



This medical device has been registered in Malaysia

English Instructions for Use

This document contains general instructions for use for ProPlan CMF. For detailed instructions, refer to the Software User Manual.

DESCRIPTION

ProPlan CMF is user-friendly scanner-based image-processing software with 3D visualization functions to plan surgical operations over the Cranio-Maxillo-Facial (CMF) region. CT images as well as MRI images can be interactively visualized and segmented to result in a 3D rendering of anatomical objects.

INDICATIONS

ProPlan CMF is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner. It is also used as pre-operative software for simulating/evaluating implant placement and surgical treatment options.

CONTRAINDICATIONS

None

WARNINGS

- This product should be used by trained technicians. The output must be verified by the responsible clinician.
- The 3D reconstructions must be compared to the slice images and verified for approval by the responsible clinician.
- It is the clinician's ultimate obligation to exercise his/her professional judgment in any decision to follow or not follow the treatment planning made using the medical device (software).
- For scans taken with an inter-slice distance of 1 mm the accuracy of the 3D reconstructions in the software varies between 0.1 to 0.2 mm. The use of larger inter-slice distances is not recommended.
- ProPlan CMF Guides are to be used by a trained physician in the performance of surgery.
- Be aware that any patient specific guides and/ or anatomical models derived from a planning created in the software have been manufactured based on

CT/MRI scans of the patient. If the patient's anatomy has changed significantly since the time of the CT/MRI scan, the guides or models should not be used.

PRECAUTIONS

- The quality of the images in the ProPlan CMF software depends on the quality of the scanned images. To obtain optimal results, please use the scan parameters specified in the scanning protocol.
- It is advised to use the guide or anatomical model within 6 months of performing the CT/MRI scans on which they are based. If the patient's anatomy has changed significantly since the time of the CT/MRI-scan, the guide or model should not be used, even if the time period of 6 months has not expired.

INSTRUCTIONS FOR USE

- Install
Close all other applications before installing ProPlan CMF. Install ProPlan CMF using the downloaded 'ProPlanCMFSetup.msi' installer file. You must have administrative privileges to install the software. This means you either need to be logged in as an administrator before running the installer or you need to right-click the installer while holding the Shift-key and choose the 'Run as administrator' option.
Follow the instructions on screen to install ProPlan CMF.
- Start
To start ProPlan CMF, double click the ProPlan CMF icon on your desktop or go via the Start > All Programs > Synthes > ProPlan CMF and choose to run ProPlan CMF.
ProPlan CMF is password protected. Run ProPlan CMF after the installation to start the Password Request Wizard. You will be presented with the options to apply for password. Follow the instructions on screen.
The start screen is opened when the software is started. Click Open Project to open a ProPlan CMF file or click Import Images to import DICOM.
When a ProPlan CMF project is opened, the ProPlan CMF Overview screen gives an overview of all available ProPlan CMF wizards and services. Hover over a menu item on the left side of your screen to display more information in the information pane. Click on the menu item on the left to enter any of the wizards.

- **Software Requirements**

ProPlan CMF can be used on the following operating systems:

- Windows Vista SP2 x64;
- Windows 7 x64;
- Windows 8 x64.

Note To maximize the full capacity of your PC and process larger datasets PROPLAN CMF Software 2.1 is now supporting x64 OS platforms only.

Additional software requirements:

- Internet Explorer 8.0 or higher
- Adobe Reader X or higher

- **Hardware Requirements**

ProPlan CMF can work on a PC with the following configuration:

- Intel Core2Duo or equivalent;
- 3 GB RAM;
- AMD Radeon or NVIDIA GeForce graphics card with 128MB RAM or equivalent.

To ensure optimal performance, we recommend using this configuration (or higher):

- Intel i3 or equivalent;
- 4 GB RAM;
- AMD Radeon or NVIDIA GeForce graphics card with 256MB RAM or equivalent.

Note: it is absolutely essential to use valid drivers for the video card and for all other hardware as provided by the manufacturer of your PC.

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