formlabs | medical

Formlabs Medical

3D Printing Applications for Hospitals and Patient-Specific Procedures

A Proven Treatment For The Future of Healthcare

Every medical facility should have access to the latest tools to improve care and provide the best patient experience. Whether you are expanding your in-house production, or just looking to get started, 3D printing is a proven, cutting-edge technology for a wide range of medical applications.

Contents

Your Partner, From Firsthand Insight to Standard of Care

Your medical facility has to be ready for anything. Formlabs 3D printing helps you provide on-demand, customized care through more effective workflows, patient-matched surgical tools, and visual aids for diagnosis and education, so the clinical innovators on the front lines can provide quick solutions to even the most unconventional problems.

As Adaptable As You Are

The most creative, versatile doctors are the ones who change the world, one patient at a time. Formlabs offers an end-to-end 3D printing solution for any anatomy that comes in the door, with a wide variety of materials and applications available on a single 3D printer, the Form 3B. Our technology has been validated in FDA-cleared workflows and we develop and manufacture our own materials.

CARDIAC SURGERY

Conduit bypass models, coronary fistulas, RVOT, VSD, ASD, DORV, LAA, hypoplastic hearts

NEUROSURGERY

Skull- and brain-based (glioma) tumors, cerebral aneurysms, and neurotrauma

ORTHOPEDIC SURGERY

Foot and ankle, shoulder, hand, hip, lower limb, scoliosis, pediatric, and trauma cases

MAXILLOFACIAL SURGERY

Orbital tumors, neurological and maxillofacial trauma, orbital floor reconstructions, mandibular reconstructions

SURGICAL ONCOLOGY

Prostate, renal, and brain cancers, bone and soft tissue neoplasm, and pediatric tumors

PEDIATRIC SURGERY

Congenital heart disease, cleft palate, scoliosis, and vascular malformations

Formlabs is trusted by leading healthcare organizations

Note: Institutions on this list have spoken publicly about use of Formlabs technology and/or published clinical research that utilized Formlabs. Use of logos does not imply endorsement.

Hospital Applications

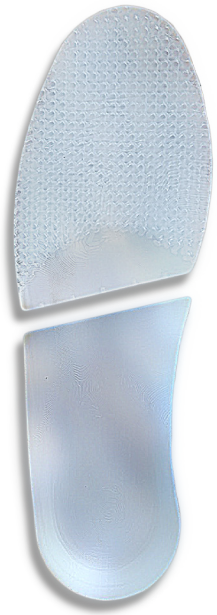
From cardiac surgery to pediatric care, 3D printing has seen rapid adoption in hospitals, powering custom healthcare solutions in multiple departments. The next few pages highlight some of the most prevalent applications.

Formlabs is committed to advancing healthcare, not just selling a printer. Formlabs is actively involved in medical advisory committees, along with developing regulatory guidelines, and providing medical-specific services and resources. SLA 3D printing technology has been validated in FDA-cleared workflows and we develop and manufacture our own materials. As hospital applications continue to expand, Formlabs is committed to serving your needs and creating new materials for doctors.

Orthotics & Assistive Devices

It is possible, for the first time, to create custom, made-tofit orthoses which are accessible, affordable, and effective.

Both (stereolithography) SLA and selective laser sintering (SLS) printed devices can be used for customer orthotics. SLS devices, such as the upcoming Formlabs Fuse 1 printer, use nylon powder to create lightweight, robust parts. These devices are superior, in both form and function, to decades old casting methods still employed in the field.



CASE STUDY

Father Helps Son With Cerebral Palsy Walk With Custom 3D Printed Orthosis

In this story, learn how Matej helped his son Nik, born with cerebral palsy, to walk with the aid of custom made assistive devices. Orthoses on the market today are generally uncomfortable to wear and only high-end, expensive models offer a custom-fit. Custom devices can cost thousands of dollars and take weeks for patients to receive. After months of research and experimentation, Matej pieced together an innovative new workflow that is now patent pending:

- The patient's feet are placed on a vacuum bag in the corrected, weight-bearing (i.e. standing) position.
- The feet are 3D scanned from the top, and the footprints are scanned from the vacuum bag using an affordable structure scanner that is mounted on an iPad.
- The scan data is merged and cleaned to produce an accurate representation of the patient's foot.
- The custom-made orthosis is designed directly on the scanned foot in CAD software.
- The orthosis is 3D printed in high resolution using a Formlabs stereolithography 3D printer and Durable Resin.

The current solutions are generally uncomfortable to wear and have a tendency to cause pain and skin irritations—often so much that children are unwilling to use them. Prices can easily run into the four figures, making orthoses cost prohibitive for most families, even those with top-tier insurance coverage. The issue is compounded as children outgrow the orthoses as quickly as they outgrow clothing.

The first prototype Matej designed reached almost to the knee, just like traditional AFOs. He realized that this only hindered his son from walking more freely. He quickly iterated and designed a prototype that was barely taller than an insole, and fit entirely within a shoe. Often, patients who wear traditional AFOs are also forced to buy special extrawide shoes, which are hard to find for children. At last, prototype number 13 was a full success.

READ MORE

Patient-Specific Anatomical Models

A proven use case for 3D printing in hospitals focused on patient-specific anatomical models.

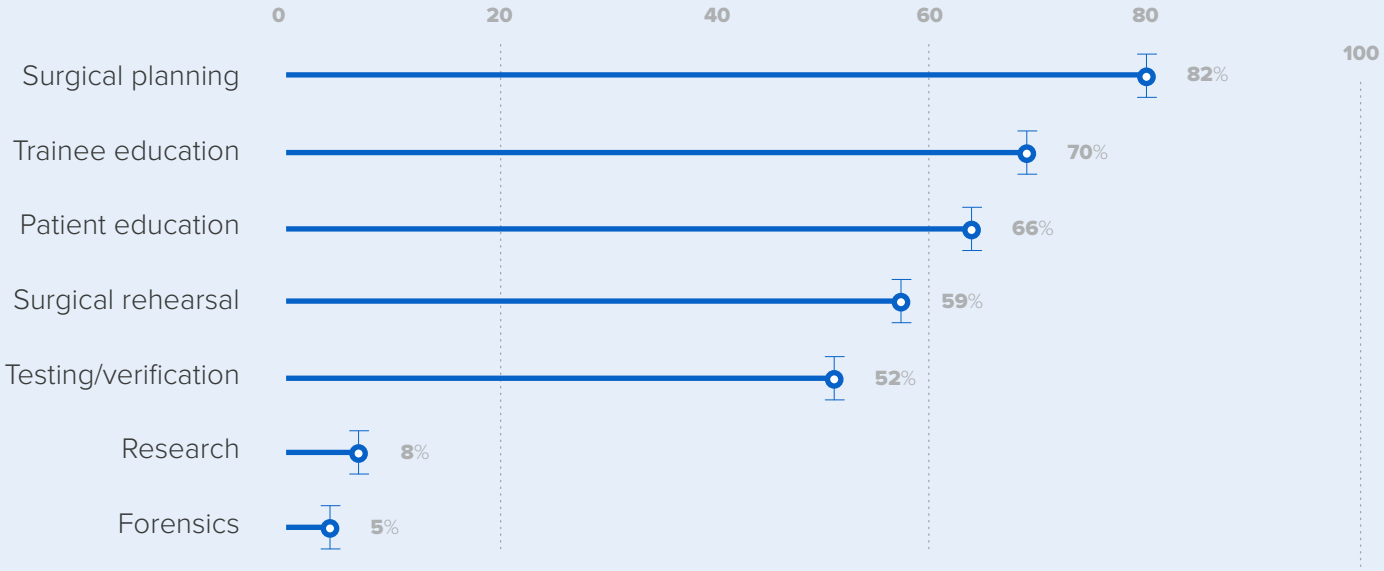
Each patient is unique in their own way, and surgery often requires a different approach in both diagnosis and treatment. As a result, there is a growing demand for custom and patient-specific medical applications across the globe that can provide clinicians with bespoke treatment solutions.

Coupled with a patient's CT or MRI scan, doctors can use segmentation software to create 3D models. Then, these models can be sent directly to a 3D printer.

Printed anatomical models can serve multiple critical purposes. One can be used directly in surgery in the form of cutting guides. Other times, the models can be used for patient education in order to help visualize what steps are necessary in an upcoming surgery. See the chart below for more use cases:

3D printed anatomical models in surgery significantly reduce operating time, improving patient care and limiting risk to the individual.

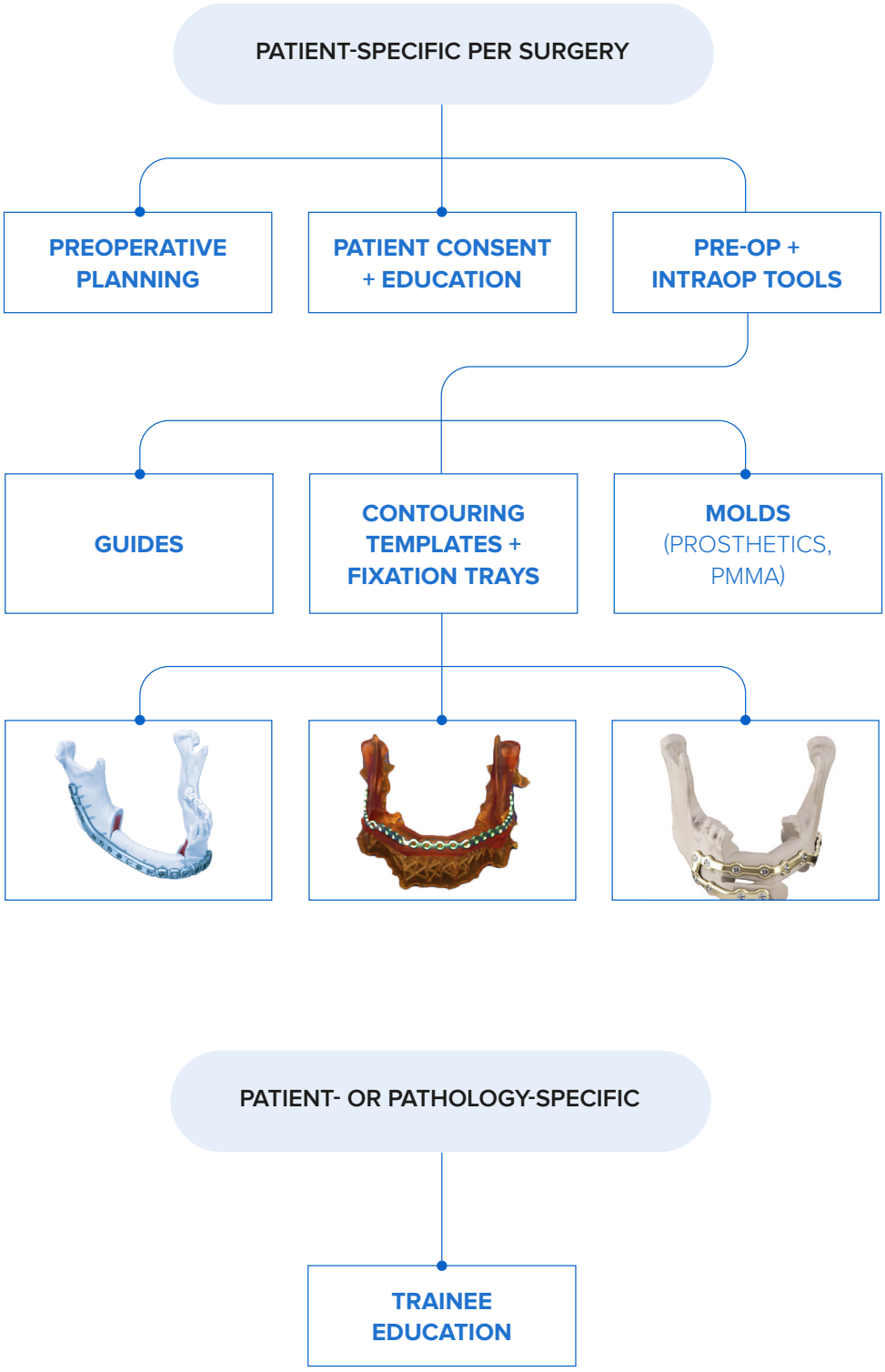
Most Common Uses of 3D-Printed Anatomical Models



Source: SME Medical Working Group, Medical Manufacturing Innovations Annual Report, 2018

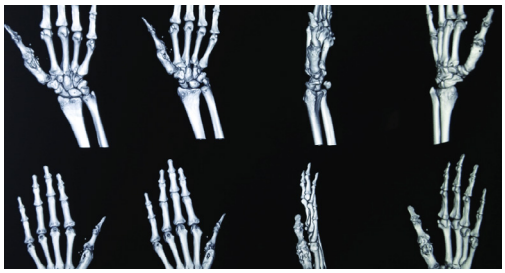
PUBLISHED USES

Patient-Specific Anatomical Models in Surgery



PUBLISHED USES

Workflow can be conducted within the institution or outsourced

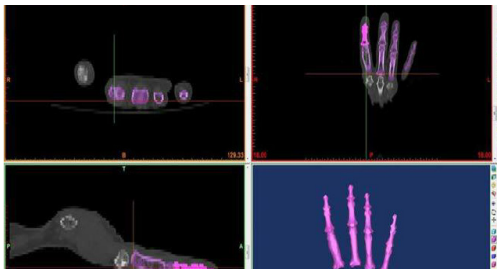


STEP 1

Scan the patient's anatomy

Collect unique patient data via CT or MRI scan, depending on the tissue, to obtain a DICOM file.

GE Healthcare



STEP 2

Segment the digital image

Turn your scan into a 3D printable model. Review the case, segment the digital image, and export an STL or OBJ file of the anatomical part.

materialise axial3D 3DSlicer

STEP 3

Print your model

Upload your file to our intuitive print preparation software, PreForm, set up your print in a single click, and send it to the Form 3B. Produce high-quality parts without any specialized training.

STEP 4

Post-processing, simplified

Stereolithography 3D prints require support removal, rinsing, and post-curing. We've made every step of the process as easy as possible, with light-touch supports and our automated post-processing system, Form Wash and Form Cure.

STEP 5

Sterilize for use

Many Formlabs materials are sterilizable, including our biocompatible materials. Follow the guidelines for your material and equipment to sterilize your final part.

STERIS

Supply Chain Shortages

For the healthcare system, supply chain shocks can cause immense disruption of patient care, as reduced levels of PPE and vital equipment required to treat patients halts surgery and basic care.

Having a in-house 3D printed offer a range of benefits in emergency situations, helping fill the gaps in PPE and medical device shortages. Benefits include:

- Produce items on site, providing surge capacity for your supply chain.
- Swap resin instantly: print multiple items of PPE equipment on each printer.
- Instal ramp: Switch your printing fleet from surgical use to plastic PPE instantly, ramping production overnight.
- FDA clearance: Formlabs printers are capable of producing FDA approved medical items.

REAL WORLD EXAMPLE
COVID-19 Test Swabs

During the COVID-19 crisis, nasal swabs for testing were in high demand and in extremely limited supply. Teams from USF Health, Northwell Health, and Formlabs worked together to design, test, and clinically validate swabs to address the shortage from traditional manufacturers. The nasal swabs have cleared all testing, which showed that the 3D printed versions perform as well as or better than traditional swabs. USF Health and Northwell Health have since printed and used 130K+ swabs.

3D printing provides critical bridge manufacturing during the ongoing stockout period. The swabs are now being clinically used across the country to complete critical testing.

Key Metrics:

- Concept, clinical trial, and clinical use in 3 weeks
- Cost per part with 3D printing: $0.23
- Capacity: 300-500 swabs/printer/day

READ MORE

Cost Savings

Healthcare costs are always a concern, for both hospitals and insurance companies. 3D printing increases hospital staff productivity, in part by decreasing preoperative planning times, to reduce costs on every surgery. Additionally, hospitals can 3D print plastic replacement parts for various items that often require expensive replacements. Oftentimes, a broken plastic tubing or clip can require an entire machine to be replaced. With 3D printing, and $1 worth of resin, these parts can be replaced within half a day.

CASE STUDY

Saving £8,000 and Two Hours of Surgery Time at the UK's Leading Spinal Unit with 3D Printing

With access to affordable, precise 3D printing technologies through their partners at Axial3D, specialist surgeons like Andrew Bowey at Newcastle Hospitals NHS Foundation Trust are able to dramatically improve preoperative planning with high-precision, patient-specific anatomical models.

Wherever possible the team utilise advanced, minimally invasive surgical techniques to minimise discomfort and reduce patient recovery time. By enlisting the expertise of Axial3D, Mr. Bowey and team are able to transmit patient CT and MRI data securely from the ward in Newcastle to the Axial3D HQ in Belfast, Northern Ireland. Within hours of the transfer, the Axial3D team can segment the data and produce tactile 360° models of the patient's anatomy.

The medical imaging experts at Axial3D then 3D print the models with their Form 3B desktop printer, and deliver them to the hospital within 48 hours. Once shipped, these models can be used to help with pre-operative planning, conducting surgical simulations, or to help educate and gain consent from the patient.

The 3D printed model also enabled the clinical team to consult with the patient and their family to manage expectations and to fully demonstrate any associated risks. By conducting a full surgical simulation before the operation, Mr. Bowey was able to save over 120 minutes of time during a complex surgical procedure, equating to around £8,000 GBP of the hospital's funds. In addition, the process also contributed to reduced blood loss and better communication with the surgical team throughout the procedure.

READ FULL STORY

AVERAGE PART COST: <$50. TIME TO PRINT: ~10 HOURS.

Average part cost: **$25,** Time to print: **~10 hrs**

HAND MODEL

White Resin V4
Elastic Resin V1

Formlabs

KIDNEY MODEL

Clear Resin V4

Painted by UPMC

HEART MODEL

Elastic Resin V1

Formlabs

BRAIN WITH TUMOR MODEL

Clear Resin V4

Painted by UPMC

PEDIATRIC RIBCAGE MODEL

White Resin V4

UPMC

"As much as I'd like to think that my brain can reconstruct a 3-D interpretation from a 2-D CT scan, I was surprised by the relative inaccuracy of the approach that I've been using for 20 years. The 3-D printed model has been invaluable in planning partial nephrectomy, particularly when using the daVinci robot."

Ronald L. Hrebinko, MD
UPMC **Urologist and Associate Professor of Urology**
University of Pittsburgh School of Medicine

UPMC
LIFE CHANGING MEDICINE

"Every one of our full time Orthopaedic surgeons and nearly all of our part-time surgeons have utilized 3D printed models for care of patients at the San Francisco VA. We've all seen that 3DP improves performance on game day.
We've tried AR and VR, but nothing can replace physical model for a surgeon. Touching a model gives me the level of feedback that only surgeons can truly appreciate. I can measure the difference between cuts with the breadth of my fingers, and rolling my hands over a model is much better than drawing a line on a computer.

The Form 3B printer is also cheaper than most AR/VR setups, and VR is just for one person at a time. As a surgeon, I often synthesize CT scan data myself, but it's difficult to communicate the plan to other people. With a model, knowledge-sharing is much easier, people feel more involved, capable, and confident. Every member that contributes in the OR can have their own model prepared. All of this at a level of costs that is equivalent to just a consumable in the OR."

Alexis Dang, MD
Orthopedic Surgeon, Associate Professor, Orthopaedic Surgery and Sports Medicine,
UCSF/ San Francisco VA

UCSF
University of California
San Francisco

"The model enabled us to gain a much greater insight into the patient's entire deformity. We were also able to place the physical models of the patient's foot onto flat surfaces to plan how we were going to correct their gait with equipment prior to surgery. This greatly improved our confidence of a successful surgery and was used to explain the procedure to clinical staff and registrars."

John Wong
Consultant Orthopedic Surgeon
Altnagelvin Hospital, Northern Ireland

"*The Formlabs tools are game changing. The Form 2 is my first line when I want a rapid, high resolution print. It is in every sense, my right hand printer and resides in my office. The interface allows individuals in my lab to quickly become comfortable with operations. The versatility of the material choices has allowed for tremendous innovation for our group and I know there are more exciting tools to come.*"

David A. Zopf MD, MS
Otolaryngology - Head and Neck Surgery, Assistant Professor,
Pediatric Division Affiliate Professor, Biomedical Engineering
Scaffold Tissue Engineering Group

M | HEALTH SYSTEM
UNIVERSITY OF MICHIGAN

"*We were in the process of purchasing a 'professional' 3D printer when we came across Formlabs Kickstarter campaign for the Form 1 back in 2012. Thankfully, we put that purchase on hold and decided to go with the Form 1 and have never considered buying a 'professional' machine again. Over the years, the Form 1, 1+, the Form 2, the PreForm software, and the ever-increasing material selection have exceeded our expectations for performance, accuracy, and resolution. The convenience of having a high resolution 'professional' 3D printer in our office allows us to print and test every implant we design from custom implants and instrumentation to production items. There honestly isn't any other desktop 3D printer that I would consider having in our R&D facility.*"

Greg van der Meulen
Director of Research & Development
BioMedtrix, LLC

BIOMEDTRIX

"*The Form 2 printer has provided access to stereolithography technology, and a range of materials, which we could previously only access using much more costly machines. As such, the Form 2 has enabled us to more rapidly explore our space of clinical applications. In particular, the ability to print anatomic models at this price point promises to be especially useful.*"

Kenneth C. Wang, M.D., Ph.D.
Staff Radiologist, University of Maryland School of Medicine

UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE

"Upon first glance, the opacity, elasticity, and level of detail were clear advantages in the eyes of our diagnostic and interventional radiologists, as well as our cardiothoracic and vascular surgeons. We were considering a far more expensive machine until we saw this new material, and we are confident that our clinicians, trainees, and patients across specialties will benefit from its use."

Summer Decker, PhD
Assistant Professor, Director of Imaging Research
Department of Radiology, USF Health Morsani College of Medicine

"Elastic resin's opacity illuminates internal cavities well and its durability means that educators, trainees, and clinicians can handle and examine models without worry of breakage. This material will be of particular interest to cardiovascular surgeons and interventional radiologists, as well as those conducting fluid dynamics studies and working in catheterization labs. The material is relatively cost effective when compared with other materials on the market that offer similar feel and functionality, which can only help accelerate adoption of 3D printing in medicine."

Sanjay Prabhu, MBBS, FRCR
Staff Pediatric Neuroradiologist, Boston Children's Hospital

"Medicine is not one size fits all and when a tool comes along that allows you to create personalized medical solutions, it is a no brainer to utilize it to its fullest capacity. From medical device prototypes, complicated anatomical models for our children's hospital, to creating training systems, and finally entering the dental clinic with implant surgical guides, the Form 2 has increased our capabilities and decreased our costs, all while allowing us to provide tools to treat patients that would be next to impossible to replicate without our go to SLA printer."

Todd Goldstein, PhD
Instructor, Feinstein Institute for Medical Research
Director, 3D Lab, Northwell Ventures, Northwell Health

Form 3B

3D print in over 20 materials in-house on the Form 3B. Our technology has been validated in FDA-cleared workflows and we develop and manufacture our own biocompatible materials in a ISO 13485 certified facility.

THE TRUSTED 3D PRINTER FOR HANDS-ON HEALTHCARE

The Form 3B is an intuitive, affordable desktop 3D printer optimized for biocompatible and engineering materials. Print patient-specific parts on-site and on-demand and be part of the next wave of dynamic, tactile medicine.

COMMITTED TO CLINICAL INNOVATION

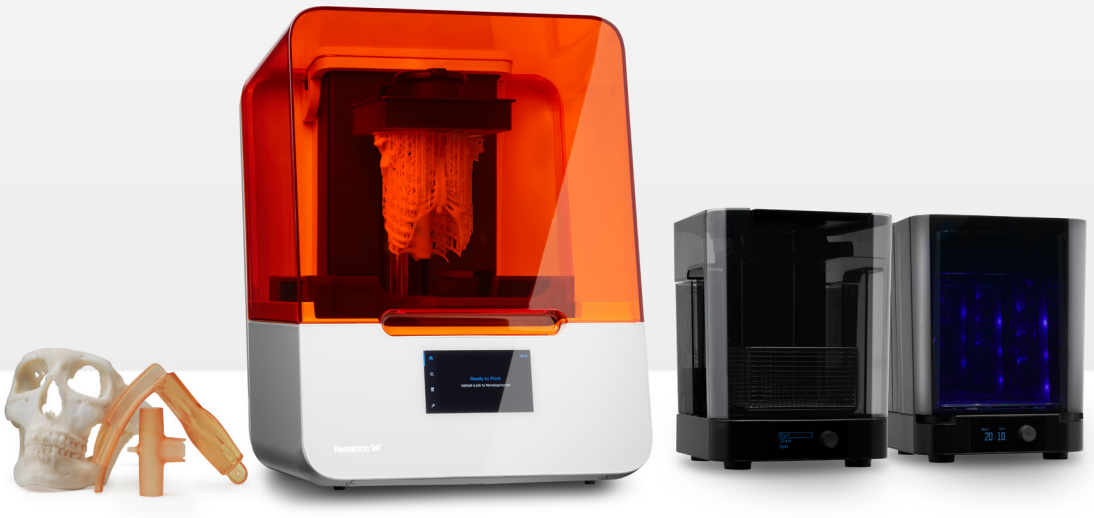
Our technology has been validated in FDA-cleared workflows and we develop and manufacture our own materials in an ISO 13485 certified facility.

SCALES WITH YOU

Start with one 3D printer or many, and add capacity as demand grows or needs change. Get helpful, personal service when you need it from a Formlabs expert with our Medical Service Plan.

AN END-TO-END 3D PRINTING ECOSYSTEM

We've made every step of the process as easy as possible, with simple print preparation software and our automated post-processing system, Form Wash and Form Cure.



LEARN MORE ABOUT THE FORM 3B

Materials

Access a library of over 20 materials available on one powerful desktop 3D printer, the Form 3B. Our technology has been validated in FDA-cleared workflows and we develop and manufacture our own biocompatible materials in an ISO 13485 certified facility.

Materials such as **Grey, Draft, Durable, Elastic, Tough 1500,** and **Tough 2000** Resin have all been used in hospitals to create various medical accessories, such as face shields, spare parts, and other PPE accessories.

Formlabs Surgical Guide Resin is our current biocompatible, sterilizable, FDA-registered material. Formlabs has created a dedicated materials team to expand what is possible with your 3D printer through new materials. More biocompatible materials are set to launch in 2020.

Surgical Guide Resin.

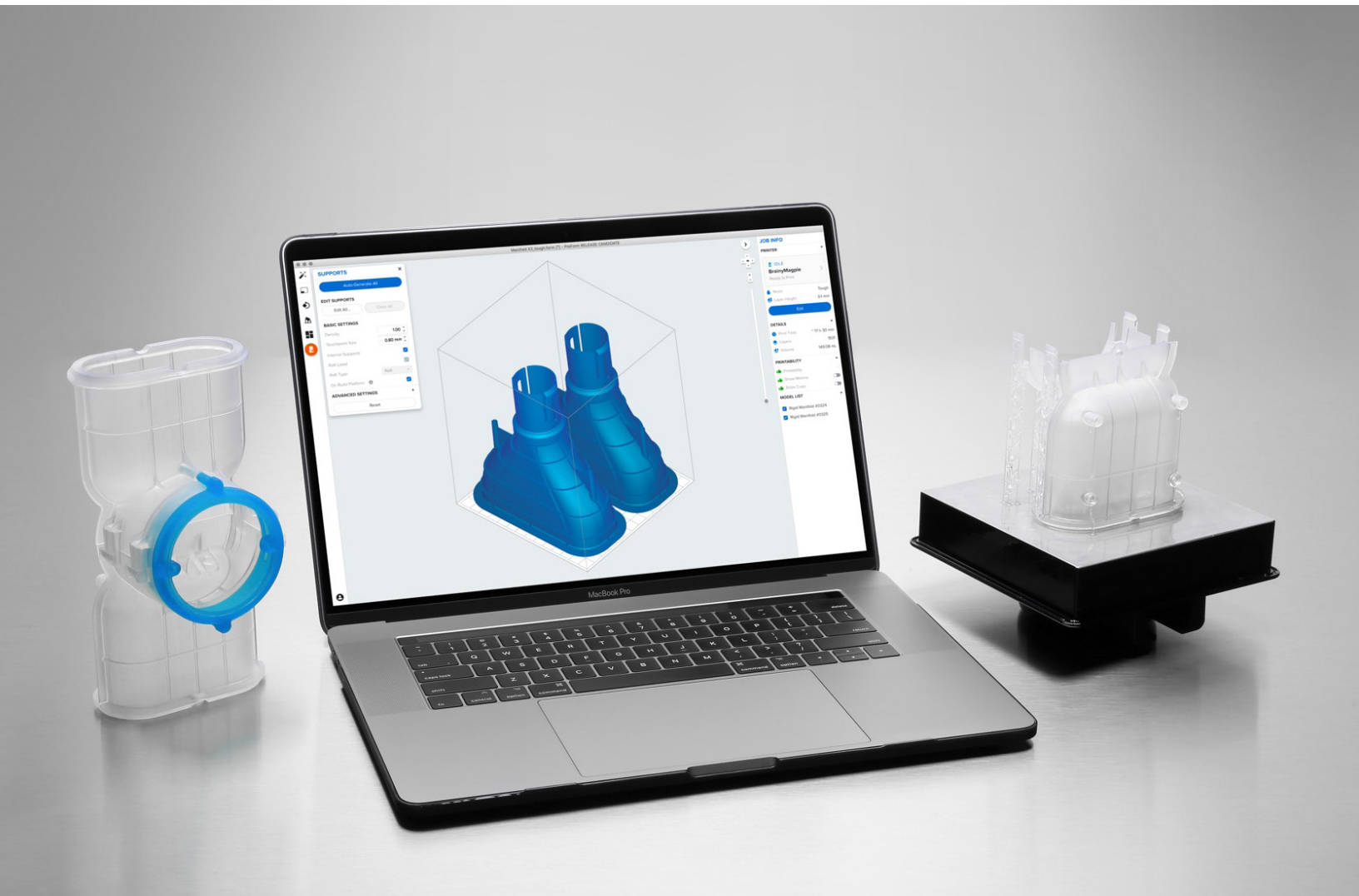
An autoclavable, biocompatible resin for applications including 3D printing dental surgical guides for implant placement. Developed specifically for Formlabs printers and rigorously tested with autoclaves, solvents, and implant systems, this material was designed from the ground up to exceed dental demands in part quality, accuracy, and performance.

Access to biocompatible material and in-house 3D printing allows new devices and tools to be created without lengthy approval processes. For example, Surgical Guide Resin was used to create medical test swabs during the COVID-pandemdic. After receiving FDA approval, hospitals were able to quickly ramp production to thousands of swabs per-day.

PreForm

PreForm is free 3D printing print preparation software, compatible with all Formlabs 3D printers. Take scans directly from, then import the STL or OBJ file into PreForm. Get your model ready in minutes, upload to your printer, and let it build.

PreForm's automatic algorithms set up your print's layout, orientation, and supports, so anyone on your team can print successfully without specialized training. Expert users can manually adjust a variety of parameters, such as support density and size, to fine tune results. PreForm was designed to automate every step of the printing process so that you can load a file, and send it directly to the printer in a few clicks.



Regulatory Considerations

*WHO HAS TO OBTAIN FDA CLEARANCE? THE CLINIC/FACILITY UTILIZING 3D PRINTER AND SOFTWARE?

Yes: The clinic/facility is marketing software that **is not** cleared for 3D printing anatomic models for diagnostic use.
The clinic/facility is marketing a software regulated by the FDA, making them a device manufacturer and as such should submit a 510(k).

No: The clinic/facility is marketing the ability to output patient-specific 3D printed anatomy for diagnostic use and the used software **is** cleared for that intended use.
The clinic/facility is using the software as intended and cleared by the FDA, there is no issue.

No: A doctor requests a 3D printed patient-specific anatomy for diagnostic use to aid with a special case he is currently working on from their hospital, but the software used **is not** cleared for that intended use.
The hospital **is not** actively marketing 3D printing services for diagnostic use. The doctor requested the model to aid in treatment of the patient under the practice of medicine. FDA does not regulate the practice of medicine.

*Please visit https://formlabs.com/industries/healthcare/regulatory-information/ for more information and links to FDA guidance documents.