Version 2021/06/30

LOCTITE®

LOCTITE® 3D MED412™

HDT40 High Impact
Ultra Clear, White

LOCTITE®
Henkel Corporation
loctite3dp@henkel.com

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ULTRA CLEAR, WHITE

LOCTITE 3D MED412™

LOCTITE 3D MED412 is a strong, durable material with excellent elongation, impact strength and surface finish. It been designed to enable the manufacture of medical devices and their component parts that require good stiffness and wear resistance.

LOCTITE 3D MED412 is capable of meeting ISO 10993-5 and -10 standards for biocompatibility when processed using a validated workflow. Certificates of compliance are available upon request.

LOCTITE 3D MED412 is compatible with a broad range of DLP machines.

Benefits:

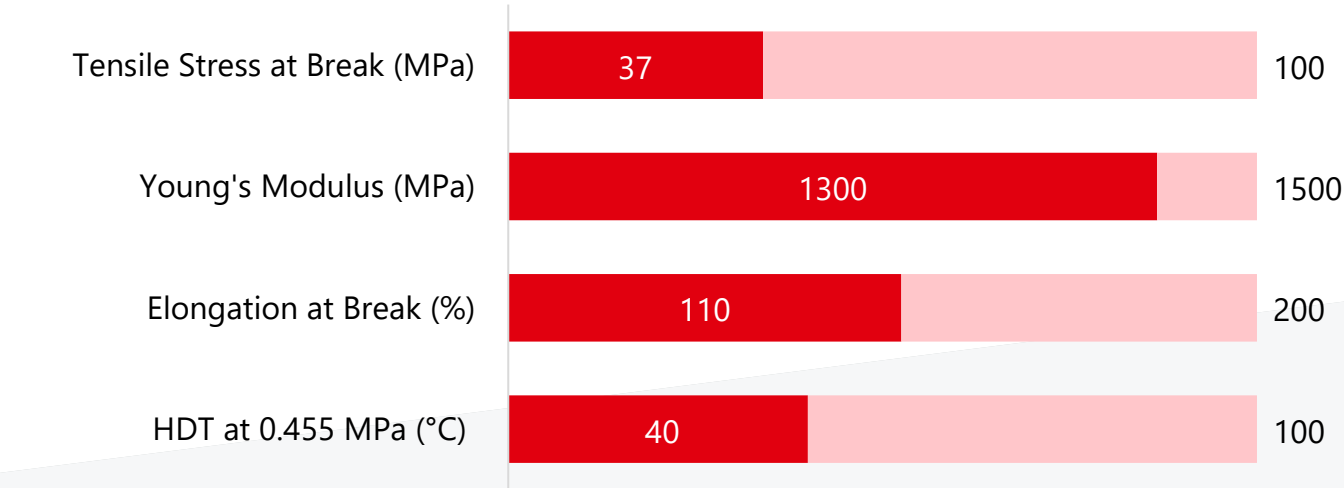
- Capable of meeting ISO 10993-5 & -10 standards for biocompatibility
- Tough with Superior Elongation
- Good Impact Strength and Surface Finish

Ideal for:

- Class I and II Medical Devices
- Medical Equipment Components

Markets:

Healthcare



**Values shown are linked to LOCTITE MED412 ULTRA CLEAR as reference, please refer to the specific mechanical properties for each of the colors shown in this document*

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MECHANICAL PROPERTIES

Mechanical Properties	Measure	Method	Green	Post Processed
Tensile Stress at Break	MPa	ASTM D638	23 ± 2 [1]	37 ± 4 [10]
Tensile Stress at Yield	MPa	ASTM D638	20 ± 3 [1]	33 ± 5 [10]
Young's Modulus	MPa	ASTM D638	935 ± 154 [1]	1305 ± 85 [10]
Elongation at Break	%	ASTM D638	1267 ± 12 [1]	110 ± 14 [10]
Flexural Modulus	MPa	ASTM D790	-	869 ± 30 [3]
Flexural Elongation at Break	%	ASTM D790	-	>5 [3]
IZOD Impact (Notched)	J/m	ASTM D256	-	50 ± 3 [6]
HDT at 0.455 MPa	°C	ASTM D648	-	39 ± 1 [7]
HDT at 1.82 MPa	°C	ASTM D648	-	35 ± 1 [7]
Shore Hardness (0s, 3s)	D	ASTM 2240	-	78, 70 [8]
Water Absorption (24 hr)	%	ASTM 570	-	0.27 ± 0.03 [9]
Other Properties				
Solid Density	g/cm^3	ASTM D1475	1.1 [2]	1.1 [2]
Biocompatibility				
Cytotoxicity		ISO 10993-5		Comply [4]
Sensitization		ISO 10993-10		Comply [5]
Irritation		ISO 10993-10		Comply [5]

Liquid Properties	Measure	Method	Value
Viscosity	cP	ASTM D7867	500-800
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 before post-cure), 6 mm x 12 mm, D570 0.125" x 2" Disc 24hr@ 25°C, D2240, Type "D" (0, 3 seconds), D7867, D1475

Internal Data Sources:
[1] FOR33154/FOR27591, [2] FOR33155, [3] FOR33156, [4] FOR19261, [5] FOR21400, [6] FOR25329, [7] FOR33159, [8] FOR33160, [9] FOR33161, [10] FOR33154/FOR30161

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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 MED412 Ultra Clear is formulated to print optimally on any DLP machine. 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	Ec (mJ/cm²)	7.81
First layer time (s)	60	Dp (mm):	0.17
Burn in region (s):	15		
Model Layer Cure Time (s):	8.5		

POST PROCESSING

LOCTITE 3D MED412 Ultra Clear 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	IPA	Ultra sonic bath	2 min	2	Allow parts to dry between intervals and use fresh IPA for second wash
Dry	n.a.	Compressed air	10 to 60 s	2	Air pressure (30 psi)
Wait	n.a.	Ambient condition	60 min	1	Room temperature

POST CURING

LOCTITE 3D MED412 Ultra Clear requires post curing to achieve specified properties. It is recommended that either an LED or wide spectrum lamp be used to post cure parts.

UC Curing Unit	UV Source	Intensity	Cure time/ side	Additional Settings (Shelf, Output Energy)
Dymax 5000 EC Flood	Mercury Arc Bulb (broad spectrum)	150 mW/cm² at 380 nm	4 min	Shelf K

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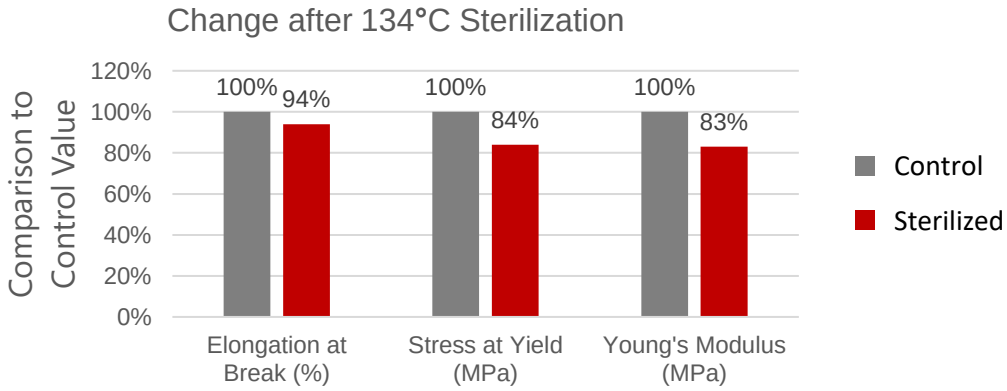
PHYSICAL PROPERTIES OF STERILIZED PARTS

ASTM D638 Type IV dog bones were printed with LOCTITE 3D MED412 Ultra Clear and sterilized with 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.

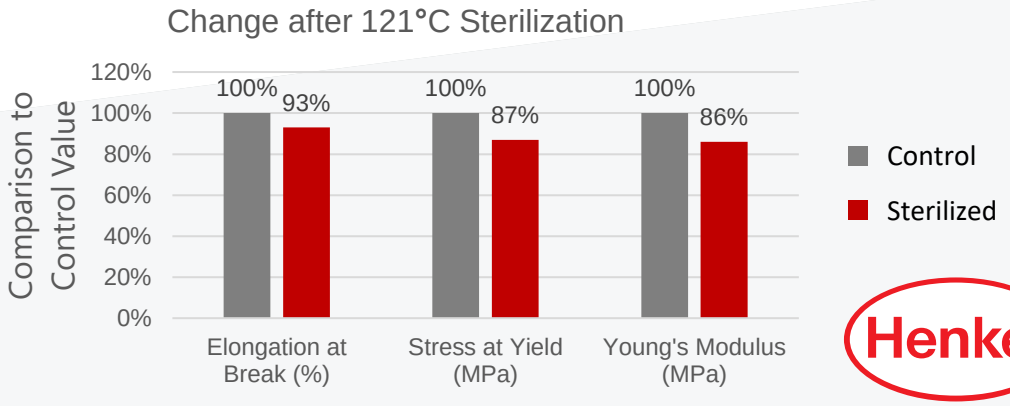
Autoclave Steam Sterilization: 134°C (270°F)

The tensile results of the sterilized dog bones parts show that the average Elongation at Break value was within the standard deviation of the non-sterilized control samples. The Young's Modulus and Stress at Yield 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 Young's Modulus and Stress at Yield, but no significant effect to Elongation at Break.



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

The tensile results of the sterilized dog bones parts showed 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 the Stress at Yield and Young's Modulus, but no significant effect to the Elongation at Break.



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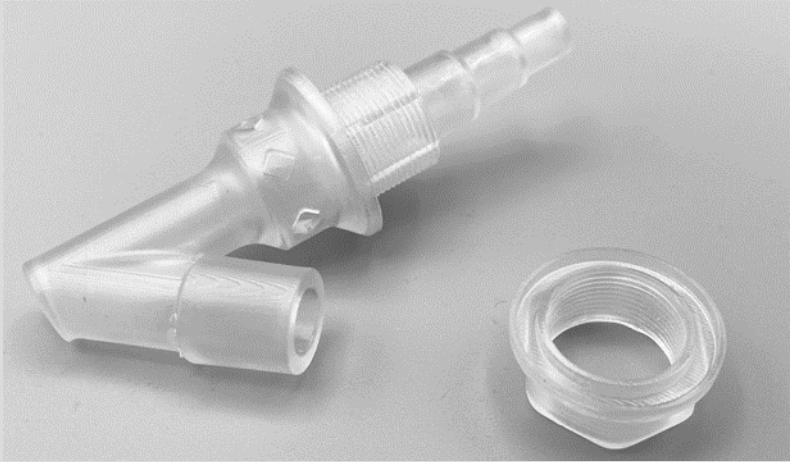
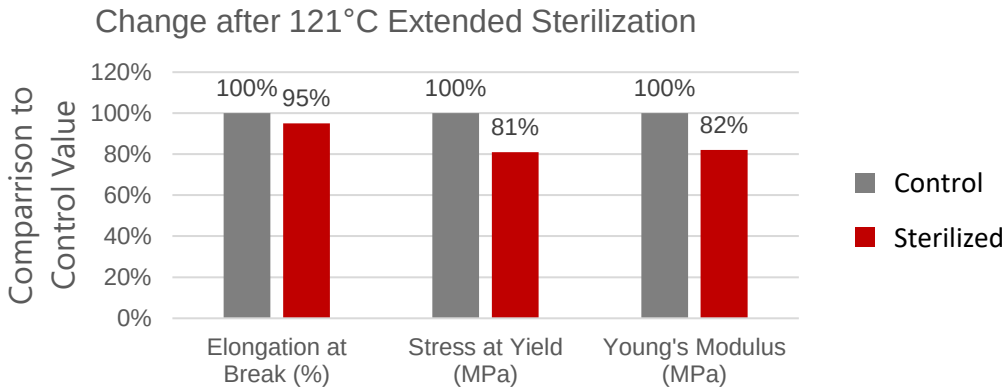


PHYSICAL PROPERTIES OF STERILIZED PARTS

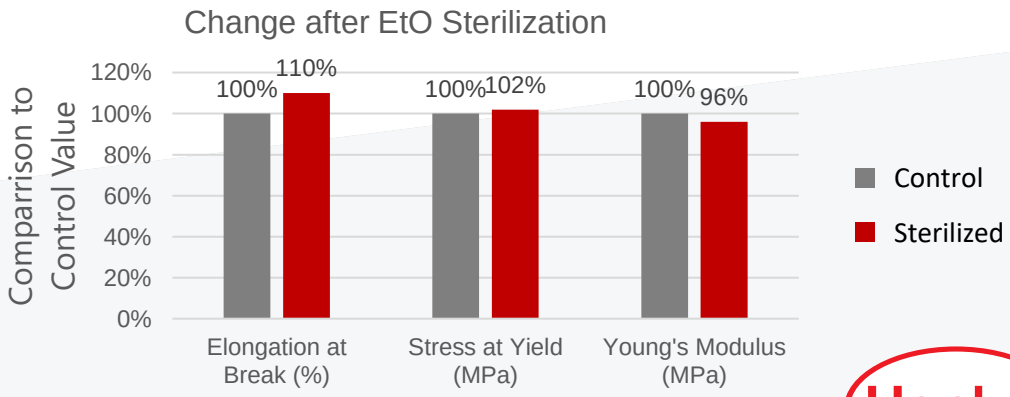
Autoclave Steam Sterilization: 121°C (250°F) Extended Drying

The tensile results of the sterilized dog bones parts showed that the average Elongation at Break value was within the standard deviation of the non-sterilized control samples. The 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 the Stress at Yield and Young's Modulus, but no significant effect to Elongation at Break.



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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Mechanical Properties	Measure	Method	Green	Post Processed
Tensile Stress at Break	MPa	ASTM D638	19 ± 2 [1]	25 ± 4 [3]
Tensile Stress at Yield	MPa	ASTM D638	17 ± 4 [1]	27 ± 2 [3]
Young's Modulus	MPa	ASTM D638	681 ± 124 [1]	1258 ± 107 [3]
Elongation at Break	%	ASTM D638	132 ± 20 [1]	94 ± 9 [3]
Flexural Modulus	MPa	ASTM D790	-	1196 ± 45 [4]
Flexural Elongation at Break	%	ASTM D790	-	>5 [4]
IZOD Impact (Notched)	J/m	ASTM D256	-	49 ± 3 [5]
HDT at 0.455 MPa	°C	ASTM D648	-	39 ± 1 [6]
HDT at 1.82 MPa	°C	ASTM D648	-	35 ± 1 [6]
Shore Hardness (0s, 3s)	D	ASTM 2240	-	76, 68 [7]
Water Absorption (24 hr)	%	ASTM 570	-	0.34 ± 0.12 [8]
Other Properties				
Solid Density	g/cm^3	ASTM D1475	1.1 [2]	1.1 [2]
Biocompatibility				
Cytotoxicity		ISO 10993-5		Comply [9]
Sensitization		ISO 10993-10		Comply [10]
Irritation		ISO 10993-10		Comply [10]

Liquid Properties	Measure	Method	Value
Viscosity	cP	ASTM D7867	600-800
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

Internal Data Sources:
[1] FOR28594/FOR29019/FOR33153, [2] FOR33084, [3] FOR29015/FOR33153, [4] FOR25403, [5] fOR25328, [6] FOR33158. [7] FOR33093, [8] FOR33094, [9] FOR33090, [10] FOR21401

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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 MED412 White is formulated to print optimally on any DLP machine. 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	Ec (mJ/cm²)	5.83
First layer time (s)	40	Dp (mm):	0.12
Burn in region (s):	25		
Model Layer Cure Time (s):	6.5		

POST PROCESSING

LOCTITE 3D MED412 White 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	IPA	Ultra sonic bath	2 min	2	Allow parts to dry between intervals and use fresh IPA for second wash
Dry	n.a.	Compressed air	10 to 60 s	2	Air pressure (30 psi)
Wait	n.a.	Ambient condition	60 min	1	Room temperature

POST CURING

LOCTITE 3D MED412 White requires post curing to achieve specified properties. It is recommended that either an LED or wide spectrum lamp be used to post cure parts.

UC Curing Unit	UV Source	Intensity	Cure time/ side	Additional Settings (Shelf, Output Energy)
Dymax 5000 EC Flood	Mercury Arc Bulb (broad spectrum)	150 mW/cm² at 380 nm	4 min	Shelf K

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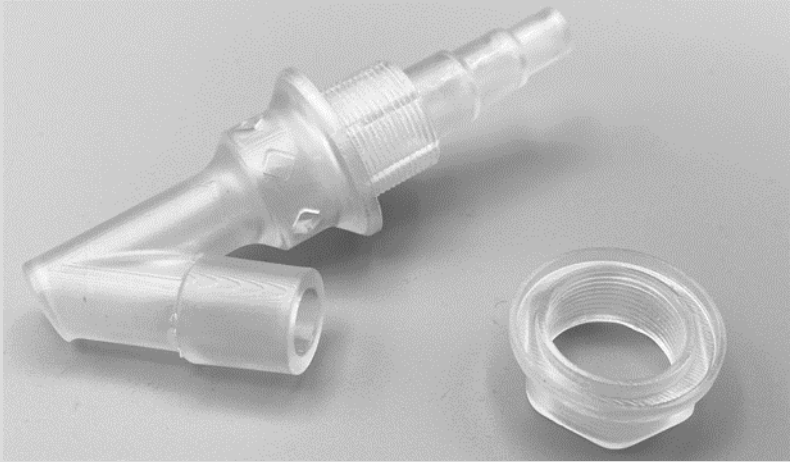
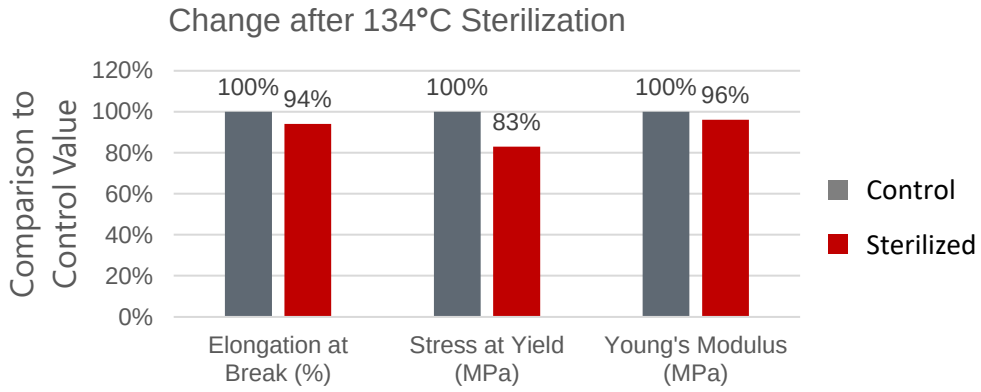


PHYSICAL PROPERTIES OF STERILIZED PARTS

ASTM D638 Type IV dog bones were printed with LOCTITE 3D MED412 White and sterilized with 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.

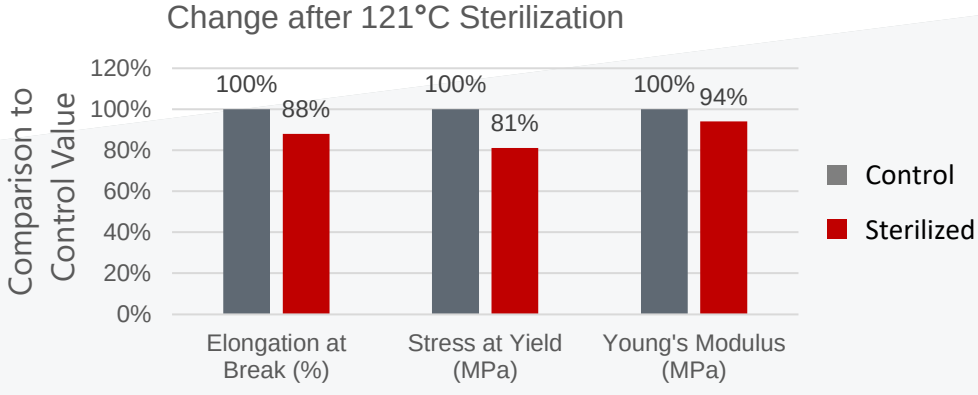
Autoclave Steam Sterilization: 134°C (270°F)

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



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

The tensile results of the sterilized dog bones parts show that the average Young's Modulus value was within the standard deviation of the non-sterilized control samples. The Elongation at Break and Stress at Yield 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 and Stress at Yield, but no significant effect to Young's Modulus.



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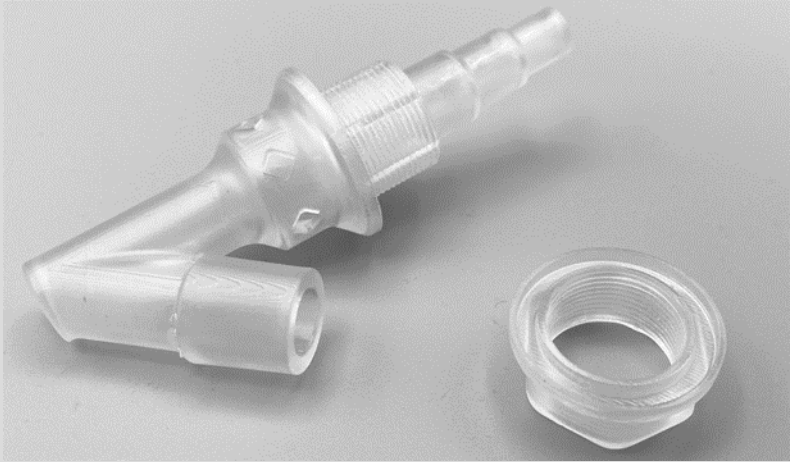
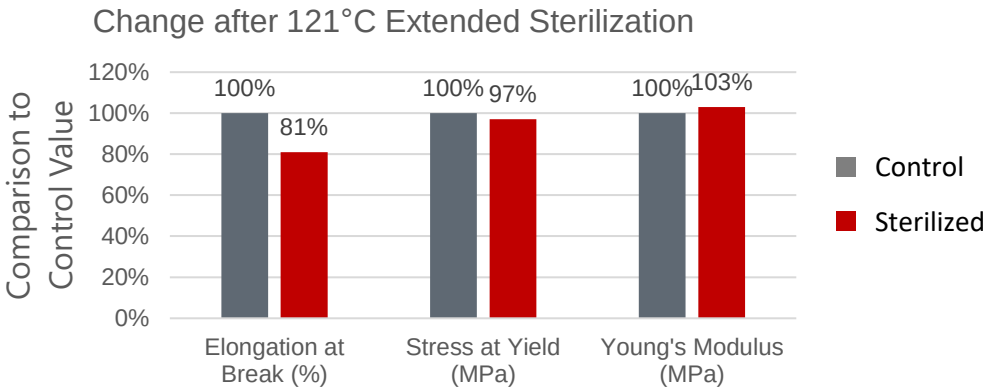


PHYSICAL PROPERTIES OF STERILIZED PARTS

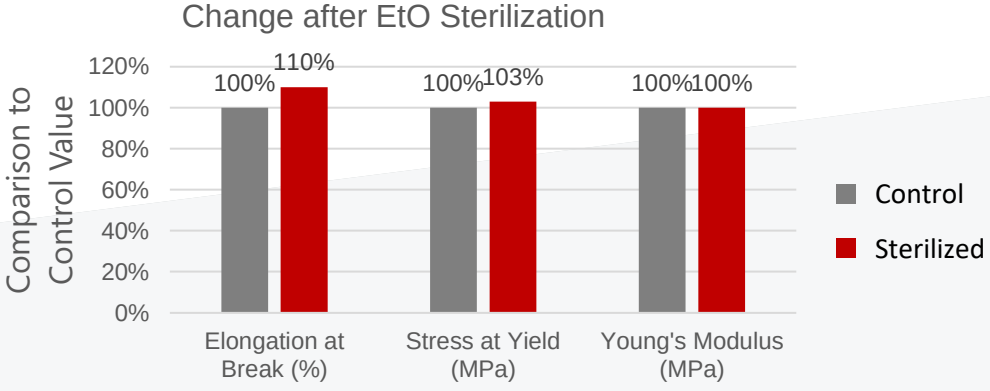
Autoclave Steam Sterilization: 121°C (250°F) Extended Drying

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



Ethylene Oxide (EtO) Sterilization

The tensile results of the sterilized dog bones parts showed that the average Elongation at Break, Stress at Yield, and Young's Modulus values were within 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 MED412 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 MED412 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 MED412 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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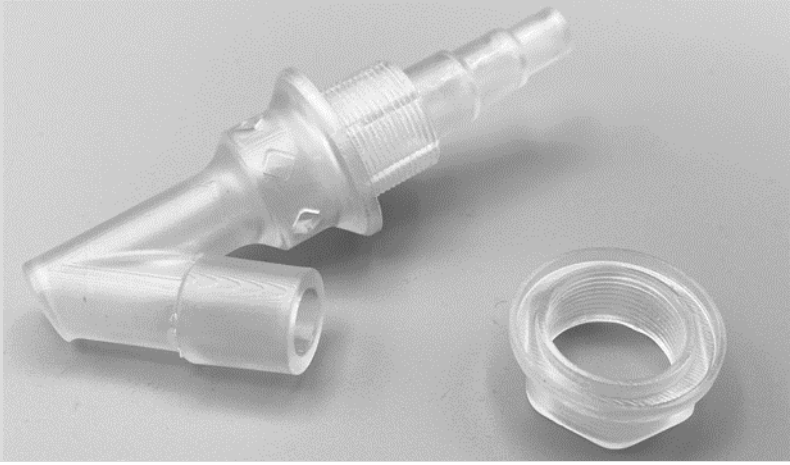

DIRECTIONS FOR STERILIZATION

LOCTITE 3D MED412 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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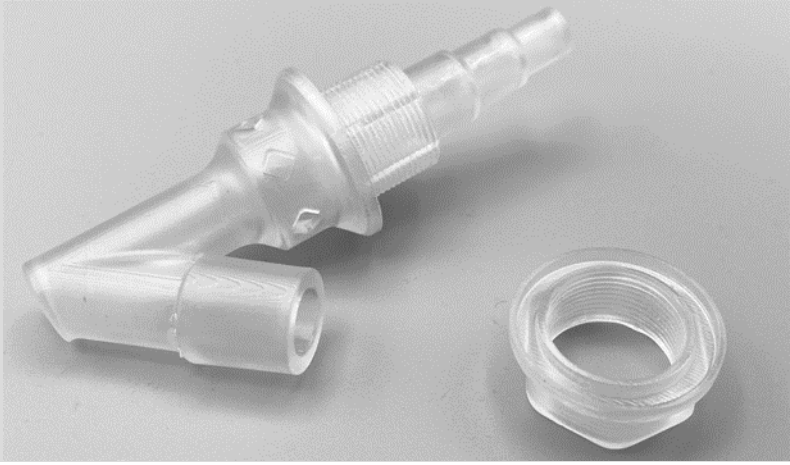

DIRECTIONS FOR STERILIZATION (CONTINUED)

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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Biocompatibility *(Provisional – awaiting legal clearance)*

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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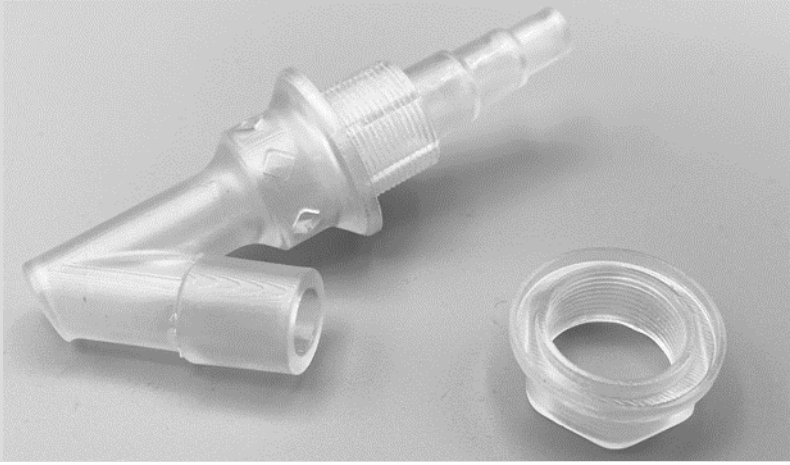

NOTE

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.

Any liability in respect of the information in the Technical Data Sheet or any other written or oral recommendation(s) regarding the concerned product is excluded, except if otherwise explicitly agreed and except in relation to death or personal injury caused by our negligence and any liability under any applicable mandatory product liability law.

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