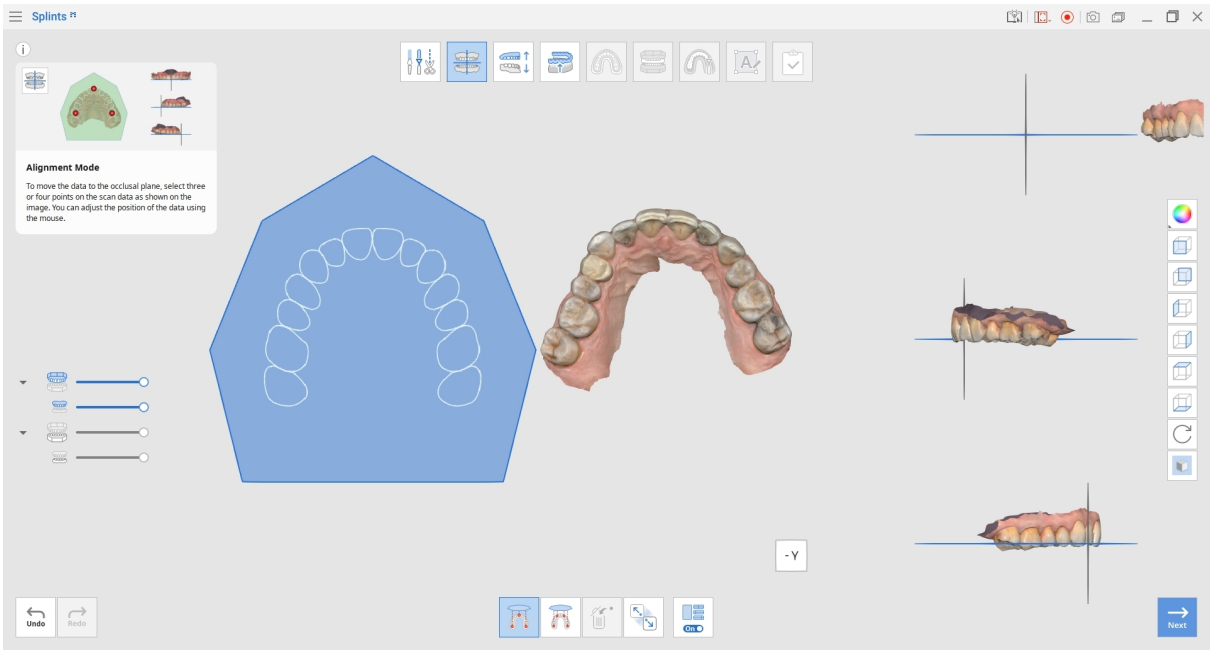
Alignment Mode

This step automatically aligns the data to the virtual occlusal plane.

Once complete, further manual adjustments can be made if required. It is recommended to always check the alignment at this step to ensure proper positioning of the data.

Note

If alignment has already been completed in Medit Scan for Clinics or Labs, this step can be skipped.



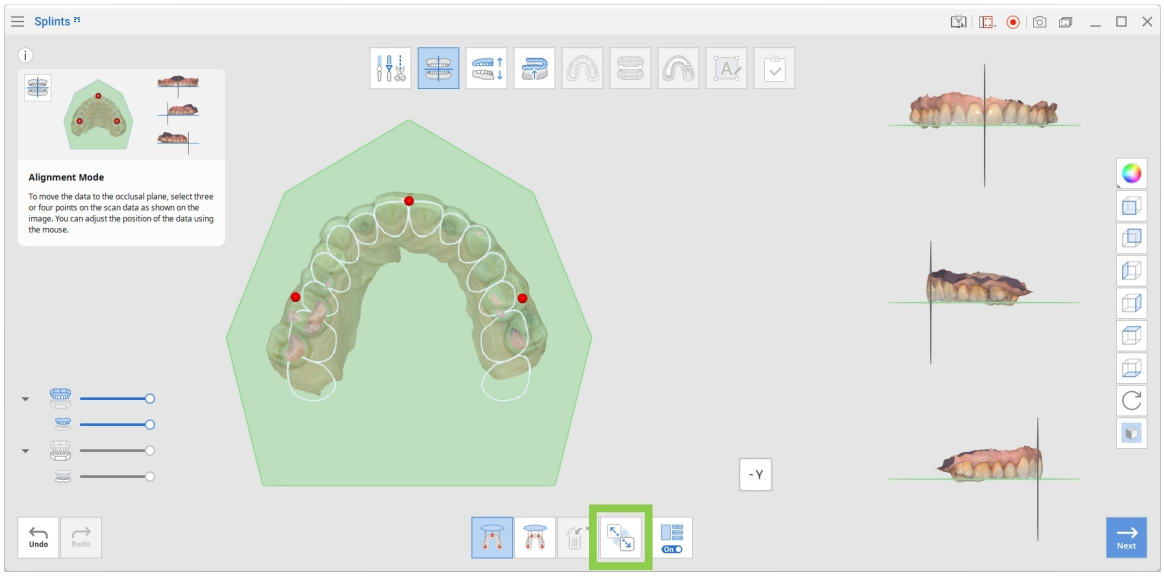
Toolbox

	Align with Occlusal Plane by Three Points	Select three points on the maxilla and mandible to align with the occlusal plane.
	Align with Occlusal Plane by Four Points	Select four points on the maxilla or mandible to align with the occlusal plane. This option is useful when anterior teeth are not present.

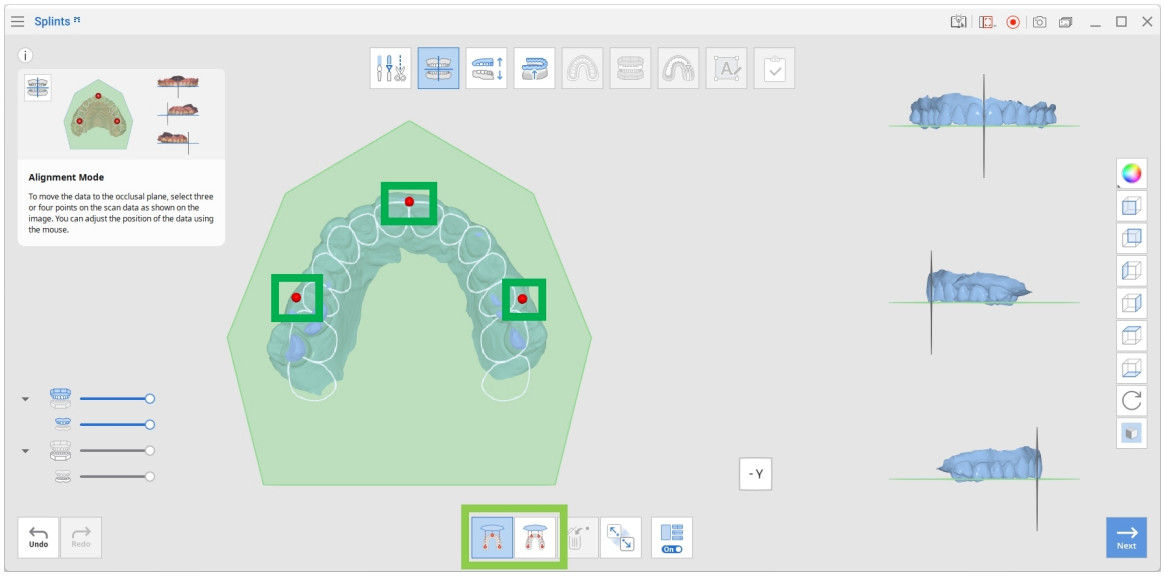
	Delete Marker Point	Remove the points selected for alignment.
	Detach Data	Separate the aligned data and return it to its original position.
	Multi-View	When enabled, this function displays the data from four different angles.

To manually realign the data to the occlusal plane, follow these steps:

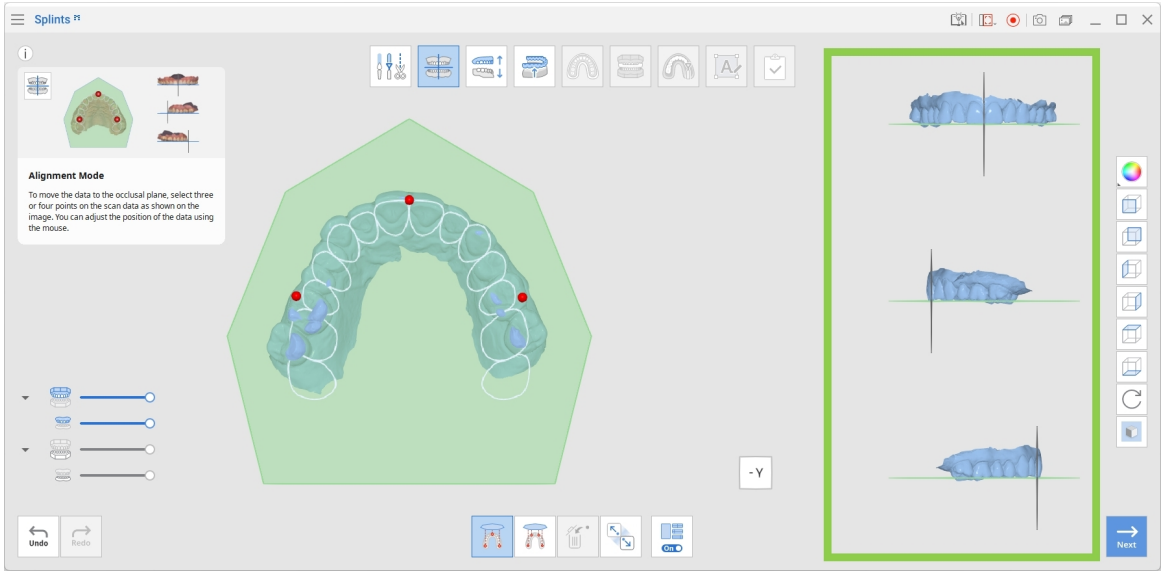
1. After automatic alignment is complete, click “Detach Data.”



2. Place three or four points on the data to align it to the occlusal plane.



3. Use Multi-View on the right to adjust the data and control the alignment process.



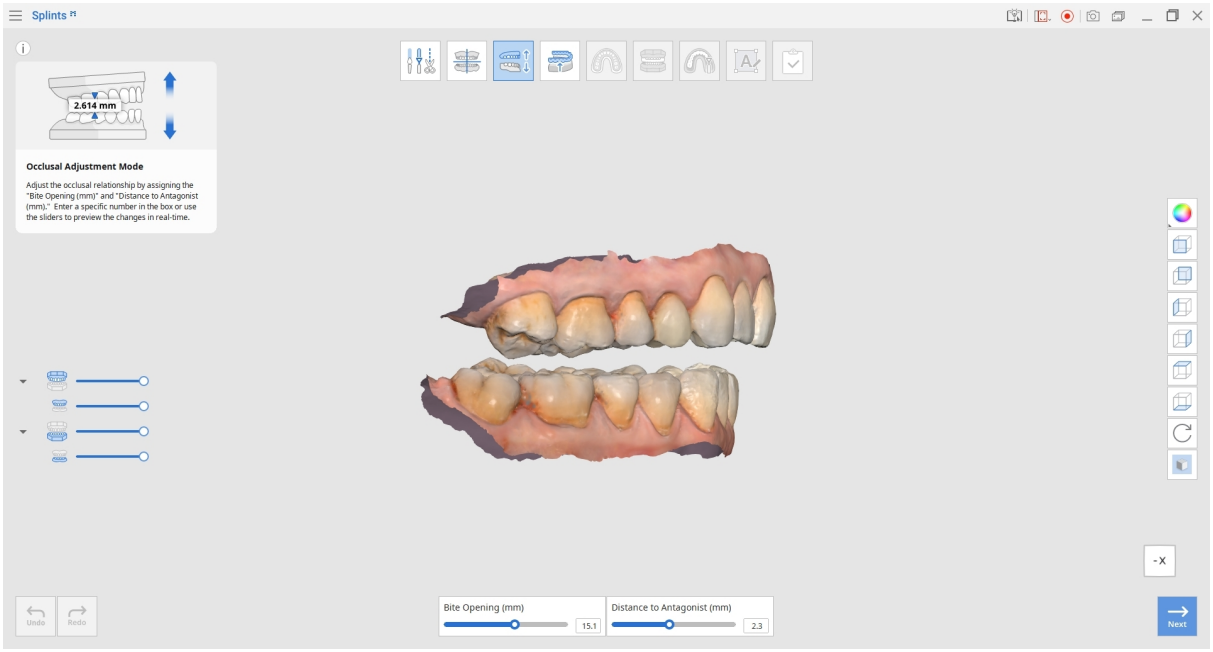
> **Note**
>
> When Multi-View is turned off, only the occlusal plane is displayed.

4. Click “Next” when finished.

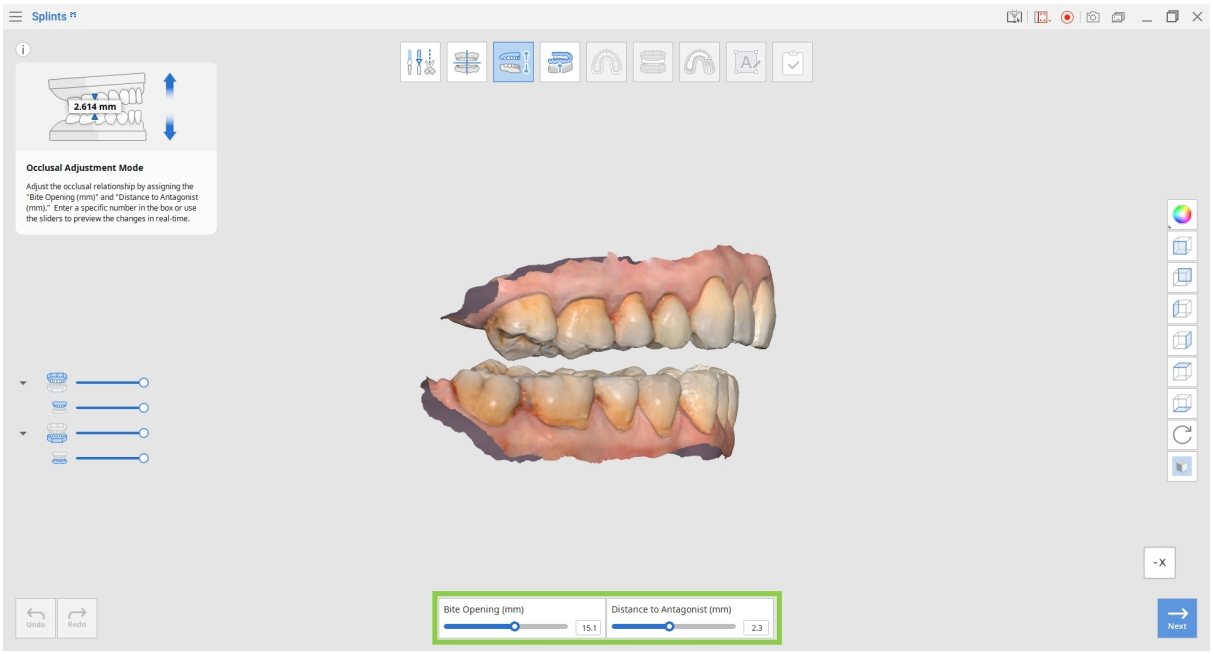
Occlusal Adjustment Mode

In this step, space for the splint is created by adjusting the occlusal relationship between the maxilla and mandible.

> **Note**
>
> If the occlusion was scanned in an open state or only one arch is available, the Occlusal Adjustment Mode can be skipped.



1. To adjust the occlusal relationship, move the slider or enter a specific value for “Distance to Antagonist” or “Bite Opening.” Note that the bite opening value is automatically calculated based on the distance to the antagonist and may be automatically adjusted.



Toolbox

Bite Opening (mm) 12	Bite Opening	Sets the degree of bite opening in the virtual articulator.
Distance to Antagonist (mm) 2.3	Distance to Antagonist	Sets the minimum distance between the occlusal surfaces of the maxilla and mandible.

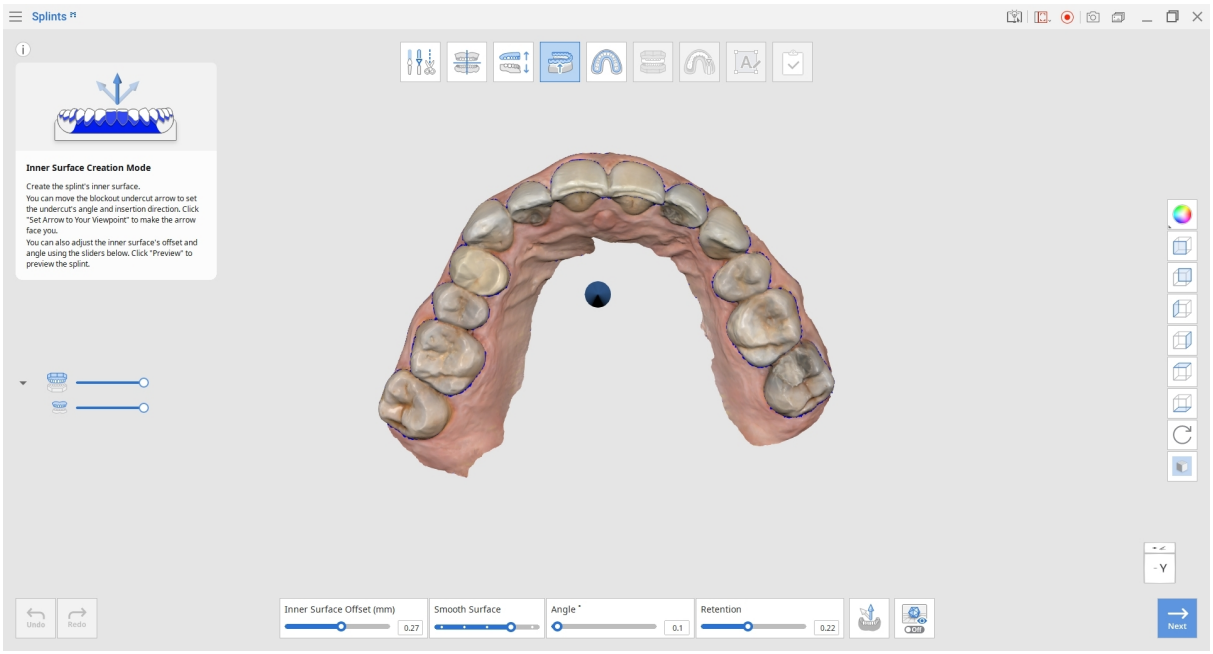
⚠ Caution

The distance to the antagonist must be greater than 0.0.
If it is set to 0.0, no space is created for the splint, and it is not possible to proceed to the next step. Adjust this value to ensure sufficient occlusal thickness for the splint.

2. Click “Next“ when finished.

Inner Surface Creation Mode

In this step, the inner surface of the splint is created by adjusting the inner surface offset, blockout direction, and blockout amount. The fit of the splint can be further refined using the “Retention” slider.

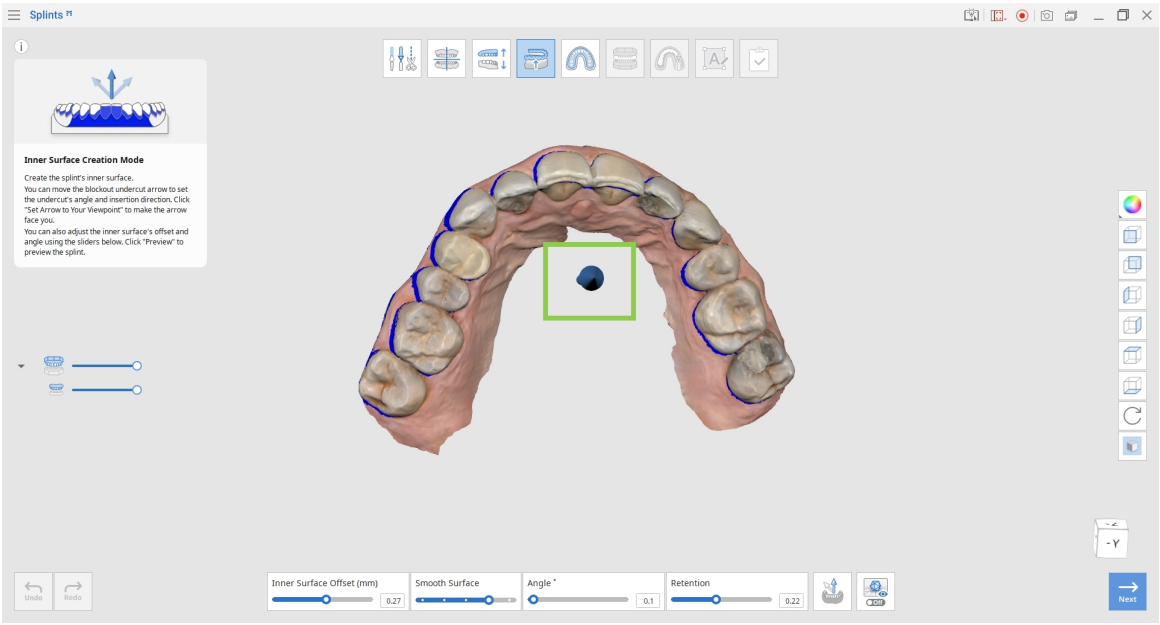


Toolbox

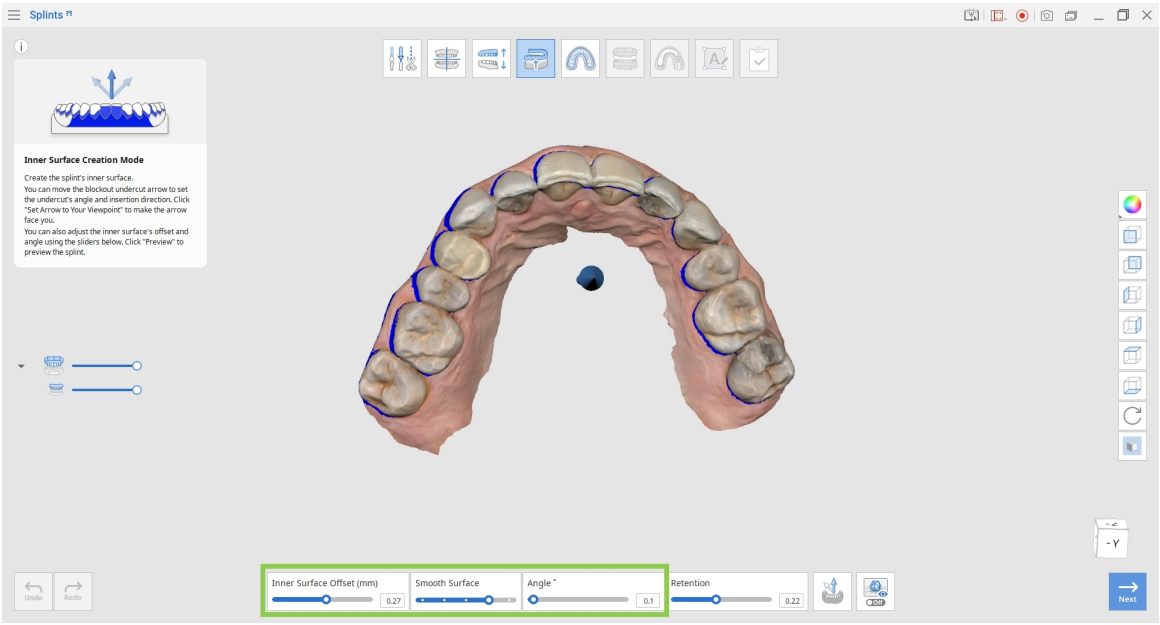
	Inner Surface Offset	Sets the offset distance from the scan data to generate the splint mesh.
	Smooth Surface	Smooths the inner surface of the splint. Move the slider to the right to increase smoothness.
	Angle	Sets the blockout angle.
	Retention	Controls the inclusion of undercut areas to improve splint retention.

	Set Arrow to Viewpoint	Aligns the blockout direction arrow to face the current view.
	Preview	Displays the blockout undercut areas on the data.

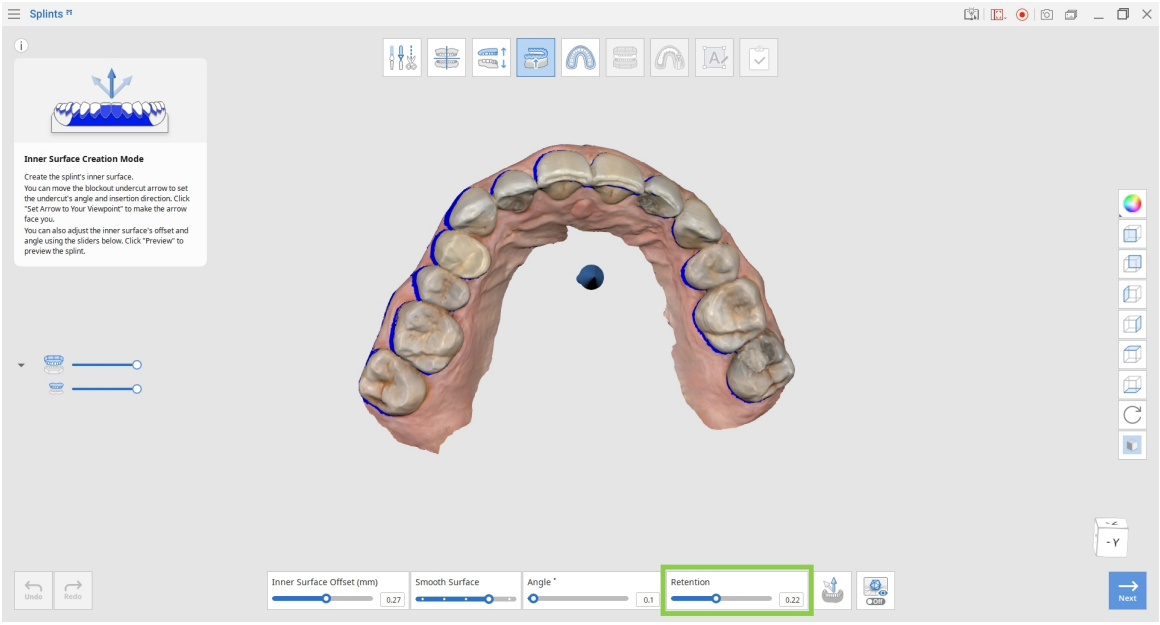
1. Click and hold the arrow to move it freely and set the blockout direction. Areas included in the blockout are displayed in blue.



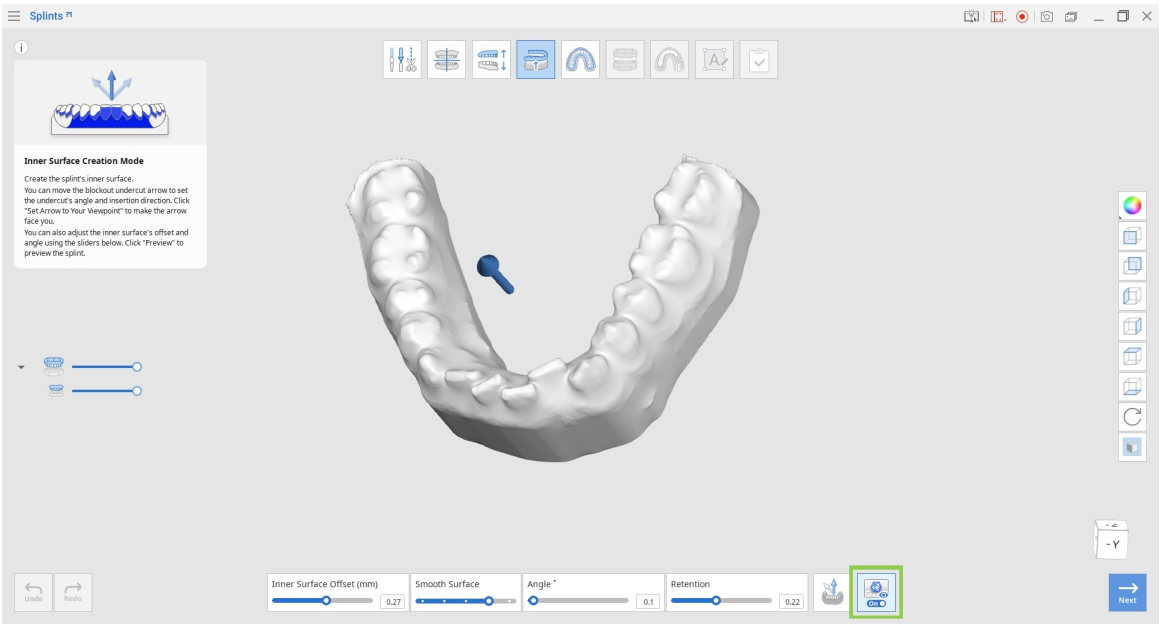
2. Set the inner surface offset, surface smoothness, and the blockout angle to adjust the splint's tightness.



3. Use the "Retention" slider to adjust the range of allowed undercut areas and improve retention of the printed splint.



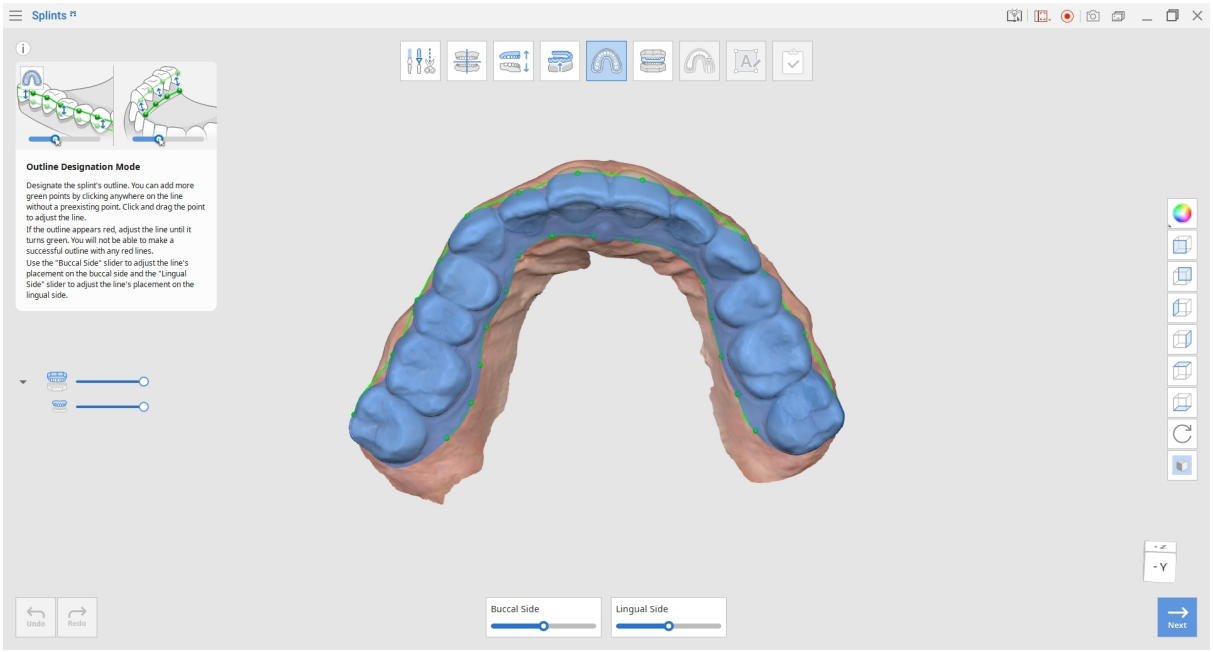
4. Click “Preview” to view the splint with blockout undercut areas.



5. Click “Next” when finished.

Outline Designation Mode

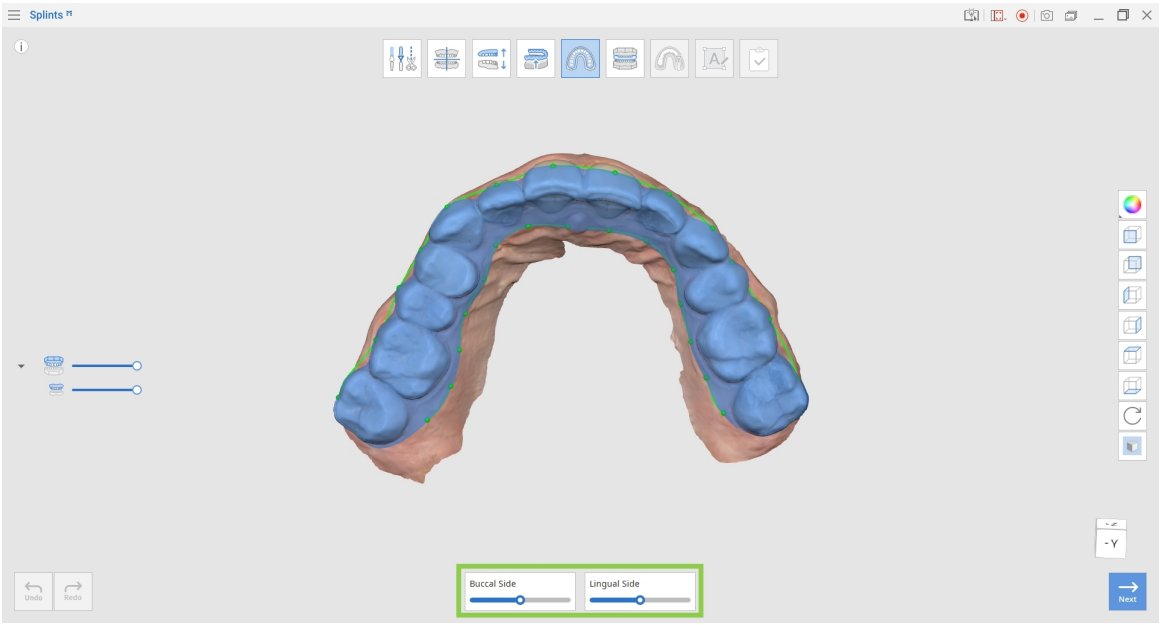
In this step, the outline of the splint is created on the buccal and lingual sides.

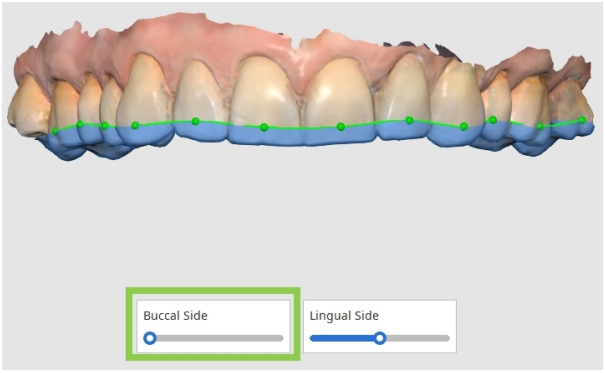
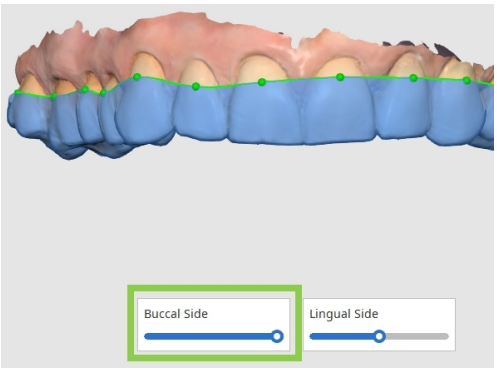
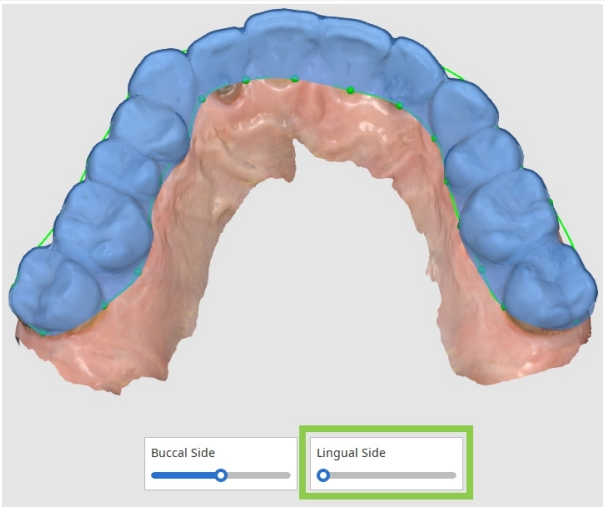
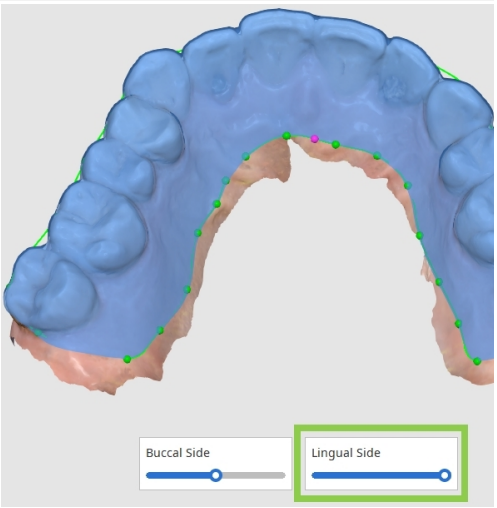


Toolbox

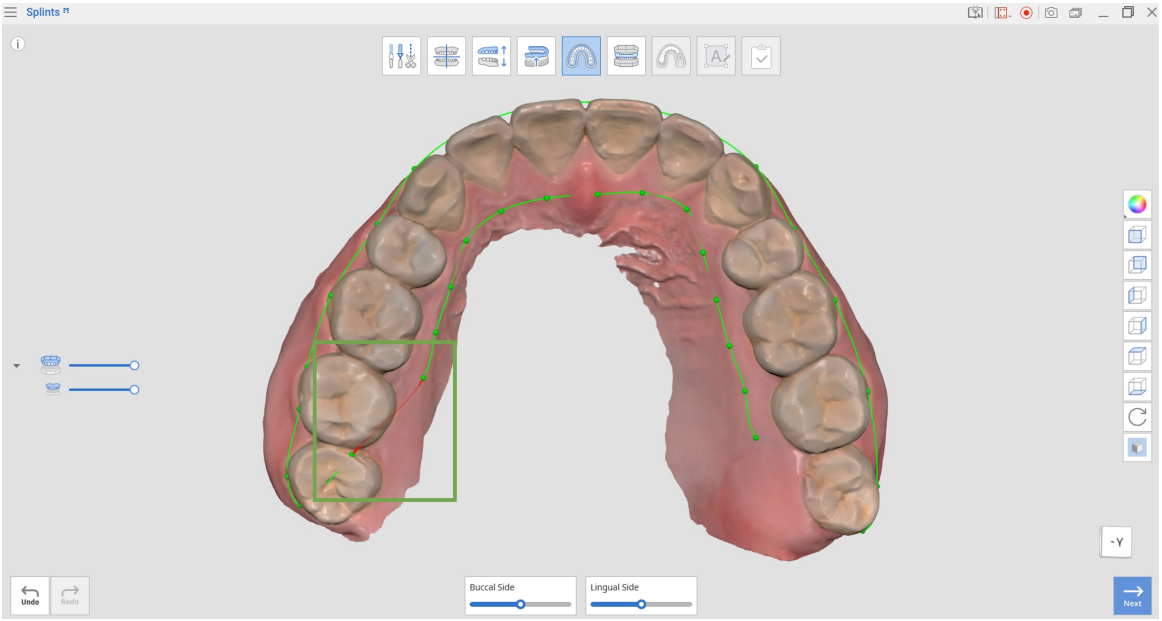
	Buccal Side	Adjust the outline on the buccal side. Move the slider to the right to bring the outline closer to the gingiva.
	Lingual Side	Adjust the outline on the lingual side. Move the slider to the right to bring the outline closer to the gingiva.

1. In Outline Designation Mode, an outline is automatically generated. To modify the outline, drag the green points using the mouse or adjust the “Buccal Side” and “Lingual Side” sliders.

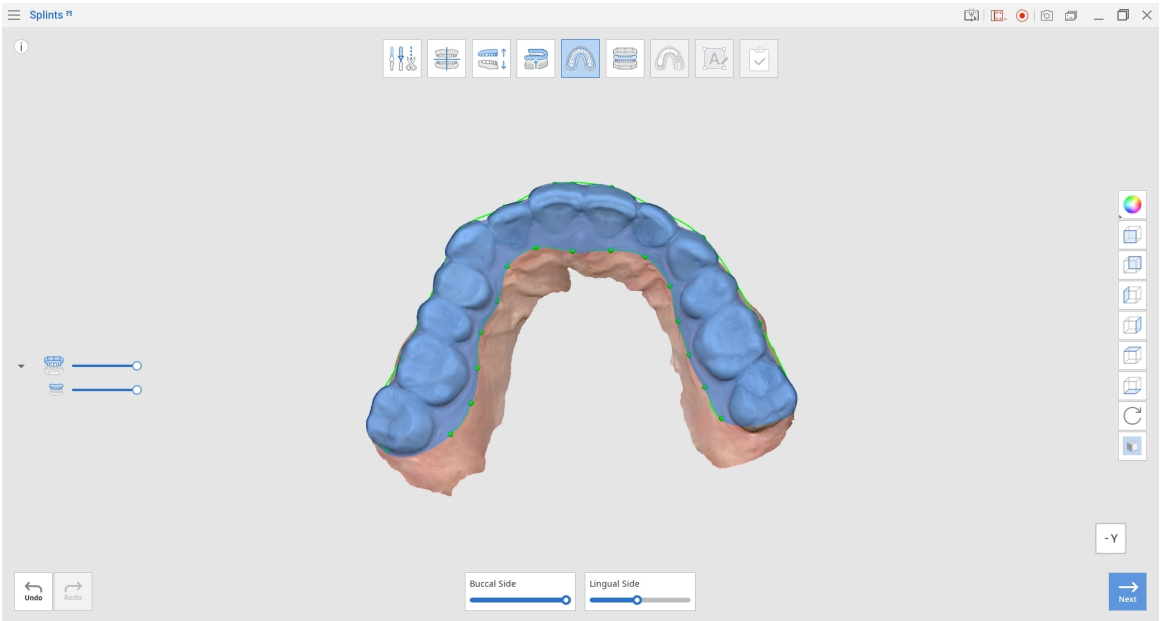


Moving slider to the left	Moving slider to the right
	
	

2. If any section of the outline appears in red, adjust the line until it turns green. You cannot move to the next step while red sections remain.



3. When the outline is correctly defined, the selected area is displayed in blue. Left-click on the outline to add green points, and right-click to remove them.

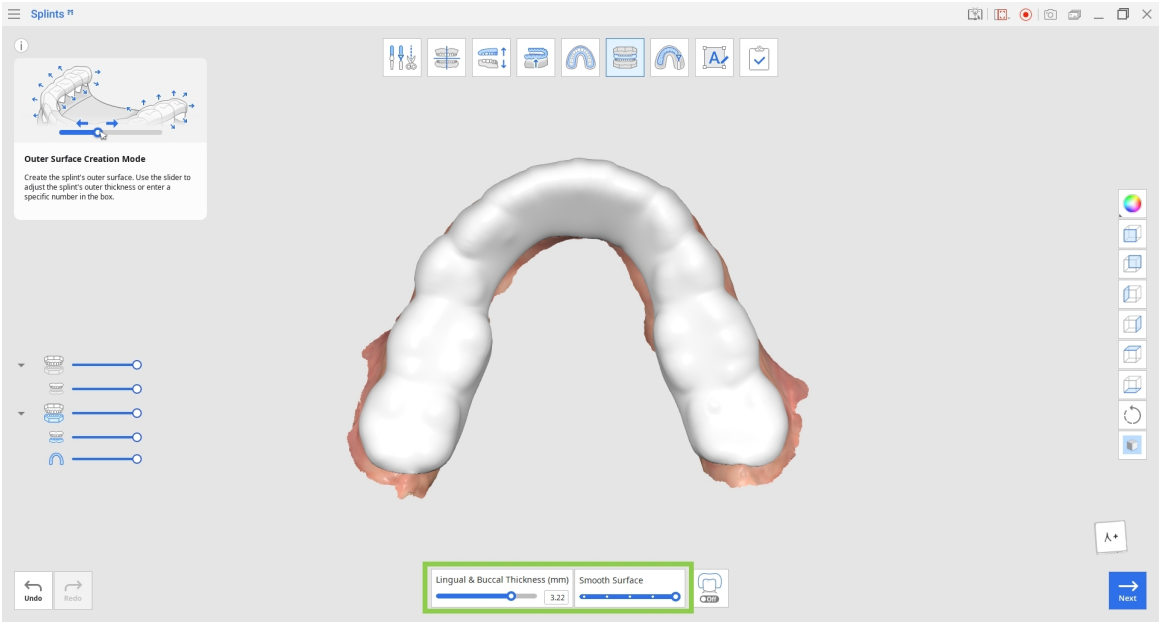


4. Click “Next” when finished.

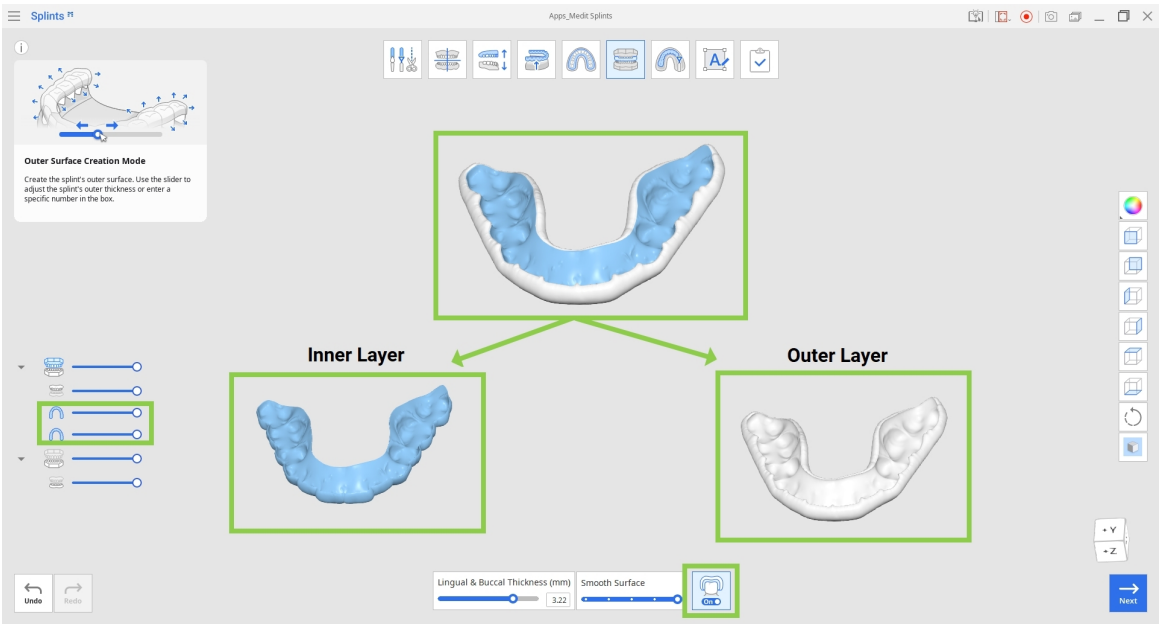
Outer Surface Creation Mode

In this step, the outer surface of the splint can be adjusted using the available tools.

1. Move the “Lingual & Buccal Thickness” slider to the right to increase the splint thickness on the lingual and buccal surfaces simultaneously. The occlusal surface thickness is automatically determined based on the distance to the antagonists.
2. Use the “Smooth Surface” slider to reduce roughness on the outer surface of the splint.



3. You can create a dual-material splint if your printer uses MultiJet printing technology. To do this, turn on "Dual Layer Splint" at the bottom, and the splint will be divided into outer and inner layers.



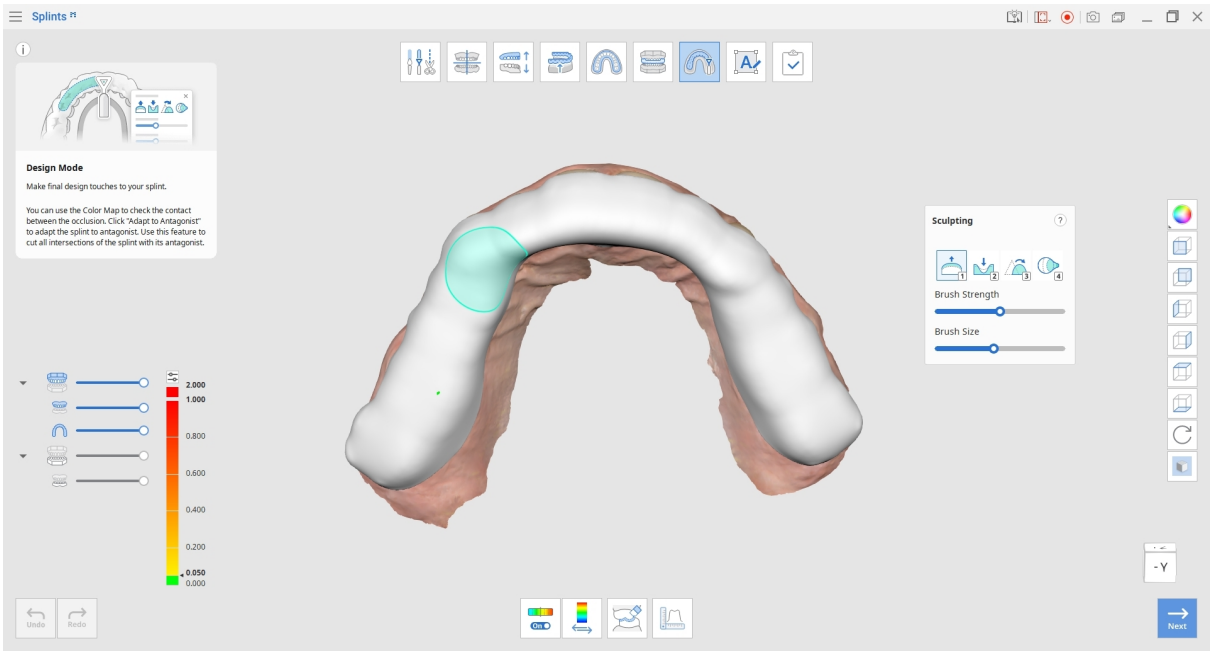
Toolbox

	Lingual & Buccal Thickness	Adjust the splint thickness on the lingual and buccal surfaces.
	Smooth Surface	Smooth out the outer surface of the splint.
	Dual Layer Splint	Split the splint mesh into outer and inner layers for dual-material printing.

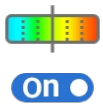
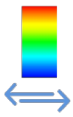
4. Click “Next” when finished.

Design Mode

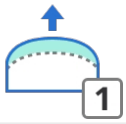
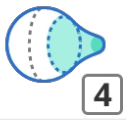
In this mode, final design adjustments can be made to the splint. Use the available tools to analyze occlusal contact points, remove intersections with the antagonist, and verify the splint's thickness.



Toolbox: Main

	Color Map On/Off	Toggle the color map display.
	Switch Deviation Display Area	Switch the deviation display between the full data and contact areas only.
	Adapt to Antagonist	Adjust the splint to remove intersections with the antagonist.
	Measurement Tools	Create section lines and measure distances between points.

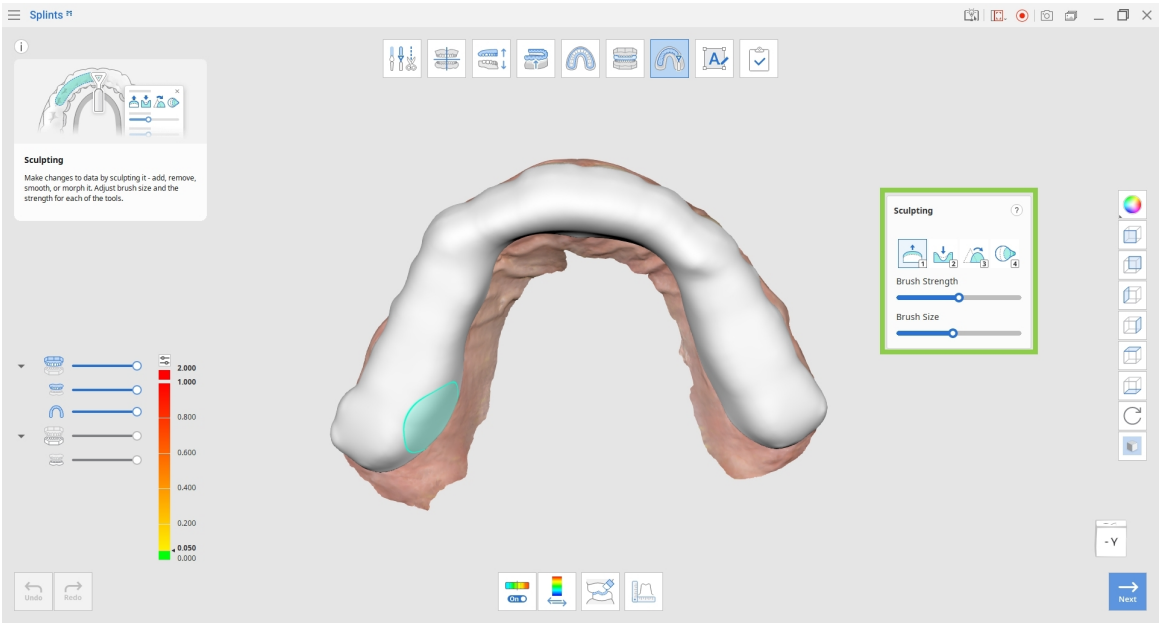
Toolbox: Sculpting

	Add	Use the mouse to add data on the surface.
	Remove	Use the mouse to remove parts of the data.
	Smooth	Use the mouse to smooth parts of the data.
	Morph	Use the mouse to morph parts of the data.

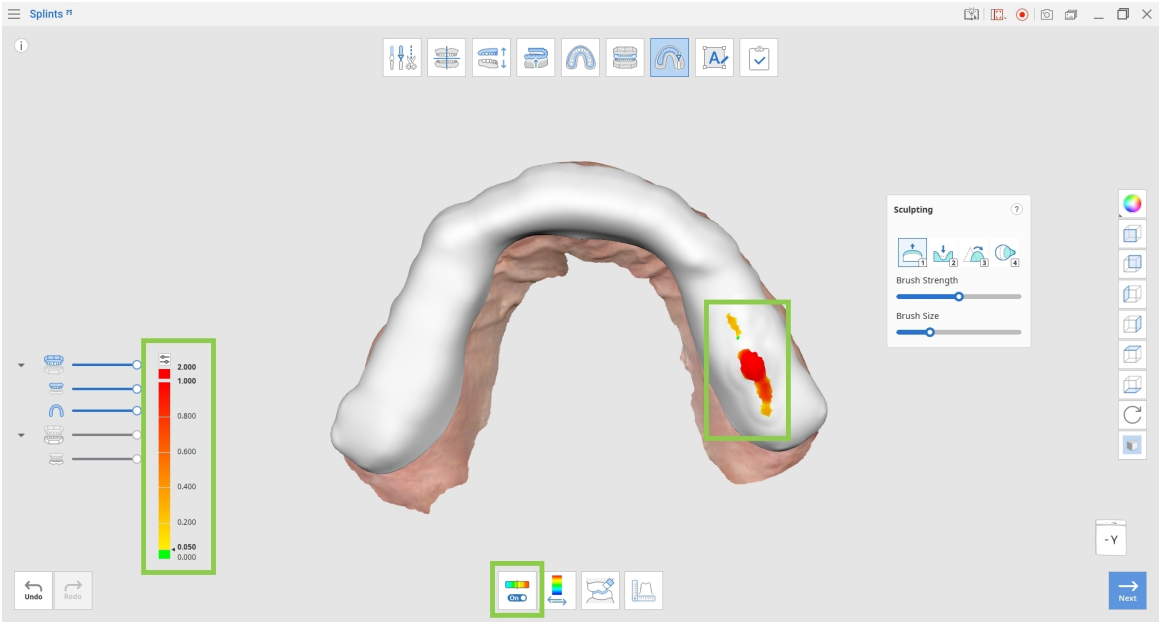
Toolbox: Measurement Tools

	Create Sections	Create section lines.
	View Perpendicularly to Section Line	Align the view perpendicular to the selected section line.
	Measure Distance by Two Points	Measure the distance between two points.
	Measure Distance by Three Points	Measure the distance between a point and a line defined by two other points.
	Delete Measurement Results	Delete measurement results and section lines.

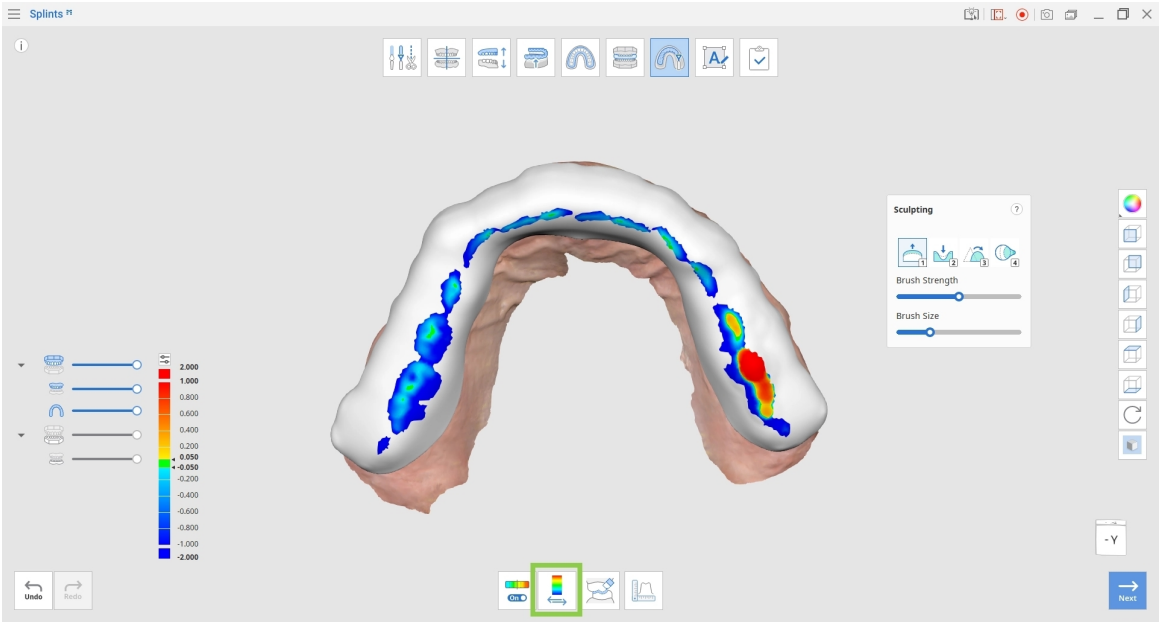
1. Use the Sculpting tools to add, remove, smooth, or morph the outer surface of the splint. This can help you make finer adjustments to the splint's design.



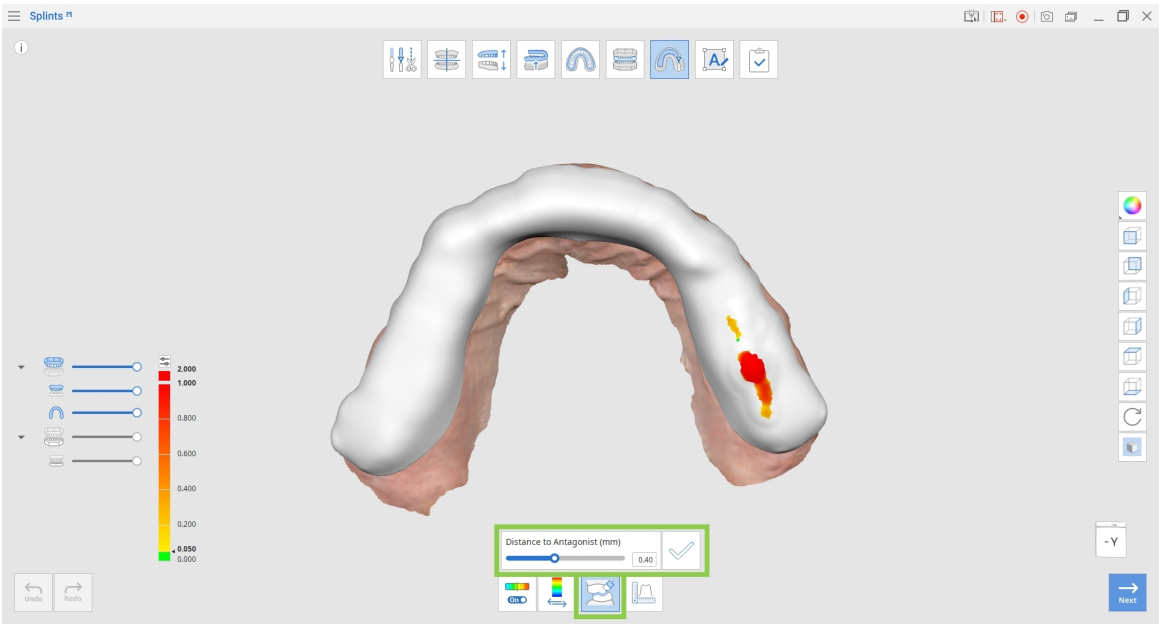
2. Enable the Color Map to identify intersections. Red areas indicate intersections between the splint and opposing data.



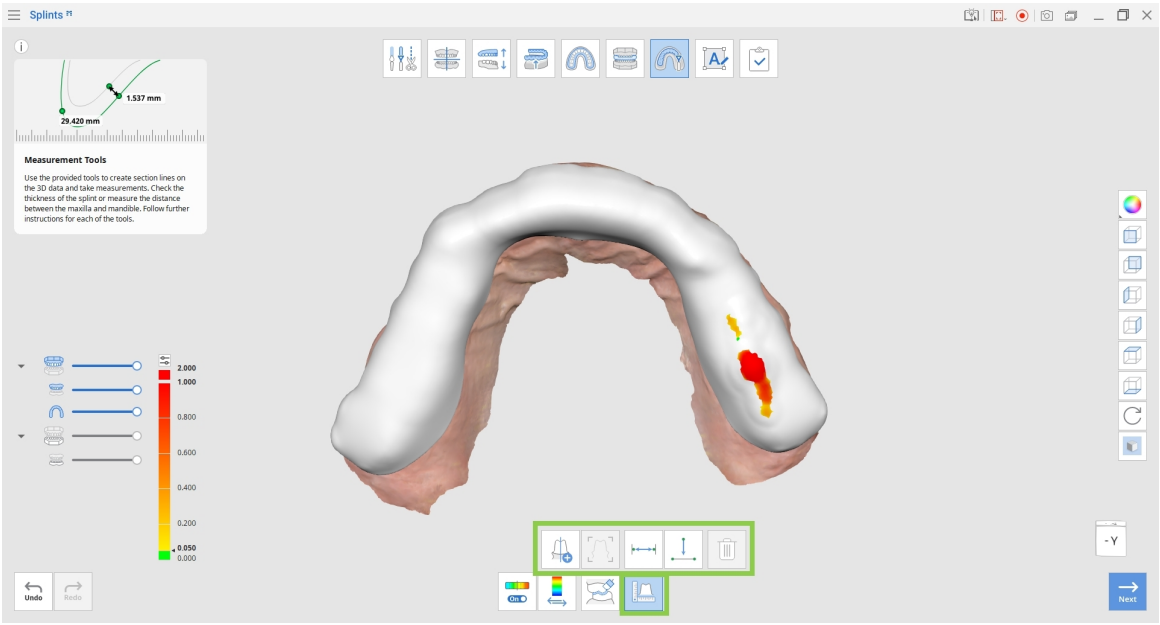
3. Click “Switch Deviation Display Area” to evaluate the distance to the antagonist.



4. Click “Adapt to Antagonist” to remove all intersections between the splint and the antagonist.



5. Use “Measurement Tools” to verify the splint thickness after editing. Create section lines and measure distances by selecting points on the data.

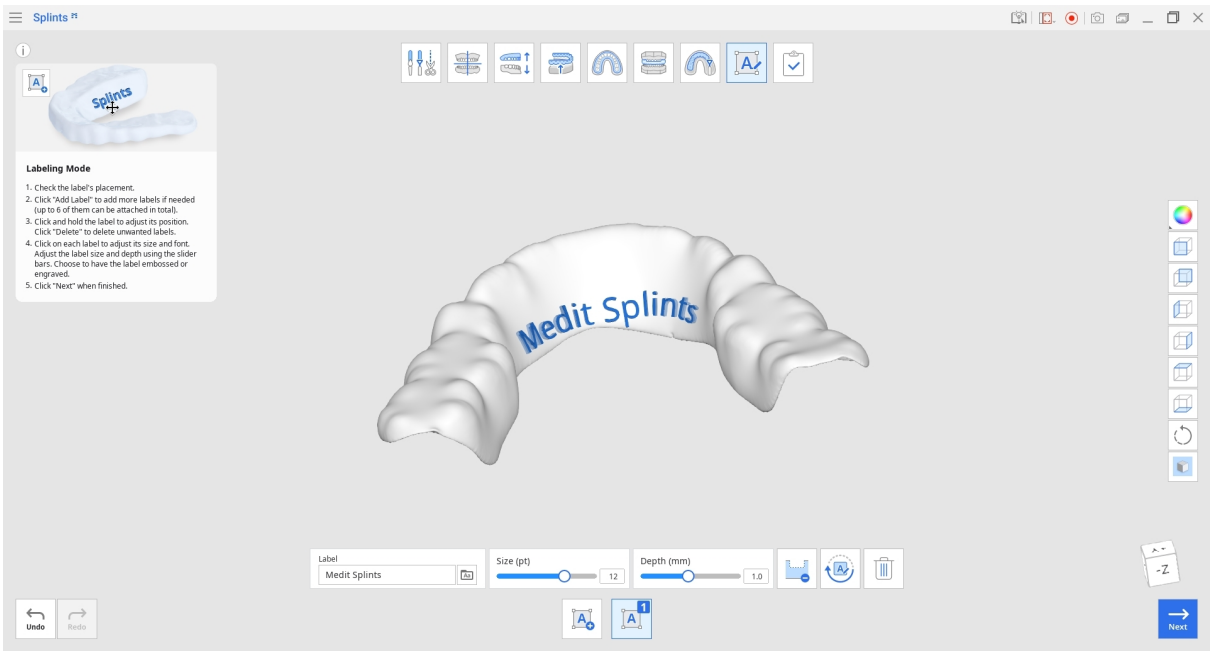


6. Click “Next” when finished designing the splint.

Labeling Mode

Labeling Mode provides tools for creating and managing labels on the splint surface. A default label (Label #1) is automatically created on the outer surface of the splint.

> **Note**
>
> Adding labels is optional.

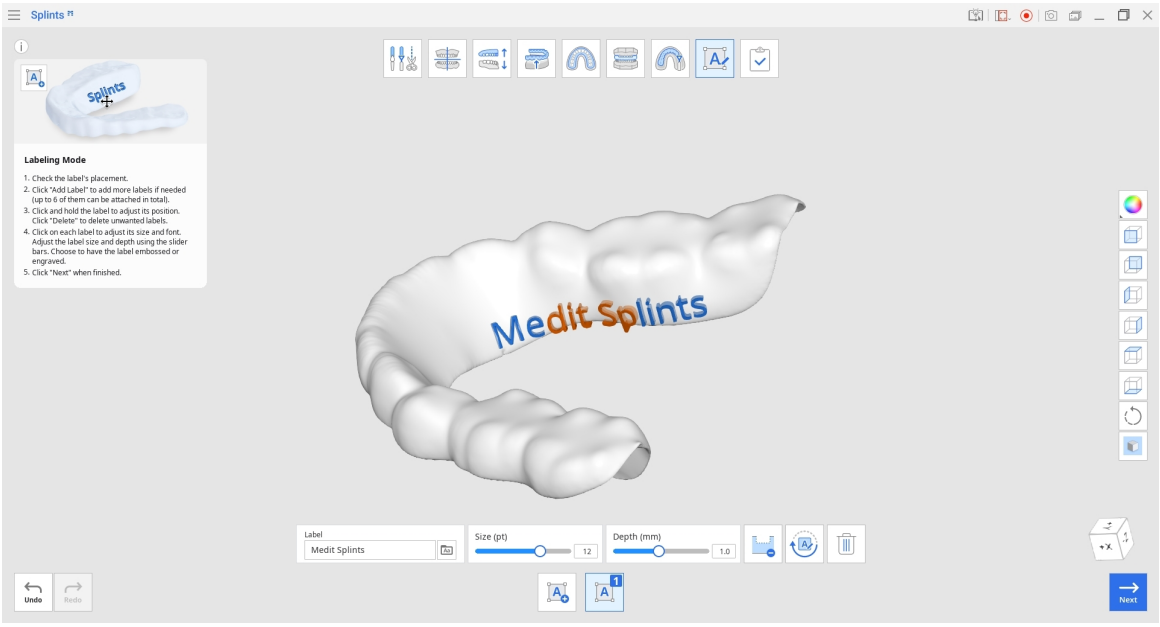


Toolbox

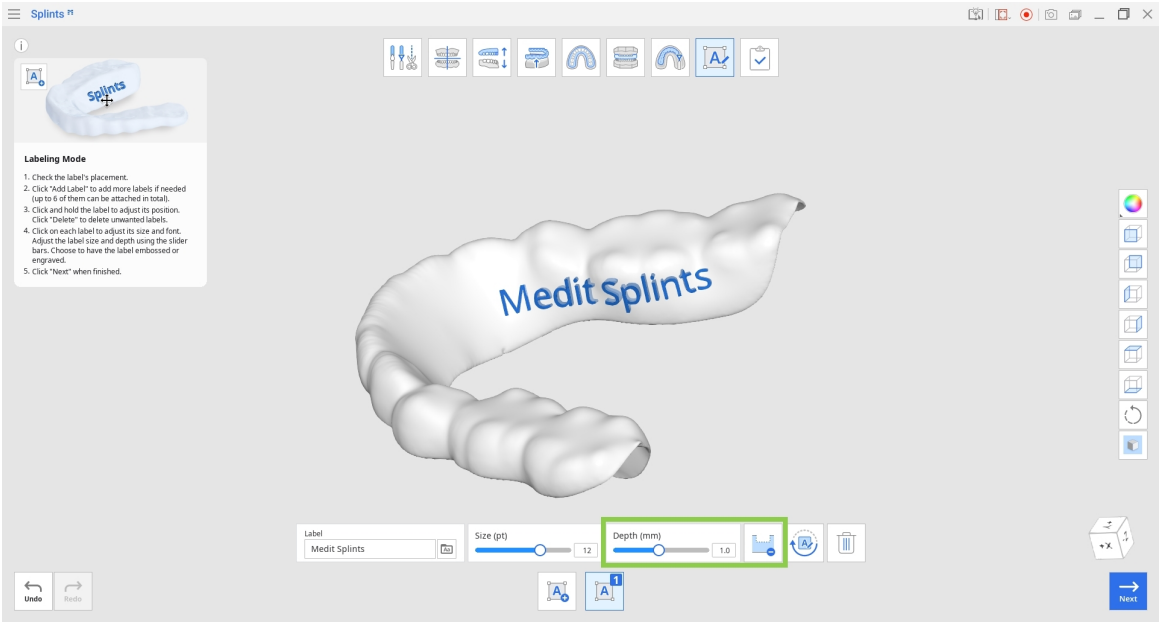
	Add Label	Add a new label to the splint.
	Manage Label #1	Edit, emboss, or engrave label #1.
	Manage Label #2	Edit, emboss or engrave label #2.

	Label	Enter the text to appear as a label.
	Font	Choose a font for the label.
	Size	Set the label size.
	Engraving	Label the splint by engraving.
	Embossing	Label the splint by embossing.
	Rotate 180°	Turn the selected label by 180°.
	Delete	Delete the current label.

1. Check the placement of the automatically created label. If any part of the label appears in orange, drag it until it is fully displayed in blue.

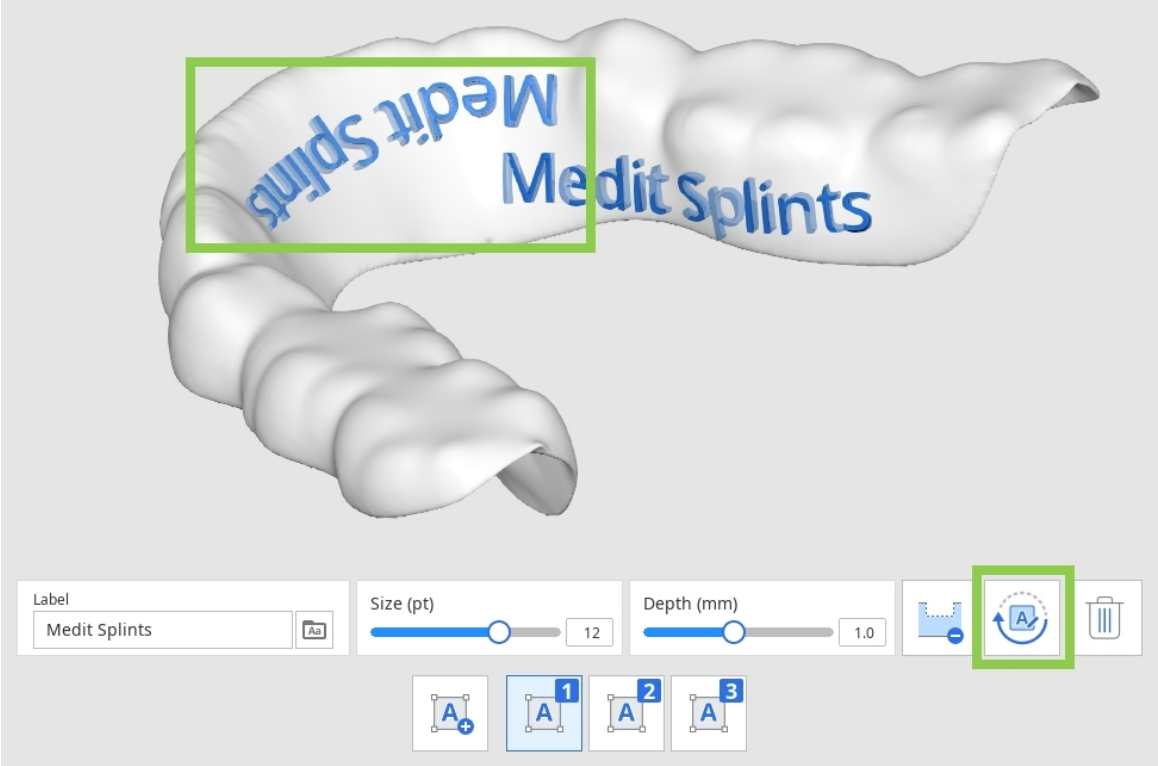


2. Click “Embossing/Engraving” to change the marking method. The labeling depth can be adjusted as needed.

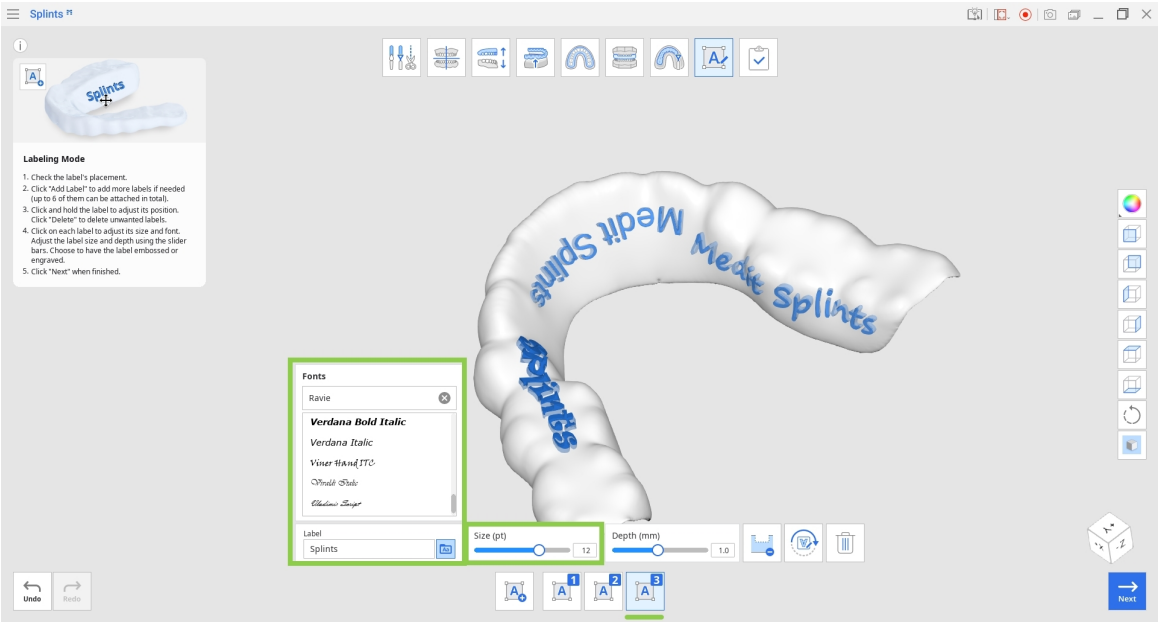


3. To add additional labels, click “Add Label.” Up to six labels can be created.

   You can rotate a label by clicking it and using “Rotate 180°.”



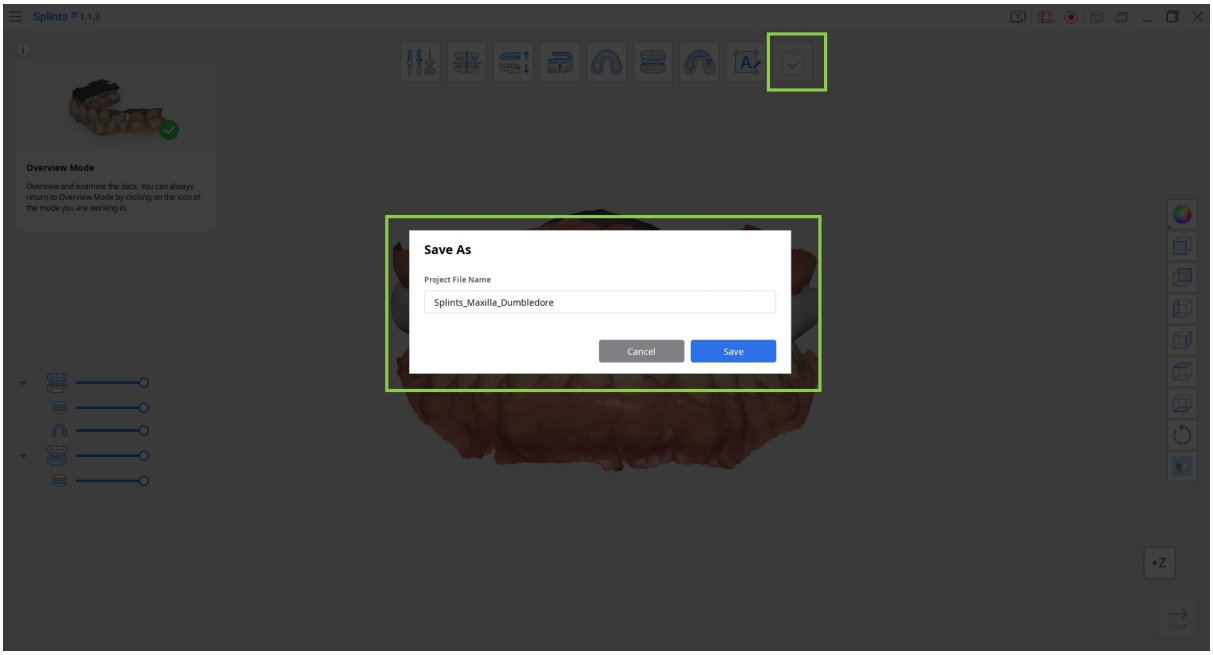
4. To delete a label, select the icon with the target label’s number and click “Delete.”
5. Select each label to adjust its font and size.



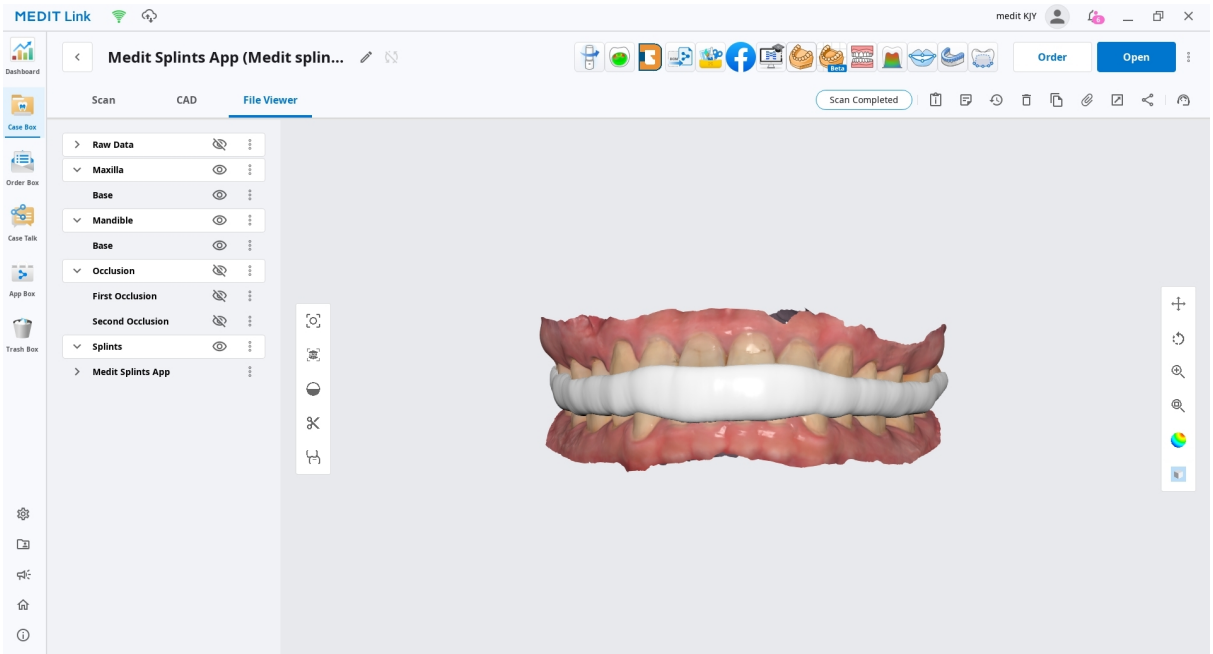
6. Click “Next” when finished.

Complete

Once the splint creation process is complete, click the final icon at the top of the screen to save the results to the Medit Link case. Enter a project file name and click “Save.”



The saved data (both the project file and the final splint design) can be checked in the Medit Link case.



Notice of Adverse Event Report

The user and/or patient should report any serious incidents that have occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Report to manufacturer at:

Telephone: +82-02-2193-9600

Website: www.medit.com

email: support@medit.com

Report to local authority at:

FDA MAUDE http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
MHRA (Medicines & Healthcare products Regulatory Agency): Medical device alert https://www.gov.uk/drug-device-alerts
BfArM : Medical device alert https://www.bfarm.de/SiteGlobals/Forms/Suche/EN/kundeninfo_Filtersuche_Formular_en.html
MFDS (Ministry of Food and Drug Safety) : Medical device alert http://www.mfds.go.kr/brd/m_548/list.do https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
European_EUDAMED https://ec.europa.eu/tools/eudamed/#/screen/search-device
Australia https://apps.tga.gov.au/prod/mdir/mdirsummary.aspx?sid=new

Canada https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html
Brazil https://notivisa.anvisa.gov.br/frmLogin.asp
Japan https://www.estrigw.pmda.go.jp/Iryo/Login/Index?ReturnUrl=%2fIryo
Taiwan https://qms.fda.gov.tw/tcbw/main/ap/index.jsp
Switzerland https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas/users---operators.html

Error and Warning Messages

Title	Message
Adjust Occlusal Relationship	There isn't enough distance between the arches. Increase the distance and try again.
Failed to Create the Outer Surface	Make sure the outline is correct and try again.
Failed to Adjust the Occlusal Relationship	Align the data to the occlusal plane in the Alignment Mode and try again.
Failed to Adjust the Occlusal Relationship	Trim unnecessary data in the Edit Mode and try again.
Failed to Automatically Create the Outline	Click on the teeth to create points and designate the outline manually.
Failed to Adapt to Antagonist	The scan data may have noise or abnormalities. Use sculpting tools to manually cut intersections or return to Edit Mode to edit your data.
Failed to Auto-Create the Splint	Make sure the entered value in "Inner Surface Creation Mode" is correct and try again.
Failed to Auto-Create the Splint	Make sure the entered value in "Occlusal Adjustment Mode" is correct and try again.
Failed to Auto-Create the Splint	Make sure the entered value in "Outline Designation Mode" is correct and try again.
Failed to Auto-Create the Splint	Make sure the entered value in "Outer Surface Creation Mode" is correct and try again.
Failed to Auto-Create the Splint	Make sure the alignment in "Alignment Mode" is correct and try again.

Title	Message
Failed to Create the Outer Surface	Make sure the entered value is correct and try again. Make sure the outline is correct in "Outline Designation Mode" and try again.
Failed to Create the Inner Surface	Make sure the entered value is correct and try again.
Failed to Create the Outer Surface	Make sure the outline is correct and try again.

Authorized Representative

Contact information for the manufacturer's authorized representatives is provided below.

Australia	**Sponsor:** LC & Partners Pty Ltd Level 25, 100 Mount Street, North Sydney, NSW, 2060 Australia

eIFU download link:

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