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Instructions for Use

Acumed Digital Surgery (ADS) Digital Planning Software



These instructions are intended for the Operating Surgeon and supporting Healthcare Professionals. The US instructions are intended for users in the United States and its territories.

Rx only

DESCRIPTION

The ADS Digital Planning Software is a web-based collaboration software for digital surgery case flow management and Orthognathic surgery planning that reflects the production process and allows for the interaction of multiple users: surgeons, sales representatives, and the ADS case planning staff using multiple devices. It allows easy collaboration in the planning process. Being web-based allows immediate and convenient sharing without the installation or maintenance of the application at the user's end.

The case management module is subdivided into wizards allowing surgeons full traceability and live tracking of cases. It also allows to schedule meetings with the ADS Case Planning Staff.

INTENDED USE/ INDICATIONS FOR USE

ADS Digital Planning Software is intended for use as a software/hardware system and a digital surgery case-flow management interface. It is also indicated as a pre-operative tool to support the diagnostic and treatment planning process of orthognathic procedures by providing surgical guides and splints. The ADS Digital Planning Software system is compatible with the ADS Titanium Implants System (K203282) and the ADS Diagnostic Models (K222577) and should be used in conjunction with expert clinical judgment.

CONTRAINDICATIONS

No contraindications were identified for ADS Digital Planning Software.

WARNINGS & PRECAUTIONS:

Warnings

Several technical warnings are visualized on the ADS Digital Planning Software.

Measurement accuracy depends on the image data and quality, the used scanner hardware, and its calibrating and acquisition settings. Digital Planning software reports the value rounded to one digit after the decimal point, based on user-picked points. However, Digital Planning Software internally saves the complete number measure.

- The patient's name is different from the patient DICOM data.
 - Please verify the patient's name and check whether the patient's name and the name in the DICOM sets correspond.
- Corrupt files.
 - Files could not be uploaded and opened. Please select other files. If the problem persists, contact customer support through support-ads@acumed.net.

- The DICOM is not aligned with the scan protocol.
 - Contact customer support through support-ads@acumed.net.
- The STL files of the preplanning case are not uploaded.
 - ADS case planner assistant needs to upload the STL pre-planning STL files with the corresponding osteotomies and dental occlusion.
- Incorrect alignment of the natural head position of the patient.
 - ADS case planner assistant uploads the STL files to conserve the frontal bottom left and right from the Off The Shelf software and ADS Digital Planning Software.
- The STLs are scaled giving inconsistent measures in Translation and Rotation
 - Contact customer support through support-ads@acumed.net.

Precautions

Users of ADS Digital Planning Software need to have clinical knowledge of digital surgery planning procedures to avoid possible complications in the surgery.

To ensure surgical accuracy, the digital surgical plan should be reviewed and validated if more than 6 months have passed since the acquisition of the patient’s imaging data, or if there is reason to believe the patient’s anatomy has changed significantly since imaging.

Cybersecurity:

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

Professional Use:

ADS Digital Planning Software is for professional use only: medical sales representatives, case planner assistants, case planners, surgeons, and administrators. Each status profile on ADS Digital Planning Software has a different configuration for button access.

The use of ADS Digital Planning Software requires the necessary training knowledge in surgery and digital planning procedures.

POTENTIAL ADVERSE EFFECTS

Important: Any adverse event that has occurred in relation to the device should be reported to Acumed through customercomplaints@acumed.net or +1.888.627.9957

SYSTEM REQUIREMENTS

Table 1 displays the system requirements for ADS Digital Planning Software.

Table 1. ADS Digital Planning Software System Requirements

Recommended system requirements	
Operating system	Operating system: - Windows 64-bit (Windows 7 and/or later) - Mac OS (Yosemite or later)
RAM	8 GB recommended
CPU	Pentium 4 Intel
Disk space	100 MB, free memory

Internet	Broadband Internet connection Chrome 2021-04-13 (Android) Chrome 2021-04-14 (Linux, macOS, and Windows) 2021-05-10 (iOS)
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