MPU 100

MPU 100 offers a unique combination of mechanical strength, biocompatibility, and sterilizability.

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MPU 100

Tensile Properties	Test Standard	Metric	US
Tensile Modulus	ASTM D638 Type I 50 mm/min	1300 MPa	190 ksi
Yield Strength (0.2% Offset)		15 MPa	2 ksi
Ultimate Tensile Strength		35 MPa	5 ksi
Elongation at Break		15%	15%
Tensile Modulus	ASTM D638 Type V 10 mm/min	1200 MPa	170 ksi
Yield Strength (0.2% Offset)		15 MPa	2 ksi
Ultimate Tensile Strength		35 MPa	5 ksi
Elongation at Break		25%	25%

Flexural Properties	Test Standard	Metric	US
Flexural Stress at 5% strain	ASTM D790-B	40 MPa	6 ksi
Flexural Modulus (Chord, 0.5-1%)		1000 MPa	145 ksi

Impact Properties	Test Standard	Metric	US
Unnotched Charpy	ISO-179-1/eU	35 kJ/m^2	15 ft-lb/in^2
Notched Charpy (Machined Notch)	ISO 179-1/1eA	2.2 kJ/m^2	1.0 ft-lb/in^2
Unnotched Izod	ASTM D4812	650 J/m	12 ft-lb/in
Unnotched Izod (-30 °C)		630 J/m	12 ft-lb/in
Notched Izod (Machined Notch)	ASTM D256	30 J/m	0.6 ft-lb/in
Notched Izod (Machined Notch) (-30 °C)		20 J/m	0.4 ft-lb/in

Thermal Properties	Test Standard	Metric	US
Heat Deflection Temperature at 0.455 MPa/66 psi	ASTM D648	50 °C	120 °F
Heat Deflection Temperature at 1.82 MPa/264 psi		40 °C	100 °F
Coefficient of Thermal Expansion (-60, 50 °C)	ASTM E831	110 ppm/°C	60 ppm/°F

Dielectric/Electric Properties	Test Standard	Metric	US
Dielectric Strength	ASTM D149	14 kV/mm	356 V/mil
Dielectric Constant	ASTM D150	3.7	3.7
Dissipation Factor		0.022	0.022

Parts were processed using an M series printer and a Smart Part Washer with VF 1 as the solvent. The washed test articles were baked following the standard baking schedule for MPU 100.

MPU 100

General Properties	Test Standard	
Shore D Hardness	ASTM D2240	81
Bulk Density	ASTM D792	1.12 g/mL
Taber Abrasion	ASTM D4060, CS-17, 1 kg, 100% vacuum	30 mg/ 1000 cycles
Water Absorption, Short Term (24 hours)	ASTM D570	< 1%
Water Absorption, Long Term (14 days)		< 2%

Parts were processed using an M series printer and a Smart Part Washer with VF 1 as the solvent. The washed test articles were baked following the standard baking schedule for MPU 100.

Liquid Properties	
Liquid Density (Part A)	1.05 g/mL
Liquid Density (Part B)	0.98 g/mL
Liquid Density (Part A+B)	1.05 g/mL
Part A:B Volume Ratio (Mass Ratio)	10.0 (10.7)
25 °C Viscosity (Part A)	4500 cP
25 °C Viscosity (Part B)	70 cP
25 °C Viscosity (Part A+B)	3300 cP

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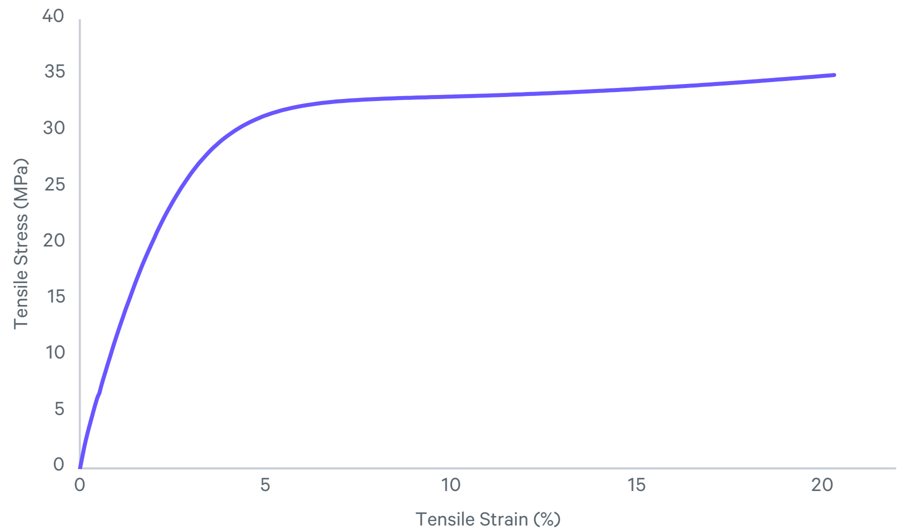
MPU 100

Extended TDS

MPU 100 Mechanical Properties

Representative Tensile Curve

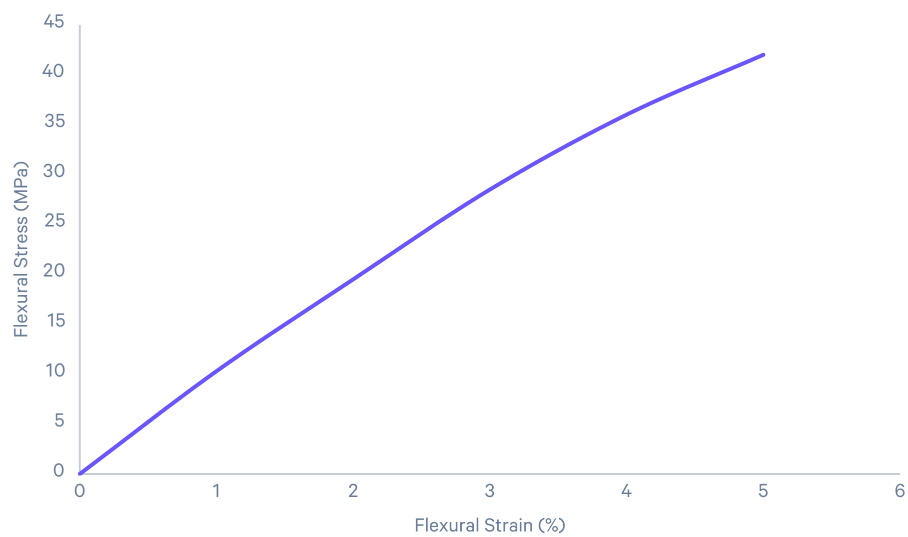
ASTM D638, Type I, 50 mm/min



Representative Flexural Curve

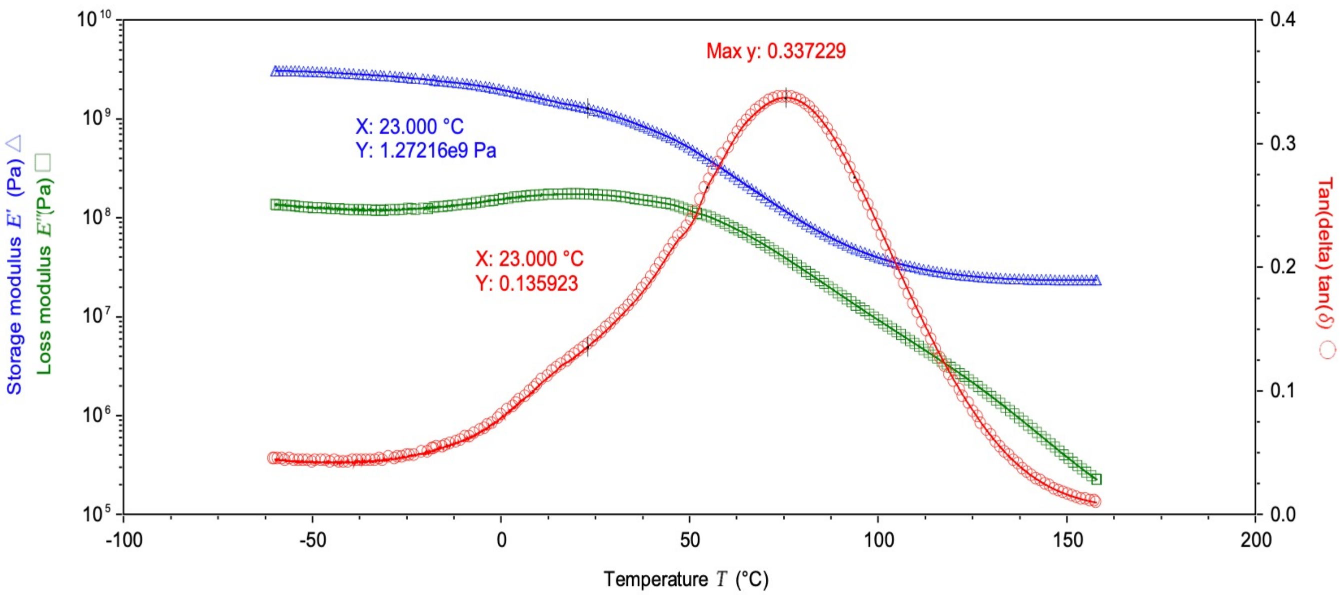
ASTM D790-B

Samples are tested to 5% extension.



MPU 100 Dynamic Mechanical Analysis (DMA)

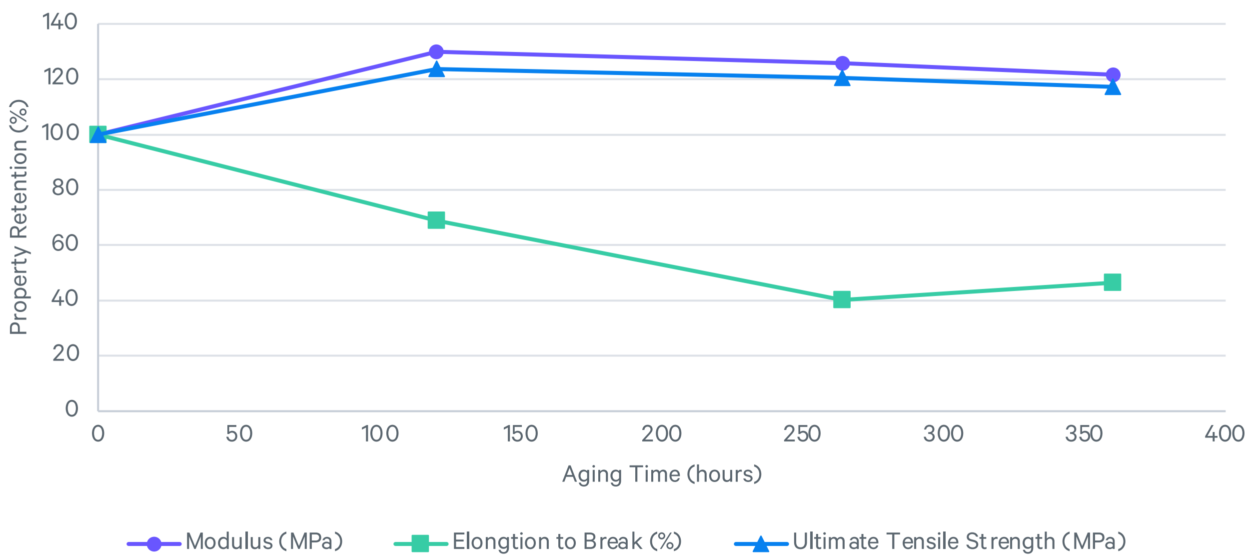
Dynamic mechanical analysis provides insight into the resin's viscoelastic properties across a range of temperatures. The figure below shows a temperature ramp of MPU 100. The peak in the tan(d) curves indicates that the glass transition temperature of MPU 100 is approximately 75 °C.



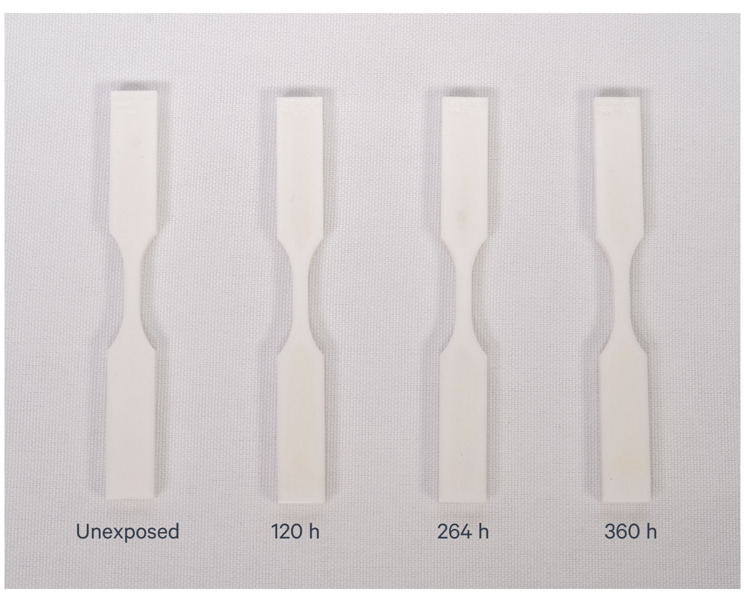
Standard: ASTM D4065
Instrument: TA DMA Q800
DMA Mode: Tension
Sample Dimensions: L=20 mm, W=10 mm, t=1 mm (rectangular block)
Strain Amplitude: 0.1% (linear regime of viscoelasticity)
Oscillation frequency: 1 Hz
Temperature Range: -60 °C to 150 °C
Ramp Rate: 1.5 °C/min
Print Conditions: Samples were hand-wiped and not washed with solvent. The thermal cure for all materials complies with the Carbon user manual. Values may differ based on post processing conditions.

MPU 100 UV Aging

Natural polymer aging can occur in the presence of light, sun, and heat. Carbon evaluated the UV aging performance of MPU 100 using ASTM D4459, which is intended to simulate indoor exposure of solar radiation through glass. Discoloration can also occur as a reaction to UV aging. Below the graph is an example of the corresponding color changes taken over 360 hours of UV exposure according to ASTM D4459.



ASTM D4459: Q-Sun XE-1, 0.8 W/m^2 at 420 nm, 55 °C
ASTM D638: Type V, 500 mm/min, average values represented



MPU 100 Biocompatibility Guide

Cleaning Agents Chemical Compatibility

MPU 100 Chemical Compatibility

MPU 100 is compatible with a range of commonly used hospital disinfectant agents including ethanol, bleach, chlorhexidine gluconate, and benzalkonium chloride. Carbon evaluated MPU 100's compatibility with these reagents using two application methods: Wipe only and 24 hours soak. Compatibility was evaluated based on change in weight, color, and tensile properties of Type V tensile specimens.

Procedure

Parts were processed using an M series printer and a Smart Part Washer with VF 1 as the solvent. The following concentrations (% by weight) were used in the evaluation:

(1) 5% Bleach
(2) 70% Ethanol
(3) 5% Chlorhexidine gluconate
(4) 0.13% Benzalkonium chloride

Control samples were also generated to serve as the baseline.

Disinfectant Application: Wipe Only Protocol

The surface of a tensile dogbone specimen was wiped with a cotton swab saturated with the disinfectant reagent and subsequently rinsed in tap water and wiped dry. This procedure was repeated every five minutes for 20 applications. The samples were left to dry overnight before testing.

Disinfectant Application: 24 Hours Soak

Tensile dogbone specimens were completely submerged in each disinfectant solution for 24 hours at room temperature. After 24 hours, the samples were rinsed in tap water, wiped dry, and left to dry overnight.

Results

Overall, the results indicate that MPU 100 is compatible with the four tested disinfectants, showing minimal changes to the tensile properties and no change in mass, dimensions, or color.

MPU 100 Biocompatibility Guide

Cleaning Agents Chemical Compatibility cont.

Chemical Compatibility: Tensile Properties

The mechanical properties of MPU 100 were evaluated after exposure to various chemical disinfectants. The impact of the reagent on the mechanical properties was dependent on the application method. As summarized in the table below, reagents applied by wiping on the tensile specimen surface showed minimal mechanical properties change compared to the control.

By contrast, tensile specimens that were soaked led to some changes in mechanical properties. Soaking MPU 100 in ethanol showed the largest deviation in mechanical properties compared to the control with a decrease in modulus and ultimate tensile strength.

	Application Method	Control	Bleach	Ethanol	Chlorhexidine gluconate	Benzalkonium chloride
Modulus	Wipe only	1200 MPa	1100 MPa	1200 MPa	1100 MPa	1100 MPa
Ultimate Tensile Strength		45 MPa	40 MPa	40 MPa	40 MPa	40 MPa
0.2% Offset Yield Strength		15 MPa	15 MPa	15 MPa	15 MPa	15 MPa
Elongation at Break		35%	35%	30%	30%	30%
Modulus	24 hour soak	1200 MPa	1000 MPa	700 MPa	1000 MPa	1000 MPa
Ultimate Tensile Strength		45 MPa	40 MPa	35 MPa	40 MPa	45 MPa
0.2% Offset Yield Strength		15 MPa	15 MPa	10 MPa	10 MPa	15 MPa
Elongation at Break		35%	35%	30%	35%	40%

ASTM D638: Type V, 500 mm/min

MPU 100 Biocompatibility Guide

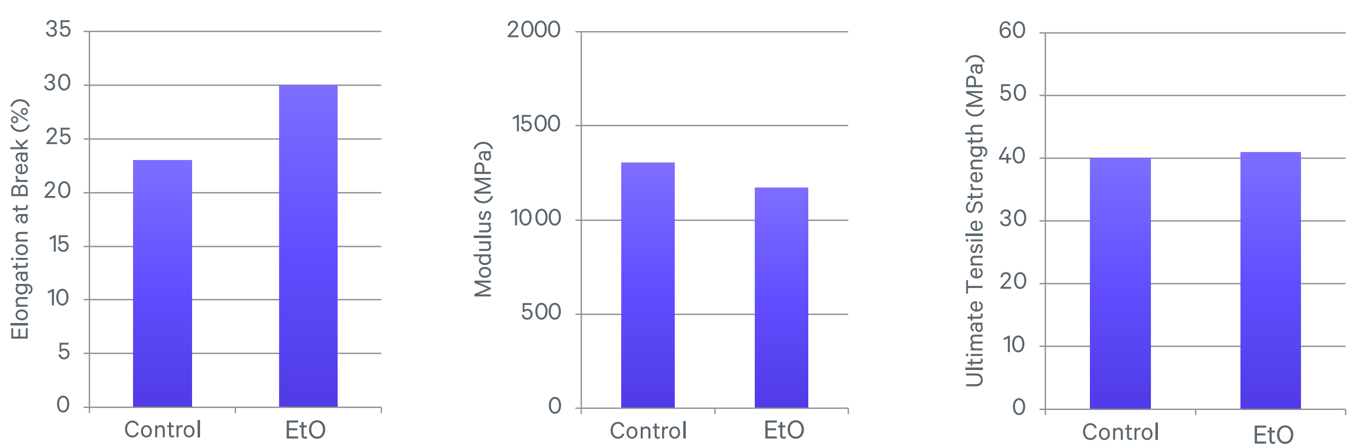
Ethylene Oxide Sterilization and Cytotoxicity

MPU 100 is a versatile material suitable for a potential range of medical applications. MPU 100 shows excellent response to ethylene oxide (EtO) sterilization with moderate change in physical properties and rapid reduction in EtO levels post-sterilization. For ionizing radiation sterilization (gamma and e-beam), MPU 100 shows some change in mechanical properties.

Ethylene Oxide (EtO) Sterilization

Carbon prepared n=10 test specimens and provided these samples to Nelson Laboratories for EtO exposure and extraction studies. The samples were conditioned at 52 °C, 55% relative humidity, and 1.3 psi for 60 minutes. The samples were then exposed to 100% EtO at 52 °C for 240 minutes. The samples were allowed to aerate for 24 hours, and residuals were measured every hour for 170 hours post sterilization.

MPU 100 is compatible with EtO sterilization, showing a 30% increase in elongation at break, a 10% reduction in modulus, and a < 5% reduction in ultimate strength. Furthermore, there is a rapid reduction in EtO levels post-sterilization, with all EtO levels measuring below limits for prolonged contact after standard 24 hours of aeration.



MPU 100 Biocompatibility Guide

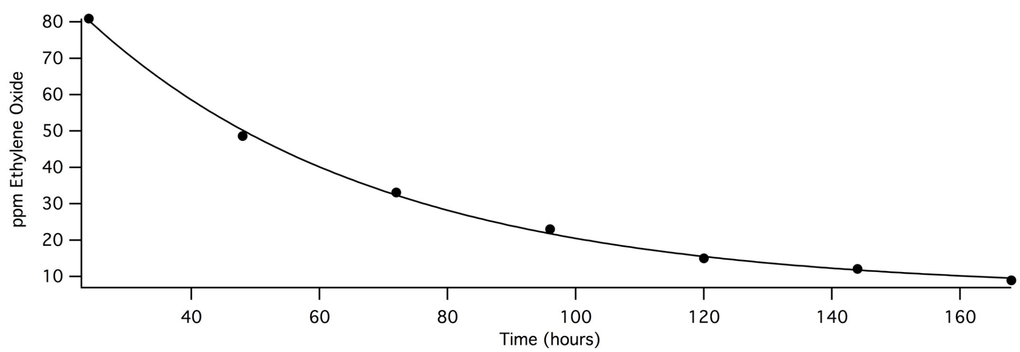
Ethylene Oxide Sterilization and Cytotoxicity

Post EtO Sterilization Cytotoxicity

After one cycle of sterilization, samples were tested for cytotoxicity (ISO 10993-5, *Biological evaluation of medical devices – Part - 5 Tests for in vitro cytotoxicity*). The results show that there is no observed cytotoxicity post-sterilization.

EtO Dissipation

Time axis: Hours post sterilization (first time point at 24 hours after exposure)



Fitting equation:

$$ppm\ EtO = \ 6.38 + 124.9\ e^{-0.022t}$$

Mean Lifetime = 45.8 hours (based on exponential decay model, ppm EtO released versus time in hours).

Ethylene oxide release for a hypothetical 100 g device would be 3 mg at 24 hours and cumulative (30 days) of 7.4 mg. Average release rate is 0.25 mg/day from day 2 to 3, and 0.093 mg/day from day 4 to 30. MPU 100 meets the requirements per ISO 10993-7: *Ethylene oxide sterilization residuals*.

The samples show no observable change in color post-EtO sterilization. The samples had a yellowness index (E313, D65/10) of 18.0 pre-sterilization (control) and 17.7 after EtO sterilization.

MPU 100 Biocompatibility Guide

E-beam Sterilization and Cytotoxicity cont.

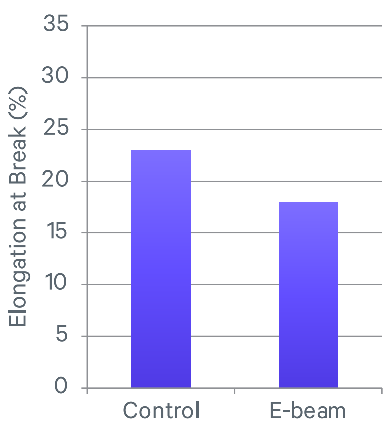
E-beam Sterilization

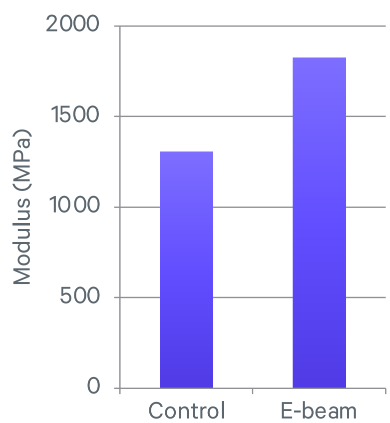
Carbon prepared n=10 test specimens and provided these samples to Steris for e-beam sterilization. The samples were exposed to 33.9 – 36.6 kGy e-beam radiation (measured by dosimeter).

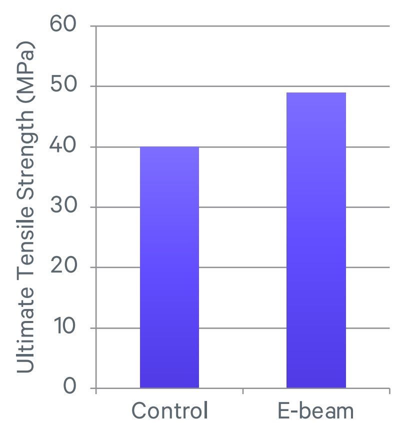
When exposed to e-beam sterilization, MPU 100 demonstrates 22% reduction in elongation at break, a 40% increase in modulus, and a 23% increase in ultimate strength. The test specimens also show some yellowing post-sterilization. The samples had a yellowness index (E313, D65/10) of 18.0 pre-sterilization (control) and 22.5 after e-beam sterilization.

Post e-Beam Sterilization Cytotoxicity

After one cycle of sterilization, samples were tested for cytotoxicity per ISO 10993-5, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*. The results show that there is no observed cytotoxicity post-sterilization.







MPU 100 Biocompatibility Guide

Gamma Sterilization and Cytotoxicity

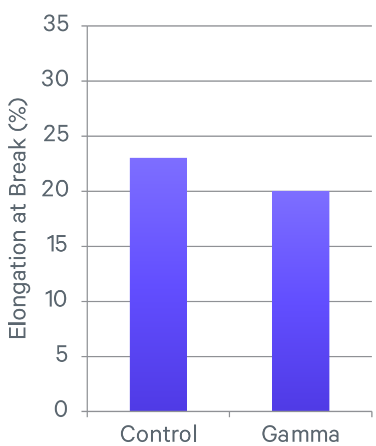
Gamma Sterilization

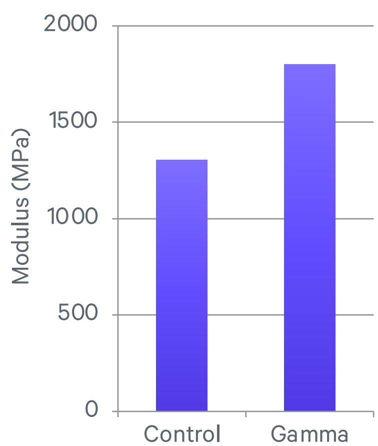
Carbon prepared n=10 test specimens and provided these samples to Steris for gamma sterilization. The samples were exposed to 34.12 – 35.61 kGy gamma radiation (measured via dosimeter).

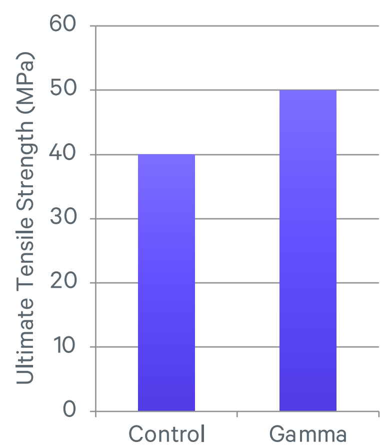
When exposed to gamma sterilization, MPU 100 demonstrates a 13% reduction in elongation at break, a 38% increase in modulus, and a 25% increase in ultimate strength. The test specimens also show some yellowing post-sterilization. The samples had a yellowness index (E313, D65/10) of 18.0 pre-sterilization (control) and 22.6 after gamma sterilization.

Post Gamma Sterilization Cytotoxicity

After one cycle of sterilization, samples were tested for cytotoxicity per ISO 10993-5, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*. The results show that there is no observed cytotoxicity post-sterilization.







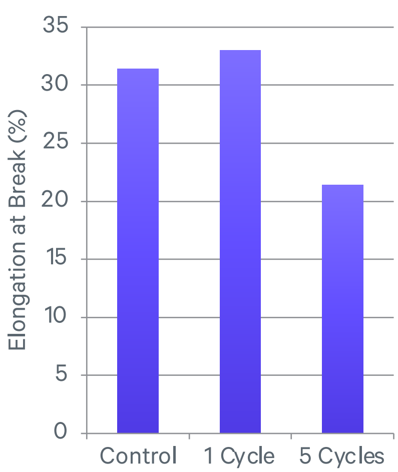
MPU 100 Biocompatibility Guide

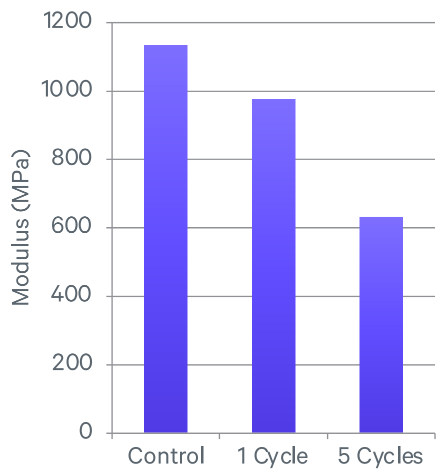
Autoclave Sterilization and Cytotoxicity

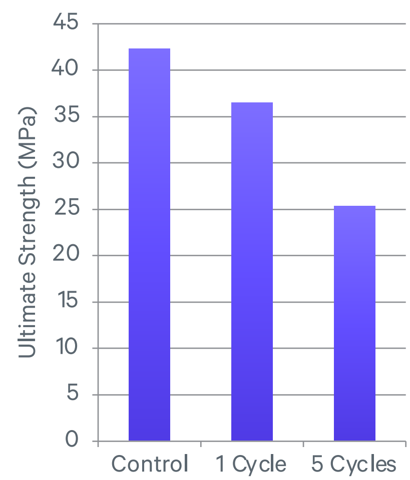
Autoclave Sterilization:

Carbon prepared tensile specimens, which underwent five cycles of sterilization, consisting of 10 minutes of autoclave at 131 °C, followed by 3 minutes of wash in 5% Deconex LIQ.

When exposed to a single autoclave cycle, MPU 100 demonstrates a 5% increase in elongation at break, a 14% reduction in modulus, and a 14% reduction in ultimate strength. After five cycles of autoclave, MPU 100 demonstrates an overall 35% reduction in elongation at break, a 35% reduction in modulus, and a 31% reduction in ultimate tensile strength.

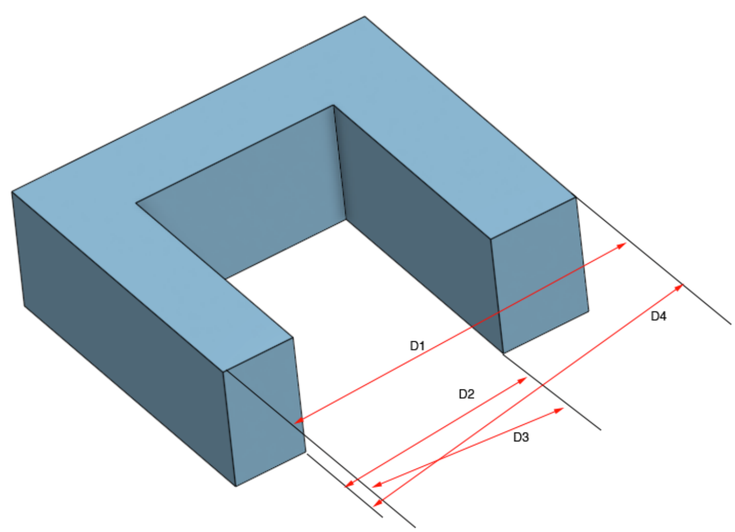






Autoclave Sterilization Impact on Part Geometry

MPU 100's heat deflection temperature (48 °C for a load of 0.455 MPa) is below typical autoclaving temperatures. While this can lead to warpage in part geometry, it is possible to autoclave MPU 100 and maintain part dimensions if the part experiences zero load during the entire autoclaving process, including the cool down stage. To assess this, we subjected a "U-shaped" geometry to two successive autoclave cycles and monitored the change in mass and dimensions after each cycle. The general geometry of this part is similar to the drawing on the right, and the dimensions, D1 to D4, are monitored.



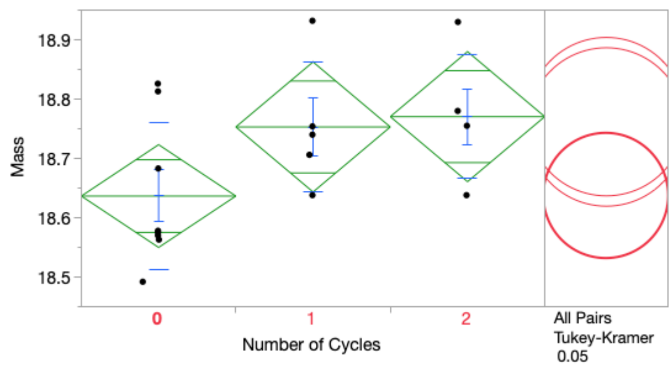
MPU 100 Biocompatibility Guide

Autoclave Sterilization and Cytotoxicity cont.

Autoclave Sterilization: Part Geometry cont.

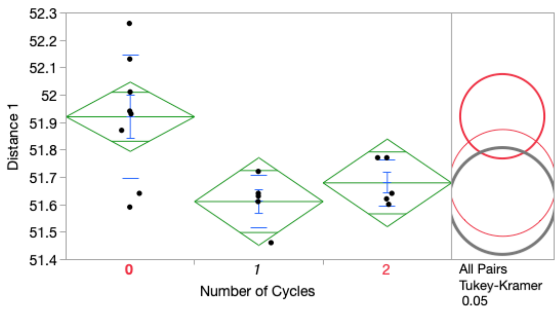
D1 and D2 will be most affected by "splay", an opening of the "U", whereas changes in D3 and D4 are sensitive to loss of planarity. Volumetric swelling could also contribute to changes in these distances. Five parts (containing four reference points to facilitate digital caliper measurement) were autoclaved at 131 °C for 10 minutes. After each autoclave cycle, the parts were allowed to return to room temperature prior to handling (5-10 minutes). These were compared with five control samples held at room temperature.

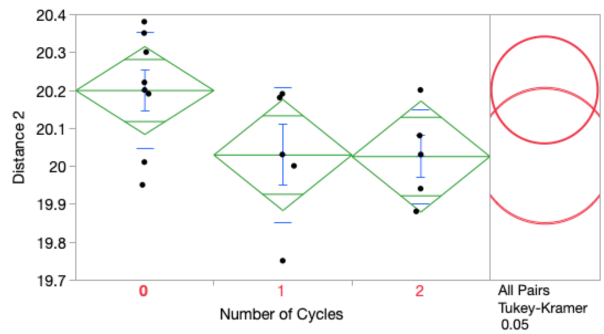
Part Mass After Autoclave Cycles:

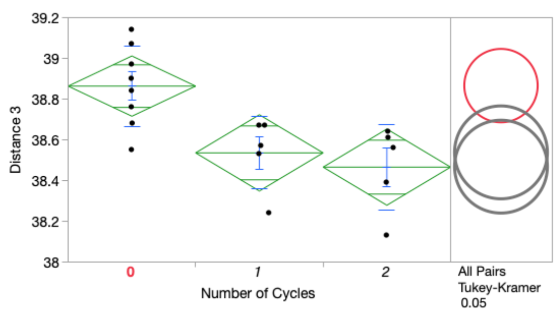


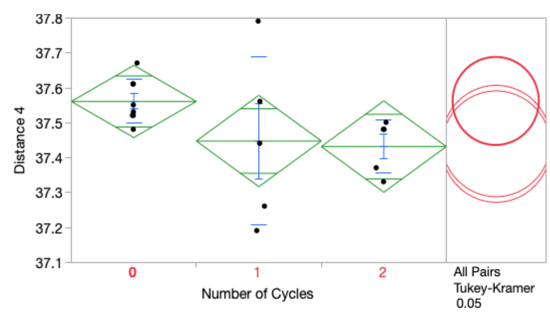
No statistically significant change in mass (0.7% mass increase) was observed. Note that after the initial autoclave, no further water uptake was noted in the second cycle.

Part Dimensions (D1 – D4) After Autoclave Cycles:









MPU 100 Biocompatibility Guide

Autoclave Sterilization and Cytotoxicity cont.

Autoclave Sterilization: Part Geometry cont.

Dimension	Measurement	% Change
D1	-310 ± 250 microns	-0.6%
D2	-170 ± 240 microns	-0.8%
D3	-328 ± 300 microns	-0.8%
D4	-113 ± 240 microns	-0.3%

All data presented at the 95% confidence limit, ±2 SD

For the "U-shaped" part used in this study, the dimensional change after autoclave cycles was minimally impacted; however, dimensional changes during autoclave sterilization can be geometry dependent. It is the responsibility of the Subscriber or manufacturer of the final end-use part to demonstrate that dimensional changes are acceptable post-autoclave sterilization.

Post-Autoclave Cytotoxicity

Both samples subjected to one and two autoclave cycles were tested for cytotoxicity per ISO 10993-5, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*. The results showed no observed cytotoxicity post-autoclave sterilization.

Summary

MPU 100 appears to be an acceptable material for single-use medical device applications, provided that the device is of suitable geometry and not under static load during autoclave. Parts should be allowed to cool completely prior to handling. Static loads could include, but not be restricted to:

- interference fits
- snaps and clasps
- parts in tension due to fasteners
- parts with long “cantilevered” components

Testing of MPU 100 suitability for use with autoclave sterilization is the sole responsibility of the Subscriber or manufacturer of the end-use product.

MPU 100 Biocompatibility Guide

Biocompatibility Testing

Biocompatibility Testing

Test articles in the form of printed parts were provided to NAMSA for evaluation and met the requirements of each of the following tests:

Biocompatibility Testing	Test Standard
Cytotoxicity	ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity (MEM extract)
Sensitization	ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for skin sensitization (Closed patch sensitization study in guinea pigs)
Irritation	ISO 10993-23: Biological evaluation of medical devices – Part 23: Tests for irritation (Intracutaneous study in rabbits)
Hemolytic Properties	ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials & ISO 10993-4: Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
Systemic Toxicity	USP, General Chapter <88>, Biological Reactivity Tests, *in vivo*. Systemic Toxicity, Muscle Implantation

Test articles were processed using an M series printer and a Smart Part Washer with VF 1 as the solvent. The washed test articles were baked following the standard baking schedule for MPU 100: 100 °C for 4 hours. Additional details about the tests are available upon request.

Disclaimer

Each Carbon customer using the resin is solely responsible for testing and evaluating the performance of any resin within the context of the customer's application or use of the resin. Many variables can affect the properties of the resin and printed article. Test results may vary based on printing and/or post-processing procedures. The information provided herein is for informational purposes only based on present data available to Carbon. The information applies only to the Resin designated herein as sold by Carbon as used to make the test article and does not apply to use in any process, use, application, or in combination with any other material. Accordingly, Carbon makes no guarantee or representation and assumes no liability for customer's use of a resin in any process, use, application, or in combination with any other material.

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