Creating full color medical models that can be sterilized.

Patient-specific 3D printed medical models serve as a powerful visual tool for surgical planning and can improve patient outcomes by decreasing operating room time, reducing length of hospital stay, and helping minimize complications.[1, 2, 3]

To create intricate, accurate medical models that can be referenced in the OR, 3D print materials must maintain their accuracy, color and mechanical properties after they are sterilized.

The new J5 MediJet™ all-in-one medical printer is designed to give academic medical centers and hospitals the power to create full color models for presurgical planning that are sterilizable.

For the first time, providers can reference colorful medical models in a sterile room with indirect patient contact.

In 2021, independent experts were consulted to evaluate the biocompatibility, mechanical property accuracy, and color continuity of J5 MediJet 3D printed full color medical models after sterilization.

Technical Application Guide

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Method

Four separate tests were performed to compare the characteristics of MediJet 3D printed full color models before and after the following sterilization methods:

Method	Gamma	Steam	EtO
Conditions	25 – 50 kGy	4 minutes at 132 °C	740mg EtO /l/6h exposure /45C/40-90%RH/degassing 48h-96h/ up to 2 cycles

Materials Tested:

- ☐ Biocompatible Clear (MED610)
- ■ VeroCyan™V
- ■ VeroMagenta™V
- ■ VeroYellow™V
- ■ VeroBlackPlus™
- ☐ DraftWhite™ (MED837)

Test 1: Biocompatibility testing based on ISO 10993-1 standard

Medical models representing all single and mixed colors variants of Vero Vivid family were sterilized and tested for cytotoxicity and tested for cytotoxity and leachables of organic compounds.

Tests 2 and 3: Dimensional accuracy and mechanical properties

To evaluate dimensional accuracy, printed NIST test models were scanned using a GOM Compact Scan 5m structured light scanner. The surfaces of the models were mapped and compared pre- and post-sterilization.

To measure mechanical properties, each test was repeated five times, based on ASTM standards.

Test 4: Color continuity

Printed test models were measured pre- and post-sterilization for color changes (ΔE).

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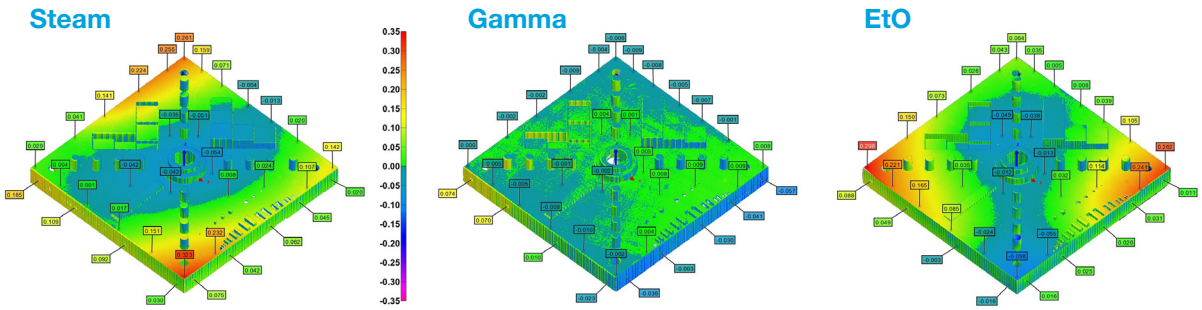
The Results

Test 1: The test concluded that models created with the J5 MediJet printer that were sterilized according to the parameters above using Steam, Gamma or EtO and handled by the medical team in the surgical room will not expose patients to a biological or toxicological hazard.

Test 2: Medical models sterilized using Steam, Gamma or EtO maintain their dimensional accuracy—minor (less than 0.35mm) to no change was observed during testing.



Test 3: After steam sterilization, models do not show a significant change in their mechanical properties. After Gamma and EtO sterilization, some changes are observed.

Test name	ASTM	Steam % of change	Gamma % of change	EtO (after 1 cycle) % of change
Tensile strength, Mpa	D-638-03	-6%	19%	11%
Elongation, %	D-638-05	-3%	-15%	9%
Flexural strength, MPa	D-790-03	-4%	42%	41%
Flexural Modulus, Mpa	D-790-04	0%	21%	2%
HDT, oC	D-648-06	0%	15%	3%
Impact, Xy, cut notch, J/m	D-256-06	-1%	-5%	-7%

Note: % change is the average difference from reference data to post-sterilization results for single color and mixed color part.

Test 4: Color differences (ΔE > 2) were observed post-Gamma sterilization, and insignificant color change (ΔE< 2) were observed post-steam and EtO sterilization.

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The Conclusion

The J5 MediJet creates ultra-realistic anatomical models that give clinicians an invaluable tool to understand complex anatomy for point-of-care planning. Bringing models into the OR is a common practice in many hospitals. It's important to sterilize these models prior to bringing them in the operating room so they do not contaminate the sterile environment and not bring any risk to the patient if the model is examined by the medical team during the procedure. The test results discussed in this guide show that hospitals and academic medical centers are able to sterilize colorful models using steam, gamma and EtO without sacrificing the visual and mechanical properties of the model.

For additional information about biological and toxicological assessment, refer to the Requirements for Using Printed Models in Sterile Environments.

All data provided herein were collected from specific specimens and test conditions and is provided for information only. Characteristics may vary if different specimens and test conditions are applied.

References:
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