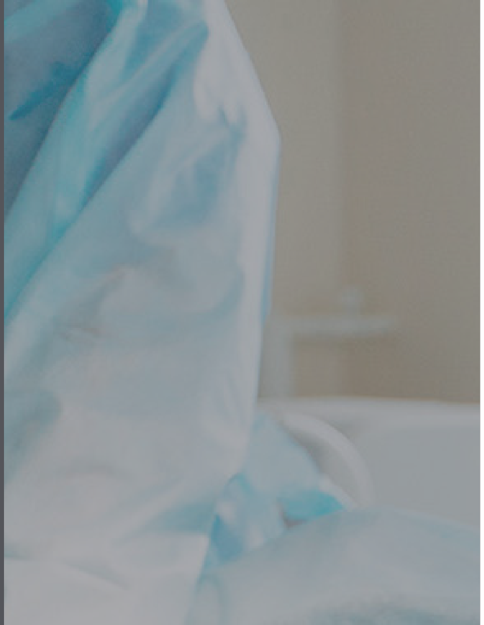


3D Printing in the Medical Device Lifecycle

A Buyer's Guide to 3D Printing

Buyer's Guide

stratasys

Your Industry, Your Challenges

The stakes are high in the **medical device field**. Innovation saves lives but the product development cycle is long, costly and full of risk for developers.

Medical device developers have four main goals: accelerate time to market, optimize product design, elevate cost efficiencies and reduce development risk.

Adding further to the challenges is finding a testing model that simulates the pathology or range of pathologies needed for testing.

Despite the challenges, medical device manufactures still need to meet all of the requirements of a complex development process including verifying designs and validating the performance of devices to ensure the product meets clinical expectations.

Shortening the development cycle while also reducing the risk of design failure requires a nimble prototyping and manufacturing process. And, while these goals can be achieved – at what cost are you speeding your design to market?

Medical device manufacturers outsource their prototypes but this generates its own challenge, namely the circulation of proprietary design information, as well as placement in scheduling queues, end-to-end production timelines, and cost. Even when designed in-house, developers struggle to design a bench test that replicates the way the product will be used and addresses the pathology targeted.

> "With 3D printing, we can be very quick in our process by developing a prototype component one week and then gather feedback from physicians the next week."
>
> Phil Besser
> **Cardiovascular Systems, Inc. (CSI)**

Your Industry, Your Challenges

Clinical trials requiring small production runs encounter frequent delays due to tooling lead times. Add to that the cost of producing small runs and the associated time delays for more challenges.

But there is a solution to the challenges medical device makers face in getting their products to market. This process is additive manufacturing or 3D printing.

3D printing helps device makers achieve clear, detailed physician feedback as well as eliminate failures faster.

75%

—

reduction in prototyping cost

50%

—

acceleration of development time

What Is 3D Printing and How Can It Help?

3D printing was once a playground for hobbyists and designers across industries looking to quickly manufacture design prototypes. Today's 3D printing gives medical device manufacturers the ability to align innovation with output. This applies to all phases of the design cycle, and for medical device manufacturers who are looking **to affordably and quickly keep innovation aligned with output.** This applies to all phases of the design cycle and gives medical device manufacturers the ability to quickly take ideas to physical prototypes and gather feedback earlier in the development process by creating clinically relevant and anatomically accurate models for validation and verification testing.

The number of 3D printing processes, each with its own array of materials seems to expand every year. **Defining your needs and goals is the first step to deciding which technology is right for you.** We'll focus on two industry-leading technologies: **fused deposition modeling (FDM™) and PolyJet™ Technology** in our exploration of 3D printing within the medical device industry.

What all 3D printing processes have in common is their computer software-driven approach to production. This digital environment means a designer can quickly and easily iterate designs, then seamlessly send their design to the 3D printer. A fully-digital workflow means greater accuracy, speed-to-print and complete iterative freedom.

Thinking through questions such as these when it comes to your needs helps pinpoint the correct AM technology for your use. 3D printing encompasses a wide range of materials, technologies and capabilities and zeroing in on what's going to best serve your needs is a good place to begin.

> "We use 3D printing technology and materials to create a lifelike vascular environment that isn't achievable any other way."
>
> Henisha Dhandhusaria
> **CSI**

What does it need to do?

Will it be a model for proof-of-concept?

Does it need to function like your finished product?

Will it actually be your finished product?

Where does it need to function?

Is it necessary for it to be biocompatible?

Will the part be used repeatably?

Is it simply a model?

What does it need to look like

Does it need to be realistic?

Does it need to print in multiple colors and materials?

Do you have specific preferences for surface smoothness?

What Is 3D Printing and How Can It Help?

Design Process

The benefits of 3D printing for medical device development come into play early-on in the design process. Small batches and early engineering tests can be verified and validated in-house, at the earliest stages of development. The ability to print 5-6 iterations of each prototype quickly and easily helps speed your design team to the next step: validation and verification testing.

Validation and Verification

The ability to 3D print fixtures that exactly match the geometries needed for proper testing support is a lesser-known benefit to 3D printing medical devices. The ability to 3D print a test rig that is a mirror image of your device means you are not limited in design freedom when it comes to design validation and verification. 3D printing eliminates the need for expensive tooling for parts that don't need to be injection molded.

“

By the end of one week we accomplished what would take four weeks with conventional manufacturing methods.”

Itay Kurgan
Syqe Medical

“

With just two weeks ahead of us...I designed the inhaler prototype and we 3D printed the parts... we wanted to show how small the device would be, how it would function, how the electronics would work, and how the airflow would work... this changed the whole conversation with the investor.”

Itay Kurgan
Syqe Medical

What Is 3D Printing and How Can It Help?

Anatomical Models

Being able to print anatomically correct medical models enables physicians to train on the device before encountering it in a clinical setting which is proven to aid surgical outcomes. Better outcomes are associated with the ability to plan, practice, and develop an optimal surgical approach.

Also, the ability to train physicians on new medical devices is proven to positively impact surgical outcomes. And training physicians on new medical devices with anatomically correct models means more physicians can be trained without the costs and limitations of animal and cadaver labs.

Final Device Manufacture

AM as a method for final manufacturing of a medical device is gaining significant traction as materials and processes become more fully vetted and the FDA recognizes the validity and benefits of AM for final device models. 3D printing jigs and fixtures is another area where the accuracy and resolution provided by this technology aids medical device manufacturing.

Ongoing Product Support

Form, fit and function testing can be done during the development process to understand the full limits of the product prior to launch. This helps ensure it meets all the challenges it will face in the field. Failure analysis is done once the product is launched on all complaints. This involves both the actual product and the anatomical model of the pathology.

Bench Testing

During pre-clinical design validation, gain the **advantage of 3D printed jigs and fixtures** to replicate how the product is positioned within the anatomy. Perform form, fit and function testing of 3D prototype devices within a 3D model of targeted pathology to optimize design selection and minimize clinical trial failure.

> "...fully verifying our products is crucial to ensuring that premium healthcare is maintained...the high levels of accuracy and overall durability of 3D printed parts that withstand the rigors of use in the clinical setting were critical to accelerating the clinical trial."
>
> Cesare Tanassi
> **Nidek Technologies**

What Is 3D Printing and
How Can It Help?

3D printing adds value through the entire product life cycle of a medical device

- From design concept and feasibility
- To pre-clinical design validation
- To clinical evaluation and testing
- to seeling/training aid

step 01 **Research Feasibility**

step 02 **Design & Develop**

step 03 **Design Transfer & Ramp-up to Full Production**

step 04 **Regulatory Approval & Launch**

step 05 **Post Market Surveillnce**

FDM
3D Printing Technology

While it is certainly possible to begin your 3D printing journey using only one of these five technologies, chances are that once you begin to see the speed, cost and design benefits of one of these technologies, it will lead you to explore the next. All of these technologies can improve and accelerate each stage of the medical device development lifecycle. Knowing when and how to use the processes in tandem during your product lifecycle, will provide you with the greatest number of options. So what are these technologies and how do they differ?

FDM

Fused deposition modeling (FDM) is a widely-used form of 3D printing whereby strong thermoplastics are deposited layer-by-layer from the bottom up by heating and extruding thermoplastic filament. Part of the beauty of FDM is its ability to allow the user to choose between speed and resolution. Choosing coarser layers means larger parts can be built more quickly, a real benefit in early-stage prototyping.

FDM technology is great for form, fit and function of prototypes and low-volume production runs. With layer resolution as fine as 0.001 inches (26 microns), great accuracy can be achieved with FDM technology.

"

The ability to quickly 3D print high-quality parts that require no post-processing has proven instrumental in cutting our iterations and directly reducing our product development cycle..."

Cesare Tanassi
Nidek Technologies

PolyJet
3D Printing Technology

PolyJet

PolyJet technology is known for its outstanding realism and aesthetics. The technology works similarly to traditional inkjet printing but instead of jetting ink onto paper, a print head jets liquid photopolymers onto a build tray where each droplet cures in a flash of UV light.

PolyJet technology offers sharp precision, smooth surfaces and ultra-fine details. Layer resolution of 0.0006 inches (16 microns) allows for precise details and smooth surfaces. PolyJet's strength and smooth surface finish make it a great process for intricate direct print prototypes and fixtures that need to hold precise components in place. Stratasys GrabCAD 3D print software also includes an advanced slicer feature, giving users slice-by-slice control to calibrate material properties to your exact specifications.

By combining a variety of photopolymers in specific concentrations and microstructures, the most sophisticated PolyJet systems can simulate everything from plastics and rubber to human tissue – in 500,000 colors, all in a single print. Digital Anatomy 3D printed models, created with PolyJet technology, even replicate the same biomechanical properties as human tissue to provide the most realistic testing and training.

When it's full-color, multi-material prototypes you're looking for, PolyJet can mimic a wide range of materials in a single model. PolyJet can combine rigid, rubber-like, heat-resistant, transparent and opaque materials to produce parts with varied color, opacity, hardness, flexibility or thermal stability. All this with a dazzling array of 500,000 colors. While PolyJet materials are excellent for prototyping and work well for certain tooling applications, they are UV-sensitive and not as durable as production-grade plastics.

Origin One
3D Printing Technology

> "We take angiographic images and use 3D modeling to recreate the complex anatomy of different coronary vessels, 3D print a realistic model and stress test different situations to see where we can improve our device."

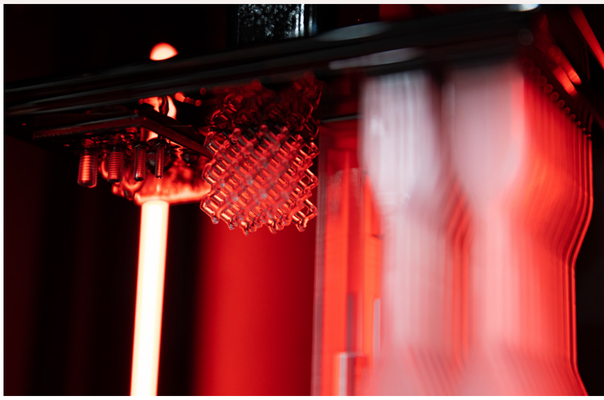
Nick Ellering
Cardiovascular Systems, Inc.

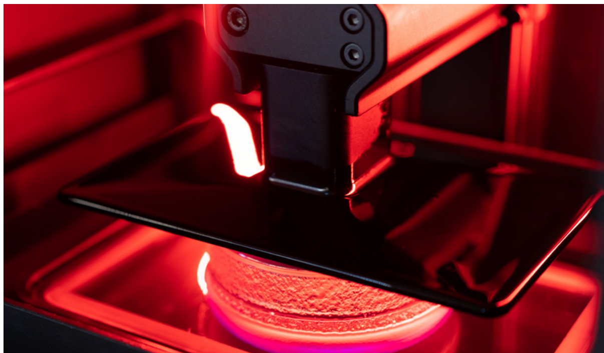
Origin One

The Origin One is our manufacturing-grade 3D printer that enables mass production of end-use parts in a diverse range of high-performance materials. Achieve industry-leading accuracy, consistency, detail and throughput with Programmable PhotoPolymerization P3™ technology, which prints details less than 50 microns in size with high-accuracy materials. In situ analytics, combined with automatic pressure, separation force and temperature regulation, ensure the first part is the same as the last.

Users can choose from a wide range of single-component, commercial-grade photopolymers, developed on and validated for Origin One. Resins are engineered to be easy to handle and rapidly post-processed, with long shelf lives, and create smooth surface quality without secondary finishing.

See powerful product improvements over time, with over-the-air software updates that unlock new advanced materials and workflow optimizations. High throughput, combined with best-in-class repeatability, helps labs produce anatomical models and teaching accessories without delays.





Neo and SAF
3D Printing Technology

Neo

The Stratasys Neo series of 3D printers utilize stereolithography (SLA), a process that uses a vat of liquid UV-curable photopolymer resin and a UV laser to build parts one layer at a time. This beam delivery system produces exceptional layer-to-layer alignment repeatability and sidewall surface finish.

SLA technology ensures highly accurate parts with extremely small variability from part to part, and layer thickness of between 50 to 200 micron. It is most commonly used as a prototyping technology to print parts or models to validate fit form and function, including clear guides for medical applications.

SAF

Selective Absorption Fusion (SAF) technology is a powder-based process that produces parts with exceptional detail and a smooth surface finish. SAF ensures consistency no matter the production volume, as the in-line, unidirectional architecture maintains precise thermal control between fusing and recoating across the bed.

SAF's industrial-grade technology helps users meet high production demands and throughput, with a one pass print-and-fuse process, 12% nesting density, and minimized consumables. Produce quality finished models for orthotics, prosthetics, and insoles and other devices that

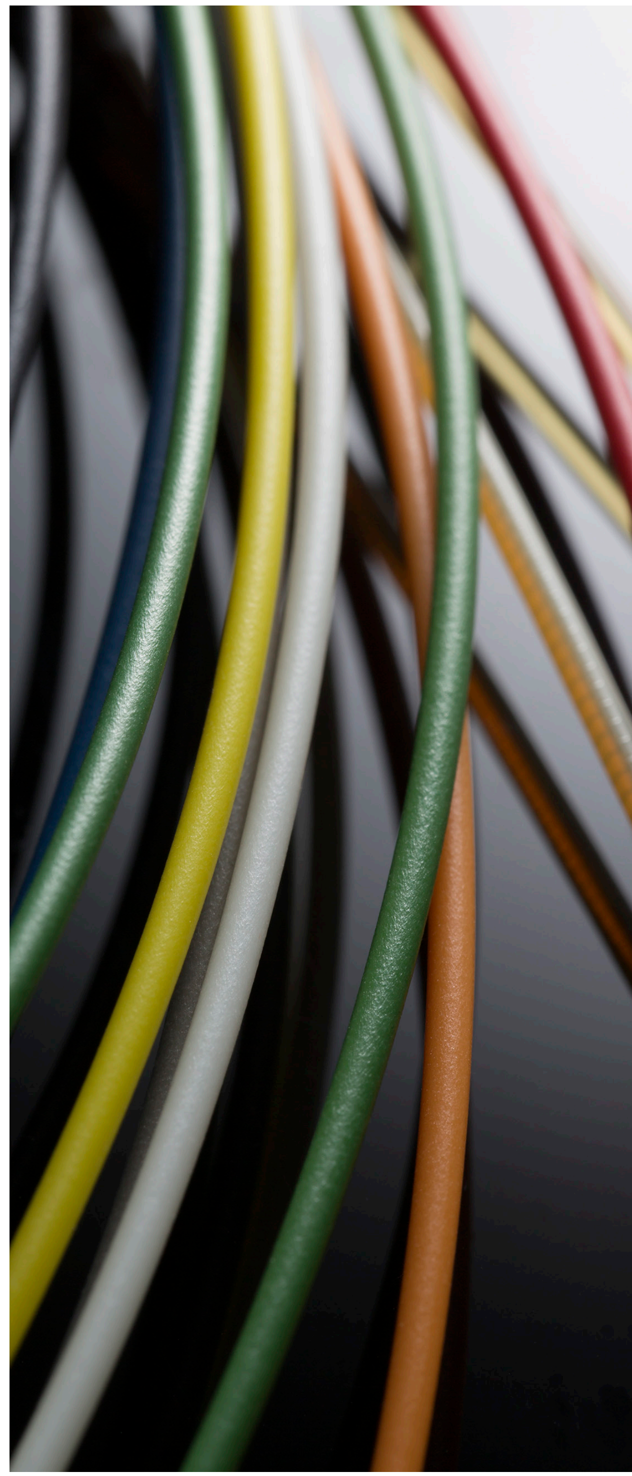
require high repeatability and accuracy.

Materials

Knowing how your part needs to look, what it needs to do, where it needs to function and how long it needs to last are the key criteria for selecting a suitable 3D printing material. FDM, high-performance plastics offer the greatest temperature stability, chemical stability and mechanical strength for the most demanding engineering applications.

From autoclave-sterilizable PPSF, FST-rated ULTEM™ 9085 resin and biocompatible ULTEM™ 1010 resin, to FDM Nylon 12 Carbon Fiber™, offering the strength of metal with the highest stiffness-to-weight ratio of any FDM material, there is an FDM material to suit your needs, including ABS, ABS M30i and PC-ISO biocompatible materials.

There are several biocompatible PolyJet materials suitable for medical applications requiring precise visualization and prolonged skin contact of up to 30 days. These materials have been tested to ensure compliance with standards for cytotoxicity, genotoxicity, delayed type hypersensitivity, irritation and USP plastic class VI.



Operations

Many businesses start with a single 3D printer, either FDM or PolyJet. This is often the clearest path to justifying the space and cost. Over time, many institutions upgrade to multiple 3D printers, locating them either in their own dedicated 3D printing lab or within an associated department.

The only requirements necessary for FDM and/or PolyJet operation are: air-conditioned environment, dedicated space and ventilation.

Building the Business Case for 3D Printing

Public hospitals are operating on tighter budgets and private facilities are receiving lower reimbursements in recent years, according to McKinsey & Company. This is transforming the purchasing process: decisions are not only made by doctors but also regulators, hospital administrators and other non-clinicians. Prioritization of cost has become the main objective.

The demand for “good enough” medical devices that are competitively priced has pushed medical-product manufacturers to develop strategies to attract and retain this new segment of customers.

Price transparency in established markets such as coronary stents and orthopedic devices is giving an advantage to low-cost players. According to McKinsey, this segment of “good enough” is growing twice as fast as the industry as a whole.

The “lean-selling model” is where much of future growth will come. However, when entering the ‘value segment,’ there are three main concerns to be noted:

- Minimizing cannibalization
- Defending against the competition
- Remaining flexible

Each of these three concerns can be successfully addressed by medical device manufactuers with 3D printing. The key is building a **business case** showing the benefits of in-house 3D printing justifies the capital expenditure. This begins with a **statement of the problem, the proposed solution and the intended results**. The proposed capex request is the recommended solution to the business challenges faced, showing that purchasing a system will bring measureable results.

In many cases, the capital expenditure of a 3D printer can quickly show financial benefit – usually in under 18 months. Once numbers showing that additive manufacturing promotes the creation of more prototypes in more stages of the product development process, for less cost, you are on your way to building your case for in-house AM.

> “The cost of sending out work versus doing it in-house is easy to capture and new can justify owning the FDM system via reducing that cost alone. But the intangibles like timing issues, communication, and the value-added services are where we see the greatest benefits.”
>
> Sofamor Danek
> **Medtronic**

Building the Business Case for 3D Printing

Expense Reduction and Income

There are many benefits to 3D printing prototypes in-house:

- Early error detection
- Less tooling rework
- Fewer engineering change orders
- Avoid product launch delays
- Avoid outsourcing expenses
- Eliminate/decrease prototype tooling costs
- Reduce in-house production costs
- Fewer rejects and less waste related to production errors
- Faster problem diagnosis
- On-demand availabilitty
- Digital inventory
- Eliminates long lead times
- Allows for rapid iteration

These benefits lead to:

- Time-to-market reduction
- Improved product quality and consistency
- More frequent iterations within development cycle
- Cost reduction
- Faster time to design freeze
- Accelerated time to market
- Design optimization
- Cost efficiencies

Additive manufacturing's greatest benefit is making things fast. Instead of waiting days for a CNC-machined prototype, an additive manufacturing system can make the part overnight. While this point may not directly help justify a capex expenditure, it is an undeniable benefit within the competitive medical device market.

To learn more, read the white paper,

"How to Justify the Cost of a Rapid Prototyping System"

18

Months to revenues

—

In many cases, the capital expenditure of a 3D printer can quickly show financial benefit – usually in under 18 months.

Stratasys Direct Manufacturing

When the budget simply isn't there or you need proof of additive manufacturing's place within your product development lifecycle, there is another option. Print-on-Demand services such as **Stratasys Direct Manufacturing**® can be another member of your team. For one-off prototypes, overflow work or evaluating technologies, get on-demand access to 3D printing.

Stratasys Direct's vast experience in manufacturing methods ranges from FDM and PolyJet Technologies to Stereolithography and Direct Metal Laser Sintering.

[Speak with a representative](#) to see how your business can leverage the power of Stratasys Direct.

Axial 3D

Stratasys partner Axial 3D's cloud-based segmentation-as-a-service converts DICOM data into 3D visualizations, printable files, or printed anatomical models made with Stratasys print technology. Personalized 3D printed anatomic models are used for pre-surgical planning, diagnostic use, education and training, and medical device development.

Creating a 3D printed model from a patient's scan data normally takes several hours and requires a high level of technical expertise and expensive software licenses, but Axial3D's artificial intelligence-powered algorithms enable healthcare providers to segment CT and MRI scans for these models without significant investments in time, specialized skills and large upfront costs.

[Learn more about Axial3D and segmentation-as-a-service.](#)

The Stratasys Solution

Stratasys offers a comprehensive selection of 3D printers and materials that cover your needs from prototypes to production-ready goods. This full-circle solution gives you the design freedom to rapidly iterate, verify, validate and manufacture with speed and reliability. Award-winning technology at the push of a button. Begin with prototyping in FDM on our most plug-n-play solution, the F123 Series™.

Prototyping

The ease-of-use of the F123 Series means your design cycle can incorporate iterations at the speed of your ideas. This FDM technology takes you from concept to validation and even functional performance. The F123 Series supports a range of capabilities and budgets for every stage of prototyping. With quick and easy material swaps you can verify and validate with a range of materials. Auto-calibration of your printer means you spend less time troubleshooting and more time iterating. When you need more than hobby-level prototyping, gain the competitive advantage with the F123 Series.

500,000 Colors

From the J5 MediJet™, your gateway to the world of multi-material color 3D printing to the J850™ Digital Anatomy™, giving you 500,000 colors and control at the voxel level, there's a colorful option available for realistic prototypes that can print multiple materials in a single print.

PolyJet technology gives you unprecedented realism in your prototypes, from smooth surfaces, to flexible and rigid parts, all in a single print.

Production Grade

When you want to move beyond prototypes into small-batch production parts, the Stratasys Fortus 380mc™ and Fortus 450mc™ build parts with advanced complexity and high requirements needed for your manufacturing.

Embed hardware, circuitry and other non-thermoplastic materials into your parts easily, with minimal downtime for changeover. Advanced additive manufacturing is combined with the latest advances in FDM technology to expand your manufacturing business with speed, agility, and the freedom of your own designs.

GrabCAD Print

For professional 3D printing made easy, GrabCAD Print™ software for Stratasys 3D printers simplifies your 3D printing workflow so you get parts faster and simpler. With the ability to print directly from CAD, you do not have convert or optimize STL files.

GrabCAD Print allows you to organize print queues to help maximize your print schedule based on machine availability, estimated job duration and other key considerations.

Monitor your material levels from any device. Cloud-connected GrabCAD Print gives you direct access from any browser to help you schedule and monitor your prints remotely. Read the GrabCAD eBook to learn more.

Digital Anatomy Creator software is based on the GrabCAD Digital Anatomy printer software, intended for advanced users seeking to expand their personalized medicine arsenal.

A user-friendly graphic interface allows users to use the different materials available on the Digital Anatomy printer, to create custom presets with the desired mechanical properties and colors. Each model layer can design with digital materials and defined by 5 different structures providing specific mechanical properties and visualization to the final model.

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