

LLZ AXIAL3D PRINTED MODEL

INSTRUCTIONS FOR USE

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Symbols & Manufacturer Information



Product reference Number



Medical Device

Desc.

Product description



Consult Instruction for Use



Manufacturer



Cautions and Warnings



Date of Manufacture



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Introduction and Intended Use

Description of Axial3D Cloud Segmentation Service

Axial3D Cloud Segmentation Service is a secure, highly available cloud-based image processing, segmentation and 3D modeling system for the transfer of imaging information to either a digital file or as a 3D printed physical model.

Axial3D Cloud Segmentation Service is made up of a number of component parts, which allow the production of patient-specific 1:1 scale replica models, either as a digital file or as a 3D printed physical model.

Indications for use

Axial3D Cloud Segmentation Service is intended for use as a cloud based service and image segmentation framework for the transfer of DICOM imaging information from a medical scanner to an output file, which 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 and/or diagnostic purposes in the field of orthopedic, maxillofacial and cardiovascular applications for pediatric and adult patients greater than 12 years old and in cardiovascular applications for pediatric and adult patients greater than 2 months of age.

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



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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, and 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 sterilization or for use within a sterile field.

Axial Medical Printing Limited recommends DICOM images for surgical planning on 3D reconstructions or physical 3D printed models.

Fragments present in orthopedic models below 5 mm 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.

Users intending to 3D print digital files provided by Axial Medical Printing Limited must be able to follow post-processing and inspection guidelines provided by Axial Medical Printing Limited to ensure diagnostic quality of anatomical model. If these processes are not followed the diagnostic quality of the final 3D printed physical model cannot be guaranteed.

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

As Axial3D Cloud Segmentation Service 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>

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Approved By:

[\(CO-62\) QIH & LLZ Labelling IFU](#)

Description

Upload of IFUS and Operator manuals

Justification

Required to ensure all Products are compliant with FDA Labeling regulations

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Neisha Kearney	Neisha Kearney	Medium	Minor

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