

IPS CaseDesigner® 2.0

Instructions for Use



Important: Please read.

Disclaimer of liability:

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

Contraindications:

None identified for IPS CaseDesigner®.

Warnings:

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

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.

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.

This patient name differs from the patient DICOM set

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.

Be aware that locally-produced surgical splints must be fabricated using validated processes and appropriate materials according to the manufacturer's instructions for use. Optimal fit should be verified prior to surgery.

Intersecting models detected. Increase the autorotation value

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

Intersecting models

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.

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.

Handling instructions:

General operating instructions:

The use of IPS CaseDesigner® requires the user to have the necessary training and domain knowledge in the practice of craniomaxillofacial surgery.

Users are advised to obtain training before undertaking a new treatment method or using a new device.

Cybersecurity:

It is recommended that you have active and up-to-date antivirus and anti-malware software – together with a correctly configured firewall – on the computer on which you are using IPS CaseDesigner®. Furthermore, always lock the computer when it is left unattended.

Professional use:

IPS CaseDesigner® is for professional use only: clinicians, nurses, dental technicians and designers of individualized surgical aids. The product is to be used in a clinic, private practice, dental laboratory or as a software tool in a design service for surgical aids.

Additional information:

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®'.

Installing IPS CaseDesigner®:

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.



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