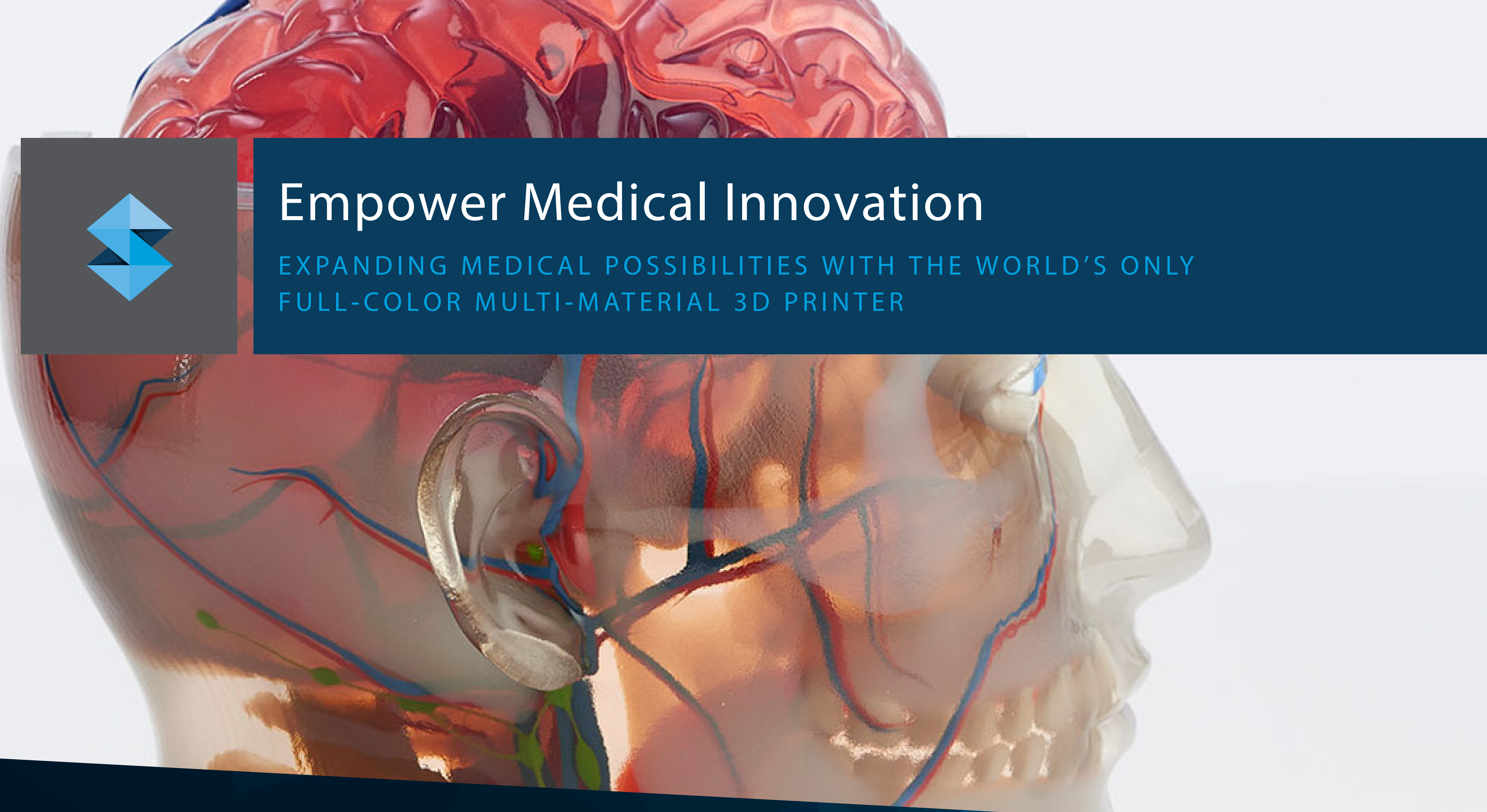
# Empower Medical Innovation

EXPANDING MEDICAL POSSIBILITIES WITH THE WORLD'S ONLY FULL-COLOR MULTI-MATERIAL 3D PRINTER



stratasys

proto3000

# INTRODUCTION

Ask anyone in the medical community what their top objectives are and they'll probably say that everything boils down to improving patient outcomes while making the healthcare system more efficient.

Having the right tools to do the job is one crucial element in solving problems and becoming more effective and productive. Additive manufacturing, widely known as 3D printing, is one of those tools that has helped inventors, educators, and researchers improve how they design, manufacture, teach and perform research. The same technology has also benefitted health care providers, with tools that can accelerate medical innovation, improve patient outcomes through patient-specific surgical planning models, and help train the next generation of physicians.

While no tool is an all-in-one solution, 3D printing is a strong step in that direction, particularly in its most sophisticated forms. With almost unconstrained manufacturing freedom, one system can prototype a new application, create realistic anatomical models for training and surgery planning, create custom research tools and fixtures, build parts for use in clinical evaluation, and many other applications.

PolyJet™ technology is an additive manufacturing process with the capability to make parts, prototypes and models in multiple materials, colors and color textures. All of these characteristics can be combined in one 3D print job, allowing complex parts with diverse properties to be produced quickly.

The latest innovation in this technology is the Stratasys J750™ 3D Printer. The most sophisticated and versatile 3D printer on the market, it represents a breakthrough in the realism of 3D printed anatomical models with the ability to build in full color and a broad range of material properties. This enables medical device manufacturers to test new innovations on reproductions of diseased anatomy to rapidly validate design. It lets training physicians practice on much more realistic simulators, accurately replicating anatomy that includes simulated pathology from actual patients.

The Stratasys J750 also maximizes uptime and the diversity of jobs that can be handled with one system. In practical terms, that means timely delivery of medical models or medical device prototypes and more efficient printer utilization through multi-print capability that can serve multiple departments.

A 3D printer won't solve all of the world's problems, but among creative minds, the Stratasys J750 is an impressive tool to bring business and research achievements in line with aspirations.

Let's take a closer look at how additive manufacturing and the Stratasys J750 provide real solutions.

A 3D printed medical model representing an aortic thrombus with calcifications.

This model of a lower spine with orthopedic implants was 3D printed with texture mapping, using darker colors to represent tissue density.

# CHAPTER ONE -

## UNPRECEDENTED VERSATILITY FOR MEDICAL APPLICATIONS

The Stratasys J750 3D Printer isn't just the latest introduction in the portfolio of PolyJet 3D Printers. It's the first-ever full-color, multi-material system, and it addresses the needs of biomedical engineers and medical researchers who want realistic anatomical models but have to contend with inconsistent color results and less-than-lifelike textures from current 3D printing technology. It also targets rapid prototyping managers using multiple technologies and messy processes, looking for a leaner, cleaner method to create exactly what the designer needs.

### MEDICAL USE CASES

The advent of 3D printing opened the door to a variety of medical use cases, from anatomical models to clinical simulators to medical devices. However, virtually all technologies had some limitations, be they limited material options, color availability or surface finish. The Stratasys J750 changes that with its versatile combination of rigid and flexible material choices, expansive array of colors and fine resolution.

- Medical Models The Stratasys J750 is uniquely suited to create realistic medical models, thanks to its combination of rigid and flexible materials that replicate hard bone and lifelike soft tissue, all in a single print operation. The printer's fine resolution allows the creation of minute details and thin walls for accurate representation of anatomical structures like vascular systems. The ability to print any color, including blended transitions and transparency, results in a system that is capable of producing very realistic, patient-specific anatomical models.

- Prototype Parts Rapid prototyping lets medical device makers move new ideas from the conceptual stage to clinical trial-ready products in the fastest time possible. The Stratasys J750 offers materials such as Digital ABS™ for prototypes that need characteristics similar to engineering plastics. Full color allows designers to create concept models and prototypes that look like their production counterparts, reducing or eliminating post-processing steps.

- Research and Manufacturing Tools/Production Parts Simulated engineering plastics and high-speed print capability make the Stratasys J750 an effective tool to produce customized fixtures and equipment for medical labs and device manufacturers. High-speed print capability means these tools can be printed quickly, as needed. The precision of the Stratasys J750's PolyJet technology along with multi-part print capability also provides the accuracy and throughput needed for low-volume production parts.

Color combines with transparency to create stunning models for training and patient education.

# CHAPTER ONE -

## UNPRECEDENTED VERSATILITY FOR MEDICAL APPLICATIONS

The following information provides a more in-depth look at Stratasys J750 features and capabilities and how it's aptly suited for multiple medical applications.

### INCREDIBLE PART REALISM

A hallmark of the Stratasys J750 is its true, full-color capability, a breakthrough in 3D printing technology. The ability to 3D print with various colors is not new, but previous offerings forced users to sacrifice either color range or part quality. The Stratasys J750 changes this by producing smooth plastic parts with over 360,000 colors.

This training model takes advantage of the ability to 3D print multiple colors and textures to differentiate various structures in the nasal cavity.

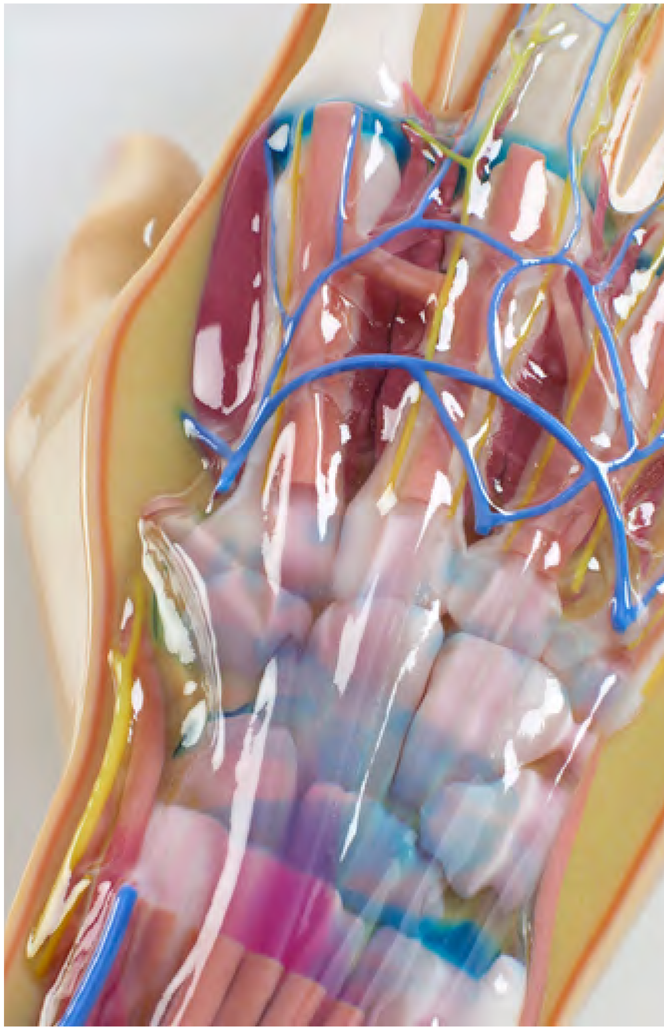
This color range is made possible because the Stratasys J750 can operate with 5 different colors: cyan, magenta, yellow, black and white. With the capacity to use all of the primary colors in the CMYK color process, including white, the Stratasys J750 creates colors similar to a full-color 2D document printer that's printing on a white background, enabling it to achieve a broad color spectrum.

Color textures and gradients are also possible. Color texture capability means parts can be 3D printed with a variety of realistic patterns like wood grain and plaid, for example, or even photographs and illustrations. Gradients allow a transition zone between colors that blend one into the other.

These aesthetics are achievable with different material characteristics too. Models with full color and color textures are possible with opaque and transparent rigid materials. The alternative option is the combination of full color with flexible materials. In practical terms that means being able to produce a rigid medical model representing various internal anatomical structures in multiple colors and gradients. Or it might mean producing a tray of multiple parts, each with different characteristics such as color textures, flexibility and transparency. Both scenarios are possible in a single print run.

One of the drawbacks of existing color 3D printing processes is the relatively rough surface finish that results. In contrast, the Stratasys J750 achieves very fine layer thicknesses, as low as 14 microns in high-quality print mode, enabling high surface quality and the creation of models and parts with very fine, delicate details.

The availability of such a wide color spectrum, combined with the fine-finish, multi-material capability, lets the Stratasys J750 produce parts with an incredible array of characteristics. Prototypes that need to look, feel and function like future products are possible in a single print operation, with minimal to no finishing steps like painting, sanding or assembly.



### UNMATCHED VERSATILITY

The Stratasys J750 not only delivers incredible realism but it's also the most versatile 3D printer available.

This versatility originates from its robust material capacity, accommodating input of up to six base resins. Because advanced PolyJet systems create composite materials right on the build tray, the number of material options is far greater than the number of input materials. In the Stratasys J750, those six base resins yield hundreds of thousands of colors, translucencies and durometers.

Before the Stratasys J750, no single 3D printer could deliver full color, smooth surfaces and multiple materials. To achieve all of these qualities would have required multiple 3D printing technologies that would still necessitate extensive post-processing, such as sanding, painting and bonding. Serving many needs with one system enables businesses to:

- Reduce the amount of rapid prototyping equipment onsite, and its associated overhead and points of failure
- Increase expertise and maximize use through familiarization with a single technology
- Protect investments against changing business needs, both cyclical and unpredictable

Print size with the Stratasys J750 is also generous, with a build area of 49 x 39 x 20 cm (19.3 x 15.35 x 7.9 in). This lets you create ample-sized parts or many smaller parts in one job.

For rapid prototyping programs, this versatility is an opportunity to meet the diverse demands of your operation without the inefficiencies associated with material changes or the need to invest in, operate and maintain a variety of technologies. You can print realistic prototypes, presentation models, Digital ABS injection molds, jigs, fixtures, educational and promotional pieces, production parts – or all of the above, with one system.

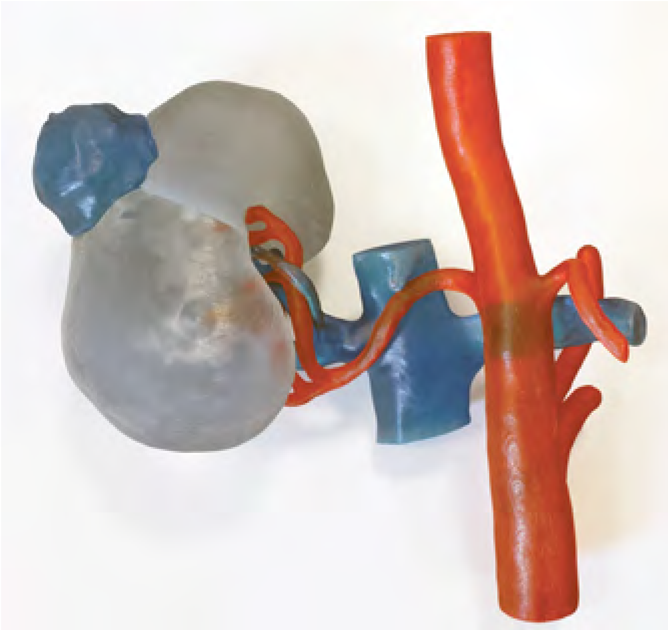
## FAST, EFFICIENT WORKFLOW AND EASE OF USE

Using the printer is easy, starting with GrabCAD Print™ software, which lets you import native CAD files directly so there's no need to spend time converting them into STL files. Simply finish your model, open GrabCAD Print and drag the file in. Then select "print" to start the build. The software lets you easily check printer availability, queues and status, all from one window. And with the mobile app, you can check print status remotely on your mobile device. GrabCAD print even fixes file problems like open meshes, so you can focus on more productive tasks.

The Stratasys J750's six-material capacity is a considerable time and material saver. Multi-material printers with less capacity need material changes for different colors or material types. This results in printer downtime and wasted material, made necessary to purge the system of the previous material. The Stratasys J750's larger material capacity lets an operator load their most-used materials and drastically reduce or even eliminate material changes, saving time and resources.

New print heads increase the printer's speed. The Stratasys J750 has three print modes: high speed, high mix and high quality. The high speed mode prints at twice the speed of Connex3 printers when using three materials, providing the ability to make multi-material models faster than previously possible. The high mix mode makes it possible to use the printer's full, six-material capacity, for the optimum number of choices in color and mechanical properties. Despite the increased number of materials, high mix mode prints at the same speed as existing Connex3 printers. And the speed at which Digital Materials such as Digital ABS can be printed has increased two-fold.

Some 3D printing processes must run in a dedicated facility because of the materials, chemicals and post-processing steps involved. In contrast, the Stratasys J750 3D Printer uses a clean, easy process, with no hazardous chemicals to handle, a particularly important consideration in a hospital setting. It's compatible with soluble support material that can be removed in a solution bath. This lets users focus on other duties while the support material is being removed and also makes it easier and less problematic to clean delicate parts and internal cavities, an important feature for intricate anatomical models.



PolyJet technology's fine resolution permits the creation of small details of this kidney model and vascular system.

## SUPERIOR 3D PRINTED MEDICAL MODELS

Biomedical Models, Inc. (BMI), is a leading maker of medical models used for surgical planning as well as to educate and train healthcare practitioners. Fabricated models are typically preferred over human cadavers due to their cost, availability, strict control requirements and limited pathology. Conventional, molded-plastic models and mannequins are an option but they don't retain the same responsiveness of real human tissue. Manufacturing them often requires post-processing such as painting to add color. Creation of these models using 3D printing also involved tradeoffs because of limitations in the physical properties and color capabilities of the technology.

But with more than 360,000 available colors and multiple textures that can replicate soft tissue and hard bone, the Stratasys J750 3D Printer enables the unparalleled ability to recreate human anatomy in a clinically relevant training simulator. BMI has used the Stratasys J750 to create surgical planning models of patients' anatomy to allow surgeons to become procedurally proficient before entering the operating room. BMI has also leveraged the printer's capabilities to create models with spectacular color, combined with clear materials, to provide dramatic see-through representations of human anatomy for instruction and technical demonstrations.

According to Crispin Weinberg, president of BMI, "The Stratasys J750 can economically produce training mannequins in a wide range of normal and abnormal anatomies, replicating realistic colors and tissue textures."

3D printing has ushered in a new age in medical anatomical models with complexity, realism and sophistication not previously possible. This realism allows surgeons to practice on a wide range of abnormal and patient-specific anatomy.

For another example of how realistic modeling plays a role in advancing health care, view this video to see how the Centre for Biomedical and Technology Integration uses the Stratasys J750 to create realistic patient-specific anatomical models for physician training.

A 3D printer with this capability is a powerful tool, enabling creative solutions for diverse challenges that impact the healthcare industry. In the following chapters, we'll look at how 3D printing benefits the development and delivery of healthcare products and services and how the Stratasys J750 fits.

As 3D printing technology evolves, its use in the medical field continues to grow. Medical device manufacturers, hospitals, doctors, medical researchers and educators can all benefit.

## RAPID PROTOTYPING AND PRODUCT DEVELOPMENT

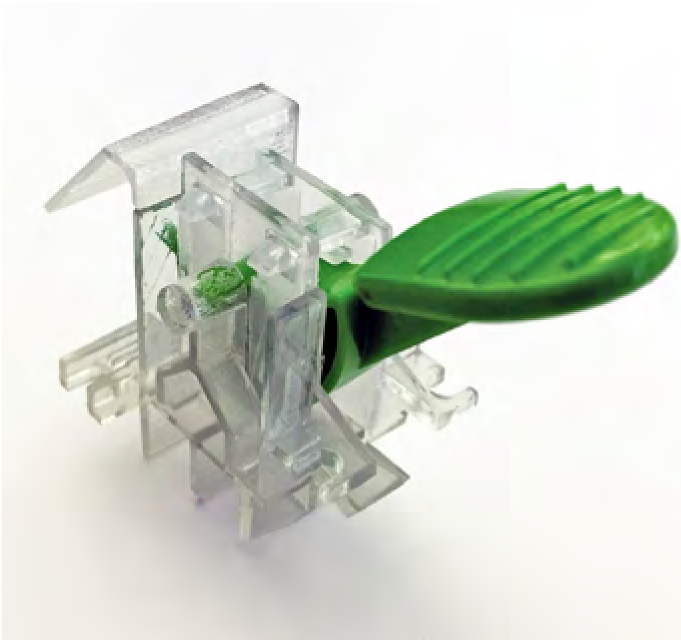
Rapid prototyping and product development are key areas where 3D printing helps medical device manufacturers. In-house 3D printing produces prototypes much more quickly and usually for less cost than traditional manufacturing methods, particularly when it replaces outsourcing. This speeds up the entire development process because designs can be changed and parts re-printed quickly. This iterative but fast-feedback loop gets products to clinical trial and to market faster, benefitting patients sooner.

3D printing also gives hospitals the power to be centers of innovation. The proximity to 3D printing technology gives physicians and medical researchers the ability to develop and advance ideas for new devices and treatment, closest to the source of information and point of potential application. This could accelerate the overall development process by laying the groundwork before engaging an industry partner that brings it to market.

## ANATOMICAL MODELS FOR SURGERY PREP, DEVICE TESTING AND EDUCATION

Scanning technology, such as computed tomography (CT) and magnetic resonance imaging (MRI), lets doctors see a patient's anatomy with intricate detail. But as helpful as these tools are, they don't offer the benefits a 3D model can in terms of being able to study all aspects of an anatomical structure like a human heart. 3D printing is the natural extension of this scanning technology, providing the ability to create physical replicas of patient anatomy in intricate detail. These models are multi-purpose too, used for surgical preparation and training as well as educational aids for medical students and for medical device developers to test their inventions before use in animals and humans.

Perhaps the most remarkable and beneficial example of this application involves modeling a specific patient's anatomy, including pathology, that lets doctors plan, rehearse and ultimately determine the optimal therapeutic approach prior to surgical intervention. The 3D printer's ability to easily produce any shape is perfectly suited to the uniqueness of an individual's anatomy, and the variety of Shore A values rendered with PolyJet technology means models offer the proper tactile resistance as well as



Clear PolyJet material was used on this medical device prototype so engineers could view the internal components during testing.

appearance. Doctors use these models to plan the best surgical approach resulting in shorter operating times and better post-operative results.

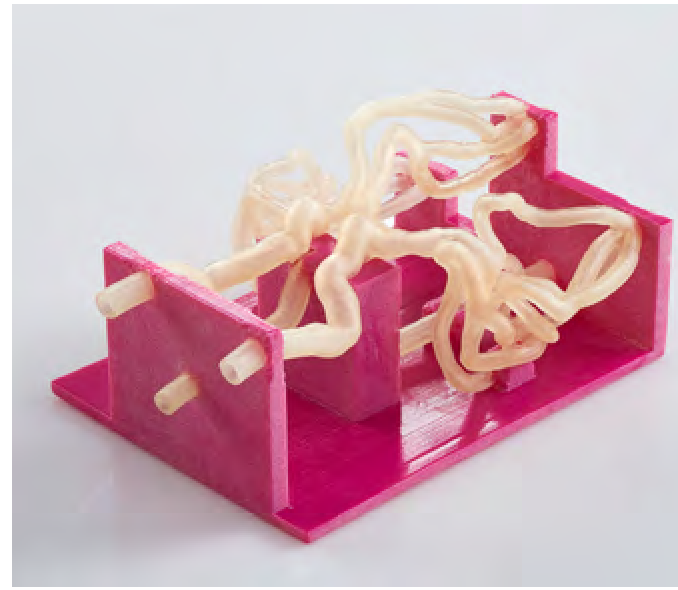
3D printed models also help train doctors to perform medical procedures and use new devices, and educate medical students on general anatomical structures. The Stratasys J750 in particular offers complex geometries and blends of material properties that would be difficult or impossible to produce with conventional manufacturing methods. Training models can mimic the look and feel of living tissue and can integrate instructional elements, such as labels or contrasting colors. These models can be produced on demand and avoid the challenges associated with human cadavers like availability shortages and handling and storage expenses.

Lastly, these same models can be used to test and validate the next generation of medical devices. Before investing in expensive cadaveric or animal testing, new devices can be deployed in models that replicate the complex reality of human pathology. These models are more clinically relevant than bench top testing analogues that replicate some aspect of the intended environment. And by creating models of multiple patient cases, you can test your devices in a range of clinical situations to ensure the device will perform well in all the challenges it will face.

## LABORATORY TOOLS, JIGS AND FIXTURES

Using 3D printed manufacturing tools like jigs, fixtures and other production aids streamlines the work process and helps shorten the product development cycle. It's also a less costly approach compared to machining, which is often a disincentive.

Lab tools in the form of pipet racks, gel combs and other small parts can often be 3D printed for a fraction of the cost of what medical suppliers charge. They can also be tailored to the specific job needs making them a more versatile option than standard stock items.



The translucent blood vessel network of this vascular phantom was created with flexible material while the pink portions were made with a rigid material for support.

## MAKING ADVANCEMENTS WITH 3D PRINTING TECHNOLOGY

Medical device manufacturers must provide the best product they can, not only to support advances in health care but also to compete in the marketplace. This typically involves a relentless pursuit of product development and improvement, which typically requires physician feedback to assess what the market wants or how to improve existing products.

Designers assimilate this information and develop initial designs. Prototyping managers take this information and create prototypes, working with the designers to refine the design. These prototypes are tested or used in trials to gauge their success and the process either continues on to full production or repeats itself until a viable product results.

This product development process can take weeks, months, or in some cases, years, depending on the type of devices being produced. Regardless of the industry, getting your product to market faster is a key determinant in generating revenue and gaining or maintaining leadership in that market.

Making physical products by traditional means usually involves machining or molding parts and assembling them together to create concept models and prototypes. Many companies have to outsource these processes, putting them at the mercy of a variable that's difficult to control – the vendor's lead time. It also means added cost, in the form of skilled labor and the associated time and material that's involved. What's more, this entire process and the associated time and financial cost limit the number of designs that can be developed.

That's where 3D printing is causing a marked disruption. It lets designers and rapid prototyping shops create products much faster, which fosters the ability to iterate more and create more designs. This ultimately lets device manufacturers eliminate failures and arrive at the optimal design.

Other benefits include the ability to produce parts and prototypes as complete products that include color and multiple textures. This eliminates additional finishing steps like assembly and painting. The end result is a much shorter product development cycle and the capacity to get products to market faster.

Simulated engineering plastics give medical device engineers the capability to create functional prototypes in fine detail.

# CHAPTER THREE -

## CREATING BETTER MEDICAL DEVICES, FASTER

### 3D PRINTING ENABLES BETTER, FASTER DESIGNS

Nidek Technologies is a manufacturer of ophthalmology equipment and its primary mission is the introduction of exclusive new products to the market. To meet that goal and maintain its position in a competitive market, the company relies on PolyJet additive manufacturing technology to create functional prototypes. These prototypes are used for validation in clinical trials, necessitating that they reflect the same features, form and capability as the final product.

A successful application of this technology was the development of a new gonioscope, a device used to examine the human eye for early glaucoma detection. Using 3D printed parts, the functional prototype was successfully tested throughout a year-long clinical trial, a testament to the durability of PolyJet technology's ability to withstand rigorous test protocol. To expedite the development process, Nidek replaced parts that would normally have been made from aluminum with 3D printed parts made from PolyJet Rigur™ material. This reduced production time from two months to just 24 hours.

PolyJet's multi-material capability also gave Nidek the ability to create other parts with a combination of characteristics such as rubber-like flexibility and features including seals, threads and transparent components. This is another time-saving feature because individual parts don't have to be created separately and assembled together. It also keeps post-machining to a minimum. And because of PolyJet's high resolution, the number of calibration steps can be significantly reduced.

For Nidek, this technology has accelerated their rapid prototyping capability, reducing development time by 50%, with a resultant cost reduction of 75%.


Nidek used 3D printed parts in their gonioscope functional prototype to reduce development time.

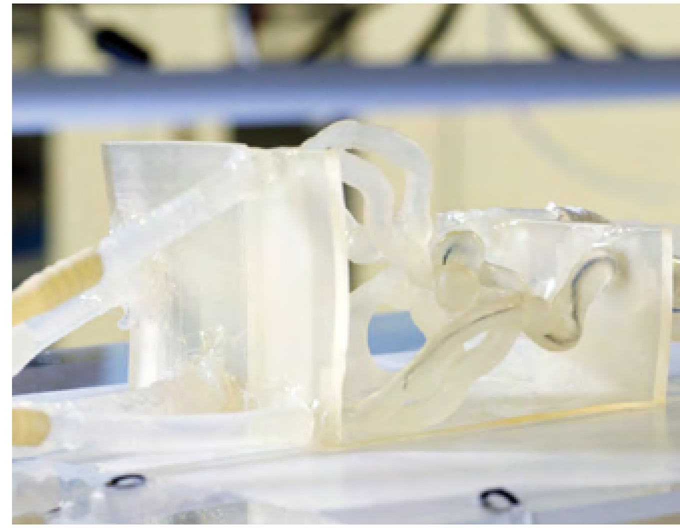
Together, three institutions are shaping the future of vascular health care and medical device development. Kaleida Health's Gates Vascular Institute (GVI), University at Buffalo's Clinical and Translational Research Center (CTRC), and the Jacobs Institute share a collective vision to design and establish a vascular care center of the future. This unprecedented co-location of a private hospital system and university research center helps researchers and clinical practitioners develop cutting-edge medical solutions. As a platform for research, 3D printing unlocks new opportunities to advance vascular care. Stratasys has been a proud partner of the collaborative medical facility since inception, providing doctors and researchers with the most advanced medical modeling options in the world. 3D printing provides the tools to develop and validate the next generation of vascular devices and create optimal therapeutic plans to treat complex diseases.

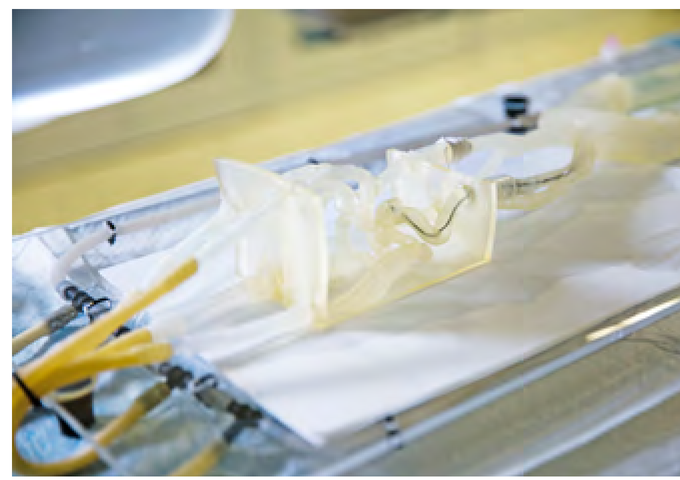
## ADVANCED TRAINING TECHNIQUES

Surgical education and training previously relied on textbook illustration, 2D scans, animal testing and an apprenticeship model that involved long observation periods prior to hands-on experience with rare procedures. Recent 3D printing advances provide doctors and researchers the tools to create patient- and condition-specific anatomy models for education and research. "We use 3D printing technology and materials to create a lifelike vascular environment that isn't achievable any other way," said Mike Springer, director of operations and entrepreneurship at the Jacobs Institute. Instead of waiting to train on new procedures, physicians at the Jacobs Institute use 3D printed models of patients with stroke, clots, aneurysms and other pathologies to develop surgical skills in a no-risk environment.

Models are customized to present a range of anatomies so physician participants are exposed to the limits of what they will see when treating living patients. "3D vascular models represent a new paradigm for training the next generation of doctors. This paradigm includes surgical and endovascular simulation and skills evaluation before they are allowed to treat patients," said Dr. L. Nelson Hopkins, founder of the Jacobs Institute and the Gates Vascular Institute.

Training on 3D printed models can be done virtually anywhere, avoiding the cost and complexity of operating in the controlled environments required for animals and human cadavers. Facilities with biohazard controls, refrigeration storage or on-site care are not required, lowering training costs significantly. Additionally, 3D printed models can mimic a range of tissues more realistically than processed cadavers, which no longer retain the feeling of live tissue. The models can incorporate access points, sensors and blood-flow simulation, enabling highly dynamic and interactive training. Complications can be designed into the model to ensure the first time a trainee faces a complex challenge is not with a patient on the table.





The clear, flexible material of this vascular model was used to assess the feasibility of a proposed aneurysm treatment, before operating on the patient.

### ACCELERATED INNOVATION

3D printing enables the Jacobs Institute to accelerate and improve medical-device design. The team at CTRC also facilitates preclinical testing for product validation using customized anatomical models to capture feedback on device performance. The sooner medical-device manufacturers gain insight into clinical performance and device interactions with patient anatomy, the faster they can respond with design changes before clinical trials. Preclinical validation testing is greatly improved when physicians can evaluate devices in realistic anatomical models that accurately simulate clinical performance. “Recently we tested how effectively a particular device could reach the brain depending on tortuosity of the anatomy. We designed a series of models with differing levels of tortuosity, then tested the devices,” said Dr. Adnan Siddiqui, chief medical officer at the Jacobs Institute, vice chairman and professor of neurosurgery at University at Buffalo Neurosurgery, and director of neurosurgical stroke service at Kaleida Health. “This is impossible to do in animals and patients, but 3D printing makes it easy in a smooth, streamlined process.”

In addition to improving new devices’ performance in treating patients, the early feedback that designers glean from real-anatomy testing lets them avoid costly, potentially unsuccessful animal testing.

### INTEGRATED SURGICAL PREPARATION

When preparing for the most challenging cases referred to GVI and CTRC, physicians look to 3D printing. Using the same techniques developed in making anatomical models for training and device testing, staff at the Jacobs Institute take patient scans and create physical models to plan procedures, communicate with surgical teams, educate patients and their families, and practice the procedure before entering the operating room. Converting real patient-derived anatomy into realistic 3D models allows physicians to integrate visual and tactile clues into their surgical plan.

“3D printing is valuable in planning complex procedures with a team. Without it we prepare for complications on a theoretical basis,” said Vijay Iyer, M.D., Ph.D. “Many times, despite the best theoretical planning, we are faced with circumstances where we don’t know what to do.”

Physical models allow the team to test theories and reveal potential complications before the patient is on the table and time is critical. In a recent case treating a female patient with a brain aneurysm, the team was able to evaluate the suitability of their surgical solution before implementation.

"Originally our plan was to treat her aneurysm with a metallic basket called a web device that we would deliver into the aneurysm using a tiny tube. In this case, we were able to try to deploy that web device and found it wasn't going to work. Based on the 3D model, we were able to preempt potential complications and devise a much more optimal means of treating the aneurysm," said Dr. Siddiqui.

## EFFICIENT CUSTOMIZED RESEARCH

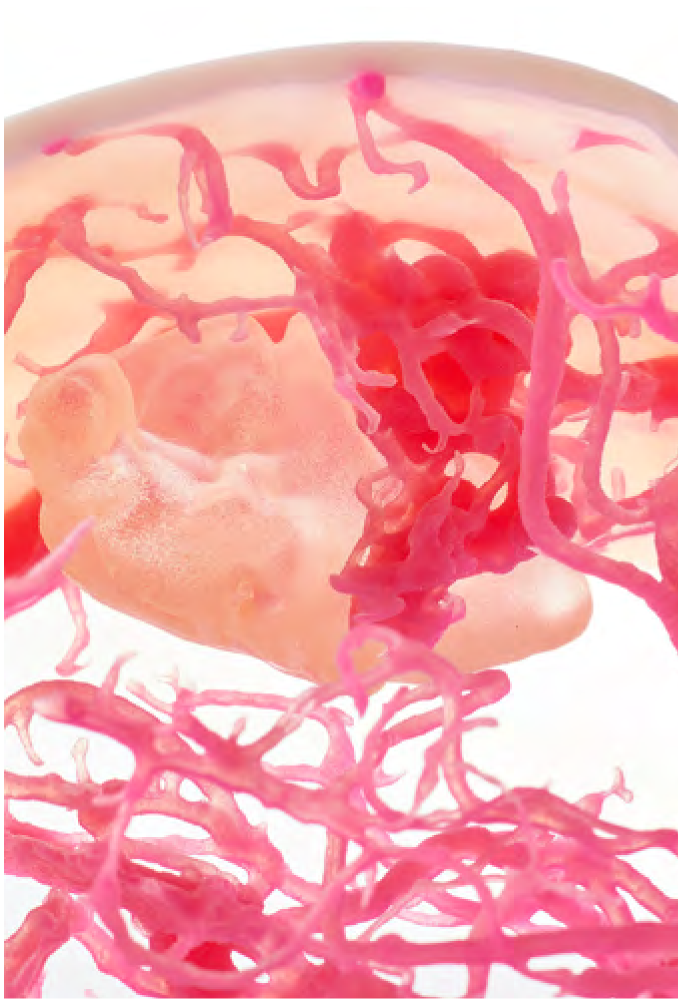
Ciprian Ionita, Ph.D., is a research assistant professor of biomedical engineering and neurosurgery at University at Buffalo. His team at the Jacobs Institute regularly uses a 3D printer to create custom fixtures for scientific equipment and experiments.

"Using our in-house printer, we don't have to rely on external machine shops that would generate both lag time and expense. Most of these fixtures and components can be 3D printed within a few hours," said Dr. Ionita. PolyJet technology's signature high resolution delivers the accuracy needed in the lab.

For high-tech X-ray components, the team designed and 3D printed an enclosure that holds an electron-multiplying change coupling device, the optic-transmission optics and the electronics for the Peltier cooling system. The system must operate at near zero degrees Celsius while ensuring perfect optical coupling, and printing using the Durus™ 3D printing material can accommodate this temperature change.

## THE FUTURE OF 3D PRINTING IN HEALTH CARE

Through its collaboration with GVI and CTRC, the Jacobs Institute is harnessing the power of a 3D printing platform in all aspects of health care. From training physicians to designing and testing life-saving devices, from preparing for surgery to conducting life-changing research, 3D printing is an indispensable tool for the future of medicine.



The fine details and color differentiation of this arteriovenous malformation model are made possible by the multi-material, multi-color capabilities of the Stratasys J750.

# CHAPTER FIVE -

## HOW THE STRATASYS J750 FITS

### MORE THAN JUST AN EFFECTIVE TOOL

Based on case studies and evidence from the field, it's clear that 3D printing makes innovation possible, speeds medical device development and provides physicians with lifelike anatomical models for training and surgical planning. The decision for medical device companies, hospitals and physicians is which specific tool to choose to take advantage of these possibilities.

The Stratasys J750 is one choice among an ever-growing array of 3D printers in the marketplace. But its capabilities and versatility make it more than just a 3D printer. It's a solution-maker. Viewing it as simply a sophisticated tool is limited because it doesn't just make prototype parts. It makes it possible for the engineer at a medical device company to produce prototype parts for evaluation and physician feedback, faster. That shortens the development cycle, lowers cost and reduces time to market, benefitting patients sooner.

It has multi-material capability but it doesn't just produce parts with flexible and rigid characteristics. Rather, it helps educate physicians through accurate anatomical training models, letting them create new procedures and enhance their skillset, ultimately enabling them to improve health care outcomes.

### CHALLENGES AND SOLUTIONS

3D printing technology isn't new and there are other 3D printers that are capable of colored models. But each system has its drawbacks and fails to completely address the full scope of pain points impacting its users. The Stratasys J750 is designed to address these problems through improved technology, workflow and capacity.

Perhaps the best way to understand how the Stratasys J750 can benefit is to see how its breakthrough technology offers real solutions, using scenarios from the medical industry. What follows is a series of challenges physicians and medical device developers typically face and how the Stratasys J750 addresses those problems.

# CHAPTER FIVE -

## HOW THE STRATASYS J750 FITS

Challenge:

A surgeon's skills rely on practice and hands-on training for mastery of existing and new surgical procedures. However, traditional training methods don't provide sufficient opportunities with anatomically-realistic tools to gain this proficiency in a low-risk environment. Current 3D printing technology is capable of producing anatomical models, but this technology is limited because it doesn't offer flexible, tissue-like materials that reproduce the organs with realistic pathology and detail.

The Stratasys J750 Solution: Realistic, 3D printed anatomical training models with colored, flexible materials and hollow channels and chambers that realistically simulate actual human tissue. Faster print times and soluble support capability reduce the time to print and clean the models.

The ability to produce 3D replicas of human anatomy from CT and MRI scans in realistic, detailed, multi-textural material lets physicians learn and train on realistic models that accurately replicate human tissue. It allows them to practice multiple times in a realistic but no-risk setting, with models that provide tactile feedback consistent with human physiology. This enables research hospitals to maximize learning resources and helps training surgeons become proficient on delicate and state-of-the-art procedures.

Other 3D printing technologies produce colored models, but not with variable flexibility and the option for clear, translucent or opaque characteristics in the same model. With some 3D printers, the color is not consistent and the amount of post-processing is time-consuming and/or messy or involves hazardous materials.

The Stratasys J750's texture mapping capability gives this heart model the variation and smooth transition of color for a realistic visual appearance.

# CHAPTER FIVE -

## HOW THE STRATASYS J750 FITS

Challenge:

A medical device manufacturer is developing a new catheter designed with greater tip articulation for better maneuverability within tortuous-path blood vessels. Validating the design intent requires functional testing to assess trackability, pushability and other key functional parameters. However, 2D models of blood vessels don't replicate the true, three-dimensional nature of actual blood vessels. Testing on animal physiology poses challenges too, due to limited availability, expense, and the difficulty matching human anatomy.

The Stratasys J750 Solution: 3D printing allows the creation of anatomically accurate blood vessel models created from human medical scans. The Stratasys J750 affords the ability to create those models in clear, flexible materials that more accurately represent the pliability of human tissue, providing greater realism in evaluating the effectiveness of the new catheter design.

With a more accurate model, the device manufacturer achieves more realistic feedback on the effectiveness of the new catheter design. That speeds the development process by identifying problems before clinical trials and provides the feedback necessary to continue with the development and certification process.

Realistic 3D printed models for device testing also avoid the cost, availability and ethical issues associated with animal testing.

# CHAPTER FIVE -

## HOW THE STRATASYS J750 FITS

Challenge:

Creating a breakthrough medical device is not always possible using traditional materials, methods and tools. The combination of unique materials and fast production development are needed to arrive at a solution that meets the design intent.

Syqe Medical faced this challenge in developing the world's first selective-dose medicinal plant inhaler for pain abatement. This breakthrough design required parts that could not be produced through any other method than additive manufacturing, and necessitated materials with a combination of rigid and flexible properties.

The Stratasys J750 Solution: As a multi-material 3D printer, the Stratasys J750 provides designers the ability to achieve exclusive material properties from the combination of rigid and flexible photopolymers. Because additive manufacturing is not limited by geometric complexity, the Stratasys J750 lets designers create parts that are free from design-for-manufacturability constraints. High-speed and high-quality print modes give developers the capabilities for both speed and accuracy in the development process.

Additive manufacturing gave Syqe Medical the precise tool it needed to create a new device that otherwise wouldn't have been possible using traditional materials and tooling methods. The ability to quickly develop and produce most (70%) of the parts for the inhaler allowed the company to experiment sufficiently within tight time constraints to successfully pass clinical trials. The unique blend of flexible and rigid materials provided the right combination to allow the inhaler to function properly.


This inhaler device developed by Syqe Medical and used in clinical trials incorporates 80% 3D printed parts, including biocompatible MED610™.

The versatile capabilities of the Stratasys J750 3D Printer let users do what they do best in a more time and cost-efficient way. More significantly, perhaps, it provides a platform to develop new solutions, better products and inspired research by the doctors, biomedical engineers and medical 3D printing technicians who use it.


An investment in this kind of technology is rightly viewed as a significant capital expense. But that expense needs to be examined in light of the potential return on investment afforded by this technology.

For medical device manufacturers, accelerating the product development process increases the chances of being first to market and gaining an advantageous competitive position. Faster product iteration also lets designers refine the design, minimizing the chance for in-service product failures and quality problems. Both scenarios carry a potential positive financial impact. Medical device makers that already leverage 3D printing but outsource to service bureaus should look at their annual 3D printing expenditures to determine if bringing this technology in-house provides more favorable economics.

For physicians, the focus on implementing 3D printing technology for medical purposes is naturally on improving patient outcomes. But the application also has positive financial implications beyond clinical results. Using 3D printed anatomical models to practice difficult surgical procedures ahead of time can reduce operating room time and minimize post-operative impact on the patient.

A 2015 experiment involving lumbar discectomy studied the impact of using 3D printed patient-specific lumbar vertebral models for preoperative planning. Doctors for one group of patients used the models for surgical planning whereas another group underwent normal lumbar revision. Among other benefits, operating time was markedly reduced by 25 minutes in the group that benefitted from the surgical planning models [1]. At an average operating room rate of $62/minute [2] in the U.S., this savings equates to over $1,500. This is consistent with an analysis of published research on 3D model-based planning showing an average operating room savings of $1,695 per procedure [3]. As it pertains to applied patient care, evidence of 3D printing's economic benefits is mounting [4].

Additional benefits of medical 3D printing use cases include avoidance of complications and readmissions. A 2016 study revealed that one in six medical procedures results in complications, with a mean additional cost to hospitals of $20,000 [5]. This reduces a hospital's profit margin from 5.8% to 0.1%, a real bottom-line impact [6]. Average readmission cost for Medicare and Medicaid in 2013 averaged $13,050 [7].

# CHAPTER SIX -
## BEYOND PATIENT OUTCOMES: FINANCIAL CONSIDERATIONS

If you develop new medical devices, provide healthcare services or are involved in medical research, consider the following questions:

- Would your medical device company benefit from a shorter product development cycle and better designs resulting from rapid creation of highly accurate parts using multi-material 3D printing?
- Could you provide better patient outcomes by using accurate, patient-specific surgical planning models that not only provide better health care but also yield positive financials?
- Would your university benefit by attracting the best and brightest medical students and leading researchers by offering access to state-of-the-art 3D printing technology and realistic training models?

Stratasys 3D Printing solutions have a proven track record helping companies and organizations meet these goals, and the Stratasys J750 continues that tradition with the next level of 3D printing capability.

Get a closer look at the Stratasys J750 3D Printer by visiting our website. Then, contact the Proto3000 team when it's time to start the conversation about how this technology can solve your business and healthcare challenges.

---

[1] Application of the polystyrene model made by 3-D printing rapid prototyping technology for operation planning in revision lumbar discectomy. Li C, Yang M, Xie Y, Chen Z, Wang C, Bai Y, Zhu X, Li M. https://www.ncbi.nlm.nih.gov/pubmed/25822935.

[2] Macario, A. What does One Minute of Operating Room Time Cost? J. of Clinical Anesthesia, Vol. 22, 2010. Available online July 2013.

[3] 3D Printing for Surgical Planning – Identification of Candidate Procedures and Resulting Value. Stratasys White Paper. November, 2016.

[4] The Clinical and Economic Promise of 3D Printing for Surgical Planning. Quorum Consulting White Paper commissioned by Stratasys. December, 2016.

[5] Healy, M. A., Mullard A. J., Campbell D. A, Dimick, J. B. Hospital and Payer Costs Associated With Surgical Complications. JAMA Surg. 2016;151(9):823-830. doi:10.1001/JAMA Surg.2016.0773.

[6] Healy et al, Hospital and Payer Costs Associated with Surgical Complications. JAMA Surg. 2016.

[7] All-Cause Readmissions by Payer and Age, 2009-2013. Healthcare Cost and Utilization Project – Statistical Brief #199. Agency for Healthcare Research and Quality. December, 2015

proto3000

stratasys

HEADQUARTERS

6260 Highway 7
Vaughan, ON L4H 4G3
+1 888 887 7686
+1 905 738 1779

1650 Rue Michelin
Laval, QC Suite 101 L4H 4G3
+1 888 887 7686
+1 514 370 5548

PROTO3000.COM
ISO 9001:2008 Certified