

LLZ AXIAL3D DIGITAL FILE

INTENDED USE

Document ID: IFU-OPS-004, Version 0
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

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

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

LLZ AXIAL3D DIGITAL FILE

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>

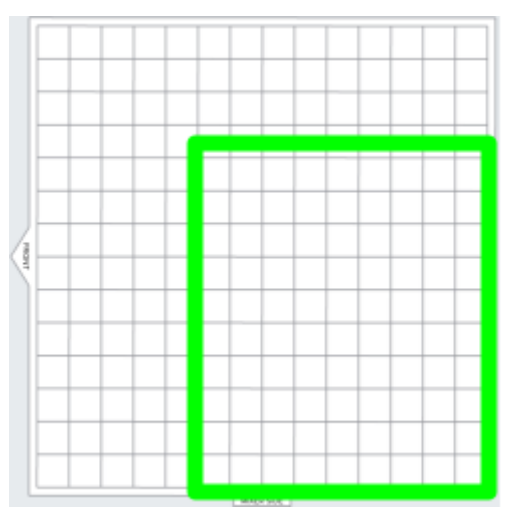
Conditions for Printing

3D printed physical models must be printed in line with the manufacturers guidelines for orientation meeting the following requirements for each printing technology.

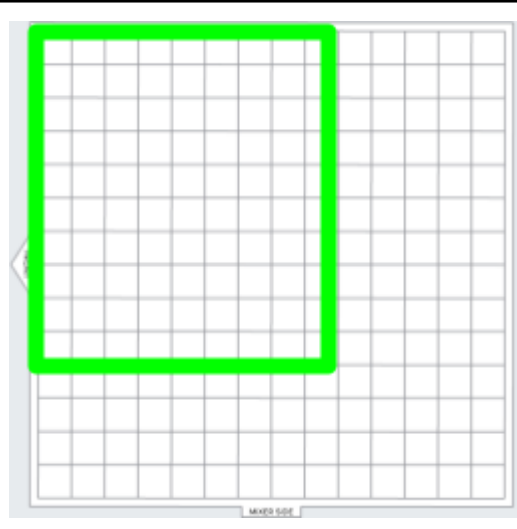
Note: Only the Stratasys Polyjet J750, the Stratasys J5 Mediprint, and the Formlabs Form3B printers are qualified to print models for pediatric indications.

Anatomical models printed on Formlabs Form 3B printers must be printed in the following orientation for optimal print orientation layout for the following materials

Draft resin Form 3B printed models	
Best printing orientation	20 degrees (Y-axis)
Best printing build plate position	Back of build plate, mixer side

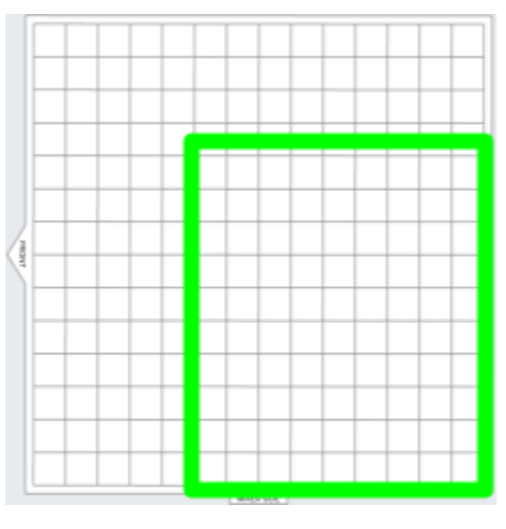


White resin Form 3B printed models	
Best printing orientation	60 degrees (Y-axis)
Best printing build plate position	Front of build plate, opposite to mixer side

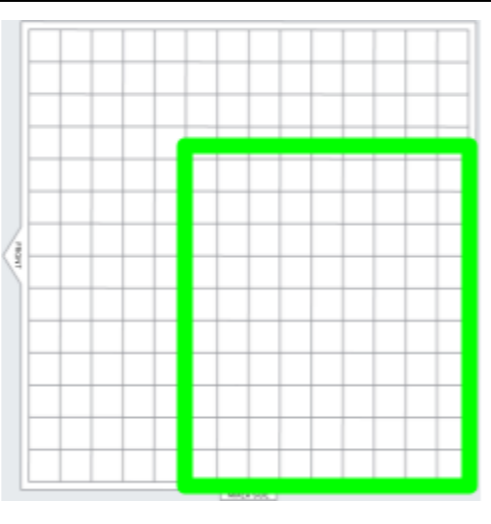


LLZ AXIAL3D DIGITAL FILE

Clear resin Form 3B printed models	
Best printing orientation	20 degrees (X-axis) / 60 degrees (X-axis)
Best printing build plate position	Back of build plate, mixer side



Flexible 80a resin Form 3B printed models	
Best printing orientation	90 degrees (X-axis)
Best printing build plate position	Back of build plate, mixer side



- 3D model is angled at a 20 - 60 degree angle to decrease the amount of surface area in contact with the resin tank which in turn reduces the amount of force on the 3D printed physical models as the build platform raises with each layer
- Orient the model to stand with the merging feature facing toward the build platform to create a shared base for branching features to grow from. Instead of layers coming together at a joint, the layers separate into individual paths
- Overhanging features are oriented to self support during the printing process
- The region of the model that is elevated to be printed towards the mixer side to reduce print time for the final layers of the model.
- Post-print processes should be followed in line with Axial3D recommended Procedures *ref:WI 02 Post-processing a 3D print*

3D printed physical models printed on Stratasys printer:

- Insert STL file in the default position (File→ Add models)
- Arrange the model in the tray with an auto arrangement set.
- Assign material and send to printer
- Post-print processes should be followed in line with Stratasys recommended procedures *ref: Guide to Post-Print Processes for PolyJet 3D Printers*

3D printed physical models printed on HP printers

When parts are added to the printer, the application automatically checks that the parts satisfy various conditions:

- In bounds, ensuring parts are positioned within the build volume
- Closed mesh
- Correctly oriented, orient each part by placing its critical features on the horizontal XY-plane as this will provide the highest resolution.
- Place small features such as pins, holes, and thin walls upside-down on the XY-plane to improve their look, feel, and strength. This also applies to raised texts, which should be printed on the XY-plane for maximum resolution
- Topologically valid: Are the parts printable? Parts beyond the boundaries of the build volume are considered out of bounds. Out-of-bounds parts can usually be fixed by clicking Auto-pack, or by manually moving the out-of-bounds part into the build volume. Parts with holes, troublesome orientations, and topologically invalid parts can be fixed by clicking Auto-Pack
- Remove the build unit from the printer after printing the parts
- Allow models to cool for the recommended time based on volume

LLZ AXIAL3D DIGITAL FILE

Build chamber	Printing time		Safety cooling time	Natural cooling time		Fast cooling time *
	Fast print mode	Default/Strength print mode		Normal	Minimum *	
100% full	10 h	16 h 20 min	20–30 min	46 h	31 h	10 h
75% full	7 h 30 min	12 h 15 min	20–30 min	35 h	23 h	8 h

Build chamber	Printing time		Safety cooling time	Natural cooling time		Fast cooling time *
	Fast print mode	Default/Strength print mode		Normal	Minimum *	
50% full	5 h	8 h 10 min	20–30 min	23 h	16 h	6.5 h
25% full	2 h 30 min	4 h	20–30 min	12 h	8 h	5 h

- Once models have been cooled you must clean the parts to remove the thin layer of material attached to the surface.
- To do this, you need a bead-blasting machine. HP recommends a bead-blasting machine with the following specifications:
- Manual or automatic operation; Air pressure in the range 2–5 bar (29–72.5 psi); Glass beads of 70–110 µm diameter (0.00276–0.00433 in)
- This process consists of shooting an abrasive media, usually a bead (size and type results in different surface finishes), at high pressure at a printed part with compressed air, knocking loose unfused powder while also smoothing the finish of the part.

If these recommended guidelines can not be met, models will not be within the quality parameters.

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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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