

# DTX Studio<sup>™</sup> Implant Version 3.6

**Instructions for Use** 

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# Introduction

# **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. Nonrecommended 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.

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.

# **Device Description**

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

To support the diagnostic and treatment planning process for dental, craniomaxillofacial, 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.

# **Intended Purpose**

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

# Intended Use / 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 craniomaxillofacial 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.

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# 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, craniomaxillofacial or related treatments.

Intended for patients needing to undergo dental treatment

# Required Compatibility with Other Devices

- DTX Studio Implant Viewer software
- NobelClinician Communicator iPad app
- OsseoCare<sup>™</sup> Pro iPad app
- DTX Studio Lab
- DTX Studio Implant has to be compatible with the most used operating systems Windows and Mac, including the latest releases.
- X-Guide<sup>™</sup> 3D navigation system (X-Nav Technologies, LLC)
- DTX Studio Clinic
- NobelGuide® Concept and Surgical templates
- Nobel Biocare implants and standard abutments
- For importing surface data in DTX Studio Implant: Surface scan acquired through NobelProcera® 2G scanner, Kavo LS 3 scanner. Encrypted format (\*.nxa)
- Third-party implants for treatment planning and guided surgery – pilot drilling only.
- DICOM import (from (CB)CT scanners) and STL/ PLY import (from desktop or intraoral scanners).
- DTX Studio Implant has to be compatible with the online portal – DTX Studio Go.

# **Devices with Measuring Function**

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.

# 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 your computer when it is left unattended. Failure to do so may lead to unintended handling of the diagnosis and planning or treatment.

# 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.

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## **Intended Lifetime**

For software the intended lifetime is three years. When used on the supported operating systems, the software 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 'System Requirements' on page 15.

# 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.

# **Facilities and Training**

It is strongly recommended that clinicians, new as well as experienced users of our software, read the IFU before using the software for the first time. A wide range of courses for various levels of knowledge and experience can be provided upon request.

For more information please visit our training website on <u>tw.dtxstudio.com</u>.

# **Notice Regarding Serious Incidents**

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

## **Professional Use**

DTX Studio Implant is for professional use only.

# **System Requirements**

We advise to check the 'System Requirements' on page 15 before starting the installation of the software. To obtain information on minimum and/ or recommended requirements, please contact customer support. New versions of the software may require higher requirements for hardware or operating system.

# Installation of the Software

To obtain information on how to install the software, please contact the authorized technician or customer support.

# **Handling Instructions**

For detailed information on how to use the software, please refer to the detailed instructions further on in this IFU.

# Warnings, Cautions and Precautions

# **Warnings**

Following warnings are shown in the software.



- 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.
- The user must be familiar with the interpretation of CT data and the way CT data are visualized by means of volume rendering.
- Improper alignment of the CBCT scan and the surface scan will result in an incorrect surgical template and may not be used for surgery.
- 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.
- 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.



### **SmartFusion™ Initialization Warnings**

Dental scan alignment is adjusted manually.

The alignment between the patient model and the dental scan has been manually adjusted. Double-check that the dental scan is correctly aligned with the (CB)CT scan, as deviations will introduce errors in the correct positioning of the implants.

- One or more pairs of points are not corresponding.
- The defined points are insufficiently distributed over the dental scan.
- Indicate at least three corresponding points.
- 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.



### **Scan Warnings**

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

- 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).



### **Template Warnings**

- Sleeves are colliding.\*
- Implant and sleeve are colliding.
- Anchor pin and sleeve are colliding.
- Annotated tooth and sleeve are colliding.
- Anchor pin sleeve is too close to the dental scan.
- Pilot sleeve is too close to the dental scan.\*
- Fully guided sleeve is too close to the dental scan.
- \* The surgical template cannot be produced until this warning is resolved.



### **Clinical Warnings - General**

- No anchor pins are planned.
- Anchor pins are colliding.
- Radiographic guide was not calibrated.
- Treatment planned with non-installed products.\*
- Low-quality visualization is enabled.\*\*
- Dental scan alignment is adjusted manually.
- SmartFusion alignment failed.\*
- Verify SmartFusion alignment
- \* 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.



### **Clinical Warnings - Implant**

### Important

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

- Implants are colliding.
- Implant and anchor pin are colliding.
- Implant is too close to an annotated nerve.\*
- Implant is too close to an annotated tooth.\*
- 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.

<sup>\*</sup> 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  $1.5 \, \text{mm}$ , the minimal distance. With this minimal distance, the warning volume coincides with the yellow zone (representing a  $1.5 \, \text{mm}$  distance around the implant and a  $2 \times 1.5 \, \text{mm}$  ( $3.0 \, \text{mm}$ ) distance at the apex). The warning volume can be increased. As seen in the picture (for a distance of e.g.  $4.0 \, \text{mm}$ ) 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.

## **Cautions / 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 or treatment method for the first time, working with a colleague who is experienced with the new device or 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 or 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
- In addition, it is recommended that active and up-to-date antivirus and antimalware software, together with a correctly configured firewall, are installed on the computer where DTX Studio Implant (NobelClinician®) is to be used
- 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.



- When warnings are triggered because of the cylinder shapes, these warnings are calculated based on an estimate of the product shape.
- The lack of knowledge and comprehension of the software may result in the delay in or rescheduling of the diagnosis and planning or the actual treatment or may lead to an incorrect treatment plan.
- When using the diagnostic and planning tools provided in the software, it is important to pay extra attention to:
  - the correctness of made indications (visualizations, measurements, critical structures, imported data, implant planning).
  - the correctness of the outcome of the automated functions (the alignment of dental scans, virtual tooth setup...)
  - the designed surgical template stl files and their optimal fit to the patient's mouth according to the developed plan.
  - the data being up to date and not outdated

Failure to do so increases the risk of the need for revision of the diagnosis and planning or treatment which, in its turn, may lead to the delay in or rescheduling of the diagnosis and planning or the actual treatment or may lead to an incorrect treatment plan.

- It is recommended to pay extra attention when loading patient data. Incorrect and incomplete data may lead to an incorrect treatment plan.
- When extracting a report or patient data from the software, it is important to know that not de-identified patient data can be used for incorrect purposes without the patient's consent.
- It is recommended to pay extra attention to the representation mode and orientation markings of the viewers. An incorrect patient orientation or representation or may lead to an incorrect treatment plan.
- After updating the software version, it is recommended to verify the critical settings of the
  open patient cases and/or treatment plan to make sure these settings are correct in the
  new software version. Incorrect settings may lead to a delay in or the rescheduling of a
  diagnosis and planning or the actual treatment or may lead to an incorrect treatment plan.
- 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. Failure
  to do so may lead to unintended handling of the diagnosis and planning or treatment.
- It is recommended to pay extra attention to the created implant planning and the positioning of the implants with respect to each other and other import anatomical structures. Extra attention should be paid as well to the warning signals withing the software. Furthermore, always verify that the correct implant planning was selected for exporting and that the exported implant plan contains all necessary information for implant surgery. Failure to do so increases the risk of the need for revision of the diagnosis and planning or treatment which, in its turn, may lead to the delay in or rescheduling of the diagnosis and planning or the actual treatment or may lead to an incorrect treatment plan.

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# **System Requirements**

# **Operating Systems**

- Windows® 11 or 10 64-bit (Pro and Enterprise edition) on desktop or notebook.
- macOS Sequoia (15), Sonoma (14), Ventura (13) or Monterey (12) (Intel-based Mac and Apple Silicon Mac with M1 Chip or Higher) on iMac, Mac Mini, Mac Pro, MacBook Pro, MacBook Air devices.

### Note

The graphics cards of some MacBook Air® and Mac® Mini configurations have restrictions with regard to volume rendering. Consider selecting low-resolution volume rendering.

# Requirements

al-core / 3 GHz clock rate
GB
dicated add-in graphics card with optimal 3D support (OpenGL 3.3) and 2 GB memory more (such as AMD or NVIDIA). For 4K displays: 4 GB memory or more. 6th generation el* CPUs or higher are supported (with embedded 9th generation GPU or higher).  Check the OpenGL® version of your graphics card, go to <a href="http://realtech-vr.com/admin/glview">http://realtech-vr.com/admin/glview</a> .
GB free disk space
padband Internet connection with 3Mbps upload and 30 Mbps download speed.
I HD (1920×1080) or higher.
d m el

# **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 . 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 .

### 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.

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# **User Indentification**

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

- 1. Double-click the desktop icon to open the software.
- 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.

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# **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**

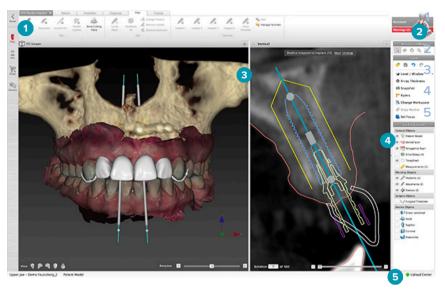
To manage the user accounts available in a practice and to set the corresponding user permissions, open the Manage Accounts dialog via the Manage Account option within the DTX Studio Implant menu.

### **Add Users**

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

# **Software Overview**

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



Toolbar with action groups specific to the selected module

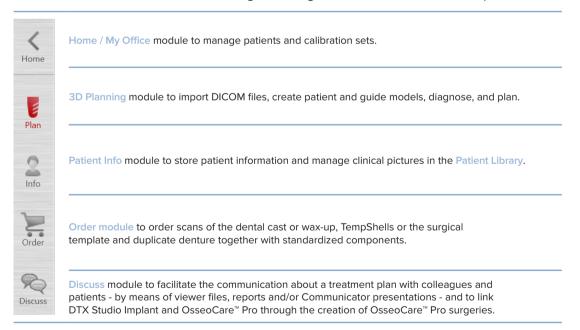
Assistant

Workspace

Module bar

**Upload Center** 

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



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.

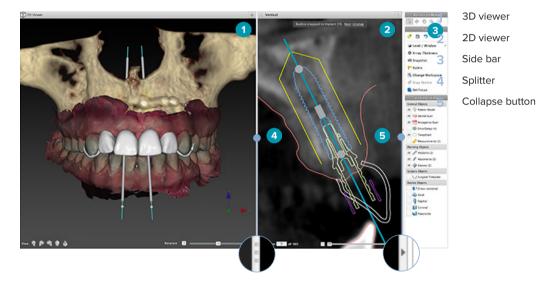
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# Workspace System

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**

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.



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## 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.

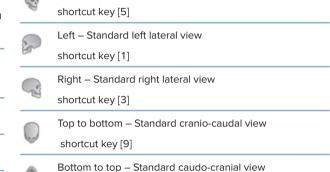
B	Interaction mode	Select an object or identify an object for an action by pressing the left mouse button.
ED	Rotation mode	Rotate the 3D scene (only 3D) by dragging the mouse.
•	Pan mode	Pan the scene by dragging the mouse.
Q	Zoom mode	Zoom in or out by dragging the mouse.
Q	Zoom Box mode	Zoom to focus 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. Click the icons to go to the corresponding standard views of the model.

Front – Standard frontal view



# **Manipulate Objects**

shortcut key [7]

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.

Select the cross-sectional reslice, an implant or an anchor pin and access related actions via the dedicated toolbar tab.

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 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:



- 1 When the black visibility icon is displayed in front of the group, all objects belonging to the group are shown.
- When the gray visibility icon is shown in front of the group, one or more objects in the group are hidden, while others are still shown.
- When no icon is displayed in front of the group, all objects belonging to the group are hidden.

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.

# 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.

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# **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.

### **Create a Patient Model**

- 1. Enter the Create Patient wizard using one of the following actions:
  - Click New in the Medical Records tab of the DTX Studio Implant toolbar and click Create a new planning.
  - In the Planning module, click Patient so 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 Reslice 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.

### Adjust the Shape of the Reslice Curve

- 1. Click Reslice curve 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.

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### **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.

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.

- 3. Check the curve and fine-tune, if necessary.
- 4. 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:

- Click Reslice curve by 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.

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# 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.

### Use the 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.
- 3. 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**

- 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.

### 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.

### **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.

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# **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

Open a patient file, click Order Products to go to the Order module and click Scan 1.



- 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.
- 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.
- 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™

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## **SmartFusion**<sup>™</sup>

### Add the Dental Scan to the Patient Model

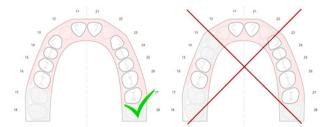
The acquired surface scan (uploaded by the dental laboratory or imported from the intraoral scanner) can be aligned with the patient model.

- 1. Open the treatment in the Planning module.
- 2. Click Dental Scan in 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

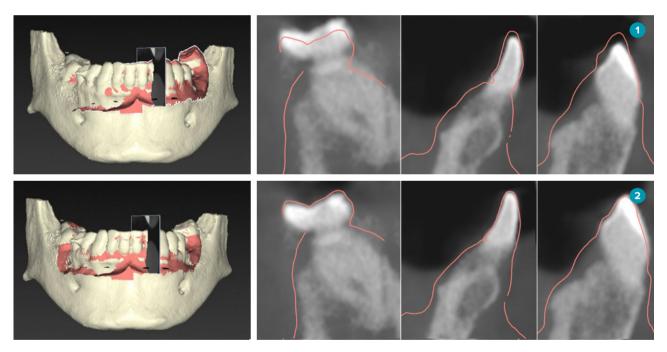
Always verify which scanner is selected, especially when importing .nxa files or when different scanners might be used to acquire dental scans. When selecting a specific scanner from the list, it will be stored and used as default scanner when creating new patient models.

- 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.
- Click Next.

- 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™.
- 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

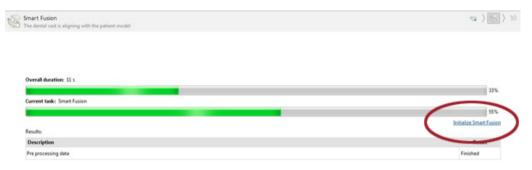
It is likely that SmartFusion™ will be less accurate when the patient has less than six remaining teeth.

### **Initialization Procedure**

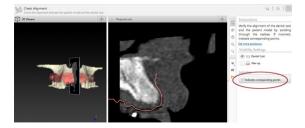
To initialize SmartFusion $^{\text{M}}$ , define at least three pairs of corresponding points, shown on the teeth of the patient model and dental scan, respectively. If the points are inaccurately placed, remove them and indicate them again. All corresponding points may be removed with a single click.

### 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.



- 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.



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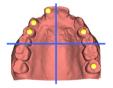
# How to Define Corresponding Points in the Initialization Wizard

### **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.
- 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.

Warning

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### **SmartFusion™ Initialization Warnings**

3	
Dental scan alignment is adjusted manually.  The alignment between the patient model and the dental scan has been manually adjusted. Double-check that the dental scan is correctly aligned with the (CB)CT scan, as deviations will introduce errors in the correct positioning of the implants.	When the user chooses to apply manual alignment for the SmartFusion™ of the dental scan and the patient model or the dental scan has been manually adjusted, 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	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.

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.

**Explanation** 

## **Face Scan**

distributed over the dental scan.

Indicate at least three corresponding points.

Load a face scan to be mapped to the patient model. It is possible to load different scans, one at a time. The way to achieve the best result is to load a neutral face scan first and map this to the patient model. Later on, a smiling face scan can be loaded and mapped e.g. to the neutral face scan.

### Add a Face Scan to the Patient Model

- 1. Click Face Scan 💂 in the Additional Scans group on the Prosthetic tab to start the wizard.
- 2. Click Select a face scan. Select a face scan (.obj) and click Open.
- 3. Click Next.
- 4. Verify the current position of the uploaded scan. To adjust the alignment between the loaded face scan and the patient model, click Adjust alignment , select the object you want to align the face scan with and click OK. The wizard allows you to indicate a minimum of five corresponding points to align the scan and the model correctly. Click Finish to exit the corresponding points wizard.
- 5. Click Finish to exit the Face Scan wizard.

To add another face scan, repeat the above-mentioned steps.

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### Trim a Face Scan

It might be useful to trim away the teeth that are showing on a smiling scan, so you can actually show the patient model with e.g. the SmartSetup $^{\text{m}}$  through the face scan.

- 1. Click Trim Face Scan >, either on the Prosthetic tab of the toolbar or in the Face Scan wizard.
- 2. Remove the region that needs to be trimmed away by clicking and dragging. Use the Adjust brush size slider when appropriate.
- 3. Click Finish.

### Note

The trimming action will work on the face scan that is on show. When multiple scans are loaded and you wish to trim one of the face scans, make sure to select the correct face scan first via the Face Scan right-click menu.

# **SmartSetup**<sup>™</sup>

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 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

### **Adjust SmartSetup™ Settings**

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

- 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.
- 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.

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- 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:

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

<b>+</b>	Translation	Click the SmartSetup $^{\text{\tiny TM}}$ , hold down the mouse button and drag to translate the SmartSetup $^{\text{\tiny TM}}$ .
		Adjust the values in the Buccal/lingual, Mesial/distal and/or Occlusal boxes to fine-tune the position of the SmartSetup $^{\rm m}$ .
Ø	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™.
R 37 E 3	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 $^{\text{\tiny{M}}}$ .

# 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.

### Create a 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 son the Prosthetic tab of the Planning toolbar.
- 2. Check the intaglio surface and click Finish.

# **Diagnose**

## **Nerves**

To delineate a nerve, click Nerve on 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 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.

## **Teeth**

To annotate a tooth, click Tooth 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.
- 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 or 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 on 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.

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

Then 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.

## Adding Implants to a Treatment 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.

## Add an Implant to a Treatment Plan

- 1. Click Implant 4 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:

- Select an implant. The gray tube on the implant turns green.
- 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.

## Place one Implant Parallel to Another One

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

- Select the implant you want to use as a base. 1.
- Click Parallel Implant 4. 2.
- 3. Click in the 3D or 2D viewer to indicate the shoulder point of the implant.
- 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:

- Select the implant you want to use as a base.
- Click Parallelize All 2.



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**

## Select an Appropriate Abutment for an Implant

- Select the implant in the scene.
- Click Abutment 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.

These options are only available if the selected impla ses not have an abutment yet. If an abutment is already present, click the Change Product menu item or icon 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.
- 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.



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:

- Freehand: no surgical template (no guided sleeve) will be used to place this implant.
- © 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.
  - 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.

## Set the Pilot Sleeve Offset

- 1. Select an implant.
- 2. Make sure the surgery type for the selected implant is pilot drilling.
- 3. 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.

## **Set 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.

## **Bone Cutting Plane**

To indicate a plane representing the ideal bone level for the patient, use the **Bone Cutting Plane** action. Nothing will actually be removed. It is a visualization of where the bone may need to be cut away, helping you to plan the treatment.

- 1. Click Bone Cutting Plane 4 in the Plan group on the Plan tab of the toolbar.
- 2. A purple plane is added to the patient model.
- 3. Click the plane to select it. Drag the colored handles at the boundaries to adjust the plane size and position. Use the Plane height slider in the right-click menu to adjust the position of the plane with respect to the Z-axis of the model.

## **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+.
- 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**

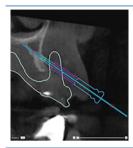
To stabilize the surgical template for implant insertion, anchor pins can be placed at strategic positions. Their angulation and depth are crucial.

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.

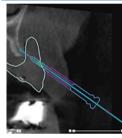
The sleeves should be placed close to the mucosa, represented by the digitized surface model of the intraoral situation (about 0.5 to 1 mm distance from the mucosa) but should not interfere or collide with the aforementioned model when using a smart-fused surface scan.

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.

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

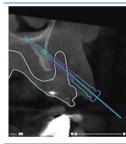


## Correct



## Incorrect

The sleeve of the anchor pin is not attached to the radiographic guide and will not be attached to the template.



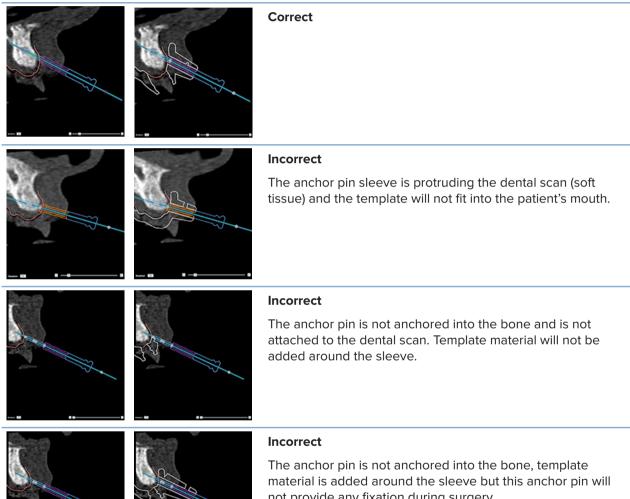
## Incorrect

The anchor pin sleeve is protruding through the radiographic guide and the template will not fit into the patient's mouth.

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## **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.



not provide any fixation during surgery.

# **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.

## Snap the Cross-sectional Reslice to an Implant or Anchor Pin

- 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

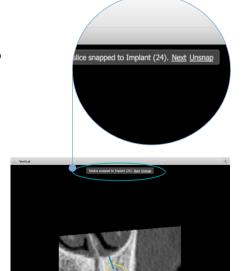
When the snap functionality is in implant or anchor pin mode, move to another implant or anchor pin by using the Next action, displayed in the Snap bar in the 2D viewer.

- 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.



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# **Inspect a Treatment Plan**

## **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.

## Create a Surgical Template According to the Treatment Plan

- 1. Click Create Template 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.
- 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.



Virtual template calculated for production by Nobel Biocare.



Virtual template calculated for local production.

## **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 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

- Click Add Connection 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:

- 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 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:

- 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 . Only approved planning files can be converted into orders. A warning is displayed in the case of a not yet approved planning file.

- 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 in the toolbar.

## Work with 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

- In the Office module click New and Order a model scan 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.

## **Work with 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.

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## Create a LabDesign Request

To request a LabDesign:

- 1. Click LabDesign 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:

- Click TempShell 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 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 Q 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.

## **Work with 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 ...
- 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.

## **Export an Approved Plan**

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

In the Order module, click Fulfill request ... 1.



- 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 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:

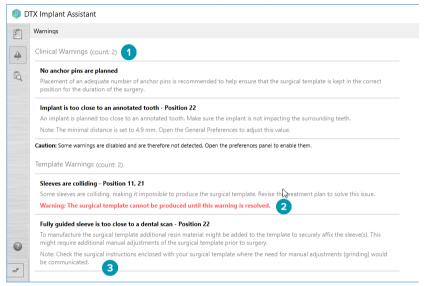
- Tasks : An overview of planning and additional tasks guides you through the planning procedure.
- Warnings 4: Warning messages make you aware of possible issues.
- Planning overview : An overview is given of the implants, abutments, and/or anchor pins used in the treatment plan. Whether or not the 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  $\bigoplus$ , 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.
- 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.
	<b>Note</b> Check the surgical instructions enclosed with your surgical template where the need for manual adjustments (grinding) would be communicated.

<sup>\*</sup> 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 by indicating corresponding points or importing a new dental scan surface. 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.

<sup>\*</sup> The surgical template cannot be produced until this warning is resolved.

<sup>\*\*</sup> 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.

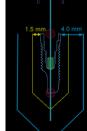
Warning	Explanation
Implants are colliding.	Some implants are colliding. This can cause issues during surgery. Revision of the treatment plan is recommended.
Implant and anchor pin are colliding.	An implant is colliding with an anchor pin. This can cause issues during surgery. Revision of the treatment 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.
	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.
	<b>Note</b> The minimal distance is set to [] mm. Open the General Preferences to adjust this value.

<sup>\*</sup> 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  $2 \times 1.5$ 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.

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### 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.

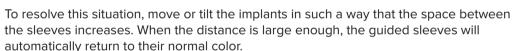
## **Technical Constraints**

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.





## 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.



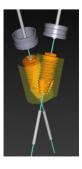
## Collision between Implants, Anchor Pins, or Implants and Anchor Pins

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

- 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.
  - 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

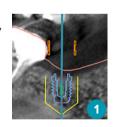
using the Depth icon in the dedicated toolbar. Alternatively, when a pilot sleeve is chosen, consider adjusting the sleeve offset.

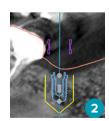
- Correctly positioned
- 2 Incorrectly positioned: the sleeve is placed too deep.

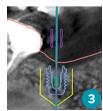
## Scan of the Dental Cast

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**

- 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.
- 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

- 1. Enter the Discuss module.
- 2. Click Viewer in the Communicate group of the Communication tab.
- 3. Select the planning file from the list and click Next.
- 4. 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.
- 5. Click Finish to save the viewer file.
- 6. The viewer file is stored and displayed in the Communication Items list. The Share a viewer dialog is shown.
- 7. Type the e-mail address or use the Contacts button to select people to share the viewer with.
- 8. Add a personal message and click Share.
- 9. 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 Implant Viewer is opened, showing the viewer file.

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

## **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**

- 1. Enter the Discuss module.
- 2. Click Communicator 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<sup>®</sup>.
  - 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 Consult or Surgery

DTX Studio Implant allows you to export the treatment plan for use in e.g. DTX Studio Clinic, X-Guide™ or OsseoCare™ Pro or to be consulted in other software products.

## **Export to DTX Studio Clinic**

To export the treatment plan for visualization in DTX Studio Clinic:

- 1. Go to the Planning module.
- 2. Click Clinic export in the Surgery plan group on the Finalize tab.
- 3. Select the folder to store the encrypted .dtxip file containing all necessary information of your treatment plan.
- 4. A message is shown confirming a successful saving as well as the location where the file is saved. Click OK to close it.

## **Export Treatment Plan for Visualization in Other Software Products (Open Export)**

- 1. Go to the Planning module.
- Click Open export ♥ in the Communicate group on the Finalize tab.
- 3. Select the folder to store the treatment plan.
- 4. Click Export.
- A message is shown confirming a successful saving as well as the location where the file is saved. Click OK to close it.

# **X-Guide<sup>™</sup> Surgical Plan**X-Guide<sup>™</sup> is a 3D dental implant navigation system, helping you to transfer the treatment plan to the patient and delivering interactive guidance during surgery.

/i\

## 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

- In the Discuss module, click X-Guide X 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**

- 1. In the Discuss module, select a created X-Guide™ surgical plan in the Communication items list.
- 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 $^{\text{\tiny M}}$ . Non-supported implants will not be included in the X-Guide $^{\text{\tiny M}}$  file.

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

# OsseoCare<sup>™</sup> Pro Surgical Plan

OsseoCare $^{\text{m}}$  Pro is a drill motor which operates through Apple's iPad $^{\text{o}}$ , 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<sup>™</sup> 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<sup>®</sup> app.

## **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 quide 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 quide (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 sign 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

# **Technical Support**

If you encounter any problems, please contact DTX Studio Technical Support:

support@dtxstudio.com

https://tech.dexis.com/support





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