

DTX Studio[™] Implant 3.5

Instructions for Use

Important - Disclaimer of liability: This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, it is his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instructions for Use may not be regulatory cleared, released or licensed for sale in all markets.

General Precautions:

It is strongly recommended that both new and experienced users of dental implants, prosthetics, and associated software always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

One hundred percent implant success cannot be guaranteed. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) may result in failure. With respect to pediatric patients, routine treatment is not recommended until the end of the jaw bone growth phase has been properly documented. Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

It is strongly recommended that NobelGuide® surgical templates and duplicate dentures are only used with appropriate Nobel Biocare implants, surgical instruments, and prosthetic components, as combining components that are not intended to be used together can lead to mechanical and/or instrumental failure, damage to tissue, or unsatisfactory esthetic results.

Prior to planning any extra-oral surgical procedure, meaning craniomaxillofacial treatment using dental implants outside the dental or zygomatic area, the user is responsible for determining whether or not an implant is intended for extra-oral use.

Additional Information: For additional information on the NobelGuide® concept and the surgical procedures, please consult a Nobel Biocare representative. DTX Studio[™] Implant performance is dependent on the operating systems used. Therefore, only use DTX Studio[™] Implant with approved operating systems. Contact customer support for more information about the approved operating systems, and how to install DTX Studio[™] Implant.

Note: In the United States, and in some other markets, the physical surgical template for endosseous dental implant placement is a medical device. Please contact your local regulatory agency for information regarding the regulatory states and requirements related to manufacture of these surgical templates.

Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Basic UDI Name	Basic UDI-DI
Diagnostic and treatment software	733274700000016275



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Consult instructions for use

Manufacturer:

MD C E 2797

Rx Only

For Prescription Use Only.

Caution: Federal (United States) law restricts this device to sale by or on the order of a clinician, medical professional or physician. Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

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Introduction

DEVICE DESCRIPTION

DTX Studio[™] Implant is software for clinical use supporting the image-based diagnostic process and treatment planning of dental, cranio-maxillofacial, and related treatments.

To support the diagnostic and treatment planning process for dental, cranio-maxillofacial, and related treatments, DTX Studio[™] Implant offers a visualization technique for (CB)CT images of the patient for the diagnostic and treatment planning process. In addition, 2D image data such as photographic images and X-ray images or surface scans of the intraoral situation may be visualized to bring diagnostic image data together. Prosthetic information can be added and visualized to support prosthetic implant planning. The surgical plan, including the implant positions and the prosthetic information, can be exported for the design of dental restorations in DTX Studio[™] Lab.

DTX Studio[™] Implant supports the NobelGuide[®] clinical concept for oral rehabilitation based on dental implants. It is part of the whole Guided Surgery System ('NobelGuide[®] concept') for the treatment of fully and partially edentulous jaws including single unit cases.

DTX Studio[™] Implant users can choose to subscribe to regular training and education sessions to master the planning software. For more information, please refer to courses available through the Nobel Biocare website at www.nobelbiocare.com.

INDICATIONS FOR USE

DTX Studio[™] Implant is a software interface for the transfer and visualization of 2D and 3D image information from equipment such as a CT scanner for the purposes of supporting the diagnostic process, treatment planning and follow-up in the dental and cranio-maxillofacial regions.

DTX Studio[™] Implant can be used to support guided implant surgery and to provide design input for, and review of, dental restorative solutions. The results can be exported to be manufactured.

INTENDED PURPOSE

Intended purpose of the software is to support the diagnostic process and treatment planning for dental and cranio-maxillofacial procedures.

INTENDED USER AND INTENDED PATIENT TARGET GROUP

DTX Studio[™] Implant is used by an interdisciplinary treatment team, to support them in treating patients who are subject to dental, cranio-maxillofacial or related treatments.

Intended for patients needing to undergo dental treatment.

DEGREE OF MEASUREMENT ACCURACY

Measurement accuracy depends on the image data, the used scanner hardware, its calibration and acquisition settings. The measurement cannot be more precise than the resolution of the image. DTX Studio[™] Implant software reports the value, rounded to one digit after the decimal point, based on user-picked points.

CONTRAINDICATIONS

None identified for DTX Studio[™] Implant.



Warning

This planning program does not automatically check all technical constraints! In some cases, the surgical templates may not be able to be manufactured even when no technical constraints are automatically identified through the software.

Before using DTX Studio[™] Implant, please read these Instructions for Use and retain it for future reference.

Please note that the information provided in this document is intended to get you up and running.

The procedures in this document are described for a Single User Setup license. For information on procedures specifically applied to a Practice Setup license, please refer to "Practice Setup" on page 12.

CYBERSECURITY

It is recommended that active and up-to-date antivirus and anti-malware software, together with a correctly configured firewall, are installed on the computer where DTX Studio[™] Implant is to be used. Furthermore, always lock the computer when it is left unattended.

COMPATIBILITY

DTX Studio[™] Implant is not connected with other medical devices, the software is compatible with previous versions of DTX Studio[™] Implant.

INTEROPERABILITY

DTX Studio[™] Implant is interoperable with DTX Studio[™] Clinic and DTX Studio[™] Lab.

INTENDED LIFETIME

For software the intended lifetime is indefinite, used on the supported operating systems will keep performing according to its intended use.

PERFORMANCE REQUIREMENTS AND LIMITATIONS

DTX Studio[™] Implant has dependencies on the operating systems it is used with. It is therefore important to make sure DTX Studio[™] Implant is used only with approved operating systems. More information about which operating systems are approved can be found in the Computer Guidelines for DTX Studio[™] Implant.

CLINICAL BENEFITS AND UNDESIRABLE SIDE EFFECTS

DTX Studio[™] Implant is a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

No side effects known.

NOTICE REGARDING SERIOUS INCIDENTS

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB

https://www.nobelbiocare.com/complaint-form

FACILITIES AND TRAINING

It is strongly recommended that clinicians, new as well as experienced users of implants, prosthetics and associated software, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit <u>nobelbiocare.com</u>.

Start

THE TREATMENT CONCEPT

A **treatment** includes all **treatment plans** concerning a patient. A new treatment can be started when creating a new patient or when working with an existing patient. For example, you can create separate treatments for the upper and the lower jaw.

A **treatment plan** contains the basic patient model, dental scan, wax-up and/or radiographic guide, as well as all the products in the current scene configuration of a specific patient.

OPEN DTX STUDIO[™] IMPLANT

To open DTX Studio[™] Implant, double-click the shortcut icon 💭 on the desktop. The software opens in the Office module, allowing you to log on and start working with patient files.

BASIC ACTIONS ON PATIENT FILES

Note: Log in to DTX Studio[™] Implant to start working on patient files.

Create a New Patient File

To create a new patient file, click **New** in the **Medical Records** tab on the toolbar. In the **New Patient** dialog, choose to create a 3D patient model, order a scan of a dental cast, or enter patient information.

Open an Existing Patient File

To open a patient file, double-click a patient name in the list. The **Medical Record** dialog pops up to determine whether to go to the module to create a 3D plan, to enter patient information, to order products, or discuss a treatment plan.

Open a Treatment Plan

When a specific patient file is opened and you want to open a treatment plan for the patient, click the **DTX Studio Implant** tab in the toolbar and click **Open** *i*. When the **Planning Overview** window appears, select the treatment plan and click **Open Scenario**.

Save a Treatment Plan

To save a treatment plan, use Save 🛗 on the DTX Studio Implant tab or press [CTRL + S].

Copy a Treatment Plan

To save a copy of the treatment, e.g. to create a treatment for the opposite jaw with a copy of data, choose **Save as** on the **DTX Studio Implant** tab and select **New Treatment** \mathcal{D}_{\bullet} .

Rename or Delete a Treatment Plan

To rename or delete a treatment plan, use the **Manage** option on the **DTX Studio Implant** tab. This is only possible when specific conditions are complied with.

Close a Treatment Plan

To close a treatment plan, click the **DTX Studio Implant** tab in the toolbar and click **Close Plan** . The treatment plan is closed and the **Planning Overview** dialog appears.

Close a Patient File

To close a patient file, click the **DTX Studio Implant** tab in the toolbar, and choose **Close Patient** in the menu. When the **Medical Record** dialog appears, click **Close Patient**. If any unsaved changes are available in the patient file, the system requests input on what to do: **Save**, **Don't Save**, or **Cancel** the closure of the patient file.

Archive Patient Files

To move patient files to the archive, click **Archive** D on the **Medical Records** tab.

User Identification

Multiple users may have access to the computer with DTX Studio[™] Implant. To ensure that only authorized users may log in and use DTX Studio[™] Implant, proper user identification is needed. The software will apply the correct user settings and patient privacy rules. Two-factor authentication can be established via DTX Studio[™] Go to increase security even more.

LOGGING IN

- 2. Select the user.
- 3. Enter the corresponding password.
- 4. Click Login.

When logging in for the first time, enter the password received in the registration e-mail. Change the password as requested. The password should be as secure and strong as possible and not contain evident wording (e.g., avoid any referral to personal data, like date of birth, etc.).

If you select **Automatic login**, the DTX Studio[™] Implant login dialog will no longer be shown on the computer used.

Two-Factor Authentication

If two-factor authentication was set up in DTX Studio[™] Go, you will need to enter a password and a six-digit verification code to log in. You will be prompted to enter a new six-digit verification code every 30 days.

SWITCH USERS

In DTX Studio[™] Implant, switch between users by clicking **Switch Account** in the **DTX Studio Implant** menu within the **My Office** module.

MANAGE ACCOUNT DETAILS

To consult license or account details, to edit details or change a password, to manage connections or permissions within a practice, open the **Manage Account** dialog:

- 1. Click the **DTX Studio Implant** tab in the **My Office** module.
- 2. Select Manage Account.
- 3. The Manage Account dialog shows the available information.

Practice Setup

The practice setup version of DTX Studio[™] Implant allows for multiple installations and login for multiple users in a dental practice. It allows for central storage of patient files in a shared network folder with easy access to these files from different locations.

INSTALL PRACTICE SETUP

For instructions on how to install and register DTX Studio[™] Implant, please contact customer support.

MANAGE ACCOUNTS

To manage the user accounts available in a practice and to set the corresponding user permissions, open the **Manage Accounts** dialog via the **Manage Account** option within the **DTX Studio Implant** menu.

ADD USERS

To add new users, contact the local Nobel Biocare customer service or support desk.

WORK WITH SCANS

Sets of DICOM files generated by the scanner, which are called 'scans' or 'patient scans', are listed in the **My Office** module in the **Scans** group. By clicking the corresponding option in the menu, scans can be filtered to view all scans, new scans or failed scans.

Tip: TeamPorter[™], a standalone application, monitors predefined folders on a central drive for newly generated DICOM files and converts them into scans, making them available in DTX Studio[™] Implant. Depending on the license type used in the practice, TeamPorter[™] is installed or not.

Scan Warnings

It will not be possible to load invalid DICOM sets. DICOM sets may be invalid due to one of the following reasons:

Warning
The DICOM set has less than two slices.
The DICOM set has a zero slice increment.
The DICOM set has inconsistent slice increments.
The DICOM set has no image orientation.
The DICOM set has wrong image orientation.

The DICOM set slice thickness is too large.

The DICOM set has a gantry detector tilt.

The DICOM set slice increment is too large (it is possible to use this DICOM set, but at your own clinical risk).

Create a New Patient File

To create a new patient file, double-click the scan in the **Scans** list in the **My Office** module. Click **Create a new Planning**. The software takes you to the **Create Patient** wizard in the 3D Planning module.

Alternatively, create a new medical record using the **New** icon in the toolbar.

The new patient file will automatically be shared with the practice.

Software Overview

The main graphical user interface components are indicated in the image below.



- Toolbar with action groups specific to the selected module
- 2 Assistant
- 3 Workspace
- 4 Module bar
- 5 Upload Center

Click the icons in the module bar to navigate through the different DTX Studio[™] Implant modules:

K	Home / My Office module to manage patients and calibration sets.
Plan	3D Planning module to import DICOM files, create patient and guide models, diagnose, and plan.
2	Patient Info module to store patient information and manage clinical pictures in the Patient Library.
Order	Order module to order scans of the dental cast or wax-up, TempShells or the surgical template and duplicate denture together with standardized components.
Discuss	Discuss module to facilitate the communication about a treatment plan with colleagues and patients - by means of viewer files, reports and/or Communicator presentations - and to link DTX Studio [™] Implant and OsseoCare [™] Pro through the creation of OsseoCare [™] Pro surgeries.

Double-click a patient in **My Office** to go to a specific section related to this patient. Click on **3D planning** to diagnose and plan a treatment.

WORKSPACE SYSTEM

When planning in DTX Studio[™] Implant, it is important to be able to view patient data in different ways. The required view depends on the information required by the user. These different ways of visualizing the data are called the workspaces.

WHAT IS A WORKSPACE?

A workspace is the arrangement of 3D and 2D viewers, in conjunction with the editor panes in the side bar on the right of the screen. A workspace allows visualization and interaction with 3D objects and/or 2D image data. Switch between the different viewer layouts available in the system to view the pre-operative image data.



TOOLBAR

DTX Studi	o Implant v	Patient	F	rosthetic		Diagnose		Plan	Ì	Finalize
Nerve	Tooth	Ktract Tooth	🧉 Point 🧷	Distance	Angle	HU Value	Implant angle	Change Workspace	Set Focus	
	Diagnos	se	Annotate		M	easure		Work	spaces	

At the top of the workspace, a context-specific toolbar provides access to the tools needed for certain tasks. In the Planning module, dedicated tabs appear when selecting specific objects (e.g. cross-sectional reslice, implants, etc.). These dedicated tabs – also called contextual tabs – offer alternative access to actions which are also available through the pop-up menus which appear when you right-click an object.

INTERACT WITH THE VIEWERS

Various interaction modes can be chosen to interact with 3D models. Switch between the interaction modes by clicking the icons in the Interaction toolbar, using an **Interaction** right-click menu, or via a combination of shortcut keys.

ß	Interaction mode	Select an object or identify an object for an action by pressing the left mouse button.
P	Rotation mode	Rotate the 3D scene (only 3D) by dragging the mouse.
	Pan mode	Pan the scene by dragging the mouse.
Q,	Zoom mode	Zoom in or out by dragging the mouse.
R.	Zoom Box mode	Zoom to focus on a specific area of the model by drawing a rectangular area (only in 2D).

Change between different interaction modes using the shortcuts:

Ctrl (Cmd) or middle mouse button	Switch to pan mode when you are in any other mode. As long as the button is pressed down, pan mode is maintained. Release the button to return to the original mode.
Alt	Switch to rotation mode when you are in any other mode. As long as the button is pressed down, rotation mode is maintained. Release the button to return to the original mode.
Shift	Switch to zoom mode when you are in any other mode. As long as the button is pressed down, zoom mode is maintained. Release the button to return to the original mode.
Tab key	Toggle between interaction mode and rotation mode.

Different standard views are available in the 3D viewer.

View 🧟 🏷 🧟

Click the icons to go to the corresponding standard views of the model.

3	Front – Standard frontal view – shortcut key [5]
P	Left – Standard left lateral view – shortcut key [1]
(C)	Right – Standard right lateral view – shortcut key [3]
	Top to bottom – Standard cranio-caudal view – shortcut key [9]
٢	Bottom to top – Standard caudo-cranial view – shortcut key [7]

MANIPULATE OBJECTS

1. To select an object, enter interaction mode and click on the object. In a 3D viewer, a white contour line indicates that the object is selected. In a 2D viewer, the outline of the selected object is colored.

Note: The patient model is an exception in this case. No contour line is shown when the patient model is selected.

- 2. Select the cross-sectional reslice, an implant or an anchor pin and access related actions via the dedicated toolbar tab.
- 3. Right-click any object to see the pop-up menu with possible actions related to that object.

SHOW OR HIDE AN OBJECT

To efficiently plan a patient's treatment, it is important to only see only objects of interest during the planning stage.

A single object can be hidden using the right-click menu or shortcut key [H].

With the Visibility Editor, the visibility of the standard objects can be toggled with a single mouse click.

Different visibility icons are available for group objects:



MANIPULATE A CT SLICE

Scroll through CT images

DTX Studio[™] Implant is equipped with a number of tools such as the mouse scroll wheel, the slider, or the slice input field to browse through the slices.

LEVEL AND WINDOW

Use the level/window tool on both 2D and 3D viewers to change the level and window of the values used to convert the data into an image or model. Depending on the type of image (2D or 3D), the result will differ.

Level/Window on 2D

The contrast of CT slices as well as panoramic views is defined by the window and level values. The level/ window setting defines which gray values are displayed on the screen. A selection centered around the level value, and with a width of the window value (equally divided at both sides of the level), is displayed. The contrast of the CT slices may be modified by adjusting these settings.

The level is modified by pressing the mouse button and moving the mouse up and down. The window is updated by pressing the mouse button and moving the mouse left (narrowing) and right (widening).

Level/Window on 3D

When working in 3D view, the level/window tool is used to control the scaling or the center of the transfer function in order to reduce the amount of noise in the patient model or to adjust the color settings. These adjustments can improve the visualization of the patient model.

Move the center of the transfer function without affecting the width of the range by pressing the mouse button and moving the mouse up or down. Press the mouse button and move the mouse left or right over the patient model to respectively widen or narrow the range of values used to generate the patient model.

Patient Model

CREATE A 3D PATIENT MODEL

To create a 3D patient model it is important to select the correct DICOM files, to set the most appropriate volume of interest, to indicate the optimal isovalue, and select the correct jaw type. The system will guide you through these steps in the Create Patient wizard.

- 1. Enter the **Create Patient** wizard using one of the following actions:
 - Click New ^{III} in the Medical Records tab of the DTX Studio[™] Implant toolbar and click Create a new planning.
 - In the Planning module, click **Patient** $\[\]$ on the **Patient** tab of the **Planning** toolbar
- 2. Select the appropriate set from the loaded DICOM sets, or import the correct one.
- 3. Click Next.
- 4. Set the volume of interest (VOI) on the Set the volume of interest and isovalue page.
- 5. Set an appropriate isovalue using the **Isovalue** slider and click **Next**.
- 6. Adjust the scanner orientation and set the occlusal plane using the sliders.
- 7. Select the jaw type you want to treat for the patient.
- 8. Click Finish

EDIT THE SHAPE OF THE RRESLICE CURVE

For the optimal reslice curve, the cross-sectional reslice should always be positioned perpendicular to the occlusal plane. When creating a new patient model, a default reslice curve is calculated based on the selected jaw type, volume of interest, and occlusal plane. The shape of this curve as well as the size of the cross-sectional reslice can be edited.

To adjust the shape of the reslice curve:

- 1. Click **Reslice curve** F in the **CT Editor** group on the **Patient** tab.
- 2. The Adjust Reslice Curve action is started.
- 3. Fine-tune the calculated curve by manipulating the existing control points or generate a new curve by placing tooth control points.

Manipulate the Existing Control Points

- 1. Click and drag the control points to manipulate the shape of the reslice curve.
- 2. Insert a point, add an end point, or select and remove a point.
- 3. Click **Finish** when the shape of the curve is satisfactory.

Use Tooth Control Points

1. Click **Re-indicate curve** 🌭 .

- 2. Follow the instructions in the tooltips to place the tooth control points appropriately:
 - Click the axial viewer to indicate the position of the right third molar (wisdom tooth).
 - Click the axial viewer to indicate the position of the next tooth, the right canine.
 - Click the axial viewer to indicate the position of the canine on the left side.
 - Click the axial viewer to indicate the position of the fourth tooth, the left third molar (wisdom tooth).

Notes:

- The dental numbers indicated in the tooltips differ depending on the dental notation system used.
 This notation can be changed in the General Preferences.
- If the tooth marker points are to be positioned where dentition is physically no longer present, position them where they would/should be located.

- 3. These four points the two third molars and the two canines together with five automatically generated control points form the basis for the reslice curve.
- 4. Check the curve and fine-tune, if necessary.
- 5. Click **Finish** when the shape of the curve is satisfactory.

Adjust the Size of the Cross-Sectional Reslice

Adjust the size of the perpendicular view to see the appropriate image in the cross-sectional reslice:

- 1. Click **Reslice curve** 1/2 to open the **Adjust Reslice Curve** action.
- 2. Drag the boundaries of the shown region in the perpendicular view up and/or down or sideways.

Note: It is possible to drag the upper or lower boundaries independently. When dragging the left or right boundary, the opposite one will move in the opposite direction and with the same distance to assure the central position of the reslice image.

VISUALIZATION OF THE PATIENT MODEL

Warning

The user must be familiar with the interpretation of CT data and the way CT data are visualized by means of volume rendering.

What is a Transfer Function?

When a patient model is created, each gray value is converted into a specific color with certain opacity to give the patient model a specific look. To achieve this a transfer function is applied which assigns RGB values and opacity to every voxel in the volume. By applying the transfer function, the 3D volume is visualized.

Transfer functions can be managed and applied to the patient model using the **Transfer Functions** gallery. This gallery contains thumbnails representing the available transfer functions as well as a number of actions that can be performed on these transfer functions. A distinction is made between **built-in templates**, **custom templates**, and '**This Patient**' transfer functions for the current patient.

HOW TO CLEAN UP THE VISUALIZATION OF THE PATIENT MODEL

When in planning mode, cleaning up artifacts and cluttering particles in the 3D scene can be done using the **Patient Mask** or the **Erase Bone Artifacts** actions.

Patient Mask

- 1. Click Patient Mask 🛃 .
- 2. In the **Patient Mask** action, click one of the following icons:
- Click **Cut** to indicate the part of the volume to be removed from the model. Everything within the drawn polygon will be hidden.
- Click **Isolate** to indicate the part of the volume you would like to show. Everything outside the drawn polygon will be hidden.
- Click Add to start re-adding part of the volume that has been cut away.

Start drawing the polygon:

- Click with the left mouse button.
- Move the mouse and click a second time. The two clicked positions are linked with a green dotted line.
- Click a third time. The linking green dotted line will change into a polygon.
- Continue until you have enclosed in a polygon the part of the model that you want to cut away.
- Right-click or press **Enter** to apply.

Erase Bone Artifacts

- 1. Click Erase Bone Artifacts In the Patient Editor group on the Patient tab. The Erase Bone Artifacts action starts.
- 2. Click Magic eraser 💜 or Eraser << in the Erase Bone Artifacts action.
- 3. Click the CT data or keep the mouse button pressed down to mark the parts to be removed from the patient model. With the **Magic eraser** *V*, the masking is removed in a small, medium or larger region around the clicked position, depending on the brush size. With the **Eraser** *A*, all masking is removed in a sphere around the clicked position. The size of the sphere depends on the brush size, which can be changed.

Note: The **Erase Bone Artifacts** action does not affect the original CT data. When artifacts have been removed and the patient model is edited afterwards via the **Edit Patient** action, the artifacts will be part of the model again. Therefore, if you need to perform both actions to obtain a better result, Nobel Biocare advises editing the patient model first and erasing possible noise and artifacts afterwards.

Disable Mask

Use **Disable Mask**¹ to toggle between the complete patient model and the specified selection.

Reset Patient Mask

Use **Reset Patient Mask** to show the complete patient model again as it was generated.

Keep the Largest Part

When fine-tuning the model using the **Patient Mask** action, it is possible to isolate the largest 'bony' part of the model instead of cutting away all the smaller particles cluttering the view.

To do so, click **Keep largest part >** in the **Patient Mask** or **Erase Bone Artifacts** actions. The smaller particles and parts with a density different from the bone density will be removed. The largest bony part remains visible.

Prosthetic Information

DIAGNOSTIC SETUP

When using DTX Studio[™] Implant, two types of scan protocols can be followed to model the virtual diagnostic setup, depending on the clinical indications:

- For small partial edentulous patient cases (preferably at least six teeth remaining), the protocol without radiographic guide can be followed (using a scan of the intraoral situation).
- For edentulous patient cases and for large partial edentulous patient cases (advised when less than six teeth are remaining), the protocol with radiographic guide must be followed.

Dental Scan

Scan of the Dental Cast

The dental cast is made from an impression and represents the patient's intraoral situation. A prosthetic restoration can be constructed on the cast using a prosthetic setup or wax-up. The surface of this model can be accurately scanned (digitized) by the dental laboratory. This surface scan can be imported into DTX Studio[™] Implant to be aligned with the patients' 3D model from the DICOM data.

After making the impression, log into DTX Studio[™] Implant, open the patient file, and order a scan of the dental cast from the dental laboratory. Once the dental laboratory has uploaded the scanned file to the cloud service, download the scan and align it with the DICOM data from the patient model via SmartFusion[™].

Order a Scan of the Dental Cast

- 1. Open a patient file, click **Order Products** to go to the Order module and click **Scan** Sec.
- 2. Indicate the scan objects on the tooth chart by dragging the region to be scanned and selecting the required option from the pop-up menu. The requested scans are shown in the list on the right.
- 3. Click Next.
- 4. Choose the connected dental laboratory that will scan the dental cast for you, enter all the necessary details, any special instructions required, and check the list of requested scans.
- 5. Click Finish.
- 6. The order is sent to the dental laboratory and added to the **Orders** list, shown with the order number retrieved from the server.

Intraoral Scan or Other Desktop Scan

The patient's intraoral situation is represented by a surface scan made, for example, with an intraoral scanner. This surface scan (i.e. .ply and .stl files) can be imported into DTX Studio[™] Implant and aligned with the patient's 3D model from the DICOM data by using SmartFusion[™].

SMARTFUSION[™]

Add the Dental Scan to the Patient Model

The acquired surface scan (uploaded by the dental laboratory or imported from the intraoral scanner) can be aligned with the patient model.

- 1. Open the treatment in the Planning module.
- 2. Click **Dental Scan** with the **Treatment Scan** group on the **Prosthetic** tab.
- 3. Select a dental scan or import a dental scan file.
- 4. When using .nxa files, the scanner that has been used to acquire the dental scan is set automatically according to the data in the selected file. When using .stl files, set the scanner:
 - In the lower-right corner of the window, click Select scanner or Change scanner, if a scanner has been selected previously.
 - Choose the scanner from the list.
 - Click Select Scanner.

Note: Always verify which scanner is selected, especially when importing .nxa files or when different scanners might be used to acquire dental scans. When selecting a specific scanner from the list, it will be stored and used as default scanner when creating new patient models.

- 5. Click Next.
- 6. If the scan range is known, the tooth range is automatically indicated. To adjust the range for the selected dental scan:
 - Hover over the tooth chart along the arch.
 - Click on the arch or within the colored highlighted area surrounding the arch and hold down the mouse button.
 - Drag over the teeth in the tooth chart until the whole scan range is covered. Indicate a dental scan range of at least three dental units. Release the mouse button.
 - Adjust the range by clicking the blue highlighted areas to include or exclude a unit. To restart adjusting the scan range, click **Reset chart**. Ensure to indicate a contiguous scan range.



- 7. Indicate the missing teeth on the tooth chart by clicking a white present tooth and turning it into a disabled missing tooth. Only teeth within the marked tooth range can be indicated as missing teeth. Include at least one remaining tooth in the scan range.
- 8. Click Next.
- 9. Indicate all tooth positions according to the tips that are given in the wizard. When indicating a molar, click in the middle of the cusp. In the case of a canine, click in the middle of the incisor edge. To redo these steps, click **Reindicate points**. The set points are removed, and you can start over.
- 10. Click Next.
- 11. The patient model and the dental scan are aligned using SmartFusion $^{\mathbb{M}}$.
- 12. On the **Check Result** page of the wizard, **verify whether the automatic alignment is correct.** The outline of the aligned dental scan (by default displayed in pink) must accurately correspond to the occlusal information of the teeth within the (CB)CT scan. **It is the clinician's responsibility to assure that this step is correct** (see the images on the next page). If it is incorrect, initialize SmartFusion[™]. If the two models cannot be accurately aligned, please contact customer support.
- 13. If the alignment is correct, click **Finish**.

14. The dental scan is added to the scene. If the virtual teeth or the prosthetic setup/wax-up scan was included in the order, it is added automatically as well.



- 1 Incorrect alignment
- 2 Correct alignment



Warning

Improper alignment of the CBCT scan and the surface scan will result in an incorrect surgical template and may not be used for surgery.

Initialization of SmartFusion™

When SmartFusion[™] of the dental scan and patient model fails, or is not sufficiently accurate, adjust the initial position of the dental scan and restart the SmartFusion[™] calculation. This is called SmartFusion[™] Initialization. **Note:** It is likely that SmartFusion[™] will be less accurate when the patient has less than six remaining teeth.

Initialization Procedure

To initialize SmartFusion[™], define at least three pairs of corresponding points, shown on the teeth of the patient model and dental scan, respectively. If the points are inaccurately placed, remove them and indicate them again. All corresponding points may be removed with a single click.

How to Start the Initialization Wizard

 To immediately adjust the initial position when SmartFusion[™] is running, enter the wizard by clicking the Initialize SmartFusion action.

Smart Fusion The dental cast is aligning with the patient model	
Overall duration: 11 s	
	33%
Current task: Smart Fusion	55%
Results:	Initialize Smart Fusion
Description	
Ber second a data	Figure 1

- When SmartFusion[™] is running, but the process fails, a warning message is displayed. Click Initialize
 Position to start the Initialization wizard. This allows you to adjust the start position of the dental scan.
 Restart SmartFusion[™].
- When SmartFusion[™] is running after an initialization attempt, but the process fails again, a warning message is displayed and you will be guided to the Check Result page. On this page enter the Initialization wizard by clicking Indicate corresponding points (see image below).
- When SmartFusion[™] is running and succeeds, but the dental scan and the patient model are not correctly aligned, enter the Initialization wizard by clicking the Indicate corresponding points action on the Check Result page of the wizard.



How to Define Corresponding Points in the Wizard

Insert a Point

- 1. When entering the wizard, the **Insert points** action ** is activated.
- 2. Click a specific position in the left pane on the teeth of the patient model.
- 3. Click the corresponding position in the right pane on the dental scan. Repeat steps 2 and 3 until you have defined at least three pairs of corresponding points.
- 4. Check whether any warnings are displayed in the warnings section of the wizard.
- 5. When a message states that the requested number of pairs is reached, click **Finish** to close the wizard. Make sure to address all warnings before closing the wizard. Otherwise, you will not be able to finish.

Tip: Make sure the points you are adding are well-distributed over the complete dental arch. Avoid clustering. The larger the area covered, the more likely that the alignment will be done correctly. Place points in at least two out of four quadrants as shown in the image below.



Remove Selected Points

Note: If the options to remove points are disabled, right-click to finish the **Insert points** action. The other actions are enabled.

To remove selected points:

- 1. Select a point in one of the viewers.
- 2. Click Remove selected points ^{**}.
- 3. The selected point and its corresponding point are removed.

Remove All Points

To remove all indicated points, click **Remove all points ***. All defined virtual points are removed.

Warnings Used in SmartFusion [™] Initialization					
Dental scan manually aligned. This option may introduce small inaccuracies. Check the dental scan alignment carefully. If incorrect, make sure the corresponding points are positioned correctly.	When the user chooses to apply manual alignment for the SmartFusion™ of the dental scan and the patient model, the system will issue a warning to double-check the alignment to avoid possible inaccuracies.				
One or more pairs of points are not corresponding.	The system measures the distance between the points placed on the patient model and the corresponding points indicated on the dental scan. If the distance is greater than expected, the system issues a warning and requests the user to adjust the pairs of points.				
The defined points are insufficiently distributed over the dental scan.	When the system detects that the defined points are not placed in at least two out of the four quadrants, a warning is generated. The user is requested to adjust the corresponding points, or to add a pair of corresponding points, taking into account good distribution over the quadrants of the dental arch. Clustering should be avoided.				
Indicate at least three corresponding points.	Not enough pairs of points have been defined to be able to finish the wizard. Place additional pairs of points until the minimum number of point pairs to be placed is reached.				

SMARTSETUP[™]

SmartSetup[™] is the solution to automatically calculate virtual teeth based on a scan of the current dental situation. The calculation takes into account:

- The size, shape and position of the existing teeth.
- The type of the tooth that needs to be designed (a canine will need to be shaped differently from, for example, a pre-molar).
- The size and shape of the mirrored tooth.
- A set of esthetic rules for teeth positioned in the front region.
- Information of the antagonist teeth, when available.

Calculate a SmartSetup™

To calculate a SmartSetup[™] ensure that a dental scan is available, including at least three remaining teeth.

- 1. Click **SmartSetup** ⁽¹⁾ in the **Additional Scans** group on the **Prosthetic** tab.
- 2. Click **SmartSetup Settings** in the bottom-right corner of the tooth chart pane and adjust the SmartSetup[™] settings to get a different SmartSetup[™] outcome.
- 3. Click **Calculate**. The SmartSetup[™] is being calculated

SmartSetup[™] Settings

In the SmartSetup[™] wizard settings can be adjusted to change the outcome of the SmartSetup[™] calculation.

- 1. On the **Check the SmartSetup**[™] page of the **SmartSetup**[™] wizard, click **SmartSetup**[™] **options** in the bottom-right corner of the tooth chart pane to open the **Settings** dialog.
- 2. In the **Quality** group, indicate whether you want to calculate the models in **Maximum** (which will take some time to be computed), **Optimal** or **Low** quality. Depending on your selection, more or less teeth will be taken into account in the calculation.
 - Maximum: all scanned teeth will be included in the calculation of the SmartSetup[™]. Calculation time will be longer than when the Optimal solution is chosen.
 - **Optimal**: the teeth needed to calculate an optimal result are taken into account, while at the same time the calculation time is kept within reason.
 - Low: a minimum number of teeth will be taken into account when calculating the SmartSetup[™].
 Calculation time will be shorter than when the **Optimal** solution is chosen.
- 3. In the **SmartSetup**[™] group decide whether or not to calculate the virtual teeth according to the following criteria:
 - Remove gaps for tooth setups: most of the time you want to reduce the gaps between neighboring teeth. There are, however, situations in which the gap to be filled is way too big. If you select this option, the virtual tooth might grow too big. In such a case it might be better to switch off the Remove gaps for tooth setup option. By default this option is selected for All teeth. You can select from the drop-down box the tooth or teeth from which you want to remove the in-between gaps.
 - Position based on opposing teeth (mirror): Select this option if you wish to position the SmartSetup[™] exactly like the opposing teeth. Be aware, however, that patients mostly do not have a fully symmetrical arch, so using this function might result in a less optimal result. Therefore, this option is switched off by default. But the user can switch it on and check whether this might end up in a better calculated result or not.
 - Optimize frontal teeth aesthetics: This action is based on a set of rules to determine or calculate the
 most aesthetic outcome. These rules include for example that the incisal edge of the central incisors
 should be at the same height and that the same width should be applied to the central incisors. This
 is also applicable to the lateral incisors and to the canines.
 - Include third molar(s): This option is selected by default if the scan range includes the third molars. The size, shape, and position of the third molar(s) are taken into account when calculating the size, shape, and position of the SmartSetup[™].

- Additional fine-tuning of the occlusion: When antagonist information is available, this option is selected by default. The antagonist information is taken into account to fine-tune the occlusion.
- 4. Click **OK** to apply the settings to the calculation of the SmartSetup[™]. Continue the wizard by clicking **Next**.

Edit a SmartSetup™

Edit the position of each calculated SmartSetup™ individually:

- 1. Click Edit SmartSetup 9 on the Prosthetic tab of the Planning toolbar. Alternatively, click Edit SmartSetup on the Check result page of the SmartSetup wizard.
- 2. Select the SmartSetup™ to be edited by clicking it in the 3D viewer or by selecting the tooth from the dropdown box.
- 3. Click the **Translation**, **Rotation** and/or **Scale** actions to adjust the position and size of the selected SmartSetup[™].

+	Translation	Click the SmartSetup [™] , hold down the mouse button and drag to translate the SmartSetup [™] . Adjust the values in the Buccal/lingual , Mesial/distal and/or Occlusal boxes to fine-tune the position of the SmartSetup [™] .
Ô	Rotation	Click the SmartSetup [™] , hold down the mouse button and drag to rotate the SmartSetup [™] Adjust the values in the Buccal/lingual , Mesial/distal and/or Occlusal boxes to fine- tune the position of the SmartSetup [™] .
к, а 219	Scale	Click the SmartSetup [™] , hold down the mouse button and drag to adjust the scale of the SmartSetup [™] . Drag up to increase the scale, drag down to decrease it. Alternatively, use the Scaling box to set a specific scaling percentage or to fine-tune the size of the SmartSetup [™] .

To undo the changes for the selected SmartSetup^M, click \bigcirc Reset tooth.

RADIOGRAPHIC GUIDE MODEL

Based on the patient's clinical diagnostics, a radiographic guide will be constructed from a clinically validated tooth setup, containing markers for the double scan procedure. The virtual model is constructed when the patient model is created.

To create the radiographic guide model:

- 1. Enter the Create Guide wizard by clicking **Guide** 🐋.
- 2. Select the correct DICOM data and click **Next**.
- 3. Set the Volume of Interest (VOI).
- 4. Using the suitable calibration set, the **Calibrated Isovalue** is loaded. Click **Next**.
- 5. Check the radiographic guide model.
- 6. Patient model and radiographic guide are automatically aligned.
- 7. Check the alignment result and click **Finish**.

INTAGLIO SURFACE

To create an intaglio surface based on the radiographic guide:

- 1. Click Intaglio 🥗 on the Prosthetic tab of the Planning toolbar.
- 2. Check the intaglio surface and click **Finish**.

Diagnose

NERVES

To delineate a nerve, click **Nerve** Son the **Diagnose** tab and a wizard opens.

- 1. Adjust the nerve reslice, if necessary.
- 2. Click to indicate the construction points of the nerve.
- 3. Right-click to stop adding points.
- 4. Click Finish.

The spheres are connected with a tube-like line, indicating the nerve.

To add another nerve, choose **Add New Nerve L** in the **Nerve Actions** group. Start indicating the points of the new nerve using the process described above.

Tip: When it is difficult to visualize the nerve canal, adjust the nerve reslice. This U-shape is not linked with or related to the shape of the reslice curve.

Теетн

To annotate a tooth, click **Tooth** $ensuremath{\overline{0}}$ on the **Diagnose** tab and a wizard opens.

1. Select the tooth in the chart at the top to be annotated.

Note: FDI notation is used here as default. If necessary, change the dental chart notation via the **General Preferences**.

- 2. Fine-tune the position of the selected tooth to adjust its central axis.
- 3. Click Magic mark fill 🞐 or Mark brush 🚄
- 4. Scroll through the CT slices and click or drag to mark the tooth bit by bit. All data in a specific area around the clicked position is colored and will be added to the tooth.
- 5. Click **Update 3D** to use the keyboard shortcut [u]. The tooth is shown in a 3D preview and it is added to the patient model in the 3D viewer.
- 6. If necessary, select a new tooth in the chart to be annotated.
- 7. When all teeth are annotated, click **Finish**.

REMOVE TEETH FROM THE MODEL

When teeth are annotated, it is possible to subtract them from the patient model, individually or simultaneously.

Subtract All Teeth Simultaneously

- 1. Click **Subtract Teeth** when the **Patient** tab. This icon is only enabled when teeth have been annotated.
- 2. If necessary, correct the patient model with the Patient Mask or Erase Bone Artifacts actions.

Note: When new tooth annotations are added or when teeth are edited after a subtraction, perform the **Subtract** action again to apply it to the newly added or edited teeth as well. It will not be executed automatically. Alternatively, use the **Extract Tooth** action.

Extract a Single Tooth

- 1. Click on the annotated tooth to select it.
- 2. Click Extract Tooth sin the Diagnose group on the Diagnose toolbar. This Extract Tooth icon will only be enabled after teeth are annotated.
- 3. The extracted tooth is colored in red.

MEASUREMENTS

Several measurement types are available.

Tip: If it is difficult to read the measurement text because the objects in the scene are hiding it, select it or its text to display the measurement result in the status bar.

Distance between 2 points	1. 2.	Click Distance 🥜 on the Diagnose tab. Click to indicate the first point and click again on a second position. The measurement is displayed.
Angle	1. 2. 3.	Click Angle on the Diagnose tab. Indicate the three points a, b, and c. The angle is visualized by means of an angle arch and the measurement value is shown.
Gray value / Hounsfield units	1. 2.	Click HU Value 🖋 on the Diagnose tab. Indicate a point to measure the HU value there.
Angle between implants or abutments	1. 2.	Select an implant and click Implant Angle M on the Diagnose tab. Select the second implant. An arched yellow line denotes the measurement together with the value.

Plan Implants

WORK WITH NON-NOBEL BIOCARE IMPLANTS

DTX Studio[™] Implant is also open to non-Nobel Biocare implant systems (e.g. Straumann dental implants, Dentsply dental implants, Camlog dental implants, etc.). Using the **Implant Products** tab within the **Preferences** dialog, the user can indicate which implant systems to include in DTX Studio[™] Implant.

Note: An Internet connection is needed to download non-Nobel Biocare implants to DTX Studio™ Implant.

Adding or removing implant systems from DTX Studio[™] Implant can only be done when all planning scenarios are closed. Therefore, close all patient files and go to the **Preferences** dialog:

- 1. Click the **DTX Studio Implant** tab.
- 2. Select General Preferences.
- 3. Click Installed Products.
- 4. Indicate which implant systems are to be added or removed from the software.
- 5. Click **OK** to finish.

Note: When products are used which are not available in the software, they will be replaced in the treatment plan with cylinder-shaped dummy products. The original product information, however, is stored and when the products do become available, the dummies in the treatment plan will be replaced with a more detailed representation of the products.

Caution: When warnings are triggered because of the cylinder shapes, these warnings are calculated based on an estimate of the product shape.

ADD AN IMPLANT TO A PLAN

This section explains how to virtually plan an implant. It is, however, recommended that you know and are aware of the quantitative and qualitative constraints related to planning oral implants. To add an implant to the treatment plan, follow these steps:

- 1. Click Implant 🆧 on the Plan tab.
- 2. Click the patient model to indicate the implant shoulder point.
- 3. Click the model to indicate the apex of the implant.
- 4. Select the proper manufacturer from the **Manufacturer** section on the **Product Selection** window.
- 5. Select an implant. Optionally, indicate also the surgery type, a compatible abutment, and check the tooth position.
- 6. Click **Select Product** to confirm.

Caution: Products which are unavailable are displayed with a red warning in the **Product Selection** window and shown in blue in the 3D view. Ordering these products is not possible.

What Does the Yellow Zone Mean?

The typical tolerance of the NobelGuide concept is within 1.5mm. The semi-transparent yellow zone helps the user to be conscious of this aspect in relation to vital structures. The zone is a cylinder that exceeds the radius of the actual implants by 1.5mm combined with a cone with a height of 3mm.

It warns the user of potential risks when the yellow zone becomes visible through the outer bone surface.

Notes:

- Drills may extend 1mm longer than planned implant(s). This yellow warning zone also takes into account this variance.
- It is advised to keep at least 3mm of vital bone in between two implant-bone interfaces and a minimal distance of 1.5mm between a tooth and an implant to allow cellular re-colonization with proper blood supply.
- The NobelGuide concept includes several clinical steps which the clinician has to take into consideration for each individual case. Therefore, the total accuracy in each individual case has to take in account the influence of these procedures.

Tooth Position

Implants get assigned to a specific tooth number. This tooth number appears in several locations in the software, such as on the **Property Panel** of an implant, the dedicated implant tab, the right-click menu of an implant, and in the status bar when the implant is selected.

Tooth Chart

Using the tooth chart, the user may check and, if necessary, adjust the estimated tooth position an implant is assigned to. The tooth numbering convention used on this tooth chart corresponds with the setting in the general preferences.



The ? position (question mark position) is used for tooth positions which are unknown or unclear (e.g. when an implant is planned between two positions where already other implants are planned.

MANIPULATE AN IMPLANT

DTX Studio[™] Implant provides various features to plan the optimal position of the implant.

Change the Implant Orientation

The orientation of an implant can be adjusted by dragging the spheres.

- 1. Select the implant. The spheres turn red.
- 2. Do one or more of the following:
 - Click the upper sphere on the implant and drag to rotate, while using the apical point as a rotation point.
 - Click the lower sphere on the implant and drag to rotate, while the shoulder point of the implant is used as a rotation point.

Move an Implant

To physically translate the implant:

- 1. Select an implant. The gray tube on the implant turns green.
- 2. Click the green tube and drag the implant to the desired position. The implant will retain its original orientation.

Depth and rotation can also be changed via icons on the dedicated **Implant** toolbar.

Make Implants Parallel

Place a Parallel Implant

To place a single new implant in parallel with a selected implant:

- 1. Select the implant you want to use as a base.
- 2. Click Parallel Implant **4**.
- 3. Click in the 3D or 2D viewer to indicate the shoulder point of the implant.
- 4. The new implant is placed parallel to the indicated implant.

Place All Implants in Parallel

- To place all implants available in the plan in parallel:
- 1. Select the implant you want to use as a base.
- 2. Click Parallelize All 🧖.
- 3. All implants are placed in parallel with the initially selected implant.

Note: After the **Parallelize All** command, carefully inspect all implant positions. If the result is clinically unacceptable, use the **Undo** function.

ABUTMENTS

To select an appropriate abutment for an implant:

- 1. Select the implant in the scene.
- 2. Click **Abutment** 4 on the Implant tab or right-click the selected implant and choose **Add Abutment** from the shortcut menu.
- 3. The **Product Selection** window is opened, showing the compatible abutments.
- 4. By default, 'No Abutment' is selected. Select an abutment, taking into account the correct dimensions.
- 5. Click Select Product.

Note: These options are only available if the selected implant does not have an abutment yet. If an abutment is already present, click the **Change Product** menu item or icon 4 to display the **Product Selection** window.

Set the Surgery Type

The clinician has different surgical options, called surgery types, how to treat the patient (freehand, using a surgical template for pilot drilling only, or using a surgical template for fully guided surgery). The surgery type can be set individually for each implant in the treatment plan.

- 1. Select the implant.
- 2. Click the **Surgery Type** icon on the dedicated tab on the toolbar. This icon differs in shape depending on the different surgery types.
- 3. Select the appropriate surgery type from the list. The available options will differ depending on the selected implant type.

Notes:

 When placing a new implant, the surgery type can be set via the Surgery Type tab on the Product Selection window.

Manufacturer: N	obel Biocare®	
Implant Products	(23): Replace Select Tape	red TiUnite RP 4.3x1
Surgery Type: Pi	lot 2.0	
Freehand	Fully Guided	Pilot 2.0
Compatible Stand	ard Abutments (20): Nor	ne selected
> Tooth Position: 1	s	

 The surgery type can be adjusted on the Check Surgery Setup window when creating a surgical template.

Different Surgery Types

Depending on the products selected in the treatment plan, different surgical options are possible. The following surgery types are available:

0	Freehand: no surgical template (no guided sleeve) will be used to place this implant.
0	Fully-guided : a surgical template with a fully-guided sleeve (enabling guided drilling and guided implant insertion) will be used to transfer the planned implant position(s) into the patient's mouth.
Q., Q.,	Pilot drilling (for NobelGuide 1.5 and 2.0mm twist drills only): a surgical template with a pilot sleeve (guided pilot drilling only) will be used to transfer the planned implant position(s) into the patient's mouth. After using this initial pilot drill, the surgical template is removed, the guided drilled depth is recorded by direction indicator or freehand twist drill in relation to an anatomic landmark (e.g. bone crest) and the freehand drilling procedure is initiated, followed by freehand implant insertion (all depths of freehand tools according to defined anatomical landmark after template removal). Depending on the implant diameter, a different pilot sleeve diameter can be selected.

Pilot Sleeve Offset

This feature is designed for pilot drilling only. In certain clinical indications, the default distance between the planned implant (implant shoulder) and sleeve is not sufficient (e.g., implant needs to be placed deeper, knife edge ridge is going to be removed after implant placement, interference of sleeve with neighboring teeth, etc.). In these indications the sleeve at default position collides with the surface model of the dental scan and a warning is triggered for pilot sleeves. In order to create a surgical template without sleeve collisions and to keep the implant at the planned clinical position, the sleeve can be moved upwards. The default relation of guided sleeves and planned implant is reflected in the depth marks of all NobelGuide guided drills for all drill protocols. The additional distance is called 'sleeve offset' and is automatically recorded and added to the NobelGuide Surgical Instructions page which is shipped with the surgical template.

- 1. Select an implant.
- 2. Make sure the surgery type for the selected implant is **pilot drilling**.
- Click the Sleeve Offset icon which is located next to the Surgery Type icon on the dedicated Implant tab. Or right-click the implant and select Sleeve Offset from the pop-up menu.
- 4. Drag the slider to reposition the sleeve in height or enter the offset height directly in the slider box.

Pilot Sleeve Rotation

If the sleeves are not in the correct rotational position, it is possible to adjust the rotation using sleeve rotation.

- 1. Right-click the implant.
- 2. Click **Sleeve Rotation** within the pop-up menu.
- 3. Drag the slider to rotate the sleeve until the correct rotational position is set.

ANCHOR PINS

To establish an appropriate fixation during the start of the surgical procedure, guided anchor pins anchor the surgical template. When planning guided anchor pins, the angulation and depth are important. Typically three or four anchor pins are placed in an edentulous jaw. The anchor pins must be placed in areas with adequate cortical bone. To minimize the risk of tissue damage, bi-cortical anchorage of anchor pins must be avoided.

Notes:

- Anchor pin position and orientation should allow easy installation (consider lip retraction and mouth opening) as well as avoid critical structures like blood vessels.
- To position the surgical template accurately into the patient's mouth, a surgical index is advised to be used.
 The surgical index should allow for access of drilling, and placement of the anchor pins. After anchor pin installation, the surgical index can be removed.

Add an Anchor Pin to the Treatment Plan

Position an anchor pin in a similar way to placing an implant.

- 1. Click Anchor Pin 🔏.
- 2. Click to indicate the anchor pin.
- 3. Click to indicate the apex of the anchor pin.
- 4. The anchor pin is placed in the scene.

Tip: It is more convenient to define the shoulder and apex points on an appropriate 2D reslice.

Correct Inclination and Depth of Anchor Pins

To stabilize the surgical template for implant insertion, anchor pins can be placed at strategic positions. Their angulation and depth are crucial.

The anchor pins can also serve as lip retractors during surgery. Anchor pins spread too widely within the arch could negatively affect mouth opening. A short-shaft version of the anchor pin is available to mitigate this potentially negative effect. Nevertheless, the anchor pins should be planned so as to offer good access, and should not interfere with the implant sites.

The sleeves should be placed close to the mucosa, represented by the digitized surface model of the intraoral situation (about 0.5 to 1mm distance from the mucosa) but should not interfere or collide with the aforementioned model when using a smart-fused surface scan.

For edentulous situations a minimum of four anchor pins is recommended. The anchor pin sleeves are positioned in the vestibulum entering extra-orally, or, in selected situations, from the opposite direction (palatally or lingually), to lock the surgical template in place from two sides.

Anchor Pins and Radiographic Guide (Edentulous Workflow)

When using a radiographic guide, the sleeve must be connected to the radiographic guide but must not protrude the intaglio surface.

Correct
Incorrect The sleeve of the anchor pin is not attached to the radiographic guide and will not be attached to the template.
Incorrect The anchor pin sleeve is protruding through the radiographic guide and the template will not fit into the patient's mouth.

Anchor Pins and Dental Scan (Partially Edentulous Workflow)

When using a smart-fused surface scan, the sleeve must be placed close to the mucosa (0.5 mm to 1 mm distance from the mucosa, represented through the surface scan) but should not protrude the smart-fused surface scan.



Inspect a Treatment Plan

When you need to inspect the path of an implant or anchor pin through the bone, it is possible to view slices through the image volume along an implant or anchor pin, and parallel to that implant or anchor pin. With this feature, detailed inspections of the bony surroundings of implants and anchor pins are possible, providing that the chosen position is suitable for placing implants or anchor pins.

WORK WITH THE SNAP FUNCTIONALITY

The snap functionality of the cross-sectional reslice works in different modes:

- In **implant or anchor pin mode**, the cross-sectional reslice is snapped to the main axis of an implant or anchor pin and is positioned in the center of the implant or anchor pin.
- In curve mode, the cross-sectional reslice is snapped to the curve of the panoramic reslice.

To snap the cross-sectional reslice to an implant or anchor pin:

- 1. Click **Snap Reslice** 🔗 in the **Tools** panel.
- 2. The cross-sectional reslice is snapped to the selected implant or anchor pin and will rotate around its axis instead of following the arch of the jaw bone. If no implant or anchor pin is selected, the reslice is snapped to the most recently selected implant or anchor pin. If no implant or anchor pin has been selected yet, the reslice is snapped to the last planned implant or anchor pin.

Tip: When selecting another implant or anchor pin, the reslice automatically snaps to the new implant or anchor pin. This functionality can be turned off within general preferences.

Note: When deleting the last implant in the scene, the cross-sectional reslice will automatically snap to the curve if it was snapped to the implant.

JUMP TO ANOTHER IMPLANT OR ANCHOR PIN

When the snap functionality is in implant or anchor pin mode, move to another implant or anchor pin by using the **Next** action, displayed in the **Snap** bar in the 2D viewer.

- 1. In the Snap bar, click **Next**.
- 2. The cross-sectional reslice moves to the next-in-line implant or anchor pin.

RETURN TO CURVE MODE

When the snap functionality is in implant or anchor pin mode, return to curve mode using the **Unsnap** action in the **Snap** bar.

- 1. In the Snap bar, click **Unsnap**.
- 2. The cross-sectional reslice is snapped to the curve.



Finalize

CREATE A SURGICAL TEMPLATE

The surgical template helps you perform surgery exactly as planned. When finalizing the plan, create a virtual surgical template, which is a preview of what you will receive.

To create a surgical template according to the treatment plan:

- Click Create Template if on the Finalize tab. A window pops up to verify the implant positions with the selected sleeves (surgery types). By default, the surgical template is produced by Nobel Biocare. If you wish to have the template created locally or by a different manufacturer, select Other. Select the manufacturer from the list. If you select your account name, you will be able to download the template yourself from DTX Studio[™] Go. If you select one of your connections the template will be available for them to download. Add the necessary details and, if needed, modify the selected surgery type.
- 2. Press **Next**, if correct. The virtual surgical template is generated.
- 3. Inspect the virtual surgical template.
- 4. Click Finish.
- 5. The **Approve planning for order** dialog appears. Read it carefully. Click **I have read and agree to all of the above** to confirm that you have read the messages and that everything is as it should be.
- 6. Click **Create order** to order the template immediately. The system takes you to the order module, showing the planning file and allowing you to order products. To postpone your order, click **Approve later**.

Note: The color of a virtual surgical template for local production is different from that of a virtual surgical template to be produced by Nobel Biocare.



Inspect the Surgical Template

When finalizing a treatment plan it is critical to watch for a number of issues which might prevent the surgical template from being created correctly:

- 1. Check the position of the anchor pins.
- 2. Check the angulations between implants and when in doubt discuss with the team whether the angulation could negatively impact the prosthetic treatment.
- 3. Check the guided sleeves in relation to neighboring teeth.
 - Make sure the sleeve does not touch the neighboring teeth.
 - Check the 3D scene to see whether the surgical template touches the neighboring teeth to determine whether or not the template needs grinding, or modification.
- 4. Check each implant in the perpendicular reslice as well as in the 3D scene to verify the plan.
- 5. Ensure there are no breaches or holes in the support structures of the surgical template that surround the sleeves of the implants or anchor pins.
- 6. Communicate the plan to the team to check all aspects.

Edit the Virtual Surgical Template

Note: this is only possible for templates created from a dental scan.

If the virtual template is not correctly distributed over the dental arch (extending evenly over the labial/buccal and lingual surfaces), its shape can be edited. Change the shape of the blue line in the **Edit Template** wizard to make the curve coincide with the dental arch.

- 1. Click Edit Template 94 in the Finalize tab.
- 2. Click and drag the dots on the curve to change the position.
- 3. When the position of the blue line coincides better with the dental arch, click **Finish**.
- 4. The virtual surgical template is regenerated.

If the shape of the virtual template is still not optimal, repeat these steps until it is.

Note: In the United States, and in some other markets, the physical surgical template for endosseous dental implant placement is a medical device. Please contact your local regulatory agency for information regarding the regulatory states and requirements related to manufacture of these surgical template.

APPROVE A TREATMENT PLAN

When a treatment is completely finalized, lock it by approving it. Please read the text in the **Approve** dialog and agree with it to continue the approval.

Its 'approved' status appears in the Planning status bar.

An approved treatment plan cannot be changed. To disapprove and make further changes, click on the **Disapprove Planning** button.

Orders

Send scan or TempShell orders to the dental laboratory to perform a scan or to design and calculate a TempShell provisional. To send the orders through the cloud service, the dental laboratory must use DTX Studio[™] Lab and a connection must be established in DTX Studio[™] Lab and DTX Studio[™] Implant.

WORK WITH CONNECTIONS

To add a connection you need the nine-digit identification number of the person, practice, or dental laboratory you want to connect with. In DTX Studio[™] Implant the connection token is shown in the **Manage Account** dialog. In DTX Studio[™] Lab the connection token is shown in the **Account Details** dialog.

Add a Connection

To add a connection:

- 1. Click Add Connection ¹ in the Medical Records tab of the My Office toolbar. Alternatively, click the DTX Studio Implant tab and click Manage Account.
- 2. In the Manage Account dialog, click Add a new connection in the Manage connections group.
- 3. Enter the nine-digit identification number of the account you want to connect with.
- 4. Click **Add Connection**. The new connection is added to the list, showing the **Invitation sent** status, and an e-mail invitation is sent to the address linked to the account used.
- 5. Click **OK**.
- 6. When the connection accepts your invitation, a confirmation e-mail is sent to you and the connection status in the list changes to **Accepted**.

Accept a Connection

New connection requests sent to you have the **Requested** status. To accept a connection request, click **Accept** in the invitation e-mail. Alternatively:

- 1. Click Add Connection in the Medical Records tab of the My Office toolbar or click the DTX Studio Implant tab and click Manage Account.
- 2. In the **Manage Account** dialog, select the connection request in the **Manage connections** group marked with the **Invitation sent** status.
- 3. Click Accept selected connection.
- 4. The connection status will change into **Accepted** and a confirmation e-mail is sent to the inviter.

WORK WITH ORDERS

Product Orders

Create a Product Order

For Nobel Biocare products a product order can be created. For non-Nobel Biocare products (e.g., non-Nobel Biocare implants) it is not possible to create a product order.

To create a product order:

- 1. Click Order 🗽 on the Finalize tab of the Planning toolbar. Alternatively, click Product in the Order module toolbar.
- 2. The list of available planning files for the current patient is displayed. In the right window pane, consult the details of the selected planning file, choose the appropriate planning file, and click **Next**.

Note: Make sure the planning file to be ordered is approved **Q**. Only approved planning files can be converted into orders. A warning is displayed in the case of a not yet approved planning file.

- 3. The **Product List** is displayed. Clear the items on the list that do not require ordering or adjust the quantity of the products to be ordered, and click **Next**.
- 4. Select the **Ship to** address, fill out who issued the order and enter notes to production, if needed.
- 5. Define to **Only save** the order or **Save and send now**.
- 6. Check the products to be ordered in the **Ordered products** pane.
- 7. Click **Finish**. The order is created and displayed in the list of created orders.

Send a Product Order

To send a created product order:

- 1. Select the created order in the list.
- 2. Click **Send** kin the toolbar.

Model Scan Orders

To receive a surface scan of the dental cast, a diagnostic setup or wax-up, and/or an antagonist scan, send a model scan order to the dental laboratory.

Create a Model Scan Order

- 1. In the Office module click New and Order a model scan Sec. Alternatively, go to the Order module and click Scan.
- 2. Indicate the scan objects on the tooth chart by dragging the region to be scanned and selecting the required option from the pop-up menu. The requested scans are shown in the list on the right.
- 3. Click Next.
- 4. Choose the connected dental laboratory that will scan the dental cast for you, enter all the necessary details, any special instructions required, and check the list of requested scans.
- 5. Click Finish.
- 6. The model scan order is sent to the dental laboratory and added to the **Orders** list, shown with the order number retrieved from the server.

TempShell Orders

Immediate provisionals enable a patient to obtain a temporary crown or bridge at their implant placement appointment. To achieve this, the DTX Studio[™] Implant user and the dental laboratory (using DTX Studio[™] Lab) work together to design a Tempshell which can be converted into a provisional by the clinician at the time of surgery.

The TempShell Workflow

The DTX Studio[™] Implant user creates a patient file, adds prosthetic information and plans the implants. A TempShell order is created and sent to the dental laboratory, which receives a request in DTX Studio[™] Lab. The dental laboratory designs a LabDesign in DTX Studio[™] Lab.

Optionally, the LabDesign is shared with the DTX Studio[™] Implant user. To check whether the design fits the treatment plan, the user adds the LabDesign to the treatment plan in DTX Studio[™] Implant. If any adjustments need to be made, the dental laboratory is contacted (by phone or e-mail) to request adjustments. Multiple iterations between DTX Studio[™] Implant user and dental laboratory might be needed. When the clinician confirms that the design fits, the TempShell is created and shared by the dental laboratory.

The DTX Studio[™] Implant user adds the TempShell to the treatment plan.

Create a LabDesign Request

To request a LabDesign:

- 1. Click LabDesign ^{IIII} in the Order module toolbar.
- 2. The list of available planning files for the current patient is displayed. In the right window pane, consult the details of the selected planning file, choose the appropriate planning file, and click **Next**.
- 3. The LabDesign request overview is displayed.
- 4. Indicate on the tooth chart the positions for which a LabDesign (single unit or bridge) is requested.
- 5. Select the dental laboratory that will process the request or choose to export the request as a file.
- 6. Check the request details and adjust when required.
- 7. Click Finish.

Create a TempShell Order

To create a TempShell order and send it to the dental laboratory:

- 1. Click **TempShell** a in the **Order** module toolbar.
- 2. The list of available planning files for the current patient is displayed. In the right window pane, consult the details of the selected planning file, choose the appropriate planning file, and click **Next**.
- 3. The TempShell order overview is displayed.
- 4. Indicate on the tooth chart the positions for which a TempShell (single unit or bridge) is ordered. Do not select the extension of the wings.
- 5. Select the dental laboratory that will process the order or choose to export the order as a file.
- 6. Check the order details and adjust when required.
- 7. Click Finish.

Add a LabDesign to the Treatment Plan

To check whether the restoration designed by the dental laboratory fits the treatment plan, the shared LabDesign can be added to the treatment plan.

- 1. Click Add LabDesign ³³ in the Prosthetic tab of the Planning module.
- 2. The Add LabDesign dialog is shown. Select the LabDesign and click Add LabDesign.
- 3. The **LabDesign** is added to the scene.
- 4. Contact the dental laboratory by phone or e-mail to either confirm that the LabDesign fits or to request some changes.

Notes:

- If you need to adjust the treatment plan, make sure to reorder the LabDesign.
- If a LabDesign file is available on a drive, import it using the Import LabDesign action in the Add LabDesign dialog.

Add a TempShell to the Treatment Plan

- 1. Click Add TempShell 🖾 on the Finalize tab of the Planning toolbar.
- 2. The Add TempShell dialog is shown.
- 3. Click an available TempShell to be added to the treatment plan.
- 4. Click Add TempShell.

Note: If a TempShell file is available on a drive, import it using the **Import TempShell** action in the **Add TempShell** dialog.

Service Requests

The Typical Service Request Workflow via DTX Studio[™] Go

The DTX Studio[™] Clinic user (requester) would like to receive from a DTX Studio[™] Implant user (the provider) a plan for a specific case. The requester creates a patient file in DTX Studio[™] Clinic and typically a service request is sent via DTX Studio[™] Go. When the provider receives a new request in DTX Studio[™] Go to create a plan, the necessary files can be downloaded. The zipfile needs to be unpacked and stored. The provider creates a new patient file in DTX Studio[™] Implant, using the received patient data as input. The provider takes the normal implant planning steps in DTX Studio[™] Implant and approves the treatment plan. Then he or she can respond to the service request and send the treatment plan back to the requester via DTX Studio[™] Go.

Respond to a Service Request

To send an approved plan back to the service requester:

- 1. In the **Order** module, click **Fulfill request I**.
- 2. Select the correct plan from the list. Click Next.
- 3. Fill out the requested information to customize the service request. Make sure to attach the report and, optionally, add notes or images.
- 4. Click Finish.
- 5. A pop-up window shows basic information such as service ID and requester information, allowing you to verify whether the treatment is sent back for the correct patient case. Click **Upload** to send the plan to the requester.

The 'Local' Service Request Workflow

If a user has both DTX Studio[™] Clinic and DTX Studio[™] Implant installed on a single computer, the workflow is slightly different. In DTX Studio[™] Clinic a patient file is created, the necessary alignments are performed to create a patient model. When DTX Studio[™] Implant is opened from within DTX Studio[™] Clinic, the patient model is exported and a new patient file is created in DTX Studio[™] Implant, based on the exported data. The implant treatment plan is created in DTX Studio[™] Implant and can be exported to and visualized directly in DTX Studio[™] Clinic.



Important: When the alignment of the dental scan and the patient model in DTX Studio[™] Clinic has been done via SmartFusion[™], a warning message pops up requesting you to check the alignment:

Verify the alignment of the dental scan and the patient model and if incorrect or uncertain, recalculate the alignment within the Edit Dental Scan wizard.

When both DTX Studio[™] Clinic and DTX Studio[™] Implant are installed on a single computer, the approved plan needs to be exported.

- 1. In the **Order** module, click **Fulfill request**
- 2. Select the correct plan from the list. Click Next.
- 3. Fill out the requested information to customize the service request. Make sure to attach the report and, optionally, add notes or images.
- 4. Click Export.
- 5. Choose the location to store the exported files. Click **Select Folder**.
- 6. The files are now available in the selected location.

Work with the DTX Studio[™] Implant Assistant

To open the DTX Studio[™] Implant Assistant, click **Assistant** in the top-right corner of the window.

The **DTX Studio[™] Implant Assistant** window is displayed. The DTX Studio[™] Implant Assistant is comprised of different tabs:

 Tasks 1: An overview of planning and additional tasks guides you through the planning procedure.

Assistant	
Warnings (4)	

- Warnings 4 : Warning messages make you aware of possible issues.
- Planning overview 1 An overview is given of the implants, abutments, and/or anchor pins used in the treatment plan. Whether or not the radiographic guide and surgical template have been created is also indicated. The position of the planned implants is indicated on the tooth chart.

DTX Studio[™] Implant Warning System

A number of technical / production / procedural warnings (e.g. guided sleeves placed too close to each other, "no anchor pins placed", implant planned too close to annotated nerve) are visualized in the DTX Studio[™] Implant software.

When warnings are generated because DTX Studio[™] Implant detected clinical or technical planning issues, they can be viewed in the **Warnings** section in the Planning Assistant.

Open the Planning Assistant and click **Warnings** 4, or click **Warnings** below the **Assistant** button. The Planning Assistant shows the warnings, categorized by clinical and template warnings.



- 1 The number of current clinical and template warnings is shown in the warning type heading.
- 2 When the surgical template cannot be produced, the specific warnings are marked with a red notification, stating that the warnings require resolution before the surgical template can be produced.
- 3 Configurable warnings are accompanied by a note mentioning the set value and where this value can be changed, should anything need to be adjusted. If a configurable warning was disabled in the preferences, a caution notification is displayed, informing you that possible issues might not be detected.

DTX STUDIO[™] IMPLANT WARNINGS

Warning

This planning program does not automatically check all technical constraints. In some cases, surgical templates may not be able to be manufactured even when no technical constraints are automatically identified through the software.

During planning, specific technical constraints have to be considered to ensure the correct production of the surgical template and the successful use of the produced template during surgery. DTX Studio[™] Implant automatically detects the possible violation of some technical and clinical constraints. When constraints are violated, a warning message will appear in the Assistant. Click on this message to view the detailed description of the notes and warnings.

In the 2D and 3D viewer, objects causing an issue are colored in red or orange depending on the type of violation. The corresponding warning messages are shown in the assistant. These messages are also visible in the **Approve** window, the planning overview, the report, etc.

Below is an overview of the possible warnings according to the type of warning.

Template Warnings

In the report the template warnings are shown on the last page.

Warning	Explanation
Sleeves are colliding.*	Some sleeves are colliding, making it impossible to produce the surgical template. Revise the treatment plan to solve this issue.
Implant and sleeve are colliding.	An implant is colliding with a sleeve. This can cause issues during surgery. Revision of the treatment plan is recommended.
Anchor pin and sleeve are colliding.	An anchor pin is colliding with a sleeve. This can cause issues during surgery. Revision of the treatment plan is recommended.
Annotated tooth and sleeve are colliding.	A sleeve is colliding with an annotated tooth. Make sure this collision will not prevent the correct seating of the surgical template.
Anchor pin sleeve is too close to the dental scan.	An anchor pin sleeve is planned too close to the dental scan. This can cause errors in the correct seating of the surgical template during surgery. Try to position the anchor pin sleeve so that it does not collide with the dental scan.
Pilot sleeve is too close to the dental scan.*	A pilot drill sleeve is positioned too close to the dental scan making it impossible to manufacture the surgical template. Revise the position of the planned implants or change the 'sleeve offset' to solve the issue.
Fully guided sleeve is too close to the dental scan.	To manufacture the surgical template, additional resin material might be added to the template to securely affix the sleeve(s). This might require additional manual adjustments of the surgical template prior to surgery. Note: Check the surgical instructions enclosed with your surgical template where the need for manual adjustments (grinding) would be communicated.

* The surgical template cannot be produced until this warning is resolved.

Clinical Warnings

Clinical warnings are subdivided into general warnings and implant warnings. Clinical warnings are shown on the implant pages of the report.

General Warnings

Warning	Explanation
No anchor pins are planned.	Placement of an adequate number of anchor pins is recommended to help ensure that the surgical template is kept in the correct position for the duration of the surgery.
Anchor pins are colliding.	Some anchor pins are colliding. This can cause issues during surgery. Revision of the treatment plan is recommended.
Radiographic guide was not calibrated.	The 3D model of the radiographic guide was created with a gray value (isovalue) as threshold, which was not calibrated for your scanner. To produce an accurately fitting surgical template it is important to follow the NobelGuide Calibration Procedure, which is described in the NobelGuide concept manual.
Treatment planned with non-installed products.*	The treatment plan contains products which are currently not installed on your computer. Make sure you have a working Internet connection and reopen the treatment plan. If the missing products cannot be installed, please contact your local support team.
Low-quality visualization is enabled.**	A low-quality visualization of the 3D patient model is used in the treatment plan.
Dental scan alignment is adjusted manually.	The alignment between the patient model and a dental scan has been manually adjusted. Double-check that a dental scan is correctly aligned with the (CB)CT scan, as deviations will introduce errors in the correct positioning of the implants.
SmartFusion alignment failed.*	The SmartFusion alignment failed and was not adjusted manually. Start the Edit Dental scan action to solve this issue.
Verify SmartFusion alignment	Verify the alignment of the dental scan and the patient model and if incorrect or uncertain, recalculate the alignment within the Edit Dental Scan wizard.

* The surgical template cannot be produced until this warning is resolved.

** Display at low-quality visualization increases the risk that some anatomical features might not be visible in the patient model. The setting will only influence the quality of the 3D volume. CT reslices will not be affected.

Implant Warnings

Some of the implant warnings are configurable. They can, for example, be enabled or disabled and/or the values used to trigger the warnings can be defined by the user. In the table below they bear the label 'configurable'.



Important

The values to trigger the implant warnings must be set according to the clinical expertise and experience of the user.

Warning	Explanation
Implants are colliding.	Some implants are colliding. This can cause issues during surgery. Revision of the treatment plan is recommended.
Implant and anchor pin are colliding.	An implant is colliding with an anchor pin. This can cause issues during surgery. Revision of the treatment plan is recommended.
Implant is too close to an annotated nerve.*	An implant is planned too close to an annotated nerve. Make sure the implant is not impacting the nerve. Note: The minimal distance is set to [] mm. Open the General Preferences to adjust this value.
Implant is too close to an annotated tooth.*	An implant is planned too close to an annotated tooth. Make sure the implant is not impacting the surrounding teeth. Note: The minimal distance is set to [] mm. Open the General Preferences to adjust this value.

* These warnings are configurable

Configurable Warnings

The configurable warnings are based on a volume around the implant, (i.e. warning volume). When this volume collides with an annotated anatomical structure, a warning is issued.

The warning volume is defined based on a pre-set distance. By default, this distance is set to 1.5mm, the minimal distance. With this minimal distance, the warning volume coincides with the yellow zone (representing a 1.5mm distance around the implant and a 2×1.5 mm (3.0mm) distance at the apex). The warning volume can be increased. As seen in the picture (for a distance of e.g. 4.0mm) the warning volume is scaled accordingly.



Warning between Implants and Nerves

When an implant is placed too close to an annotated nerve (i.e. when the warning volume collides with the visualization of the annotated nerve), a warning is issued. The affected implant is shown (if it was not visible yet) and turns orange.

Warning between Implants and Tooth Roots

When an implant is placed too close to a tooth root (i.e. when the warning volume collides with the annotated tooth), a warning is issued. The implant is shown and turns orange.

Note: The minimum distance of the warning volume should be set via **DTX Studio Implant** > **General Preferences**. The values are saved on the computer you are working on. When opening the treatment plan on a computer other than the one used when creating the plan, the warnings shown are in line with the settings of the computer currently in use. This may result in different warnings based on the computer settings. The configurable values can be adjusted in the settings and the values are shown in the warning overview when a warning is issued.

TECHNICAL CONSTRAINTS

A number of technical constraints which are crucial to the correct creation of the surgical template are explained. When these constraints are not taken into account, it is not guaranteed that the surgical template can be produced or that it can be used correctly.

Minimal Distance between Guided Sleeves

For the surgical template, a minimal distance between guided sleeves needs to be respected. When the distance is too small, the surgical template cannot be produced.

When the minimal space between the guided sleeves is violated, the guided sleeves will become visible automatically and will be colored in red. In this configuration, the surgical template cannot be produced.

To resolve this situation, move or tilt the implants in such a way that the space between the sleeves increases. When the distance is large enough, the guided sleeves will automatically return to their normal color.

Minimal Distance between Sleeves and Implants / Sleeves and Anchor Pins

When sleeves and implants or sleeves and anchor pins are positioned very close or are colliding, they will automatically become visible and turn orange. Too short a distance between a sleeve and an implant or anchor pin might be difficult during surgery to prepare an osteotomy or to place an implant or anchor pin.

To solve this issue, move or tilt the implants or anchor pins in such a way that the space between them and the sleeve increases. When the distance is long enough, they will automatically return to their normal color.

Collision between Implants, Anchor Pins, or Implants and Anchor Pins

When the implants, anchor pins, or implants and anchor pins are colliding, they automatically become visible and turn orange. The collision of these objects might cause problems during surgery.

To solve this issue, move or tilt the implants or anchor pins in such a way that they are not colliding. When the distance is large enough, they will automatically return to their normal color.

Note: In some cases, the implant site is utilized for an anchor pin first. Before the implant is inserted, the anchor pin must be removed.

Relation between Guided Sleeve and Radiographic Guide and/or Dental Scan

During planning, besides all clinical considerations, it is important to consider the technical constraints for the position of the guided sleeves in relation to the radiographic guide and/or the dental scan. The position of the guided sleeves needs to be verified with the radiographic guide and/or the dental scan shown.

Radiographic Guide

Position

Each guided sleeve should be positioned within the radiographic guide to ensure that there is sufficient material in the surgical template to support the guided sleeve.

- 1 Correctly positioned
- 2 Incorrectly positioned: the sleeve is placed too far and is not connected to the radiographic guide.







Depth

It is necessary to verify the depth of the sleeve in relation to the radiographic guide. The sleeve should not penetrate the surface facing the gingiva (intaglio surface) in order to secure the correct position of the surgical template. In order to verify the depth of the sleeve, view the position of the sleeve and fine-tune the implant depth using the **Depth** icon \swarrow in the dedicated toolbar. Alternatively, when a pilot sleeve is chosen, consider adjusting the sleeve offset.

- 1 Correctly positioned
- 2 Incorrectly positioned: the sleeve is placed too deep.

Scan of the Dental Cast

Verify sleeve positions after implant planning. The following situations must be resolved:

Lateral Collisions

Lateral collisions are collisions with neighboring teeth, or potentially with soft tissue (surface scan of the intraoral situation). If a collision occurs, verify whether the position of the implant can be changed so that the collision warning is not triggered. If this is not possible, try to narrow the sleeve diameter or choose the pilot drilling only option. Advanced users can also consider skipping parts of the guided drilling procedure and finalize the drill protocol with the freehand protocol after removal of the surgical template. The implant is then placed freehand.

- 1 Incorrectly positioned: too close to or colliding with neighboring teeth or soft tissue.
- 2 Correctly positioned: changed diameter.
- 3 Correctly positioned: changed to pilot sleeve.

Vertical Collisions

Vertical collisions are collisions with potentially soft tissue (surface scan of the intraoral situation). If a vertical collision occurs and you have chosen a pilot drilling option, consider adjusting the sleeve offset.

- 1 Incorrectly positioned
- 2 Correctly positioned: sleeve offset adjusted.











Relation between the Guided Sleeve and Bone

During planning, it is important to consider the technical constraints for the position of the guided sleeves in relation to the bone surface which might include teeth. When the guided sleeve collides with the bone surface, or the remaining teeth being part of the bone model, it might not be possible to correctly seat the surgical template during surgery.

However, in some cases, this error could be acceptable (e.g., if the sleeve collides with a tooth that will be extracted before surgery, or when a sleeve collides with an artifact).

Guided Abutments

When guided abutments are planned to be used, ensure that the angle between the most angulated implants does not exceed 30 degrees.

Radiographic Guide Was Created without Calibrated Isovalue.

It is recommended to use the calibrated isovalue when creating a radiographic guide model, if a surgical template is exported to production. If the calibration set is not used, a calibration warning is issued ("The radiographic guide model was created without a calibrated isovalue") to highlight the importance of this automated step.

Discuss the Treatment Plan

The **Discuss** module allows you to create reports, read-only viewer files and Communicator presentations.

REPORTS

Create a Report

To create a report:

- 1. Make sure a patient file is opened. Click **Report** in the **Communicate** group on the **Finalize** tab of the Planning Module.
- 2. The list of planning files is shown. Select the appropriate planning file and click **Next**. The system loads the data and generates the report pages.
- 3. Preview images of the report pages are displayed: an overview of the available general information on the patient, treatment, the scanner used, the planning warnings, used products, images of the surgical plan, etc.

Note: The preview images are generated with a lower resolution than the actual pdf file.

- 4. Give the report an appropriate name.
- 5. Optionally, add a note (up to 700 characters) to the report.
- 6. Customize the report by selecting the pages to be included: deselect the pages you want to remove from the report. The deselected pages will be displayed in gray and will not be included in the final generated report.
- 7. If necessary, make the report anonymous.
- 8. Click **Finish** to create the report or **Cancel** to discard the request.
- 9. Upon confirmation, a preview is shown displaying the selected pages for the report. Scroll through the pages to check them.

Print a Report

To print the created report, export the report and save it as a pdf file.

- 1. Select the report in the **Communication Items** list.
- 2. Click **Export** in the **Report** group on the **Communication** tab of the toolbar.
- 3. Browse to the location where you wish to save the report.
- 4. Click Save.
- 5. The report is saved as a pdf document. By default the report will be opened, allowing you to print the document.

VIEWER FILES

When DTX Studio[™] Implant is not available on the computer of the person you want to discuss the treatment plan with, a viewer file can be used to communicate about the treatment plan. A viewer file is a version of the treatment plan which is saved in a read-only file, created in DTX Studio[™] Implant, containing the treatment plan of a specific patient. A viewer file can be opened, provided that DTX Studio[™] Implant Viewer is installed on the computer you are using.

Create a Viewer File

To create a viewer file:

- 1. Enter the **Discuss** module.
- 2. Click **Viewer** in the **Communicate** group of the **Communication** tab.
- 3. Select the planning file from the list.
- 4. Click Next.
- 5. Fill out the viewer details on the customization page:
 - Enter an appropriate name for the viewer file.
 - Click the images to be included in the viewer file.
 - Indicate whether the CT image data should be compressed or not.
 - If the patient details should not be shared, anonymize the file here, by selecting **Anonymize all patient information**.
 - To share the viewer file immediately when it is finished, select the corresponding check box.
- 6. Click **Finish** to save the viewer file.
- 7. The viewer file is stored and displayed in the **Communication Items** list. The **Share a viewer** dialog is shown.
- 8. Type the e-mail address or use the **Contacts** button to select people to share the viewer with.
- 9. Add a personal message and click **Share**.
- 10. An e-mail with a download link is sent to the selected people.

Open a Viewer File via DTX Studio™ Implant

- 1. Double-click a viewer file in the **Communication items** list.
- 2. The DTX Studio[™] Implant Viewer application opens and shows the selected viewer file.

Open a Viewer File via the Download Link

When you have recieved an e-mail with a download link to a viewer file:

- 1. Click the download link in the e-mail.
- 2. The viewer file is downloaded.
- 3. Browse to the location where the downloaded file is stored and double-click the saved viewer file.
- 4. DTX Studio $^{\rm M}$ Implant Viewer is opened, showing the viewer file.

COMMUNICATOR PRESENTATIONS

Communicator presentations provide an overview of the treatment plan, as well as the ability to make annotations while communicating the procedure to the patient. Communicator presentations can be used to communicate a dental treatment to patients and colleagues. Furthermore, the presentations can be made available via the cloud service.

Communicator presentations are uploaded to the cloud and can be consulted through the Communicator iPad® app.

Create a Communicator Presentation

To create a Communicator presentation:

- 1. Enter the **Discuss** module.
- 2. Click **Communicator** [1] in the **Communicate** group of the **Communication** tab.
- 3. Select the planning file from the list.
- 4. Click Next.
- 5. Fill out the Communicator presentation details on the customization page:
 - Enter an appropriate name for the presentation.
 - Include notes about the presentation, if desired. These are shown in the Communicator presentation when it is opened on an iPad[®].
 - Define which images are to be included in the presentation. Only images included in the Patient Library are available to be included.
 - If the patient details should not be shared, anonymize the file here, by selecting **Anonymize all patient information**.
 - To upload the Communicator presentation to the iPad[®] when it is finished, select the corresponding check box.
- 6. Click Finish.
- 7. The Communicator presentation is stored and displayed in the **Communication Items** list.

Export a Treatment Plan for Surgery

The **Discuss** module allows you to export the treatment plan for use in e.g. X-Guide[™] or OsseoCare[™] Pro.

X-GUIDE[™] SURGICAL PLAN

X-Guide[™] is a 3D dental implant navigation system, helping you to transfer the treatment plan to the patient and delivering interactive guidance during surgery.



Warning

Please be aware that differences in the visualization of data (e.g. viewer orientation, object colors) as well as warnings may exist between DTX Studio[™] Implant and X-Guide[™] software.

Create an X-Guide[™] Surgical Plan

To create an X-Guide[™] surgical plan:

- 1. In the **Discuss** module, click **X-Guide** in the **Communicate** group.
- 2. Select the proper approved planning file from the list.
- 3. Click Next.
- 4. Fill out the details on the **Customize surgery setup** page. Anonymize if needed.
- 5. Click Finish.

Export an X-Guide[™] Surgical Plan

To export an X-Guide™ surgical plan:

- 1. In the **Discuss** module, select a created **X-Guide**[™] surgical plan in the **Communication items** list.
- 2. Click **Export** in the **X-Guide** group on the **Communication** tab.
 - 🔨 Warning

DTX Studio[™] Implant supports only a selection of implants to be exported to X-Guide[™]. Non-supported implants will not be included in the X-Guide[™] file.

- 3. In the dialog, click **Browse** and go to the location where the X-Guide[™] surgery file should be saved.
- 4. Click Save.

OSSEOCARE[™] PRO SURGICAL PLAN

OsseoCare[™] Pro is a drill motor which operates through Apple's iPad[®], making it possible to plan and set up the treatment sequence prior to the surgery. The device is intended for use by dentists and surgeons to cut hard and soft tissue with appropriate tools.

An OsseoCare[™] Pro surgical plan combines the consecutive steps in the treatment sequence and guides the dentist or surgeon through the surgery process step by step via the iPad[®] app.

$Create \ an \ OsseoCare^{\scriptscriptstyle \rm TM} \ Pro \ Surgical \ Plan$

To create an OsseoCare[™] Pro surgical plan:

- 1. In the **Discuss** module, click **OsseoCare Pro** in the **Communicate** group.
- 2. Select the proper approved planning file from the list.
- 3. Click Next.
- 4. Fill out the details on the **Customize surgery setup** page.
- 5. Click **Finish**. By default the finished surgical plan will be uploaded to the cloud.
- 6. Click **I agree** on the legal disclaimer to continue.

Scanner Calibration

Note: This scanner calibration procedure is only needed for the creation of a radiographic guide.

To correctly and accurately transfer the treatment plan from the computer to the patient for surgery, it is important to generate a surgical template which fits as well as the radiographic guide on the surrounding soft and hard tissue. This requires an accurate 1:1 copy involving digitization by a (CB)CT scanner and the creation of a virtual radiographic guide model in the software using the scanner dependent appropriate settings. The identification of this value, the "isovalue", can be done manually, by manual interaction, or can be determined automatically using a calibration scan from the unique NobelGuide® calibration object acquired by the scanner used with the suitable settings. The NobelGuide® calibration object is an object with the same radiolucent properties as the radiographic guide (PMMA) and has an accurately defined shape known to the software. Examining the reference scan (calibration scan) automatically and comparing it to the known original shape, DTX Studio[™] Implant is able to automatically determine and apply the most appropriate isovalue (the **Calibrated** Isovalue) for extracting (segmenting) the correct dimensions and shape from the radiographic guide scan. The software stores all scanner specific calibration sets. For each scan of a radiographic guide, it automatically looks for a suitable calibration set from the "known" scanners. If such a scanner is detected, the corresponding Calibrated Isovalue is suggested and applied automatically. The isovalue editor in the radiographic guide wizard provides information about the used calibration set, the type of scanner that is used, and the calibrated isovalue.

The use of the calibrated isovalue is recommended when creating a radiographic guide model if a surgical template is exported to production. If the calibration set is not used, a calibration warning is issued (**The radiographic guide model was created without a calibrated isovalue**) to highlight the importance of this automated step.

When calibration is used, the isovalue editor shows **Calibrated Isovalue** instead of **Isovalue**. When using a system generated calibration set, **Suggested isovalue** is displayed.

CREATE A NEW CALIBRATION SET

The first time image data from a specific (CB)CT scanner and particular protocol are used, a new calibration set must be created. Once this calibration set has been developed it may be used for all patients scanned with this imaging unit. The creation of a new calibration set at least every six months or when the imaging unit has been updated, upgraded or had maintenance performed, is recommended.

To create a new calibration set, click **New** in the **Calibration** set group on the **Scanner** tab of the **My Office** module. The **Create Calibration** wizard is started.

The calibration wizard leads you through the calibration procedure in three steps:

- 1. Load the calibration DICOM files
- 2. Calculate calibration settings
- 3. Fill out the details and save the calibration set

Symbols Glossary



Batch code

Consult Instructions for Use

Do not re-sterilize

Rx Only

For prescription use only

Keep dry

MR

Magnetic resonance conditional

i

REF

Catalog number

Do not re-use

ID

Patient identifier

Manufacturer

Non-sterile

STERILE R

Contains or presence of phthalate

PHT



Caution



Date of manufacture



Do not use if package is damaged



Keep away from sunlight



Medical device



Patient number



Serial number

SN

Sterilized using irradidation





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