formlabs | healthcare

Accelerating Medical Device Time to Market

Industrial 3D Printers with **Surgical Precision**

3DZ

Print the Future

www.3dz.group.com

The Formlabs Advantage

ACCELERATE PRODUCT DEVELOPMENT

Eliminate outsourcing costs by prototyping in hours instead of days. Leverage functional, medical-grade materials for clinical validation.

INCREASE SPEED TO MANUFACTURING

Achieve the quality of injection molding without costly tooling or long lead times. Produce biocompatible, sterilizable devices for end-use production.

DELIVER PATIENT-MATCHED DEVICES

Print affordable, patient-matched surgical tools, reducing costs and improving patient outcomes.

OPTIMIZE INVENTORY COSTS

Reduce inventory costs and streamline supply chains with on-demand, cost-effective surgical tool production.

CLINICAL VALIDATION AND MATERIAL EXPERTISE

Our technology has been validated in numerous FDA- and MDR-cleared workflows and processes. We manufacture our own biocompatible, sterilizable medical materials in an FDA-registered, ISO 13485-certified facility.

REGULATORY SUPPORT AND FDA RECOGNITION

Regulatory clearance can be the difference between medical product success and failure. We offer RA/QA support, including IQ/OQ/PQ documentation – so you can go from concept to clearance and commercialization faster, more affordably, and with less risk.

NEED HELP OBTAINING FDA CLEARANCE?

Find out how much time and money you'll save with Formlabs.

"We are uniquely capable of delivering true just-in-time products because of our in-house manufacturing and the ability to quickly tune design and geometry based on feedback from the field. With directly printing single-use instruments, we're able to iterate and revise our designs pretty nimbly."

Cambre Kelly, Chief Technology Officer, restor3d

Resin-Based Stereolithography (SLA)

Powered by our patented Low-Force Stereolithography (LFS)™ – an advanced form of stereolithography (SLA) resin 3D printing that captures unprecedented detail and surface quality

Form 4B

BLAZING SPEED MEETS SURGICAL PRECISION FROM THE DESKTOP

Form 4B is our medical-grade desktop 3D printer designed to rapidly deliver functional, biocompatible, and sterilizable devices that fit perfectly, every time. Equipped with a 30% larger build platform, 4x more speed, and our Low Force Display™ (LFD) print engine, Form 4B offers unparalleled throughput by curing each layer of resin quickly, regardless of part quantity or size. Embrace the future of personalized care with Form 4B.

Form 4BL

SPEED AT SCALE. LARGE FORMAT 3D PRINTING YOU CAN DEPEND ON.

Built on our next-generation Low Force Display print engine, the Form 4BL unlocks extreme speed, reliability, and print quality. Produce large medical devices and life-size anatomical replicas in under 6 hours. The Form 4BL is our large-format printer for biocompatible applications, compact enough for the clinic and robust enough for the factory floor.

Trusted by Industry Leaders

FORMLABS IS THE TRUSTED CHOICE OF 17 OUT OF THE TOP 20 MEDICAL DEVICE COMPANIES ACROSS THE GLOBE.

"We have been running six Formlabs machines, and the impact has been profound. Our rate of prototyping has quadrupled, costs have been reduced by 60%, and the level of print detail allows for clear communication of designs with orthopedic surgeons. We have also been able to reduce the cost of some production fixture applications by 80%. No other printing technology we evaluated combined reliability, cost-effectiveness, and quality in the same way. Formlabs has revolutionized our workflow."

Alex Drew, Engineering Manager, Enovis

45+ SLA Materials

FEATURED BIOCOMPATIBLE & STERILIZABLE MATERIALS

Formlabs SLA Resins are ultra-low odor and free from ACMO, a potentially hazardous chemical often present in lower-cost resin and 3D printing solutions. For more information on the risks associated with ACMO, visit Formlabs.com.

FORMLABS OPEN PLATFORM

Maximize the potential of your Formlabs 3D Printer. Print with certified third-party resins, custom print settings for tailored print performance, or the ability to experiment with any 405 nm photopolymer resin.

BioMed Clear Resin	Transparent, Rigid, Strong
BioMed Durable Resin	Clear, High Impact, Abrasion Resistant
BioMed Elastic 50A Resin	Elastomeric, Soft, Shore 50A
BioMed Amber Resin	Transparent Amber, Rigid, Strong
BioMed Flex 80A Resin	Elastomeric, Flexible, Shore 80A
BioMed White Resin	White, Opaque, Rigid
BioMed Black Resin	Black, Opaque, Rigid

Resin Biocompatibility

Contact Type	Skin	Mucosal Membrane	Bone, Tissue, & Dentin	Pharmaceutical Containers, Drug Delivery & Medical Device Components	Mucosal Membrane	Breathing Gas Pathways	Sterilization Compatibility
Contact Duration	> 30 days	< 24 hours	< 24 hours		>30 hours	>30 hours	
Application ISO Standard	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	USP <151> Pyrogen ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-23	USP <88> Class VI	EN ISO 10993-1 EN ISO 10993-3 EN ISO 10993-5 EN ISO 10993-10 EN ISO 10993-11 EN ISO 10993-23	ISO 18562-2 ISO 18562-3	
BioMed Clear*	✓	✓	✓	✓	✓	✓	Steam, Gamma, EtO, E-Beam, VHP
BioMed Durable*	✓	✓	✓	✓	✓		Steam
BioMed White	✓	✓	✓	✓			Steam, Gamma, EtO,E-Beam
BioMed Amber	✓	✓	✓				Steam, Gamma, EtO, E-Beam, VHP
BioMed Black*	✓	✓		✓			Steam, Gamma, EtO,E-Beam
BioMed Flex 80A	✓	✓					In Progress
BioMed Elastic 50A	✓	✓					Disinfection

*Formlabs holds Master Device Files (MAF) with the FDA and can grant authorization for use upon request.
The data above indicates the extent of the testing conducted by Formlabs.
VHP testing was conducted independently by Steris.

Selective Laser Sintering (SLS)

Truly rapid Selective Laser Sintering (SLS) fuses polymer powder into industrial-quality, print-in-place parts without any need for supports.

Fuse 1+ 30W

TRULY RAPID SLS 3D PRINTING FOR HIGH PERFORMANCE PARTS IN HOURS, NOT DAYS

Equipped with unmatched ease of use and affordability, the Fuse 1+ 30W empowers you to start 3D printing customized, high-performance, and cost-effective medical-grade products in-house, including prosthetics, orthotics, and other patient-specific devices. Create parts with comfort and performance for patients, improving quality of life, and streamlining the medical device manufacturing process.

Fuse Sift

ALL-IN-ONE POWDER RECOVERY FOR THE FUSE SERIES

The Fuse Sift serves as the ultimate companion to Fuse Series SLS printers by providing an all-in-one solution that effortlessly handles powder recovery, part extraction, and material storage and mixing. Its negative air pressure system and integrated vacuum hose ensure mess-free post-processing. Automate powder dispensing and mixing to reduce waste and lower cost per part. With Fuse Sift, SLS printing is more efficient and streamlined.

Fuse Blast

FULLY AUTOMATED SLS POST-PROCESSING SOLUTION

Fuse Blast seamlessly integrates into the Fuse Series ecosystem and streamlines your post-processing workflow, empowering you to clean a whole build chamber of printed parts within 15 minutes. Deliver consistently professional parts that are clean to the touch with a fully automated workflow that reduces overhead costs and labor time by 80%. Elevate your parts with a smooth, semi-gloss, and dye-ready surface finish with an optional polishing system.

SLS Materials

NYLON 11
POWDER

High Ductility, Impact Resistant Parts

Nylon 11 Powder is our high-performance material that boasts high ductility and reduces brittleness. You can print thin walls, making it ideal for functional prototyping and resilient end-use parts, such as insole inserts.

Tensile Strength	49 MPa
Izod Impact Strength	71 J/m
Elongation at break (X/Y)	40%

NYLON 12 TOUGH
POWDER

A Material That Does It All with a Best in Class Refresh Rate of 20%

Balancing strength and detail, Nylon 12 Tough Powder is a highly capable, biocompatible material for both functional prototyping and end-use production of complex medical devices and durable parts. It is also compatible with several sterilization methods, including steam.

Tensile Strength	42 MPa
Tensile Modulus	1450 MPa
Elongation at break (X/Y)	25%

NYLON 12 WHITE
POWDER

Durable, Biocompatible, and Dyeable Parts

Nylon 12 White Powder enables colored end-use parts, that maintain the versatile and biocompatible properties of Nylon 12 Powder. Capable of printing highly detailed features with great dimensional accuracy.

Tensile Strength	47 MPa
Tensile Modulus	1950 MPa
Elongation at break (X/Y)	8%

POLYPROPYLENE
POWDER

Durable, Ductile, Weldable

Produce genuine polypropylene (PP) parts for prototypes and durable end-use parts that are chemically-resistant, weldable, and watertight. PP offers high ductility without the need for inert atmospheric control.

Tensile Strength	29 MPa
Izod Impact Strength	1640 MPa
Elongation at break (X/Y)	34%

TPU 90A
POWDER

A Tough SLS Elastomer for Resilient, Skin-Safe Products

Create flexible TPU parts with unmatched design freedom and ease. TPU 90A Powder enables you to produce flexible, skin-safe prototypes and end-use parts that withstand the demands of everyday use – all at a low cost per part thanks to a 20% refresh rate.

Tensile Strength	8.7 MPa
Elongation at break (X/Y)	310%
Elongation at break (Z)	110%

NYLON 11 CF
POWDER

Carbon Fiber for Strong, Stiff and Lightweight Parts

NYLON 12 GF
POWDER

Stiff, Stable, Functional Parts

NYLON 12
POWDER

An All-Around General Purpose Material

* SLS Powders available now, many other materials are in development.

Powder Biocompatibility

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Nylon 11 Powder	✓	✓					
Nylon 11 CF Powder	✓	✓					
Nylon 12 Powder	✓	✓	✓				Steam, Gamma, Et0,E-Beam
Nylon 12 Tough Powder	**BIOCOMPATIBILITY TESTING IN PROGRESS**						
Nylon 12 White Powder	**BIOCOMPATIBILITY TESTING IN PROGRESS**						In Progress
Nylon 12 GF Powder	✓	✓					
TPU 90A Powder	✓	✓					Disinfection
Polypropylene Powder	✓	✓					

Technical and Hardware Specifications

SPECIFICATIONS	Form 4B	Form 4BL	Fuse 1+ 30W
TECHNOLOGY	Masked Stereolithography (MSLA)	Masked Stereolithography (MSLA)	Selective Laser Sintering (SLS)
LIGHT SOURCE	Backlight Unit (LEDs) and collimating lenses 405 nm optical wavelength 50 microns pixel size	Backlight Unit (LEDs) and collimating lenses 405 nm optical wavelength 50 microns pixel size	Ytterbium Fiber 30W laser 1070 nm wavelength 247 microns laser spot size
BUILD VOLUME	20.0 × 12.5 × 21.0 cm 7.9 × 4.9 × 8.3 in	35.3 × 19.6 × 35.0 cm 13.9 x 7.7 x 13.8 in	16.5 x 16.5 x 30.0 cm 6.5 x 6.5 x 11.8 in
LAYER THICKNESS	25 - 200 microns	25 - 200 microns	110 microns (0.001 - 0.012 in)
MATERIALS	45 Formlabs Resins, including biocompatible, or third-party materials using Open Platform	37+ Formlabs Resins, including biocompatible, or third-party materials using Open Platform	8 Formlabs Powders
RESIN TANK ESTIMATED LIFETIME	75,000+ layers with any Formlabs material	75,000+ layers with any Formlabs material	Not applicable
PRINTER DIMENSIONS (W x D x H)	39.8 × 36.7 × 55.4 cm 15.7 × 14.5 × 21.9 in	66.4 x 52.8 x 79.4 cm 26.1 x 20.8 x 31.3 in	64.5 × 68.5 × 107 cm (165.5 cm with stand) 25.4 × 27.0 × 42.0 in (65.0 in with optional stand)
SUPPORTS	Auto-Generated, Light-Touch Removal	Auto-Generated, Light-Touch Removal	No supports required
VENTILATION	None Required	None Required	None Required
POWER REQUIREMENTS	100–240 VAC 4.8A 50/60HZ 480W	100–240 VAC 9A 50/60HZ 900W	EU: 230 VAC, 7.5 A (dedicated circuit) US: 120 VAC, 15 A (dedicated circuit)

"Because this is a Class II device, an implant, the threshold for product release was pretty high. So we did have to do a very detailed human factor study, and we did that fully with the 3D printed parts. Some companies might have to wait until they actually have the injection molded parts to do human factor study, but we were able to save three to four months by 3D printing."

Radu Postole, Product Design Lead, Arbutus Medical

Not convinced yet?

LEARN HOW MEDICAL PROFESSIONALS HAVE BEEN ADVANCING HEALTHCARE USING FORMLABS 3D PRINTING SOLUTIONS.

Transforming Surgery with 3D Printed, Single-Use Devices: How restor3d is Revolutionizing Surgery

The restor3d team drives innovation in precision surgery by changing the way implants, surgical instruments, and preoperative models are developed and utilized. Traditional instrumentation systems are slow to evolve, have significant upfront costs, and often present complications in the surgical workflow. restor3d leverages 3D printing capabilities to drastically improve surgical care delivery by printing procedure-specific and often patient-specific metal implants and polymer instrumentation.

Concept to Commercialization in Four Months: How Arbutus Medical Utilized 3D Printing for Rapid Device Development

Arbutus Medical leverages Formlabs 3D printers to speed up medical device development and human factors testing. This fast-tracks prototypes, supports clinical validation, and provides immediate stopgap production, ensuring quicker market entry and enhanced patient care. Formlabs technology offers a streamlined, efficient solution for rapid innovation and validation in medical device manufacturing.

3D Printing Patient-Specific Cutting Guides With ISO-Certified Materials

The Aarhus University Hospital's 3D Innovation Center in Denmark uses 3D printing with BioMed Clear Resin, a highly validated biocompatible material, to create patient-specific surgical guides. This approach enhances surgical precision, minimizes radiation exposure, and aids in replicating a patient's cranium for improved surgical planning and outcomes. Joakim Lundtoft Lindhardt, the lab's leader, emphasizes the critical role of 3D printing in healthcare.

Digitizing Insole Production With SLS 3D Printing

Kriwat GmbH, an orthopedic medical provider in Germany, has revolutionized insole production by using selective laser sintering (SLS) 3D printing. Their traditional workflow required foam molds and chemicals, leading to a laborious and messy process for both the customer and provider. Michael Kriwat's son, Lais Kriwat, developed a digital workflow for insole production that minimized contact with chemicals and addressed the challenge of the industry's shortage of skilled labor. Kriwat GmbH is now producing 10,000 pairs of insoles annually with 3D printing.