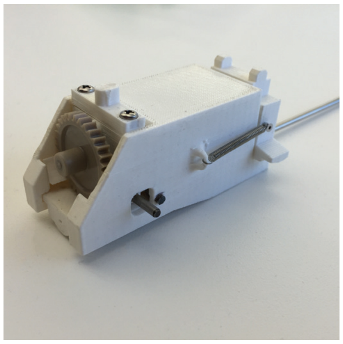
Life-Saving Solutions

3D PRINTING IMPROVES MEDICAL DEVICE DEVELOPMENT FOR HEART DISEASE TREATMENT

"Moving 3D printing in-house made it possible for us to evaluate more design alternatives than in previous generations, resulting in a product that makes a substantial leap in performance over its predecessors."

– Nick Rydberg, Cardiovascular Systems, Inc.

CASE STUDY



CSI engineers built a new prototype mechanism every few days using FDM technology to test new designs. An early prototype of the mechanism is shown above.

More people die from coronary heart disease than any other disease. According to the Centers for Disease Control (CDC), each year every one in four deaths in the United States is due to heart disease. One of the most common and severe forms involves the formation of calcified plaque inside the coronary arteries. Patients with highly calcified arteries do not respond well to common treatments such as stents and balloons.

But Cardiovascular Systems, Inc. (CSI) is creating innovative solutions to assist physicians in treating patients with complex cases. CSI developed an orbital atherectomy system (OAS) to safely reduce arterial calcium with sanding and centrifugal force, enabling safe and effective stent deployment. The OAS device makes conventional treatment methods more effective in many cases.

Improving Device Design

The OAS device contains a complicated mechanism that enables the surgeon to control the motion of the device, while monitoring its movement through the artery on a computer screen.

With more than 30 actively moving parts, everything needs to fit together perfectly for the device to deliver maximum results. CSI builds prototypes for each component to test the fit, function and overall performance. Previously, CSI contracted a machine shop to build the prototypes, which cost about $12,000 and took three weeks.

"In developing products, the schedule and budget limited us to about three prototype iterations," said Nick Rydberg, mechanical engineering manager for CSI. "We often had to abandon far-fetched ideas because it would have been too expensive to build a prototype to test them."

To reduce costs and accelerate product development, CSI switched to using a 3D printing service bureau. This cut costs down $4,500 and took only one week of lead time. To establish an even more agile design process, CSI went one step further and brought 3D printing in-house.

"With our FDM and PolyJet 3D printers, we can build a new prototype in only two days at a cost of about $500," Rydberg said. "Our engineers are able to manage everything themselves, including maintenance, material and jobs, eliminating the need for an additional resource."

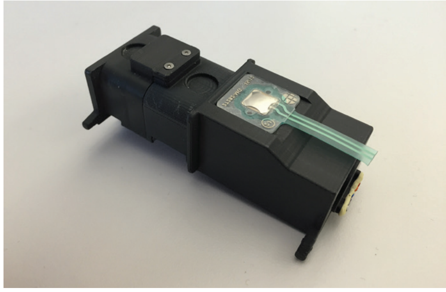
CSI uses PolyJet™ for flexible and transparent parts so engineers can view internal components. FDM® technology is used to produce parts with strength and wear resistance to withstand functional testing.

3D printing has been an invaluable tool for CSI engineers in developing their latest-generation product. During the design process, engineers were able to make alterations that saved time and improved the device greatly, thanks to 3D printing.

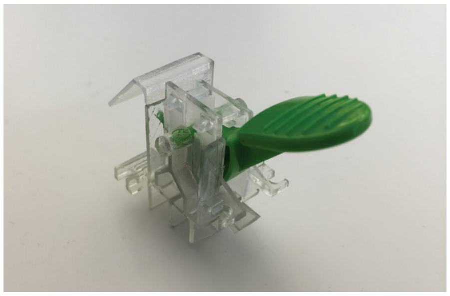
"Moving 3D printing in-house made it possible for us to go through more than 30 prototype iterations, each with dozens of parts," Rydberg said. "We were able to build a new prototype every couple of days to try out new ideas and see how the mechanism worked. This made it possible to evaluate more design alternatives than in previous generations, resulting in a product that makes a substantial leap in performance over its predecessors."

3D Printing Anatomical Models for Testing and Training

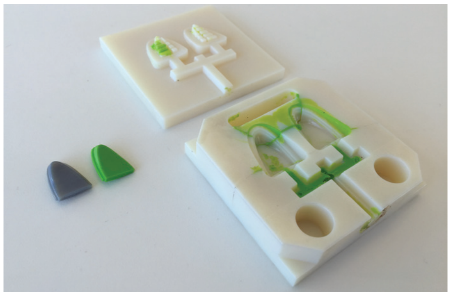
CSI also 3D prints anatomical models to test their devices and train surgeons on the optimal uses of the OAS. CSI engineers can 3D print realistic models that replicate patient-specific anatomy using angiograms and computed tomography (CT) scans. 3D printing arterial models with rubber-like PolyJet materials provides a similar feel and responsiveness to live human tissue, adding to the realism and similarity to the clinical environment.



CSI engineers built a new prototype mechanism every few days using FDM technology to test new designs. The final prototype is shown above.



This mechanism was printed in VeroClear™ so engineers could view internal components during testing.

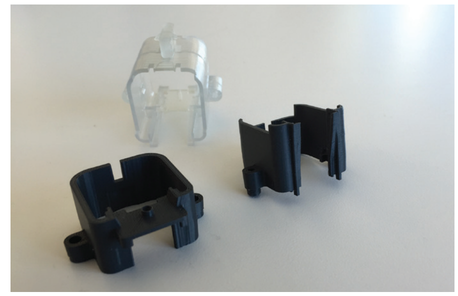


Santoprene finger grips were produced with a 3D printed mold.

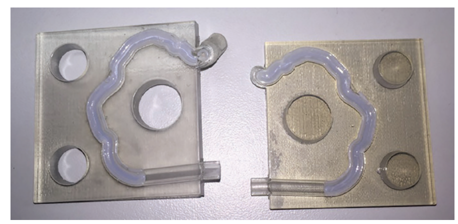
By using their devices on these anatomical models, engineers can simulate how a device will perform in a particular case. This provides clinically relevant feedback without the cost and complexity of traditional testing, and leads to design changes that can improve patient outcomes. A recent clinical study showed successful stent delivery in 97.7% of patients receiving OAS treatment with less than 50% stenosis in 98.6% of the patients.

METHOD USED TO PRODUCE PROTOTYPE MECHANISM WITH ABOUT 30 COMPONENTS	TIME	COST
CNC Machining	21 days	$12,000
3D printing service bureau	7 days	$4,500
In-house 3D printers	2 days	$500
Savings vs. service bureau	5 days **71%**	$4,000 **88%**

Large housings were printed with FDM because ABS wear resistance made it possible to test sliding surfaces.



These parts were printed in VeroClear to check fit, then in ABS for functional testing.



This mold for an anatomical model of a coronary artery was printed with VeroClear and TangoPlus™ material.

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