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Materialise NV Technologielaan 15 3001 Leuven Belgium the CT/MRI scan, the guides or models should not be used.

PRECAUTIONS

- The quality of the images in the SurgiCase 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 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.

English Instructions for Use

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

DESCRIPTION

SurgiCase CMF is user-friendly scanner-based imageprocessing 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 objects.

INDICATIONS

SurgiCase 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

INSTRUCTIONS FOR USE

Install

Close all other applications before installing SurgiCase CMF. Install SurgiCase CMF using the downloaded 'SurgiCaseCMFSetup.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 SurgiCase CMF.

Start

To start SurgiCase CMF, double click the SurgiCase CMF icon on your desktop or go via the Start > All Programs > Materialise Software > SurgiCase CMF and choose to run SurgiCase CMF.

SurgiCase CMF is password protected. Run SurgiCase 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 SurgiCase CMF file or click Import Images to import DICOM.

When a SurgiCase CMF project is opened, the SurgiCase CMF Overview screen gives an overview of all available SurgiCase 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.

• System Requirements

Minimal Software

> Microsoft Windows XP SP2 Internet Explorer 6.0 Adobe Reader 7.0 or higher Hardware

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Intel Pentium 4 2.4GHz or equivalent
512MB RAM
Graphics card supporting 1024x768 and 24-bit
color with 4MB RAM
Non-interlaced 15" color monitor
Three-button optical mouse with scroll wheel
Recommended
Software

Microsoft Windows XP SP3, Microsoft Windows Vista or Microsoft Windows 7 Internet Explorer 8.0

Adobe Reader 7.0 or higher

Hardware

Intel Core2Duo 2.0 GHz or equivalent 2GB RAM ATI Radeon or NVIDIA GeForce graphics card with 256MB RAM Non-interlaced 19" color monitor or 17" LCD display Resolution of 1280x1024 or higher Three-button optical mouse with scroll wheel

CONTACT

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