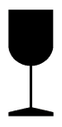
QIH AXIAL3D PRINTED MODEL

INSTRUCTIONS FOR USE

Document ID: IFU-OPS-001, Version 2

Symbols & Manufacturer Information

LOT	**Product reference Number**
Desc.	**Product Description**
	**Manufacturer**
	**Date of Manufacture**
	**Axial3D Alexander House 17a Ormeau Avenue Belfast, BT2 8HD**
MD	**Medical Device**
	**Consult Instructions for Use**
	**Cautions and Warnings**
	**Device is "fragile" and should be handled with care**
	**Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner**

Introduction and Intended Use

INTENDED USE

Axial3D Insight 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.

The Axial3D Insight 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 output file or the physical replica can be used for diagnostic purposes in the field of trauma, orthopedic, maxillofacial and cardiovascular applications.

Axial3D Insight should be used in conjunction with other diagnostic tools and expert clinical judgment.

CONTRAINDICATIONS

Axial3D Insight is not intended for use with Ultrasound and X-Ray imaging.

CAUTIONS AND WARNINGS

Axial3D Insight is intended for use by trained medical professionals for surgical planning in the following applications: trauma, orthopedics, maxillofacial, and cardiovascular.

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.

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

QIH AXIAL3D PRINTED MODEL

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 the diagnostic quality of the anatomical model. If these processes are not followed, the diagnostic quality of the final 3D printed physical model cannot be guaranteed.

Axial3D defines trauma as orthopedic trauma and craniomaxillofacial trauma including complex fractures in which the 3D images and associated physical models would be used for surgical planning. Fragments present in orthopedic trauma and craniomaxillofacial trauma 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

As Axial3D Insight 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 are available at a URL https://orders.axial3d.com