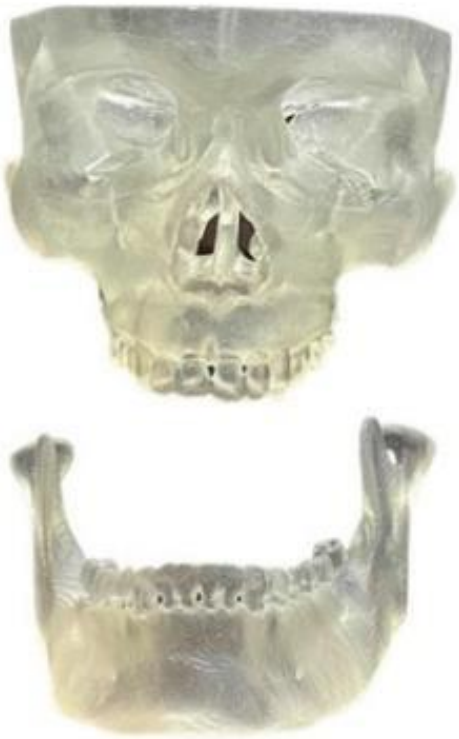
acumed®

Acumed Digital Surgery (ADS) Diagnostic Models



Instructions for Use

Acumed Digital Surgery (ADS) Diagnostic Models

US **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

ADS Diagnostic Models are virtual and additive manufactured anatomic models intended to make a diagnosis during maxillofacial surgery planning.

The models are created from a CT scan of the patient's anatomy, which is segmented through Commercial-Off-The-Shelf (COTS) software and converted into virtual 3D models. The surgeon uses these 3D models to make the initial plan/diagnosis based on examination or physical measurement of the patient´s anatomy, this includes planning anatomic structures movements (for example, maxilla and mandible movements for occlusion), the resections, measurement of anatomic distances (e.g., the facial symmetry), and determining fixation points and the size and shape of the implants if requested. These functions are those that the surgeon can perform, not functions that the subject device provides by itself.

Acumed creates a design proposal for the case based on the information given by the medical professional and the process continues until the final design proposal is approved. Finally, the digital file can be used as an input to produce physical anatomic models through additive manufacturing.

INDICATIONS FOR USE

The ADS Diagnostic Models are patient-specific devices intended to be used as a pre-operative planning tool for treatment in the field of maxillofacial surgery.

The input data file (DICOM imaging information from a medical scanner file) is processed by commercial off-the-shelf software, and the result is an output data file that may then be provided as digital models or used as input to produce physical anatomic models using additive manufacturing.

The physical replica can be used for diagnostic purposes in the field of maxillofacial applications.

ADS Diagnostic Models should be used in conjunction with other diagnostic tools and expert clinical judgment.

ADS Diagnostic Models are not intended to enter the operating room.

ADS Diagnostic Models are indicated for adults (People over the age of 21).

CONTRAINDICATIONS

- ADS Diagnostic Models are not intended to enter the operating room.
- Do not reuse ADS Diagnostic Models. They are intended for single use only.
- ADS Diagnostic Models are patient-specific models. Do not attempt to use them for different patients.
- Do not sterilize ADS Diagnostic Models.

WARNINGS AND PRECAUTIONS

Do not allow the interaction of the ADS Diagnostic Models with other implants or surgical instruments. These models are non-sterile and should not interact with the elements that are intended to be implanted or used during surgery.

ADS Diagnostic models were validated using the "automatic orientation" tool from the Formlabs 3B or 4B printers, any other methods of orientation are out of the scope of the device.

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

LIFETIME

The shelf life of ADS Diagnostic Models is 90 days. ADS diagnostic models shelf life is defined as the time between the CT scan and the diagnosis. This shelf life is a conservative time frame estimate during which, patient's anatomy should not have noticeable changes that would compromise the accuracy of the ADS anatomical models. After this period, the use of diagnostic models is at the surgeon's risk.

MATERIALS

MATERIALS

ADS Diagnostic Models are manufactured from Clear resin and are printed with the Form 3B or Form 4B printer by Formlabs.

SINGLE USE

ADS Diagnostic Models are designed for single-use and must not be reused in different patients.

STORAGE CONDITIONS

HANDLING

The ADS Diagnostic Models should be unpacked and handled carefully to avoid damage to the surface or to the geometry.

TRANSPORT

The ADS Diagnostic Models must be carefully transported inside the packaging to avoid damages that may alter the technical details.

STORAGE

- The ADS Diagnostic Models must be stored in a dry and clean environment.
- Clear resin devices must be stored protected from direct sunlight.
- Before use, the ADS Diagnostic Models should be stored in places where their shape is not altered.

NON-CLINICAL PERFORMANCE DATA

A table with the summary of the performance data is included below.

Test Performed	Description	Results
3D Printing process validation	A manufacturing process characterization was performed to validate that the manufacturing process can correctly print the ADS Diagnostic Models. The process validation strategy included the Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).	The acceptance criteria were met
Dimensional Validation	The 3D printed devices were manufactured and scanned with CT scan. The 3D printed devices consisted of multiple anatomic models from different patients (mandibles and maxilla) as the worst-case to evaluate the accuracy. The original model and scanned model were digitally aligned and overlapped. Then, the dimensional error was estimated by comparing the difference between the overlapped images on a point-by-point basis.	All the measurements complied with the acceptance criterion

Packaging Validation	The packaging system was subjected to simulated shipment following the Standard Practice for Performance Testing of Shipping Containers and Systems (ASTM D4169-16), and environmental conditioning as per ISTA 3A.	The acceptance criteria were met
Diagnostic Qualitative Evaluation	A clinician review report was performed with the intention to evaluate the diagnostically significance of ADS Diagnostic Models according to the clinical experience of maxillofacial surgeons	The interviewed surgeons deemed ADS Diagnostic models a significant help when it comes to identifying different pathologies and plan a more precise surgical intervention when used in conjunction of other diagnostic tools.
Fidelity Validation of detectable anatomical landmarks	A test was performed to validate the device´s replicability of anatomical landmarks from educational anatomic models and maintain dimensional accuracy.	All selected landmarks in the educational anatomic model were identified in the virtual models and the 3D printed models

Symbols Glossary

Symbol	Description	ISO 15223-1
	Consult the electronic instructions for use (eIFU) at www.acumed.net/ifu	5.4.3
	Non-sterile	5.2.7
	Catalogue number	5.1.6
	Batch code	5.1.5
	Manufacturer	5.1.1
	Date of manufacture	5.1.3
	Do not re-use	5.4.2
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.	U.S. 21 CFR 801.109
	The reticle is a registered trademark of Acumed. It may appear alone or with the Acumed name.	

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