

# AXIAL3D DIGITAL FILE

## INTENDED USE

Prepared: 14 Jun 2022, Revision 03

### Symbols & Manufacturer Information



Product reference Number



Medical Device

Desc.

Product description



Consult Instructions for Use



Manufacturer



Cautions and Warnings



Date of Manufacture



Device is "fragile" and should be handled with care

**Rx Only**

Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner



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## Introduction and Intended Use

### INTENDED USE

Axial3D Cloud Segmentation Service is intended for use as a cloud based service and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file.

The Axial3D Cloud Segmentation Service output file can be used for the fabrication of physical replicas of the output file using additive manufacturing methods.

The output file or physical replica can be used for treatment planning.

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

Axial3D Cloud Segmentation Service should be used in conjunction with other diagnostic tools and expert clinical judgment.

### CONTRAINDICATIONS

Axial3D Cloud Segmentation Service is not intended for use with Ultrasound and X-Ray imaging

### CAUTIONS AND WARNINGS

Axial3D Cloud Segmentation Service is intended for use by trained medical professionals for surgical planning in the following applications; orthopedics, maxillofacial, cardiovascular for adult populations.

The physical 3D printed model or digital file should be used in conjunction with expert clinical judgment and alongside the original DICOM images. Changes in patient anatomy may occur between the time of imaging and surgery, this may impact the performance of the 3D printed physical model, the patient should be assessed for changes in anatomical structures prior to the procedure.

The 3D printed physical models are not intended for sterilisation or for use within a sterile field.

Axial Medical Printing Limited recommends DICOM images which are below 1mm slice thickness for surgical planning on 3D reconstructions or physical 3D printed models.

Fragments present in orthopaedic models below 5mm shall be removed from the digital file to be printed, this is to reduce the risk of these fragments breaking away from the model during post-processing practices.

Please ensure that you are using the latest version of the supported browsers, and you have antivirus protection installed on your end user device. To access the service, all communication is via HTTPS and only port 443 is required to be open. Any issues with the service will be communicated to you via your registered email address.

### Technical Information

Axial3D Cloud Segmentation Service is a secure, highly available cloud based image processing, segmentation and 3D modelling framework for the transfer of imaging information as a 3D printed physical model.

# AXIAL3D DIGITAL FILE

The user interface is a web based application; it is accessible via the listed compatible browsers, and operating systems capable of running those versions.

Safari, Microsoft Edge and Google Chrome, is available at a URL <https://orders.axial3d.com>