





Materialise NV Technologielaan 15 3001 Leuven Belgium

English Instructions for Use

This document contains general instructions for use for ProPlan CMF Connect. For detailed instructions, refer to the user manual.

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DESCRIPTION

ProPlan CMF Connect is your window to the CMF services provided by Synthes.

ProPlan CMF Connect allows you to upload CT/MRI that will be reconstructed to a 3D model. We collaborate on the surgical plan and communicate the result in ProPlan CMF Connect. Finally, our engineers will design and produce surgical guides to transfer the surgical plan to the operation room. This entire workflow can be tracked in ProPlan CMF Connect.

INDICATIONS

ProPlan CMF Connect 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 Connect 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 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/MRIscan, the guide or model should not be used, even if the time period of 6 months has not expired.

INSTRUCTIONS FOR USE

<u>Install</u>

First, go to the <u>ProPlan CMF Connect website</u> (<u>http://link.materialise.com/Synthes/ProPlanCMFC</u> <u>onnect</u>) and click the *Install* button. Your browser will offer to download the *setup.exe* installer file, accept and run the installer. The Application Install Window will appear. Confirm the installation by clicking Install.

Synthes ProPlan CMF Connect is now installed and will start automatically. If not, click the ProPlan CMF Connect icon on your desktop to start the application.

• <u>Start</u>

To use Synthes ProPlan CMF Connect, a user account is required. If you don't have a user account, click "Request account for ProPlan CMF Connect" and follow the instructions on screen.

After signing-in, the Welcome Screen provides you directions to find your way in ProPlan CMF Connect. In this screen you can:

- Add a new case (Add Case).
- Go to the Case Overview screen to view all your cases (View Cases).
- User Manual.
- Edit your account information (My Account).

Minimal System Requirements

 Intel Pentium 4 2.4GHz or equivalent
 512 MB RAM
 1 GB of free disk space
 Graphics card & screen supporting at least
 1024x768 resolution with true color visual
 (24 or 32 bit) and 256MB of memory
 Three-button optical mouse with scroll wheel
 1.5MBit/s internet connection
 Microsoft Windows XP Service Pack 2, Windows
 Vista, Windows 7 or higher
 Microsoft .NET 3.5 Framework SP1 or higher
 Adobe Reader 7.0 or higher

CONTACT

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