Certified Point-of-Care 3D Printing Tools

Compatibility overview of **Materialise software**
and **Stratasys materials and printers**
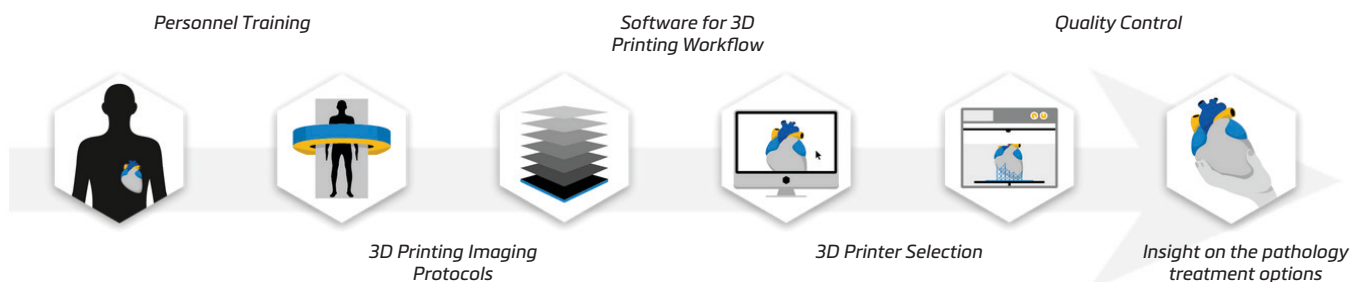
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Introduction

Point-of-Care 3D printing is changing the way physicians interact with medical images. As diagnostic usage of 3D prints created at the Point-of-Care is increasing, scrutiny around the safe and effective use of this technology is required to give healthcare providers reliable and validated support. Materialise's mission is to bring products to the market that result in a better and healthier world, reflected in its ambition to create a safe environment to enable hospitals to 3D print at the Point-of-Care.

Materialise Mimics inPrint[1] was thereby created as a software that enables hospitals to easily create anatomical models that may be also used for diagnostic purposes in specific clinical indications[2] . To create such models, users should use one of the compatible printer-material combinations that Materialise has identified for this purpose[3]. **Materialise** and **Stratasys** have engaged in a partnership to identify compatibility for Stratasys printers and materials with the Materialise Mimics inPrint software. Materialise determines this compatibility by either performance testing or by determining equivalence to a printer-material combination that has been performance tested.

Personnel Training   Software for 3D Printing Workflow   Quality Control

3D Printing Imaging Protocols   3D Printer Selection   Insight on the pathology treatment options

Performance Testing

Typically, 3D printers have spatial resolutions superior to any imaging technique used clinically and discrepancies between segmented anatomy and the 3D printed model are on the order of an imaging voxel size. Potential differences between the virtual model and the printed model could arise from incorrect print settings, geometrical distortions (temperature changes, model detachment, chemical reactions), slicing errors, print errors, poor calibration, color deviations, post-processing and cleaning modifications, etc. These could lead to an inaccurate representation of the anatomy on the 3D printed models.

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[1] Materialise Mimics inPrint is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file. It is also used as pre-operative software for treatment planning. For this purpose, the Mimics inPrint output file can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods. The physical replica can be used for diagnostic purposes in the field of orthopedic, maxillofacial and cardiovascular applications. Mimics inPrint should be used in conjunction with other diagnostic tools and expert clinical judgment.

[2] Please note that the 3D printed anatomical models are an assistive tool and should always be used as a complementary source to traditional diagnostic methods.

[3] https://www.materialise.com/en/medical/software/materialise-mimics-inprint/regulatory-information

Performance testing includes a rigorous testing and analysis of a specific material-printer combination to determine whether, when adhering to the technical instructions from the machine manufacturer, models are printed accurately compared to specific acceptance criteria for each clinical indication. These steps are followed in the performance testing:

1. Models for all clinical indications were **created** using Materialise Mimics inPrint software.

2. Models were **3D printed and post processed** adhering to the manufacturer's instructions.

3. Models were **inspected** by trained QA staff, at Materialise's ISO 13485 certified medical production unit using calibrated equipment. Data analysis is performed by a Materialise software expert using Materialise medical software technology.

4. Models were **evaluated** with respect to indication-specific acceptance criteria.

If performance testing indicated results better than the acceptance criteria, printer-material combinations are described as compatible with Materialise Mimics inPrint. Some printer-material combinations are equivalent to tested printers.

Test results

Stratasys requested a certification for the J750, J735 and Objet 30 Prime printers, with the associated materials for each of those printers.

Performance testing was completed for the J750 with Agilus and VeroMagenta. Equivalence was determined between VeroMagenta and the other Vero materials. Equivalence was also determined with the J735 printer in comparison to the J750 printer. For the Objet 30 Prime, the MED610 material was tested.

Stratasys requested a certification for the J5 MediJet printers. Performance testing was completed for the J5 MediJet with VeroUltraClear™S and Elastico™ Clear materials. Equivalence was also determined with the J5 MediJet printer with VeroVivid™ Cyan, VeroVivid™Magenta, VeroVivid™Yellow, DraftWhite, MED610 and MED615RGD.

The following table shows the material-printer combinations that passed performance or equivalence testing:

	Objet30 Prime	J750	J735	J5 MediJet
Agilus™		✓ (performance)	✓ (equivalence)	
MED610	✓ (performance)			✓ (equivalence)
MED615RGD				✓ (equivalence)
Vero™ BlackPlus		✓ (equivalence)	✓ (equivalence)	
Vero™ Clear		✓ (equivalence)	✓ (equivalence)	
Vero™ Cyan		✓ (equivalence)	✓ (equivalence)	
Vero™ Grey		✓ (equivalence)	✓ (equivalence)	
Vero™ Magenta		✓ (performance)	✓ (equivalence)	
Vero™ PureWhite		✓ (equivalence)	✓ (equivalence)	
Vero™ Yellow		✓ (equivalence)	✓ (equivalence)	
VeroVivid™ Cyan				✓ (equivalence)
VeroVivid™ Magenta				✓ (equivalence)
VeroVivid™ Yellow				✓ (equivalence)
DraftWhite				✓ (equivalence)
Elastico™ Clear				✓ (performance)
VeroUltraClear™S				✓ (performance)

✓ Passed [performance testing]   ✓ Passed [equivalence]

Materialise and Stratasys have hereby identified that the above printer- material combinations may be safely used in combination with the Materialise Mimics inPrint software for printing models that are used in diagnostic scenarios such as multidisciplinary team communication or surgical planning.

For more information, please refer to materialise.com/medical and stratasys.com/medical

TESTED - APPROVED

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