IPS CaseDesigner® 2.1
Instructions for Use

Nobel Biocare™

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Description:

IPS CaseDesigner® is a software solution supporting the diagnostic process and treatment planning of craniomaxillofacial and related treatments.

IPS CaseDesigner® has specific functionalities to visualize the diagnostic information, e.g. from CT-imaging, to perform specific measurements in the image data and to plan surgical actions in order to support the diagnostic and treatment planning process.

Based on the diagnostic and planning data, the IPS design service can offer individualized surgical aids.

IPS CaseDesigner® is a user interface supporting the diagnostic process and treatment planning of craniomaxillofacial and related treatments.

Intended Purpose:

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

Intended Use:

IPS CaseDesigner® is a software for the transfer and visualization of imaging information from equipment such as a CT scanner to support the diagnostic and treatment planning process in cranio-maxillofacial regions.

IPS CaseDesigner® facilitates the service offering of individualized surgical aids.

Indications for Use:

IPS CaseDesigner® is indicated for use as a software and image segmentation system for the transfer of imaging information from a scanner such as a CT scanner. It is also indicated to support the diagnostic and treatment planning process of cranio-maxillofacial procedures.

IPS CaseDesigner® facilitates the service offering of individualized surgical aids.

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. IPS CaseDesigner® software reports the value, rounded to one digit after the decimal point, based on user-picked points.

Contraindications:

None identified for IPS CaseDesigner®.

Cautions:

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications.

Warnings:

A number of technical warnings (e.g. inconsistent CT data, corrupt STL data) are visualized in IPS CaseDesigner®.

A warning panel may show one or more of the following warnings during the creation of models, diagnostics or osteotomy simulations.

Incorrect alignment of upper jaw detected.

Use the **Manual initialization** action to obtain a correct alignment of the upper jaw to reduce the risk of incorrect surgical planning**.**

Incorrect alignment of lower jaw detected.

Use the **Manual initialization** action to obtain a correct alignment of the lower jaw to reduce the risk of incorrect surgical planning.

Incorrect alignment of both jaws detected.

Use the **Manual initialization** action to obtain a correct alignment of the jaws to reduce the risk of incorrect surgical planning.

To separate both jaws, hard separation was used.

To reduce the risk of using incomplete (planning) information in the surgery plan, adjust the **Expert settings** for fossa-condyle separation if you do not wish to use hard separation.

To separate both jaws, normal separation was used.

To reduce the risk of using incomplete (planning) information in the surgery plan, adjust the **Expert settings** for fossa-condyle separation if you wish to use a different type of separation.

Incorrect jaw separation detected.

Adjust the **Expert settings** for fossa-condyle separation to obtain a correct jaw separation and to reduce the risk of incorrect surgical planning.

Upper jaw is manually initialized.

The alignment calculation of the upper jaw is initialized by the corresponding points placed in the **Manual initialization** action. Ensure correct jaw alignment before finalizing the surgical plan to reduce the risk of incorrect surgical planning.

Lower jaw is manually initialized.

The alignment calculation of the lower jaw is initialized by the corresponding points placed in the **Manual initialization** action. Ensure correct jaw alignment before finalizing the surgical plan to reduce the risk of incorrect surgical planning.

Both jaws were manually initialized.

The alignment calculation of both jaws is initialized by the corresponding points placed in the **Manual initialization** action. Ensure correct jaw alignment before finalizing the surgical plan to reduce the risk of incorrect surgical planning.

The DICOM set slice thickness is too large

Please turn to the help files for information on how to create valid DICOM files according to the recommended scan protocol.

The DICOM set has inconsistent slice increments

Please turn to the help files for information on how to create valid DICOM files according to the recommended scan protocol.

The DICOM set slice increment is too large

Please turn to the help files for information on how to create valid DICOM files according to the recommended scan protocol.

Corrupt file

File of ["upper scan","lower scan", "occlusion scan"] could not be opened, please select another file. If the problem persists, contact customer support.

Corrupt files

Both files could not be opened, please select other files. If the problem persists, contact customer support.

The name in the DICOM file differs from the patient name

To reduce the risk of using incorrect data to create the patient model, verify the patient name and check whether patient name and the name in the used DICOM set correspond.

Finalize splint for current surgical plan

The generated splint files are only valid for the planned surgery. If you want to change the surgical plan, use the unlock action to remove the splint and make changes.

Intersecting models detected. Increase the autorotation value

Increase the autorotation value to reduce the risk of a surgical misfit.

Intersecting models detected.

Adjust the autorotation to avoid intersecting models. Press Continue if you want to proceed creating the splint.

Fragments might be intersecting

When in the **Virtual Occlusion** wizard upper and lower jaw intersect, grinding will be required to be able to achieve the final occlusal position.

Surgical splint for pre-op position

Be aware that a splint will be created for the pre-op position of the patient.

Intended Users and Patient Groups:

IPS CaseDesigner® 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.

Cybersecurity:

It is recommended that active and up-to-date anti-virus and anti-malware software, together with a correctly configured firewall, are installed on the computer where IPS CaseDesigner® is to be used. Furthermore, always lock your computer when it is left unattended.

Compatibility:

IPS CaseDesigner® is not connected with other medical devices.

This version of IPS CaseDesigner® is compatible with previous versions of IPS CaseDesigner®.

Interoperability

N/A since the software is not exchanging data with any other medical device.

Intended Lifetime

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

Performance Requirements and Limitations:

IPS CaseDesigner® has dependencies on the operating systems it is used with. It is therefore important to make sure IPS CaseDesigner® is used only with approved operating systems. More information about which operating systems are approved can be found in the 'Computer Guidelines for IPS CaseDesigner®'.

Clinical Benefits and Undesirable Side Effects

IPS CaseDesigner® is a component of craniomaxillofacial surgery. Clinicians can expect the software to support the diagnostic and treatment planning process.

No side effects known.

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Facilities and Training:

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

Handling Instructions:

Installation of the software:
Install the software according to the IPS CaseDesigner® Installation Guide.

How to start the software:
To open the application, double-click on the IPS CaseDesigner® shortcut icon on the desktop. The software opens, allowing you to start working with patient files.

IPS CaseDesigner® workflow steps:
The patient undergoes a scan according to the scanning protocols defined for IPS CaseDesigner®. The models are scanned in final occlusion. Both parts of the dental cast are also scanned, individually but within one DICOM set. The resulting DICOM files are used to create the patient model, surgery models, occlusion models and skin.

Diagnostic tools are available for the user to indicate the mandibular nerve or to measure distances, angles or values. A cephalometric framework allows the user to indicate the landmarks to be used in the cephalometric analysis.

With the surgery tools the virtual model can be osteotomized according to different osteotomy types, including Le Fort I, sagittal split, ramus, segmental and chin osteotomies. The movements of the different bone segments can be simulated. A surgical splint file can be created and the list of osteosynthesis plates can be consulted to select the plates to be used in the surgery.

For more detailed information on how to perform specific actions, please refer to the help files that can be accessed via the IPS CaseDesigner® software.

If you wish to have a printed hardcopy of the IFU, please contact customer support.

Manufacturer and Distributor Information:

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Rx Only

Consult instructions for use

Symbols Glossary:

The following table describes symbols which may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

LOT — Batch code	REF — Catalog number	⚠ — Caution
Consult instructions for use	PHT/DEHP — Contains or presence of phthalate	Date of manufacture
Do not re-sterilize	Do not re-use	Do not use if package is damaged
Rx Only — For prescription use only	ID — Patient identifier	Keep away from sunlight
Keep dry	Manufacturer	MD — Medical device
MR — Magnetic resonance conditional	NON STERILE — Non-sterile	Patient number
SN — Serial number	STERILE R — Sterilized using irradiation	Use-by date