



LOCTITE®

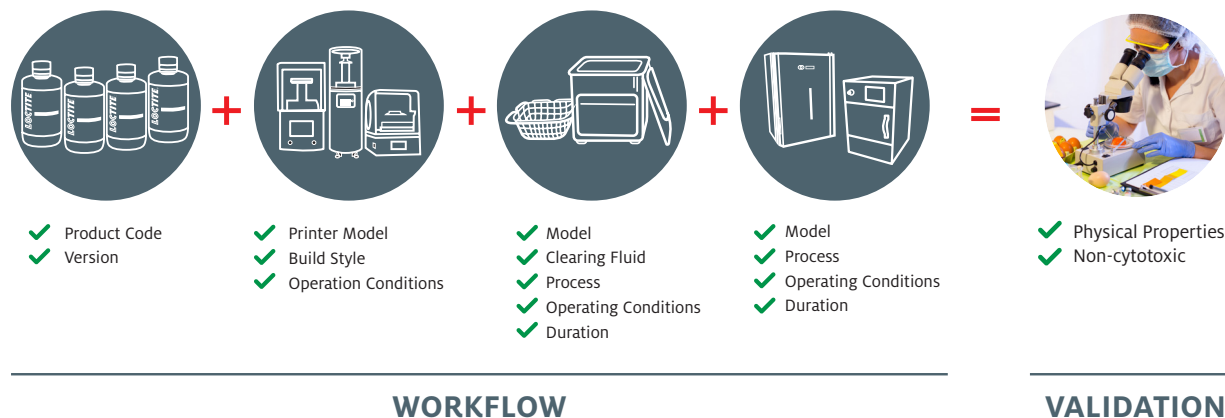
3D PRINTING MATERIAL SOLUTIONS FOR HEALTHCARE

Loctite Additive Manufacturing

Henkel

LOCTITE 3D Printing Resins for Healthcare Applications

MEDICAL WORKFLOW VALIDATIONS



LOCTITE Additive Manufacturing delivers high performance photopolymers with a validated workflow to ensure reproducible, repeatable results are generated in accordance with our Technical Data Sheet and test results. For medical device solutions, it is recommended to consult with the LOCTITE 3D Printing team to ensure the use of a workflow that has been validated for the intended use or specific requirements.

BIOCOMPATIBILITY

The biocompatibility of photopolymers in additive manufacturing (AM) needs to take into account the unique parameters of the manufacturing processes, which can influence the physical, chemical, and biological properties of AM-produced devices. The quality of AM-produced devices may consequently vary when identical parts are built using different materials, 3D printers or even when the same 3D printer, parameters, post processing steps, and materials are used. Here is where the importance of workflow validation comes into focus.

Our resins are validated across multiple DLP printing systems to fit your specific requirements. Biocompatibility (according to ISO 10993-5*, ISO 10993-10* and ISO 10993-23*) is achievable for highlighted resin when they are processed according to a validated workflow.

- **ISO 10993-5:2009*** describes test methods to assess the cytotoxicity of medical devices. These methods specify the incubation of cultured cells in contact with a device and/or extracts of a device either directly or through diffusion. These methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters.
- **ISO 10993-10:2010*** describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and skin sensitization. ISO 10993-10:2010 includes pretest considerations for irritation, including in silico and in vitro methods for dermal exposure, details of in vivo (irritation and sensitization) test procedures and key factors for the interpretation of the results.
- **ISO 10993-23:2021*** describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation. The tests are designed to predict and classify the irritation potential of medical devices, materials or their extracts according to ISO 10993-1 and ISO 10993-2.

Please note that if any part of this workflow changes, a new workflow needs to be validated.

ISO 13485 CERTIFIED QUALITY STANDARD FOR PRODUCTION FACILITY

Henkel's Concord laboratory and Dixon production facilities in California, USA, which are dedicated to developing and manufacturing resins for 3D printing, have achieved ISO 13485:2016 certification. ISO 13485 is an international quality standard that enables medical device manufacturers to specify and implement process and production controls, in addition to providing them with documentation and traceability. In Henkel's case specifically, it covers the design and manufacturing of biocompatible resins and other materials used to produce non-implantable medical devices.

ISO 13485 certification requires an organization to review many aspects of its operations with the goals of identifying, implementing and complying with industry quality standards and practices. Henkel engaged DQS, Inc., to conduct an audit and document a report which confirms its compliance. Areas of emphasis include:

- Design control: All processes involved with product design are identified and documented, including user needs, workflow, design inputs and outputs, verification and validation
- Process and production controls: Managed with a quality management software, including over 2,000 pages of supporting documents
- Change management control: As problems are uncovered over a product's lifecycle, processes are audited and improved to eliminate or minimize the issue
- Product traceability: Cradle to grave visibility and surveillance from raw material to finished resin and from component to final printed part
- Risk management: Each process is documented and analyzed for risk based on probability and severity

With the ISO 13485 certification, Henkel is well positioned to support medical device manufacturers. Customers in that industry can benefit from additive manufacturing and have peace of mind knowing LOCTITE's portfolio of products and validated workflows are designed, developed and manufactured with quality in mind.



LOCTITE 3DP Product Overview

MEDICAL RESINS					
Product		MED412		MED413	
Colour		Clear	White	Clear	White
Packaging		kg 1	kg 1	kg 1	kg 1
HDT at 0.455 (MPa) in °C	ASTM D648	39	39	68	68
Tensile Stress at Break (MPa)	ASTM D638 (D412 ⁵)	37	25	44	43
Elongation at Break (%)	ASTM D638 (D412 ⁵)	110	94	51	52
Young's Modulus (MPa)	ASTM D638	1,305	1,258	1,673	1,817
Flexural Modulus (MPa)	ASTM D790	869	1,196	1,598	1,437
IZOD Impact (Noched, J/M)	ASTM D256	50	49	59	53
Shore Hardness	ASTM D2240	78 D	76 D	79 D	79 D
Biocompatibility	ISO 10993-5	✓	✓	✓	✓
	ISO 10993-10	✓	✓	✓	✓
	ISO 10993-23	✓	✓	✓	✓
Ideal for		Nasal Swabs		Hearing Aids	

¹ For further information please see TDS, contact Technical Service Centre or Customer Service Representative. The physical properties provided in this document are typical results of printed parts and are provided for reference purposes only. ² All data after post-cure. ³ Preliminary test data. ⁴ HDT: Heat Deflection Temperature. ⁵ Test method: D412. ⁶ Stored in metal cans. * Data shown reflects properties from resin highlighted with " * ", for additional information please refer to the respective TDS

LOCTITE 3DP Product Overview

		RESINS TO SUPPORT HEALTHCARE APPLICATIONS					
Product		IND405	3843	3172	IND406	IND402	IND475
Colour		Clear	White	Gray	Black	Black	White
Packaging		1 kg, 5 kg	1 kg, 5 kg	1 kg, 5 kg	1 kg, 5 kg	1 kg, 5 kg	1 kg, 5 kg
HDT at 0.455 (MPa) in °C	ASTM D648	53	60	51	108	-	-
Tensile Stress at Break (MPa)	ASTM D638 (D412 ⁵)	52	49	39	52	6	3.9
Elongation at Break (%)	ASTM D638 (D412 ⁵)	127	48	105	24	230	201
Young's Modulus (MPa)	ASTM D638	1,378	1,720	1,494	1,658	42	2.3
Flexural Modulus ((MPa	ASTM D790	1,500	1,673	1,150	-	-	-
IZOD Impact (Noched, J/M)	ASTM D256	72	58	73	35	-	-
Shore Hardness	ASTM D2240	79 D	70 D	72 D	79 D	76 A	60 A
Biocompatibility	ISO10993-5	✓	✓	✓	✓		
	ISO 10993-10						
	ISO 10993-23	✓	✓	✓	✓	✓	✓
Ideal for		Medical equipment components, Manufacturing aids, Fluid routing prototypes, Consumer goods prototyping	Medical equipment components, Manufacturing aids, Jigs and fixtures, Housings and covers	Medical equipment components, Manufacturing aids, Jigs and fixtures, Housings and covers	Medical equipment components, Manufacturing aids, Jigs and fixtures, Housings and covers	Mid-soles	Seating

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MED412 HDT40

TOUGH HIGH IMPACT RESIN



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.

Benefits

- Full Biocompatibility achievable, ISO 10993 -5, -10 & -23
- Tough with Superb Elongation
- Good Impact Strength and Surface Finish

PROPERTY ¹	METHOD	Ultra Clear	White
Colour	-	Ultra Clear	White
Tensile Stress at Break (MPa)	ASTM D638	37	25
Elongation at Break (%)	ASTM D638	110	94
Young's Modulus (MPa)	ASTM D638	1,305	1,258
HDT at 0.455 MPa	ASTM D648	39	39

Note

- 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 for Use with the proper regulatory authority
- Strict adherence to our Instructions for Use and Validated Workflow is critical in assuring a safe, bio compatible and effective printed appliance
- Henkel resins may not be used in applications that are Class III medical devices and/or involve implantation in the human body.

¹ All data after post-cure in accordance with TDS.

² % value of visible light through a 3D printed object (standard 7.0 mm block).

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Case Study: 3D Printed Nasopharyngeal (NP) Swab

RAPID AGILITY AND INNOVATION



Challenge

- Depleting supplies of NP Swabs impacting ability to test patients for Covid-19 during pandemic
- Demand on supply resulting in longer lead times
- Supply Chain ability to respond to rapidly changing situation limited
- Fabrication of material that does not contain any DNA to impact test

Solution

- Consultative Process to address
 - Lattice Structure Design to drive effective nasal secretion collection
 - Post process requirements
 - Sterilization techniques matched to Henkel resin
- Resin high print accuracy & function (flexural & tensile)
- Ability to validate an FDA approved 3D printed Medical Device in short time frame

Benefit

- FDA Registered Device
- Clinically validated for Safety & Conformance
- Able to print thousands of parts per week

MED413 HDT60

TOUGH HIGH ACCURACY RESIN



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.

Benefits

- Full Biocompatibility achievable, ISO 10993 -5, -10 & -23
- Parts can function at body temperature
- Outstanding surface finish
- Excellent machineability

PROPERTY ¹	METHOD		
Colour	-	Clear	White
Tensile Stress at Break (MPa)	ASTM D638	44	43
Elongation at Break (%)	ASTM D638	51	52
Young's Modulus (MPa)	ASTM D638	1,673	1,817
HDT at 0.455 MPa	ASTM D648	68	38

Note

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Case Study:

End-Use Part for Head Lice Treatment

REDUCE DEVELOPMENT AND PRODUCTION COSTS



Photos source: Enventys Partners

Challenge

- Designing and manufacturing a new head lice treatment device offering a better user experience with improved ergonomics for technicians.
- Demand for 200-300 devices annually, and each device requiring many plastic components, the costs were unjustified.
- Achieve cost-savings without sacrificing product quality.

Solution

- LOCTITE 3843, IND403 and MED413 matched the requirements for toughness, temperature and color needs, providing high part dimensional stability and an exceptional surface finish.
- The final material is also sterilizable, allowing FloSonix to reusable tips for head lice treatment.

Benefit

- Component consolidation, adding assembly features, and final tuning parameters
- Initial prototyping and end-use manufacturing accomplished on a single printing platform (Origin)

IND405 HDT50

HIGH IMPACT, HIGH ELONGATION RESIN



Rigid, high elongation and high tough one-part material with excellent surface finish properties. Properties are comparable to an unfilled thermoplastic like Polypropylene (PP).

Benefits

- Basic Biocompatibility achievable, ISO 10993 -5/-23 passed
- High impact resistance with high elongation
- Easy to print (one-part material)
- Tough and Durable

PROPERTY ¹	METHOD	
Colour	-	White
Tensile Stress at Break (MPa)	ASTM D638	52
Elongation at Break (%)	ASTM D638	127
Young's Modulus (MPa)	ASTM D638	1,378
HDT at 0.455 MPa	ASTM D648	53

Note

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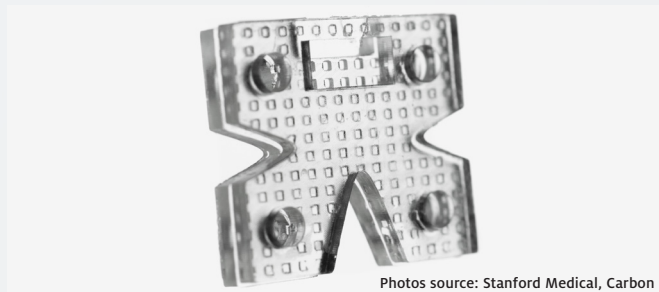
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Case Study:

Mechanical Testing Fixture

STANFORD MEDICAL



Photos source: Stanford Medical, Carbon

Challenge

- Needed to develop a transparent 'holder' for heart leaflet tissue subject to mechanical testing
- Need high resolution, to ensure the heart leaflet tissue is adequately sandwiched between the 'holders' in order to mimic physiological conditions (adequate tension)

Solution

- Mechanical Testing Fixture printed with LOCTITE 3D IND405 Clear withstood the stress of mechanical testing without bending or cracking

Benefit

- High resolution with small indentations and rectangular protrusions (0.5mm x 0.5mm x 0.5mm across a flat surface)
- Great accuracy
- Hands on visualization in the prototyping process

3843 HDT60 HIGH TOUGHNESS

TOUGH HIGH IMPACT RESIN



Semi-flexible resin with moderate temperature resistance, high impact strength, and versatility for a broad range of applications. Ideal for a wide variety of tooling applications on the production floor.

Benefits

- Basic Biocompatibility achievable, ISO 10993 -5/-23 passed
- Moderate heat resistance, HDT 60° C
- Tough with outstanding surface finish
- Superior strength and impact resistant

PROPERTY ¹	METHOD	
Colour	-	White
Tensile Stress at Break (MPa)	ASTM D638	49
Elongation at Break (%)	ASTM D638	48
Young's Modulus (MPa)	ASTM D638	1,720
HDT at 0.455 MPa	ASTM D648	60

3172 HDT50 HIGH IMPACT

TOUGH & HIGH IMPACT RESIN



Durable photopolymer resin that enables functional parts production where high stiffness with a good surface finish and high impact resistance are required. Parts manufactured with this resin can be machined, tapped or polished.

Benefits

- Basic Biocompatibility achievable, ISO 10993 -5/-23 passed
- Tough & durable
- Superior impact strength
- Nice surface finish, machine-able

PROPERTY ¹	METHOD	
Colour	-	Gray
Tensile Stress at Break (MPa)	ASTM D638	39
Elongation at Break (%)	ASTM D638	105
Young's Modulus (MPa)	ASTM D638	1,494
HDT at 0.455 MPa	ASTM D648	51

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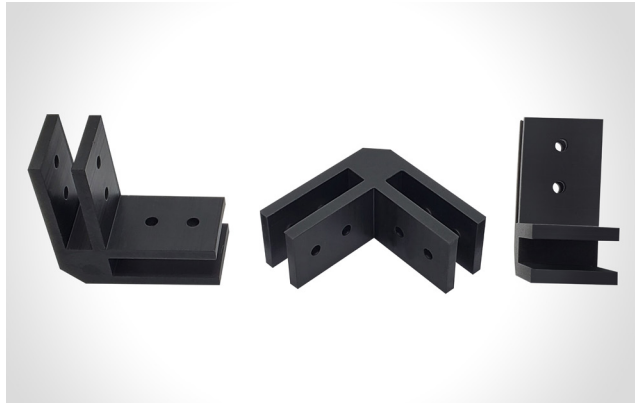
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IND406 HDT100 HIGH ELONGATION

OUR TOUGHEST HIGH TEMPERATURE RESIN



Tough resin designed for interior applications in Automotive, due to its high surface quality, dimensional accuracy and temperature resistance.

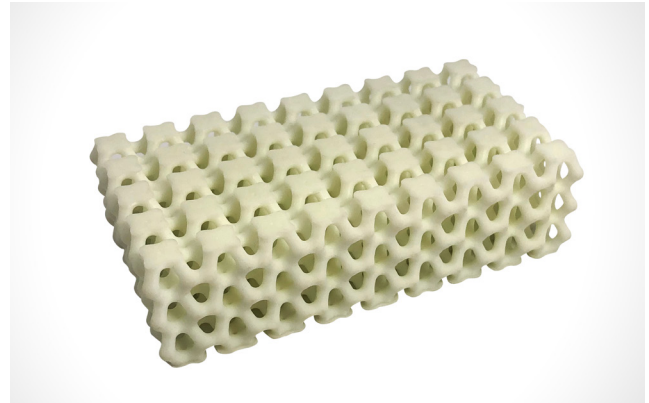
Benefits

- High heat deflection temperature, HDT >100 °C
- Tough and durable
- Good surface finish
- Safe to touch (ISO 10993-23 passed)
- Basic Biocompatibility achievable, ISO 10993 -5/-23 passed

PROPERTY ¹	METHOD	
Colour	-	Black
HDT at 0.455 MPa	ASTM D648	108°C
Tensile Stress at Break (MPa)	ASTM D638	52
Elongation at Break (%)	ASTM D638	24
Young's Modulus (MPa)	ASTM D638	1,658
IZOD Impact (Noched, J/m)	ASTM D256	35
Shore Hardness (D)	ASTM D2240	79

IND475 A60 HIGH REBOUND

EASY TO PRINT



An industrial strength UV resin that cures to a soft, elastomeric material. IND475 is suitable for applications where resilience, snap back, and tear resistance is desired, such as lattice structures and functional prototyping. This single component resin is easy to print of a variety of platforms, making it a superior material for elastomeric applications.

Benefits

- True elastomeric behavior
- Fast Printing with low shrinkage behavior
- High resilience / High energy return
- Exceptional durability compression forces
- For White color version - Safe to touch (ISO 10993-23 passed)

PROPERTY ¹	METHOD	
Colour	-	White, Black & Gray
Tensile Stress at Break (MPa)	ASTM D638	3.9
Elongation at Break (%)	ASTM D638	201
Young's Modulus (MPa)	ASTM D638	2.3
Shore Hardness (A)	ASTM D2240	60

Note

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IND402 A70 HIGH REBOUND

HIGH REBOUND ELASTOMERS



Single component elastomer material with high elongation and high resilience, excellent tensile strength and high energy return while also not requiring thermal post processing.

Benefits

- True elastomeric behavior
- Excellent interlayer adhesion
- Good rebound performance
- For Black color version - Safe to touch (ISO 10993-23 passed)

PROPERTY ¹	METHOD	
Colour	-	Black
Tensile Stress at Break (MPa)	ASTM D638	6
Elongation at Break (%)	ASTM D638	230
Young's Modulus (MPa)	ASTM D638	42
Energy Return (J/m)	Internal method	33
HDT at 0.455 MPa	ASTM D2240	76

Note

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SUMMARY

- Every application has its own unique requirements, and we are here to support your journey towards additive manufacturing at industrial scale
- LOCTITE offers you a broad material portfolio of general purpose, high impact, high temperature resistant and elastomeric resins for a broad range of leading DLP systems
- We work with industry leaders and equipment manufacturers to ensure our materials are validated within a qualified industrial workflow
- LOCTITE materials allow you to produce functional, repeatable and reliable parts



Value for You



Promise of LOCTITE Branding

We leverage decades of industrial experience of solving real manufacturing challenges, across markets



Technology Experts

We are the photopolymer technology experts



Trusted Eco-System Partners

We work with ecosystem partners like service bureaus, OEM printer partner and experts in post processing to ensure production of functional, repeatable and reliable parts



Validation

Unlocking Customer Readiness with validated

- Workflows
- Materials properties/ customization
- Parts design
- Quality management system



Test your application with our materials.

Contact our engineers to get support:
Loctite3DP@henkel.com

Learn more about our application cases.
Visit [LoctiteAM.com](https://www.loctiteam.com)

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