LOCTITE® 3D MED413™

HDT60 Tough
Clear, White

LOCTITE®
Henkel Corporation
loctite3dp@henkel.com

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LOCTITE 3D MED413™

LOCTITE 3D MED413 a high-performance, high modulus material with excellent flexural and tensile physical properties. Stiffness combined with toughness make this material ideal for use in a wide variety of impact resistant medical device applications.

LOCTITE 3D MED413 is capable of meeting ISO 10993-5, -10 and -23 standards for biocompatibility when processed using a validated workflow. Certificates of Compliance are available upon request.

LOCTITE 3D MED413 is compatible with a broad range of DLP machines.

Benefits:

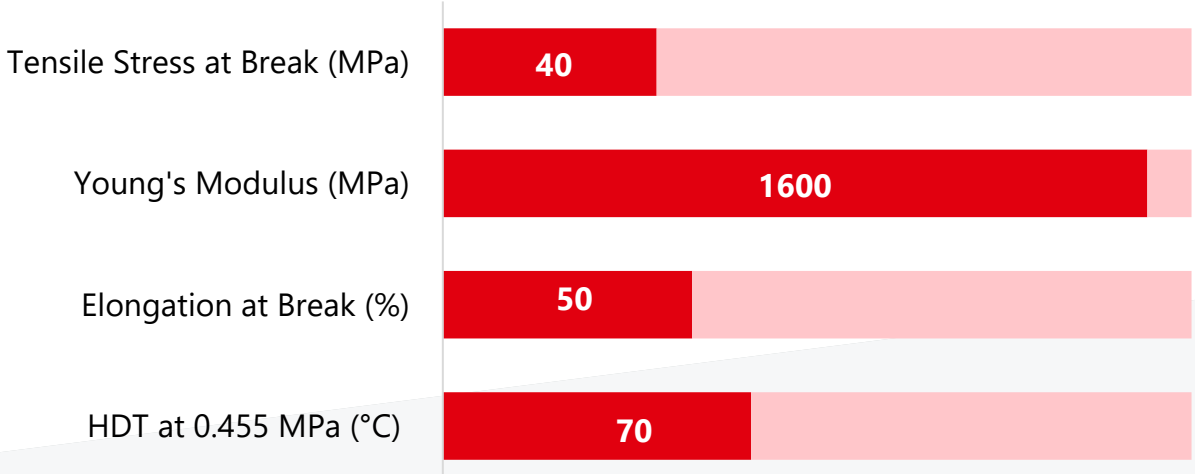
- Capable of meeting ISO 10993-5 & -10 standards for biocompatibility
- Parts can function at body temperature
- Outstanding surface finish
- Excellent machineability

Ideal for:

- Medical devices
- Hearing Aids
- Medical equipment components

Markets:

Healthcare



**Values shown are linked to LOCTITE MED413 CLEAR as reference, please refer to the specific mechanical properties for each of the colors shown in this document*

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PROPERTIES

Mechanical Properties	Measure	Method	Green	Post Processed
Tensile Stress at Break	MPa	ASTM D638	30 -34[1]	40 - 48[4]
Tensile Stress at Yield	MPa	ASTM D638	32 - 38[1]	43 -49[4]
Young's Modulus	MPa	ASTM D638	1350 - 1450[1]	1600 - 1750[4]
Elongation at Break	%	ASTM D638	54 - 68 [1]	40 - 55[4]
Flexural Modulus	MPa	ASTM D790	-	1500 -1600[5]
Flexural Strain at Break	%	ASTM D790	-	>5 [5]
IZOD Impact (Notched)	J/m	ASTM D256	-	50 - 65[8]
HDT at 0.455 MPa	°C	ASTM D648	-	66 - 70 [9]
HDT at 1.82 MPa	°C	ASTM D648	-	52 - 54[9]
Shore Hardness (5s)	D	ASTM D2240	-	76 [10]
Water Absorption (24 hr)	%	ASTM D570	-	2.7 – 2.8 [11]
Other Properties				
Solid Density	g/cm^3	ASTM D1475	1.2 [2]	1.2 [2]
Biocompatibility				
Cytotoxicity		ISO 10993-5	-	Comply [6]
Sensitization		ISO 10993-10	-	Comply [7]
Irritation		ISO 10993-23*	-	Comply[12]

Liquid Properties	Measure	Method	Value
Viscosity	cP	ASTM D7867	500-600 [3]
Liquid Density	g/cm^3	ASTM D1475	1.1 [2]

*All the properties above are specific to a validated workflow using an Origin One printer and Dymax 5000-EC post-cure unit. Deviations from this workflow may lead to deviations in the properties. All specimen are printed unless otherwise noted. All specimen were conditioned in ambient lab conditions at 19-23°C / 40-60% RH for at least 24 hours." ASTM Methods: D638 Type IV, 15 mm/min, D790-B, 2 mm/min, D648, D256 Notched IZOD (notched after post-cure), 6 mm x 12 mm, D570 0.125" x 2" Disc 24hr@ 25°C, D2240, Type "D" (0, 3 seconds), D7867, D1475

*The biological assessment has been performed based on the in vitro method according to ISO10993-23

Internal Data Sources:
[1] FOR25854/FOR27583/FOR36108, [2] FOR36096, [3] FOR34279, [4] FOR27584/FOR30160/FOR36105, [5] FOR36104, [6] FOR19950, [7] FOR21402, [8] FOR36117, [9] FOR36121, [10] FOR36122, [11] FOR36128, [12]FOR52784(in vitro)

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WORKFLOW

Validated workflows need to be followed to achieve properties as provided in the TDS. Examples of validated workflow steps are listed below. Users should defer to the most current workflow information for best results which can be found at https://www.loctiteam.com/printer-validation-settings

PRINTER SETTINGS

LOCTITE 3D MED413 CL is formulated to print optimally on industrial DLP printer. Read the safety data sheet carefully to get details about health and safety instructions. Recommended print parameters:

- Shake resin bottle well before usage
- Temperature: 20°C to 25°C
- Intensity: 4 mW/cm² to 8 mW/cm²

Exposure time for an intensity of 5 mW/cm²

Layer Thickness (µm):	100	E_C (mJ/cm²)	10.31
First layer time (s)	15	D_P (mm):	0.27
Burn in region (s):	8		
Model Layer Exposure (s):	5		

CLEANING

LOCTITE 3D MED413 CL requires post processing to achieve specified properties. Prior to post curing, support structures should be removed from the printed part, and the part should then be washed. Use compressed air to remove residual solvent from the surface of the material between intervals.

Post Process Step	Agent	Method	Duration	Intervals	Additional Info
Cleaning Cycle 1	IPA	Ultra sonic bath	2 min	1	Allow parts to dry between intervals
Cleaning Cycle 2	IPA	Ultra sonic bath	2 min	1	Use fresh IPA
Dry	n.a.	Compressed air	10 to 60 s	2	Air pressure (30psi)
Wait before post curing	n.a.	Ambient condition	60 min	1	Room temperature

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WORKFLOW

Validated workflows need to be followed to achieve properties as provided in the TDS. Examples of validated workflow steps are listed below. Users should defer to the most current workflow information for best results which can be found at https://www.loctiteam.com/printer-validation-settings

POST CURING

LOCTITE 3D MED413 CL requires post curing to achieve specified properties. It is recommended that either an LED or wide spectrum lamp be used to post cure parts.

UV Curing Unit	UV Source	Intensity	Cure time/ side	Additional Settings (Shelf, Output Energy)
Dymax 5000 EC Flood	Mercury Arc Bulb (broad spectrum)	150 mW/cm^2 at 380 nm	4 min	Shelf K
Loctite UVALOC 1000	Mercury Arc Bulb (broad spectrum)	30 mW/cm^2 at 365 nm	5 min	500 W, 3rd shelf from bottom
Loctite CL36	405nm LED	80 mW/cm^2 at 405 nm	30 min	100% top & side

STORAGE

Store LOCTITE 3D MED413 CL in the unopened container in a dry location. Optimal Storage: 8°C to 30°. Storage below 8°C or above 30°C can adversely affect product properties. Material removed from containers may be contaminated during use. For this reason, filter used resin with 190µm mesh filter before placing back into proper storage container.

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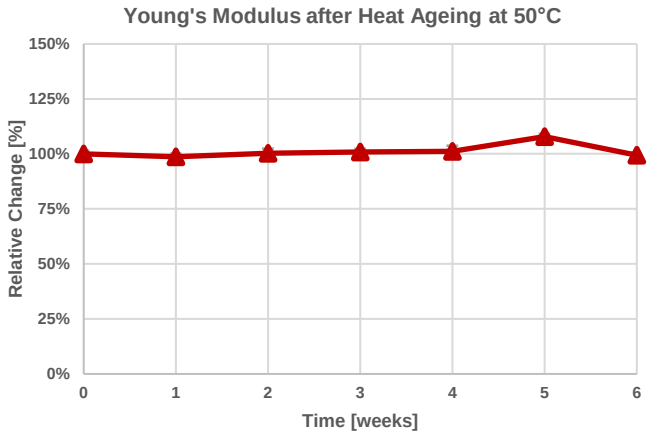
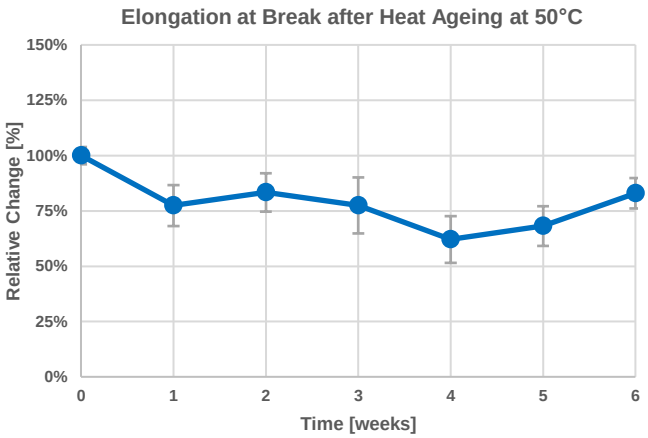
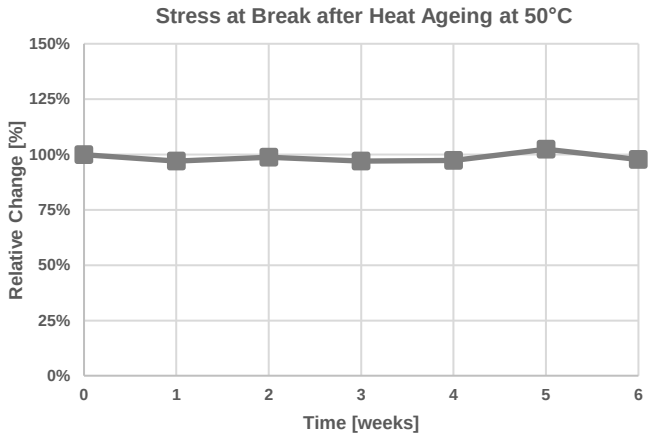
AGEING AND ENVIRONMENTAL EFFECTS – HEAT AGEING

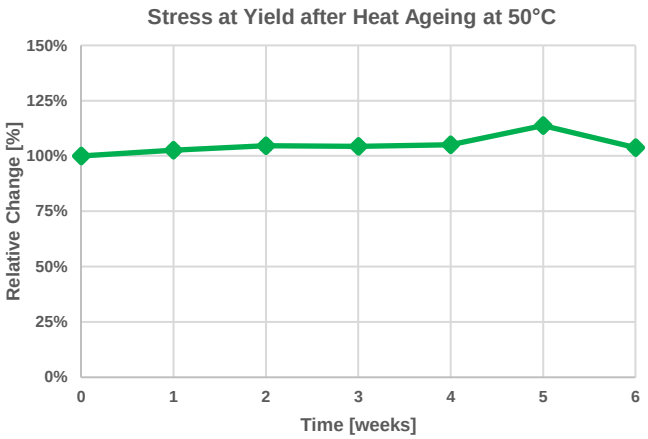
LOCTITE 3D MED413 CL was heat aged without load according to ASTM D3045. Test samples were exposed for a defined time at 50°C and conditioned for 24 hours at 22°C before mechanical testing. Control samples were stored at a constant 22°C. All samples were printed in the same print job using a validated workflow. Mechanical testing was conducted according to ASTM D638 at standard lab conditions (22°C). "0 weeks" represents non-aged samples stored at 22°C and tested 24 hours after post-processing.

Based on temperature dependence of reaction rates a test time of 6 weeks at 50°C can be interpreted as approximately 12 months at ambient temperature.









Test parameters:
ASTM D638: Type IV, Pull speed: 5 mm/min, Young's modulus measured at 0.1-1.0% (regression), 22°C

Internal Data Sources:
FOR116848, FOR116849

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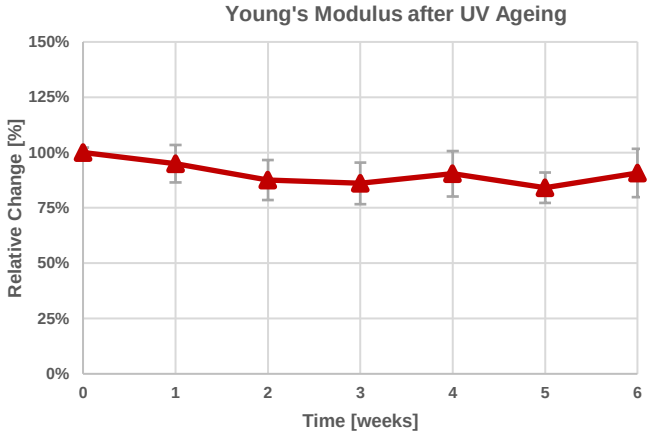
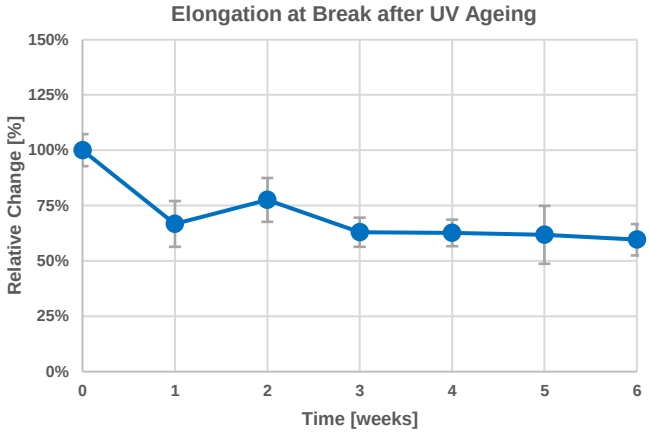
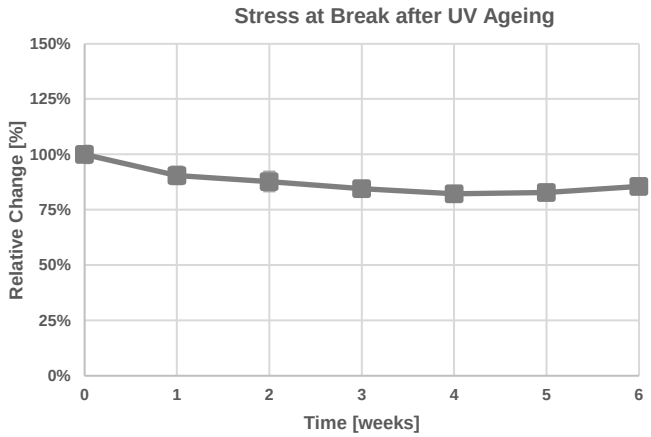
AGEING AND ENVIRONMENTAL EFFECTS – ACCELERATED WEATHERING (UV AGEING)

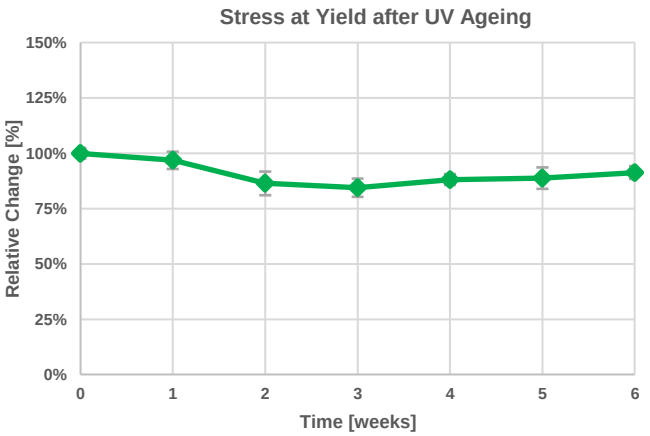
LOCTITE 3D MED413 CL has been tested after accelerated outdoor weathering according to ASTM D4329 (Cycle A). Test samples were exposed to defined conditions of heat, water condensation and UV light. Exposed samples were conditioned for 24 hours at 22°C before mechanical testing. Control samples were stored at a constant 22°C. All samples were printed in the same print job using a validated workflow. Mechanical testing was conducted according to ASTM D638 at standard lab conditions (22°C). "0 weeks" represents non-aged samples stored at 22°C and tested 24 hours after post-processing.

Please note, accelerated weathering testing can never fully represent real outdoor conditions and complexity. It is therefore recommended to conduct additional (outdoor) testing relevant for your specific application needs.









Test parameters:
ASTM D638: Type IV, Pull speed: 5 mm/min, Young's modulus measured at 0.1-1% (regression), 22 °C
ASTM D4329: cycle A for general applications, QUV/se, UVA 340 nm, 0.89 W/m²·nm, 8 hours UV light at 60°C followed by 4 hours at 50°C condensation in the dark. To reduce any sample warpage during test time samples were placed in tailor-made holders without any fixation clamps or mechanical load. Exposed samples were always removed from QUV before next condensation cycle to avoid samples that are soaked excessively with water before testing.

Internal Data Sources:
FOR167570, FOR167584

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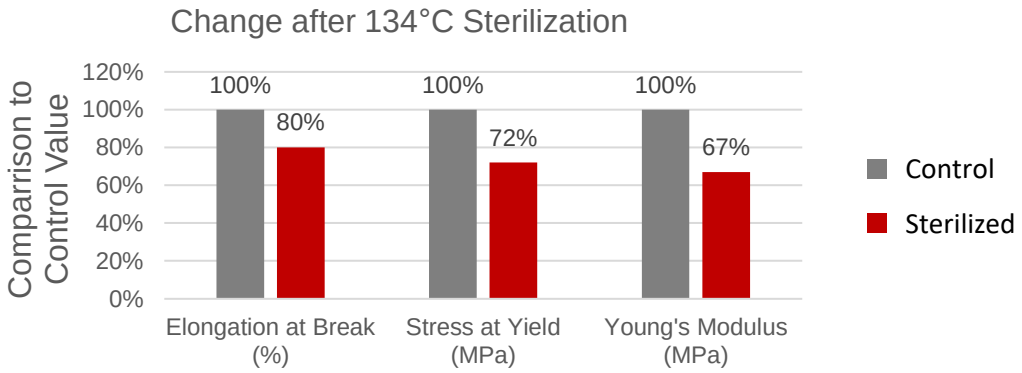
PHYSICAL PROPERTIES OF STERILIZED PARTS

ASTM D638 Type IV dog bones were printed with LOCTITE 3D MED413 CL and sterilized with autoclave steam and Ethylene Oxide sterilization processes. Each sterilization method had a sample set of n=8. Test samples were tested 24 hours after sterilization and compared to a control sample set of n=8.

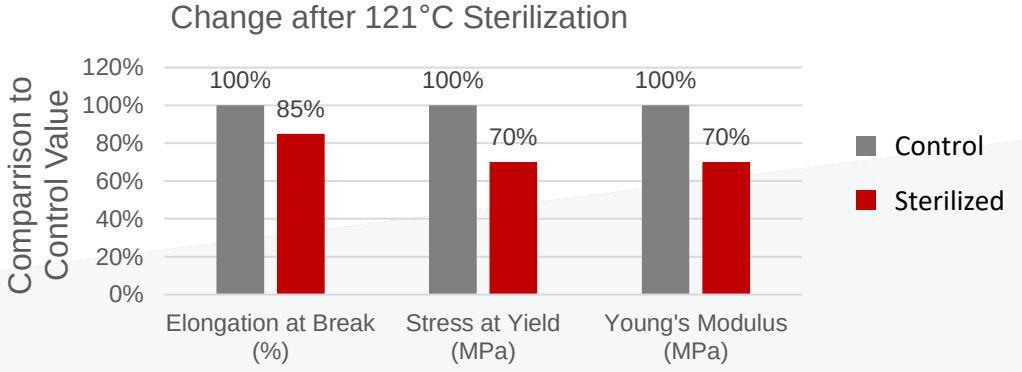
Autoclave Steam Sterilization: 134°C (270°F)

The tensile results of the sterilized dog bones parts show that the average Elongation at Break , Stress at Yield, and Young's Modulus values were outside the standard deviation of the non-sterilized control samples. After one cycle of 134°C steam sterilization, there is an effect to Elongation at Break , Stress at Yield, and Young's Modulus.



Autoclave Steam Sterilization: 121°C (250°F)

The tensile results of the sterilized dog bones parts show that the average Elongation at Break , Stress at Yield, and Young's Modulus values were outside the standard deviation of the non-sterilized control samples. After one cycle of 121°C sterilization, there is an effect to Elongation at Break , Stress at Yield, and Young's Modulus.



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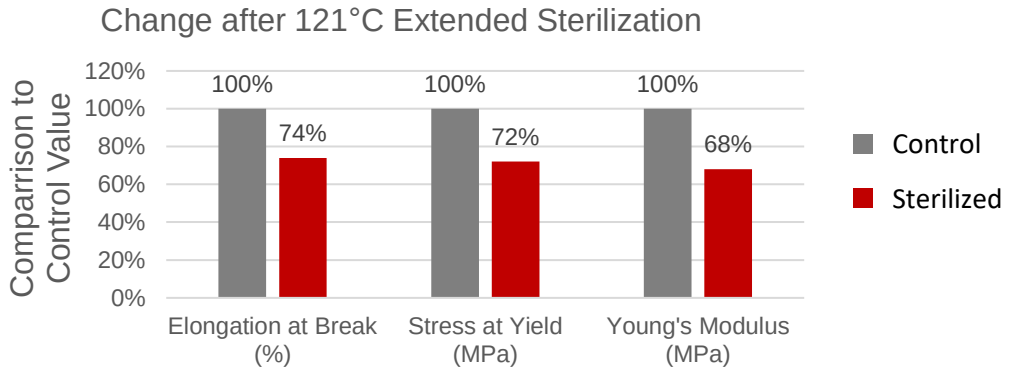
PHYSICAL PROPERTIES OF STERILIZED PARTS

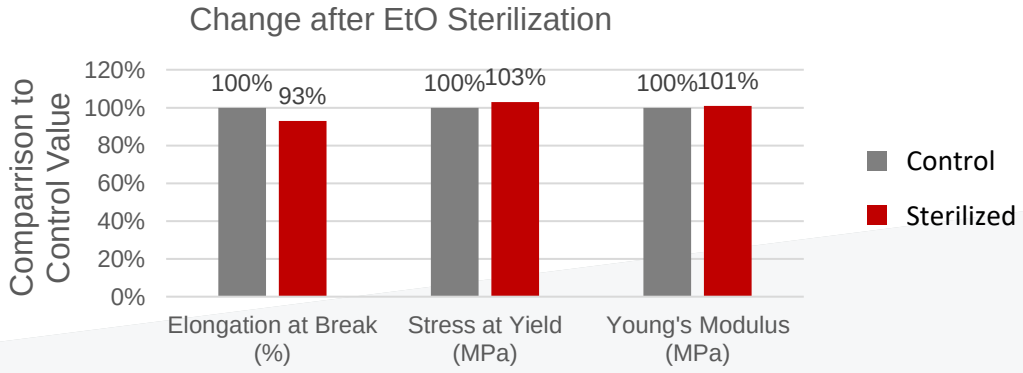
Autoclave Steam Sterilization: 121°C (250°F) Extended Drying

The tensile results of the sterilized dog bones parts show that the average Elongation at Break , Stress at Yield, and Young's Modulus values were outside the standard deviation of the non-sterilized control samples. After one cycle of 121°C extended drying steam sterilization, there is an effect to Elongation at Break , Stress at Yield, and Young's Modulus.



Ethylene Oxide (EtO) Sterilization

The tensile results of the sterilized dog bones parts showed that the average Elongation at Break and Young's Modulus values were within the standard deviation of the non-sterilized control samples. The average Stress at Yield value of the sterilized samples was outside the standard deviation of the non-sterilized control samples. After one cycle of Ethylene Oxide sterilization, there is no significant effect to Elongation at Break, Stress at Yield, or Young's Modulus.



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PROPERTIES

Mechanical Properties	Measure	Method	Green	Post Processed
Tensile Stress at Break	MPa	ASTM D638	32 - 36[1]	41 - 44[4]
Tensile Stress at Yield	MPa	ASTM D638	37 - 40[1]	45 - 47[4]
Young's Modulus	MPa	ASTM D638	1500 - 1600[1]	1650 - 1800[4]
Elongation at Break	%	ASTM D638	60 - 75[1]	47 - 55[4]
Flexural Modulus	MPa	ASTM D790	-	1400 - 1600[5]
Flexural Strain at Break	%	ASTM D790	-	>5 [5]
IZOD Impact (Notched)	J/m	ASTM D256	-	48 - 58[8]
HDT at 0.455 MPa	°C	ASTM D648	-	68 - 69[9]
HDT at 1.82 MPa	°C	ASTM D648	-	53 - 55[9]
Shore Hardness (5s)	D	ASTM D2240	-	72 [10]
Water Absorption (24 hr)	%	ASTM D570	-	1 - 2[11]
Other Properties				
Solid Density	g/cm^3	ASTM D1475	1.2 [2]	1.0 [2]
Biocompatibility				
Cytotoxicity		ISO 10993-5	-	Comply [6]
Sensitization		ISO 10993-10	-	Comply [7]
Irritation		ISO 10993-23	-	Comply [12]

Liquid Properties	Measure	Method	Value
Viscosity	cP	ASTM D7867	525-625 [3]
Liquid Density	g/cm^3	ASTM D1475	1.1 [2]

*All the properties above are specific to a validated workflow using an Origin One printer and Dymax 5000-EC post-cure unit. Deviations from this workflow may lead to deviations in the properties. All specimen are printed unless otherwise noted. All specimen were conditioned in ambient lab conditions at 19-23°C / 40-60% RH for at least 24 hours." ASTM Methods: D638 Type IV, 15 mm/min, D790-B, 2 mm/min, D648, D256 Notched IZOD (notched after post-cure), 6 mm x 12 mm, D570 0.125" x 2" Disc 24hr@ 25°C, D2240, Type "D" (0, 3 seconds), D7867, D1475

*The biological assessment has been performed based on the in vitro method according to ISO10993-23

Internal Data Sources:
[1] FOR27567/FOR38326, [2] FOR38325, [3] FOR30596, [4] FOR28603/FOR38327, [5] FOR27825/38324, [6] FOR38849, [7] FOR21402, [8] FOR38323/FOR25330, [9] FOR38322, [10] FOR38321, [11] FOR38320, [12]52784 (in vitro)

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WORKFLOW

Validated workflows need to be followed to achieve properties as provided in the TDS. Examples of validated workflow steps are listed below. Users should defer to the most current workflow information for best results which can be found at https://www.loctiteam.com/printer-validation-settings

PRINTER SETTINGS

LOCTITE 3D MED413 WH is formulated to print optimally on industrial DLP printer. Read the safety data sheet carefully to get details about health and safety instructions. Recommended print parameters:

- Shake resin bottle well before usage
- Temperature: 20°C to 25°C
- Intensity: 4 mW/cm² to 8 mW/cm²

Exposure time for an intensity of 5 mW/cm²

Layer Thickness (µm):	100	E_C (mJ/cm²)	6.28
First layer time (s)	10	D_P (mm):	0.14
Burn in region (s):	6		
Model Layer Exposure (s):	7		

CLEANING

LOCTITE 3D MED413 WH requires post processing to achieve specified properties. Prior to post curing, support structures should be removed from the printed part, and the part should then be washed. Use compressed air to remove residual solvent from the surface of the material between intervals.

Post Process Step	Agent	Method	Duration	Intervals	Additional Info
Cleaning Cycle 1	IPA	Ultra sonic bath	2 min	1	Allow parts to dry between intervals
Cleaning Cycle 2	IPA	Ultra sonic bath	2 min	1	Use fresh IPA
Dry	n.a.	Compressed air	10 to 60 s	2	Air pressure (30psi)
Wait before post curing	n.a.	Ambient condition	60 min	1	Room temperature

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WORKFLOW

Validated workflows need to be followed to achieve properties as provided in the TDS. Examples of validated workflow steps are listed below. Users should defer to the most current workflow information for best results which can be found at https://www.loctiteam.com/printer-validation-settings

POST CURING

LOCTITE 3D MED413 WH requires post curing to achieve specified properties. It is recommended that either an LED or wide spectrum lamp be used to post cure parts.

UV Curing Unit	UV Source	Intensity	Cure time/ side	Additional Settings (Shelf, Output Energy)
Dymax 5000 EC Flood	Mercury Arc Bulb (broad spectrum)	150 mW/cm^2 at 380 nm	4 min	Shelf K
Loctite UVALOC 1000	Mercury Arc Bulb (broad spectrum)	30 mW/cm^2 at 365 nm	2 min	500 W, 3rd shelf from top
Uvitron Intelliray 600	Mercury Arc Bulb (broad spectrum)	130 mW/cm^2 at 380 nm	2 min	66% power, 3rd shelf from top

STORAGE

Store LOCTITE 3D MED413 WH in the unopened container in a dry location. Optimal Storage: 8°C to 30°. Storage below 8°C or above 30°C can adversely affect product properties. Material removed from containers may be contaminated during use. For this reason, filter used resin with 190µm mesh filter before placing back into proper storage container.

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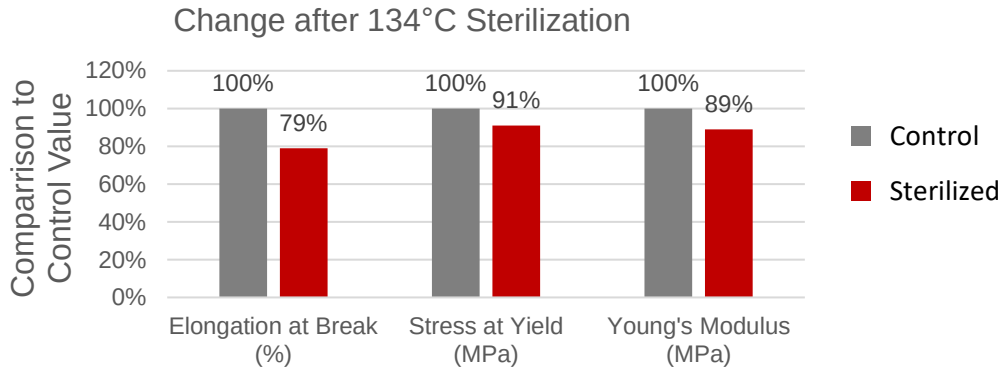
PHYSICAL PROPERTIES OF STERILIZED PARTS

ASTM D638 Type IV dog bones were printed with LOCTITE 3D MED413 WH and sterilized with autoclave steam and Ethylene Oxide sterilization processes. Each sterilization method had a sample set of n=8. Test samples were tested 24 hours after sterilization and compared to a control sample set of n=8.

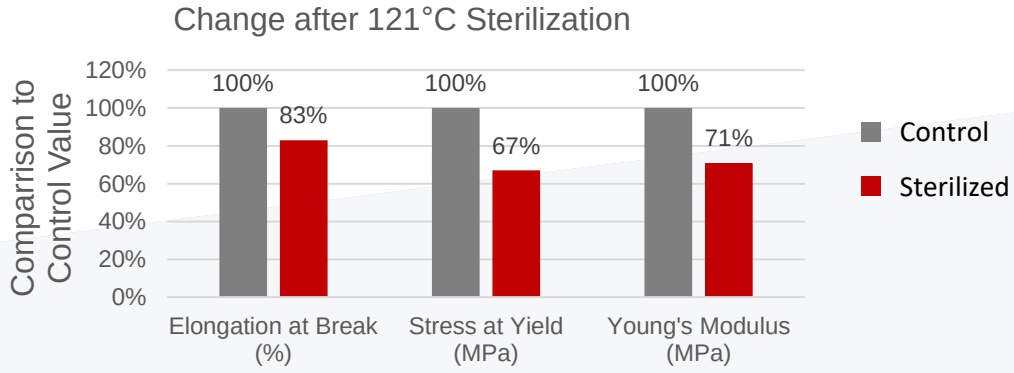
Autoclave Steam Sterilization: 134°C (270°F)

The tensile results of the sterilized dog bones parts show that the average Elongation at Break , Stress at Yield, and Young's Modulus values were outside the standard deviation of the non-sterilized control samples. After one cycle of 134°C steam sterilization, there is an effect to Elongation at Break and Young's Modulus, but no significant effect to Stress at Yield.



Autoclave Steam Sterilization: 121°C (250°F)

The tensile results of the sterilized dog bones parts show that the average Elongation at Break , Stress at Yield, and Young's Modulus values were outside the standard deviation of the non-sterilized control samples. After one cycle of 121°C steam sterilization, there is an effect to Elongation at Break , Stress at Yield, and Young's Modulus.



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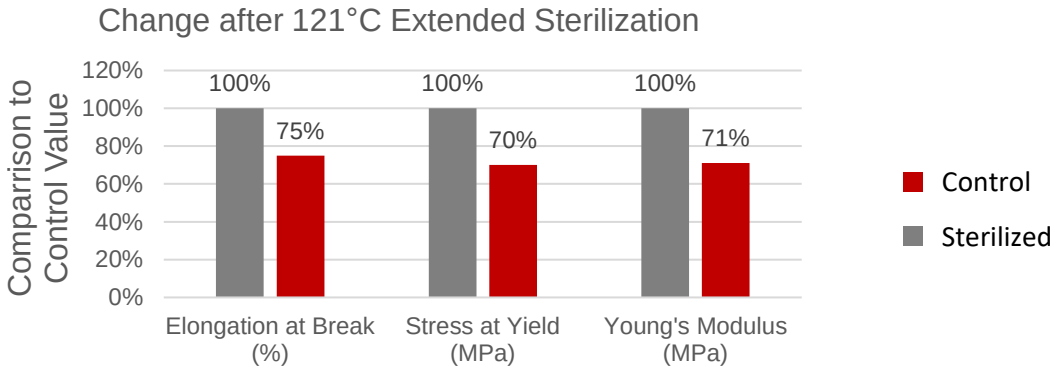
PHYSICAL PROPERTIES OF STERILIZED PARTS

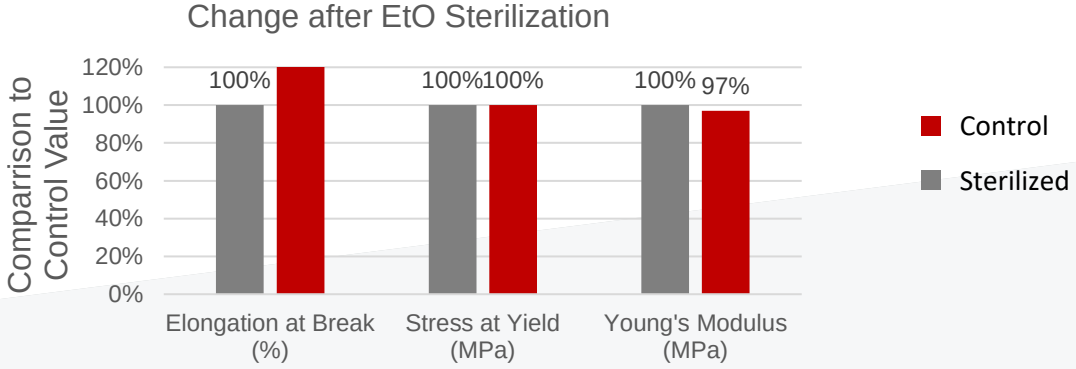
Autoclave Steam Sterilization: 121°C (250°F) Extended Drying

The tensile results of the sterilized dog bones parts show that the average Elongation at Break , Stress at Yield, and Young's Modulus values were outside the standard deviation of the non-sterilized control samples. After one cycle of 121°C extended drying steam sterilization, there is an effect to Elongation at Break , Stress at Yield, and Young's Modulus.



Ethylene Oxide (EtO) Sterilization

The tensile results of the sterilized dog bones parts showed that the average Elongation at Break and Stress at Yield values were within the standard deviation of the non-sterilized control samples. The average Young's Modulus of the sterilized samples was outside the standard deviation of the non-sterilized control samples. After one cycle of Ethylene Oxide sterilization, there is no significant effect to Elongation at Break, Stress at Yield, or Young's Modulus.



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FURTHER INFORMATION REGARDING INSTRUCTIONS FOR USE

OVERVIEW

LOCTITE 3D MED413 is an energy-curable resin used to manufacture a variety of 3D printed biocompatible medical devices. Due to the physical properties and biocompatibility of the finished material, 3D printed parts can be used in a variety applications when processed in accordance with validated workflows. If sterile parts are required, please follow the guidance in this IFU to obtain an effective final device.

Warnings and Precautions

When this product is used to create a Regulated Medical Device, either the user assumes all responsibility to use this product only for Henkel supported and approved Indications for use or the user must take all responsibility to register their indication of use with the proper regulatory authority. Strict adherence to our information for use and validated production workflows (printer, washing, and post processing procedures), is critical in assuring a safe, biocompatible and effective printed appliance.

Follow all recommended validated settings for safe and effective print results.

LOCTITE 3D MED413 contains (meth)acrylate monomers and oligomers which, although rare, may cause an allergic reaction in individuals sensitive to acrylic containing products. Always review and understand all safety data sheets (SDS) and labels prior to use. Do not use any devices or components that have not been validated and deemed acceptable by Henkel. Parts must be printed and post processed in accordance with approved workflows prior to use. Always keep finished parts stored in a cool, dry place (15-30°C) and away from direct sunlight. Finished parts are not meant to be used for prolonged periods in outdoor environments.

Exact workflows with detailed information can be obtained by contacting us at www.loctiteAM.com.

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DIRECTIONS FOR USE

1. Prior to printing, agitate the bottle of resin and allow the resin to adjust to an ambient temperature between 20-25°C / 68-77°F for a period of one hour.
2. Once the design is completed per CAD software manufacturers direction for use, import the CAM software unique to the printer manufacturer.
3. Nest the parts you would like to print in a CAM software.
4. Only print LOCTITE 3D MED413 with the printer-specific pre-determined settings for DLP printers Henkel has validated. Contact us at www.loctiteAM.com for validated printer settings. Alternative printers must be validated by Henkel to determine print settings needed to generate a safe and effective device.

DIRECTIONS FOR POST-PROCESSING

1. When the print is complete, gently remove parts from the printer build platform and remove support structures from the part if applicable.
2. Wash the parts for the pre-determined duration and number of wash cycles. Henkel will have validated the workflow you will be using. Contact us at www.loctiteAM.com for validated post-processing procedures.
3. Dry the parts with compressed air and inspect parts for any residual resin, which will have a glossy appearance. If any residual resin is observed, repeat step 2.
4. Allow the parts to rest at room temperature for 30-90 minutes before progressing.
5. Place parts in a single layer in a post-cure unit Henkel has validated and use the post-cure unit specific settings. Contact us at www.loctiteAM.com for validated post-cure unit settings. Alternative post-cure units must by validated by Henkel to determine post-cure settings to generate a safe and effective device.

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CLEAR, WHITE

DIRECTIONS FOR STERILIZATION

LOCTITE 3D MED413 is suitable for sterilization using standards methods described below

Autoclave Steam Sterilization: 134°C (273°F)

1. Samples should be packaged and distributed in the appropriate sterilization bags.
2. Bags should be laid flat and not stacked on top of one another to ensure adequate steam saturation.
3. Ramp temperature up to 134°C (273°F) and pressurize to 2.1 bar (30.5 psi) and hold for 4 minutes.
4. Depressurize chamber to -1.0 bar (-14.5 psi) and hold for a minimum of 5 minutes.
5. Temperatures may vary during the depressurization. If the temperature stays above 60°C in the depressurization phase, the finished parts will be in compliance.
6. Check that the bag sterilization confirmation marks are fulfilled and inspect parts for clarity. If parts are cloudy or opaque, parts were not dried completely and should not be used.

Autoclave Steam Sterilization: 121°C (250°F)

1. Samples should be packaged and distributed in the appropriate sterilization bags.
2. Bags should be laid flat and not stacked on top of one another to ensure adequate steam saturation.
3. Ramp temperature up to 121°C (250°F) and pressurize to 1.1 bar (16.0 psi) and hold for 10 minutes.
4. Depressurize chamber from -0.7 (10.1 psi) to -1.0 bar (-14.5 psi) and hold for 5 minutes.
5. Temperatures may vary during the depressurization. If the temperature stays above 60°C in the depressurization phase, the finished parts will be in compliance.
6. Check that the bag sterilization confirmation marks are fulfilled and Inspect parts for clarity. If parts are cloudy or opaque, parts were not dried completely and should not be used.

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DIRECTIONS FOR STERILIZATION (CONTINUED)

Autoclave Steam Sterilization: 121°C (250°F) Extended

1. Samples should be packaged and distributed in the appropriate sterilization bags.
2. Bags should be laid flat and not stacked on top of one another to ensure adequate steam saturation.
3. Ramp temperature up to 121°C (250°F) and pressurize to 1.1 bar (16.0 psi) and hold for 30 minutes.
4. Depressurize chamber from -0.7 (10.1 psi) to -1.0 bar (-14.5 psi) and hold for 60 minutes. Hold temperature at 97°C (207°F) during drying phase.
5. Temperatures may vary during the depressurization. If the temperature stays above 60°C in the depressurization phase, the finished parts will be in compliance.
6. Check that the bag sterilization confirmation marks are fulfilled and Inspect parts for clarity. If parts are cloudy or opaque, parts were not dried completely and should not be used.

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STORAGE

Store LOCTITE 3D MED413 in the unopened container in a dry location. Optimal storage: 8°C to 30°C, storage below 8°C or greater than 30°C can adversely affect products properties. More specific information is given in the Safety Data Sheet. Material removed from container may be contaminated during use. For this reason, filter used resin with 190µm mesh filter before placing back into proper storage container.

BIOCOMPATIBILITY

Printed parts were prepared in accordance to the instructions provided in this document and submitted to an external lab for evaluation in accordance with ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

When this product is used to create a Regulated Medical Device, either the user assumes all responsibility to use this product only for Henkel supported and approved Indications for use or the user must take all responsibility to register their indication of use with the proper regulatory authority. Strict adherence to our information for use and validated production workflows (printer, washing, and post processing procedures), is critical in assuring a safe, biocompatible and effective printed appliance.

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NOTE

The information provided in this Technical Data Sheet (TDS) including the recommendations for use and application of the product are based on our knowledge and experience of the product as at the date of this TDS. The product can have a variety of different applications as well as differing application and working conditions in your environment that are beyond our control. Henkel is, therefore, not liable for the suitability of our product for the production processes and conditions in respect of which you use them, as well as the intended applications and results. We strongly recommend that you carry out your own prior trials to confirm such suitability of our product.

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