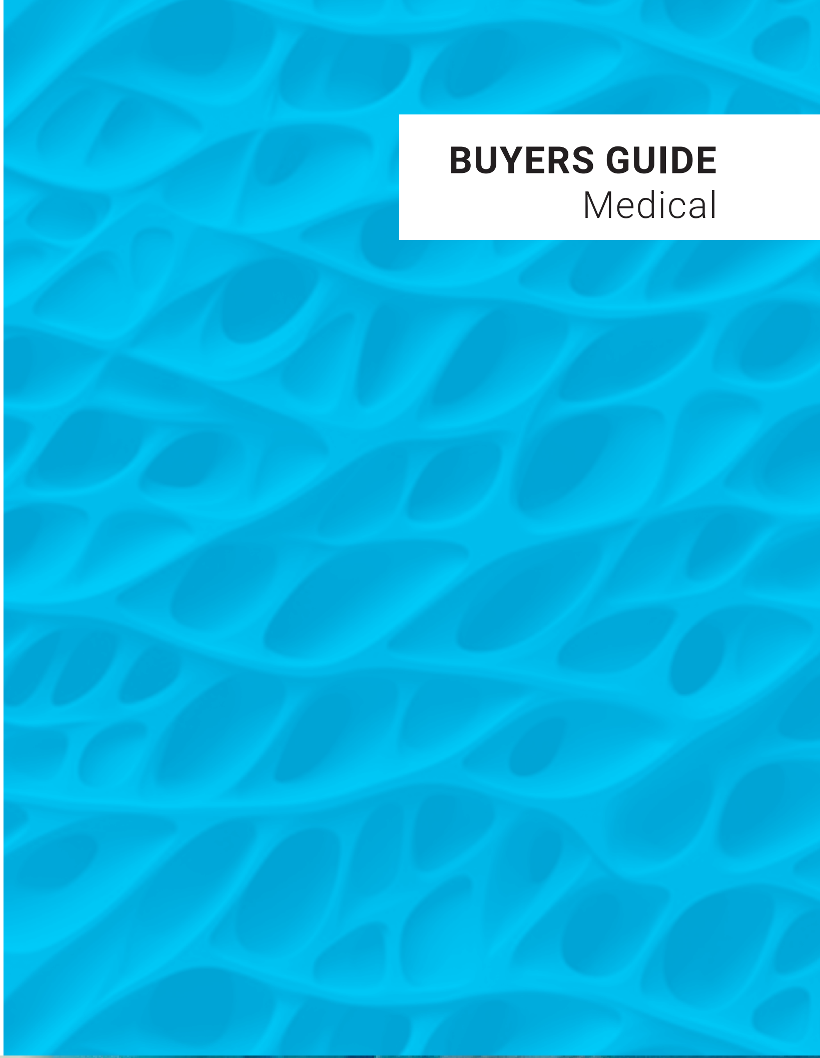
BUYERS GUIDE
Medical

Medical Device Lifecycle



From Concept to Production

A Buyer's Guide to 3D Printing

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 risks for developers.

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

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

Despite the challenges, there is still a 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 often outsource their prototype fabrication, but this can generate its own challenges, 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 can struggle with benchmarks that replicate 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 can 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 manufacturers face in delivering their products to market. This process is additive manufacturing or 3D printing.

3D printing helps manufacturers 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. In today's context, 3D printing has evolved to empower medical device manufacturers, enabling them to seamlessly integrate innovation with production. This capability holds true for every stage of the design cycle, catering to manufacturers who aim to maintain a cost-effective and swift alignment between innovation and output. This versatility spans across all phases of the design cycle, efficiently transforming concepts into physical prototypes. It facilitates the early acquisition of valuable feedback during the development process by enabling the creation of clinically relevant and anatomically precise 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 five industry-leading technologies: **fused deposition modeling (FDM™), material jetting (PolyJet™), selective absorption fusion (SAF™), digital light processing (P3™ DLP) and Stereolithography (SLA™)** in our exploration of 3D printing technologies 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 Additive Manufacturing (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?

What are the requirements?

Is it necessary for it to be biocompatible?

Will the part be used repeatably?

Is it simply a model?

What material properties does it need?

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 and Development

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.

Design Validation and Verification

One of the major advantages of 3D printing in the validation process is its repeatability. With the ability to produce multiple prints quickly and accurately, tests can be conducted over and over again, ensuring thorough validation. This speed and efficiency accelerate the overall process, from the initial idea to the final printed product. 3D printing enables the creation of fixtures and test rigs that perfectly match the geometries required for proper testing support. This often-overlooked benefit allows for unmatched design freedom in design validation and verification. By eliminating the need for expensive tooling for parts that don't require injection molding, 3D printing significantly reduces costs while maintaining design flexibility.

“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

Equipping medical device companies with visual and functional models is crucial to enhance their product development and testing. By using models that accurately mimic real tissue bio-mechanically, companies can ensure that their products function effectively in real-world surgical environments. This approach not only improves device reliability but also helps companies refine optimal design and usage strategies through iteration and feedback.

Final Device Manufacture

Additive Manufacturing (AM) as a technique for the ultimate creation of medical devices is becoming increasingly popular as materials and methodologies are more comprehensively evaluated. More and more companies acknowledge the effectiveness and advantages of AM for finalizing device designs. Additionally, the use of 3D printed jigs and fixtures offers the advantage of rapid customization, ensuring precise alignment and placement during medical procedures. This precision can lead to more consistent results, reduced production time, and cost savings, further emphasizing the potential of AM in medical applications.

Addressing Field Challenges

During the development phase, it is possible to conduct form, fit, and function testing to gain a comprehensive understanding of the product's complete capabilities before its launch. This proactive approach not only assists in guaranteeing that the product can effectively address any challenges it may encounter in the field but also allows for swift issue analysis, even while the product is deployed in the field, encompassing both the actual product and the anatomical model of the target pathology.

Bench Testing

In the pre-clinical design validation phase, the ability to 3D print jigs, fixtures, anatomies, and product components offers a distinct advantage. This capability allows for swift benchtop setups, simulating the product's interaction within the specific anatomy. Leveraging these 3D models enables design teams to rapidly iterate and hone their prototypes. Such a streamlined approach not only optimizes design decisions but also substantially minimizes the potential for clinical trial issues.

> "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:

- Research Feasibility: Assess the concept of using 3D printing technology prior to committing to a lengthy production cycle, through market research, feasibility studies, and identification of potential benefits and risks.
- Design & Development: Utilize rapid design and development cycle to meet changing regulatory requirements and address specific healthcare needs.
- Design Transfer and Ramp-up Production: Transfer the finalized design to manufacturing stage, optimize the production process, and ensure scalability and consistency in the manufacturing of 3D printed medical devices.
- Regulatory Approval and Launch: Navigate the regulatory landscape, comply with necessary standards and regulations, and obtain regulatory approvals for the safe and effective use of 3D printed medical devices.
- Post Market Surveillance (PMS): Implement a robust post-market surveillance system to monitor the performance, safety, and effectiveness of 3D printed medical devices, gather feedback from users, and make necessary improvements if required

step 1 — **Research Feasibility**

step 2 — **Design & Development**

step 3 — **Design Transfer & Ramp-up to Full Production**

step 4 — **Regulatory Approval & Launch**

step 5 — **Post Market Surveillance**

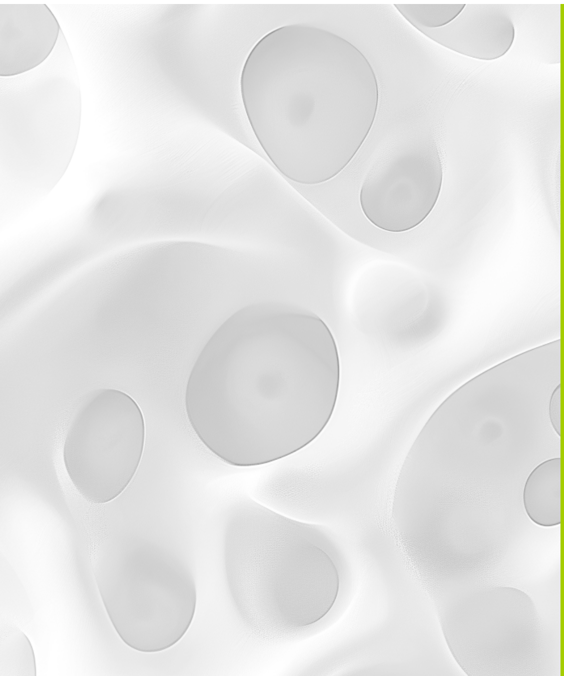
3D Printing Technologies

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 rest. 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, will provide you with the greatest number of options. So what are these technologies and how do they differ?

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 unique advantage of FDM is its ability to allow the user to choose between speed and resolution. Opting for thicker layers allows for the faster construction of larger parts, which is especially advantageous during the initial stages of prototyping.

FDM technology is great for form, fit and function of prototypes and low-volume production runs. With layer resolution as fine as 0.005 inches (0.127 mm), depending on material choice, greater 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

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.

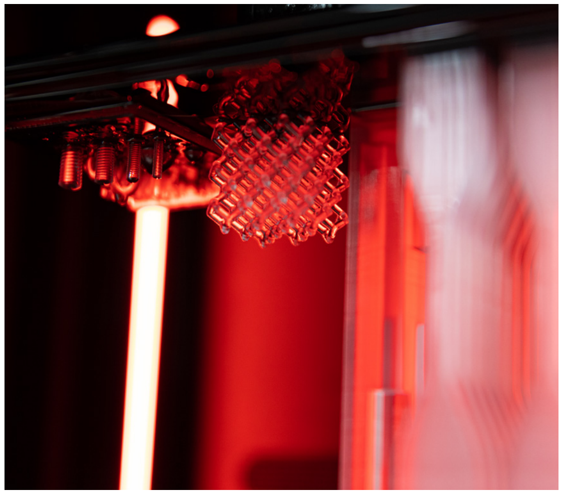
PolyJet technology offers sharp precision, smooth surfaces and ultra- fine details. Layer resolution of 0.0006 inches (14-30 microns depending on print mode) allows for precise details and smooth surfaces. PolyJet's strength and smooth surface finish make it a great technology for intricate direct print prototypes and fixtures that need to hold precise components in place. Stratasys GrabCAD Print software also supports multiple advanced modules such as the Digital Anatomy Creator and the Research package giving users slice-by-slice control to calibrate various material properties to exact specifications.

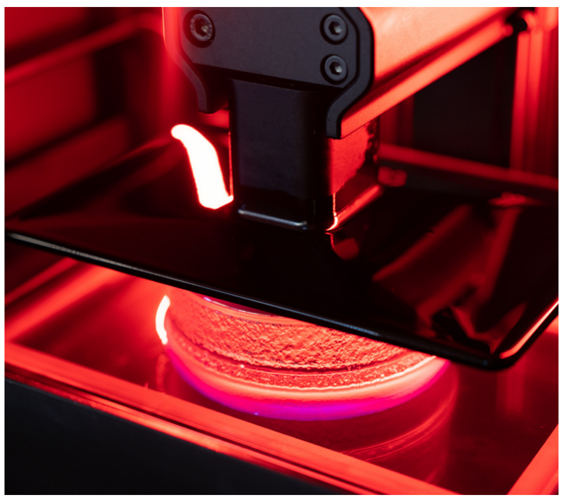
By combining a variety of photopolymers in specific concentrations and microstructures, the most sophisticated PolyJet systems can simulate everything from plastics and rubber to human tissue – in over 640,000 colors, all in a single print. Digital Anatomy™ 3D printed models, created with PolyJet technology, 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 colors and Pantone Validated pallets. 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.

P3™ Programmable PhotoPolymerization

> "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.**





The Origin One is our manufacturing-grade 3D printer that enables mass production of end-use parts in a diverse range of high-performance, open-platform materials. Achieve industry-leading accuracy, consistency, detail and throughput with Programmable PhotoPolymerization P3™ technology, which prints as small as 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 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.

Stereolithography

Neo® series of 3D printers utilize stereolithograpy (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.

From hardware to software, the reliable Stratasys Neo 3D printer is developed as next-generation stereolithography and features:

- Large build volume with a compact footprint resulting in larger parts with fewer joins and/or higher production quantities.
- High-power laser and dynamic beam size control for greater accuracy. Variable beam size also featured for faster build speeds and maximum productivity.
- Excellent Titanium software functionality including part traceability and reporting function with an easy to use interface.
- Accessible support with remote diagnostics or convenient on-site support from our exceptional service team.

SAF Selective Absorption Fusion

SAF technology is a powder-based technology 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

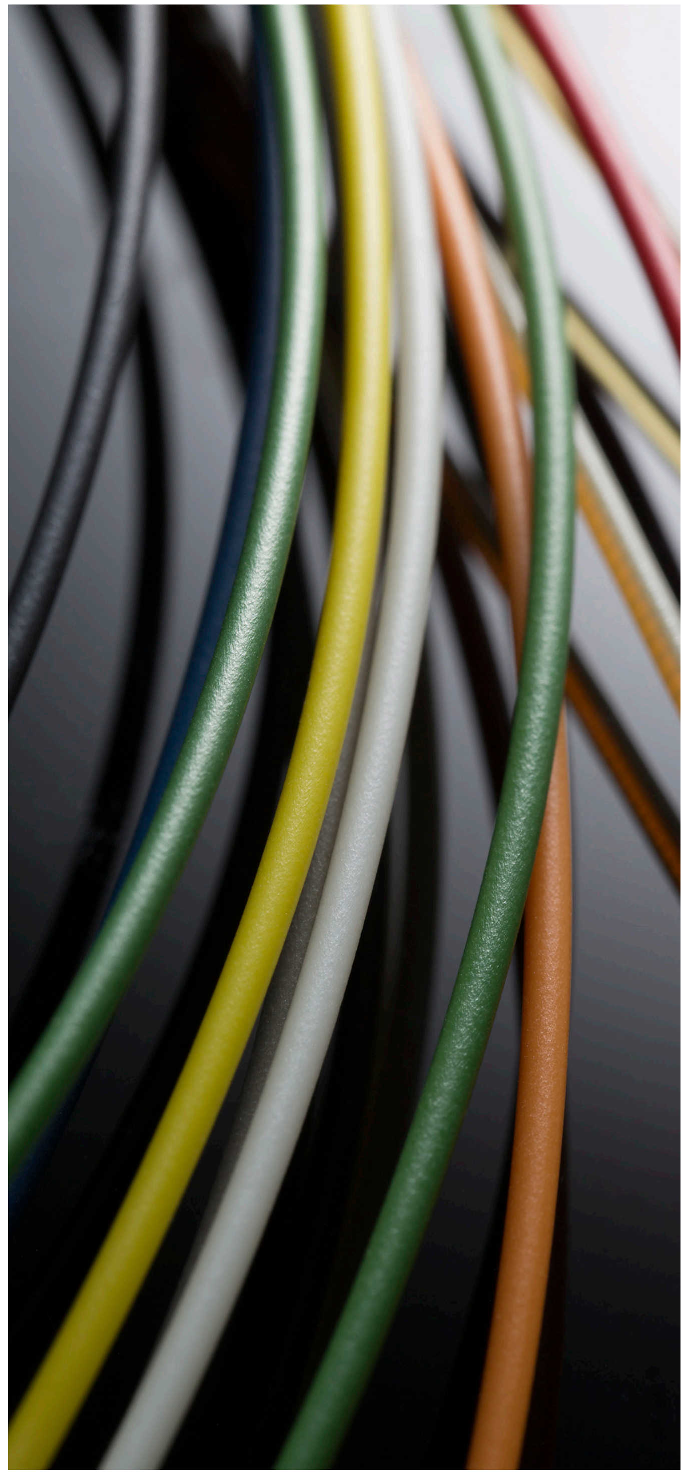
Knowing how your part needs to look, what it needs to do, where it needs to function, and how long it needs to last are the key criteria for selecting a suitable 3D printing material.

Choose from a vast selection of materials, including high-performance plastics, a variety of bio-compatible, realistic and sterilizable materials, that replicate bio-mechanical properties of human tissue, and a wide range of color and elastomer options.

Stratasys biocompatible materials have been tested and shown to be safe for use in medical applications. They are certified to be non-toxic, non-allergenic, and not to cause irritation or inflammation. These biocompatible materials can be used to create a wide variety of medical devices, including prosthetics, surgical guides, and biocompatible prototypes and end-use parts to be used in the surgical environment. The level of certification required for biocompatible 3D printed materials depends on the body contact type such as skin or bone, and the duration of contact.

Some of the most common biocompatible materials the Stratasys offer:

- PA12 on SAF: strong, lightweight, and flexible.
- ULTEM™ 1010 resin on FDM: high-strength, heat-resistant, and biocompatible.
- MED610 on Polyjet: clear and biocompatible. It is often used for medical devices that require precise visualization and limited (< 24 hours) contact with bone and blood.
- MED412 on Origin: flexible and biocompatible. It is often used for medical devices that need to bend or flex, such as swabs.



Technology	Material	Main Properties
PolyJet	MED 610™	Translucent and rigid
	MED 615RGD™	Ivory colored and rigid
	Biocompatible Digital ABS™	High temperature resistance High toughness and impact resistance
Neo SLA	BioClear™	Rigid translucent
SAF	PA12	High toughness and impact resistance High accuracy
Origin One DLP	LOCTITE® 3D IND402	High rebound, elastomeric behavior
	MED412	Medical grade resin Strong, durable, high elongation at break
	MED413	High modulus Good for end use parts
FDM	ABS-M30Ii	Real ABS Good for end use parts and functional prototypes
	PC-ISO	Biocompatible, heat-resistant thermoplastic suitable for food packaging, medical and pharmaceutical applications
	ULTEM 1010 resin	Best in class strength-to-weight ratio Extremely high temperature resistance

When choosing biocompatible 3D printed materials, it is important to consider the specific application of the device and the level of certification required.

Note:

The manufacturer or end user must obtain clearance or approval from the relevant authorities before the device can be used for medical purposes. Always ensure compliance with local regulations and standards.

For more information regarding Biocompatibility requirements, approved sterilization processes, safety guidelines and datasheets, please visit our support center webpage or contact us.

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 since 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 manufacturers with 3D printing. The key is building a **business case that 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 measurable 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 supports 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.

"

On average, we estimate FDM parts cost 80% less to produce when compared to machined parts. Over a four-year period we estimated a $6 million savings versus what would have been spent if we had contracted the parts to an outside machine shop"

Richard Booth, Senior Design Engineer
Medtronic

*Resourced from 'Innovation Comes to Life' Case Study

Building the Business Case for 3D Printing

Expense Reduction and Income

There are many benefits to 3D printing for production and tooling:

- 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 availability.
- Digital inventory.
- Eliminates long lead times.
- Allows for rapid iteration.

These benefits lead to:

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

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”]

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Months to revenues

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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. Leverage **Stratasys Direct Manufacturing®** as your print-on-demand service partner. 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.

Speak with a representative to see how your business can leverage the power of Stratasys Direct.

Patient Specific Solutions Powered by 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. Axial3D solutions are 510k cleared for diagnostic purposes for multiple clinical indications.

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. 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.

GrabCAD Print

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

GrabCAD Print allows you to organize print queues to help maximize print schedules 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 Software Brochure to learn more.

The Digital Anatomy Creator software is an add-on to the GrabCAD J850 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 J850 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.

The Stratasys Solution

Stratasys offers a comprehensive portfolio of 3D printers and materials to meet the needs of medical device manufacturers, from prototyping to tooling to production. Stratasys end-to-end solutions give you the power to rapidly iterate, verify, validate and manufacture with the speed and reliability you can expect from award-winning technology.

Prototyping

Stratasys offers a range of 3D printing technologies for rapid prototyping. Fused Deposition Modeling (FDM) technology allows for fast concept-to-validation iterations without the high cost and lead time of traditional methods. For highly-realistic, detailed models and parts, the J850 Digital Anatomy™ 3D Printer, J5 Digital Anatomy™ 3D Printer and J5 MediJet® utilize PolyJet technology to enhance product quality, Biomechanical and visual reality, testing consistency, reducing costs, and speeding up time to market. The Neo series with Stereolithography (SLA) technology is suitable for creating a large volume of prototypes with unparalleled accuracy and repeatability.

Tooling

Stratasys' FDM-powered 3D printers enable the production of lightweight, complex, ergonomic jigs and fixtures to accelerate time to market. The Origin One 3D printer, using P3™ DLP technology, allows for flexible production of precise, biocompatible tooling with high part quality and throughput.

Production

The Stratasys Neo series is designed for small-batch production, providing high-quality parts with superior surface quality and detail for medical devices. The H350 - SAF 3D Printer, using powder bed fusion technology, ensures exceptional detail and consistency for multiple end use applications such as orthotics and prosthetics production, while being cost effective - regardless of volume. The P3-powered Origin One is relied upon by medical device manufacturers for creating small to medium batches of end-use parts with agility, efficiency, and scalability.

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