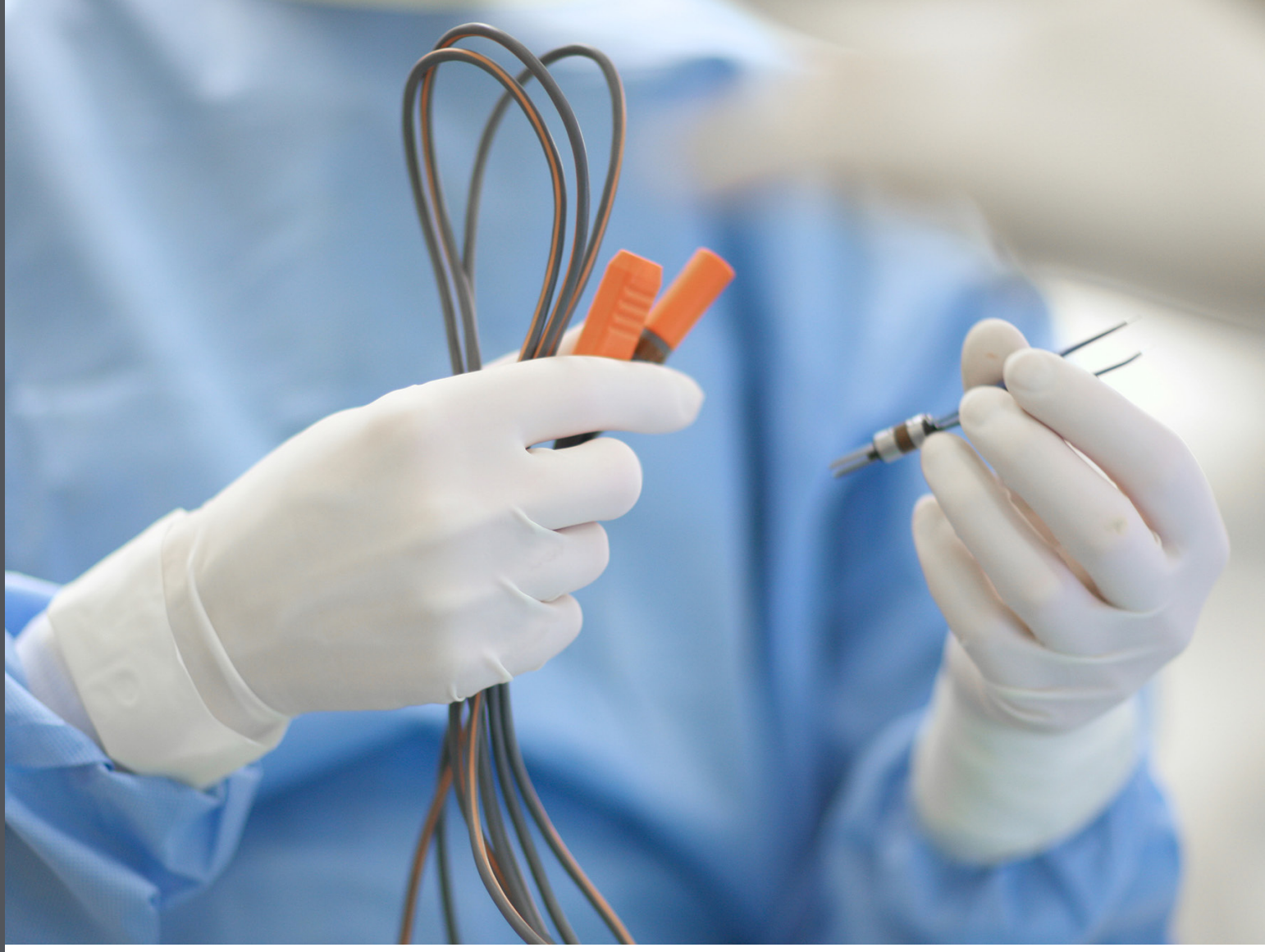
2018



Transforming the Medical Device Industry

Medical devices are a $150B+ industry. Increased life expectancy and an aging population are driving the market but the challenges of the regulatory environment and fierce competition can still leave device-makers scrambling. **Success in this fast-moving field means delivering better solutions quicker and at a lower cost.**

Getting a leg-up on the competition requires a product development process that adds value at every stage of the product development lifecycle. Circumventing traditional manufacturing methods and integrating **3D printing** at every stage of the design cycle – from concept to post-market – saves time and cost while helping **speed your device to market**.

3D printing is a proven technology, delivering state-of-the-art capabilities to fuel your competitive advantage. **Accelerate innovation with 3D printing for the medical device industry.**

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Solution Brief

Prototype at the Speed of Design

Medtronic, a global leader in the medical device industry knows they don't have all the answers when they begin the design process.

"We often see one or two VIP surgeons per day," said Medtronic design engineer Richard Franks. "They come in with a problem to solve in the morning. They explain their need to an engineer who will model a solution and make a prototype. Often by the next morning we'll have a prototype in [the surgeons'] hands."

3D printing enables fast iterations more often, allowing them to test what works best and change course as often as needed without the high cost and delays of conventional manufacturing.

Speeding Time to Market

Syqe Medical, a med-tech start creating an advanced inhaler knew 2D drawings were simply not enough to show the innovation of their breakthrough inhaler concept to potential investors. "We turned our 3D printer into our R&D hub. 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. Our 3D printed model changed the whole conversation with the investor," said head of design Itay Kurgan.

3D printing creates a fast feedback loop that fast-tracks development. Gaining feedback early helps identify areas of improvement, resulting in devices that lead to better clinical outcomes for innovators like Syqe.

"When we were designing the inhaler, we would design a part on Monday morning and by Tuesday morning it would have already been changed five or six times. By the end of one week we accomplished what would take four weeks with conventional manufacturing methods," said Perry Davidson, Syqe Medical founder and CEO.

75% Time Savings

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

Perry Davidson

The Value of Realism

The Jacobs Institute (JI) knows the value of evaluating medical device designs using realistic anatomical models. Not only is pre-clinical validation testing more effective but it also saves cost when 3D printed anatomical models are used to capture feedback.

The JI wanted to evaluate how effectively a particular device could reach the brain. “We designed a series of models with different levels of tortuosity, then tested the devices,” said Dr. Adnan Siddiqui, chief medical officer at JI. “This is impossible to do in animals and patients, but 3D printing makes it easy in a smooth, streamlined process.”

Comparing performance over a period of time in these models leads to faster design breakthroughs, minimized clinical trial failures and accelerated regulatory filings and approvals.

Cardiovascular Systems Inc. (CSI), a medical device company treating peripheral and coronary artery disease couldn’t properly test their devices using conventional models. Replicating the exact anatomical features and desired pathology proved both costly and difficult.

CSI’s Savings

	Time	Cost
CNC Machining	21 days	$12,000
3D printing	2 days	$500
Savings	**90%**	**96%**

3D printed anatomically correct models paved the way for repeatable bench tests. “Our previous model simulated calcium deposits with cow bone...but it doesn’t replicate complex anatomical features,” said Nick Ellering, product development engineering manager, CSI. CSI experimented with multi-color, multi-layer anatomical models. “As our device removes simulated lesion material, we can easily see and measure how far into the multicolored layers it’s orbiting. We take those learnings, go back to the lab, improve things and are continuously striving to develop products that are safer and more effective.”

Accelerating Clinical Evaluation

Nidek Technologies, manufacturers of ophthalmological devices, knows the key to verifying manufacturability is accurate prototypes. But the multiple iterations usually necessary for success are costly and time-consuming to produce.

"The ability to validate designs early in the product development cycle helps us eliminate costly iterations during manufacturing, as well as significantly reducing our time-to-market compared to traditional prototyping methods," said Cesare Tanassi, CEO at Nidek.

3D printing also proved critical for the development stage of clinical trials. "For the Gonioscope, the quality of the 3D printed components helped the device pass a year-long clinical trial where eight global medical centers examined it. This device will soon be utilized by clinics and hospitals around the globe, contributing to a novel way to diagnose glaucoma," said Tanassi.

Nidek Streamlines Prototyping

3D Printing vs. CNC

75% Less Cost

50% Faster Time-to-Market

80%

of Syqe's clinical trial device was 3D printed.

Syqe first tried creating its novel inhaler for clinical trials using traditional CNC machining. But frequent iteration became costly. "One of the biggest design challenges was the inhalation system. Different patients inhale in different ways, different age groups have different lung volumes. We needed to create an airflow system that is completely patient-agnostic," said Perry Davidson, Syqe founder and CEO.

Ultimately, Syqe's successful clinical trial used a device that was 80% 3D printed. Its final product also contains many 3D printed parts, even ones that come into contact with the human body. For example, the inhalation mechanism is 3D printed using Stratasys MED610™, a biocompatible material.

Advance Physician Training

Cardiovascular Systems Inc. (CSI) realized there's nothing like the real thing – real cases their customers shared from the field – to better understand and train physicians in treatment methods. The medical device company 3D prints training boards that replicate the anatomy and tortuosity of the vessels – a transportable tool their sales training representatives depend on to demonstrate proper techniques.

"We started 3D printing coronary training boards several years ago," said Jake Draxler, a CSI product development engineer. "Every sales training rep used those to interact with circulating nurses, techs and physicians at their sites, and trained them on techniques related to our "Instructions For Use." It's a valuable tool...because it's small, transportable and very mobile. We can do many different lesion models on it...that allow us to demonstrate proper treatment technique within various coronary arteries."

Medical device developers like CSI use 3D printed models that mimic a range of tissues, incorporate access points, sensors and blood-flow simulation. These anatomical models replicate hard plaque and pliable, durable vessels without the need for biohazard controls. The digital model inventory also makes it easy to print more as needed anytime, anywhere.

Resolving In-Market Failures

Medtronic, a global leader in the medical device industry, was able to discover the root cause of a product failure three months earlier than expected – all thanks to 3D printing. The ability the device maker had to iterate quickly meant many possible solutions could be tested in a flexible material that mimicked the flexibility of the device.

"Unfortunately, we launched a product with a cable...that was failing at an unacceptable rate. Once I was done finding the root cause, I was able to attack it with a number of different ideas using 3D printing to model it up and functionally test it. We qualified it, launched it and most importantly, there were no failures again. We were able to get back into the market a few months earlier than expected and regain the confidence of our customers. We wouldn't have been able to do that without 3D printing," said Scott Hanson, a TDS Design Manager for Medtronic.

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Scott Hanson
Medtronic

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