> “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.

Peripheral model 3D printed using PolyJet technology utilizing three different materials.

CASE STUDY

Printing Pathways to Medical Innovation

3D PRINTING’S VERSATILITY PAVES THE WAY FOR MEDICAL ADVANCEMENTS BY CARDIOVASCULAR SYSTEMS, INC.

Cardiovascular Systems, Inc., based in St. Paul, Minnesota, is a medical device company focused on developing and commercializing innovative solutions for treating peripheral and coronary artery disease (PAD and CAD). The company’s Orbital Atherectomy Systems treat calcified plaque in arterial vessels throughout the leg and heart in a few minutes of treatment time, and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. To help fight the battle against CAD and PAD, CSI works continuously to advance their devices and develop new innovations. Work that relies greatly on a wide scope of 3D printing applications.

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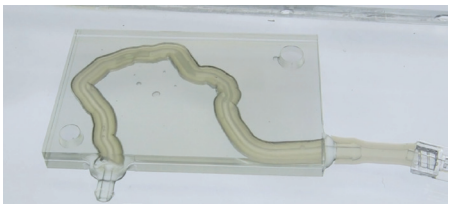
“3D printing gives us the versatility to rapid prototype, test our device from a reliability standpoint and print case recreations,” said Jake Draxler, a product development engineer. “We take those learnings, go back to the lab, improve things, and are continuously striving to develop products that are both safer and more effective.”

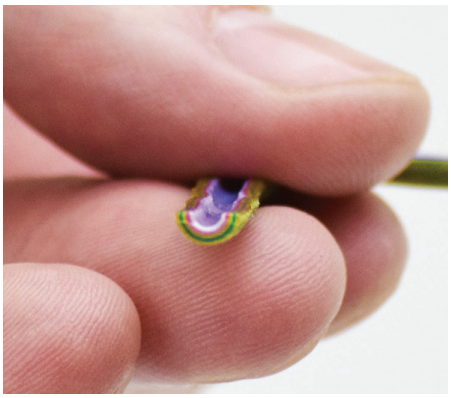


CSI 3D prints coronary blend plates using PolyJet technology.

Fast, Responsive Product Development

Developing the tools to help safely treat atherosclerosis requires constant ideation and in-depth analysis. 3D printing enables CSI to quickly create prototypes of new design ideas, or improvements to existing tools.

“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,” said Will Besser, a senior product development engineer. “The earlier in the development process you find and fix issues, the less expensive it is. That’s where rapid prototyping really shines, it helps get actual physical objects in your hand, saving us time and money.”



CSI’s 3D printed lesion model that uses multi-material and multi-color PolyJet materials.

Advancing Benchtop Testing and Physician Training With 3D Printed Models

Benchtop testing on clinically relevant anatomical models enables a deeper understanding of the effectiveness of CSI’s Orbital Atherectomy System (OAS) during the preclinical stage and after devices are in the field. CSI evaluates some performance using 3D printed models based on patient imaging data. Using 3D recreations of actual anatomy allows for faster, more clinically relevant feedback.

“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,” said Nick Ellering, a product development engineering manager.

CSI’s Reliability Engineering team also benefits from in-house 3D printing during failure analysis process on complaint devices, in addition to standard failure analysis procedures.

“We’re able to quickly model clinically relevant anatomical pathways to recreate field failures on the bench in an effort to understand the mechanism by which they occurred,” said Henisha Dhandhusaria, a reliability engineer. “We experiment with different vessel path models and print materials while making iterative design modifications to the models during failure analysis investigations. This helps find the root cause of failure more efficiently and in a controlled manner.”

Printing with Stratasys PolyJet™ technology allows the models to incorporate both soft tissue vessels and hard calcification analogues within the same model to replicate atherosclerosis. Once the device has been deployed in a 3D printed model, CSI splits the model in two so engineers can measure how effectively the device removed calcifications from different types of vessels.

“It’s a great way to get instantaneous feedback,” said Draxler. “We’ve also experimented with multi-colored, multi-layered materials. As our device removes simulated lesion material, we can easily see and measure how far into the multicolored layers it’s orbiting.”

Anatomical Models of Complex Cases Enhance Physician Training

By using 3D printers to create anatomical models that replicate hard plaque and pliable, durable vessels, CSI can more closely simulate complex cases, which is ideal to supplement training for clinicians using their device.

“We’re able to print clear replications of lesions we can see through while treating with our device,” said Ellering. “This allows us to better explain and help them understand how our device works in different situations, and is very useful in explaining to physicians the best method of treating with our device.”

CSI can recreate challenging cases their customers share directly from the field, which enables more specific physician training and a better understanding of how to treat those complex cases.

“We started 3D printing coronary training boards several years ago,” said Draxler. “Every sales training rep used those to interact with circulating nurses, techs and physicians at their sites, and trained them on proper treatment techniques related to our Instructions For Use.”

CSI rapidly iterated on the 3D printed training boards, changing the anatomy, flow rates and stress test prototypes within the 3D printed models to simulate specific cases physicians needed to treat.

“It’s a valuable tool we could rapidly deploy, because it’s small, transportable and very mobile. We could do many different lesion models on it, including 3D printed ones, that allowed us to demonstrate proper treatment technique with various coronary arteries,” said Draxler.

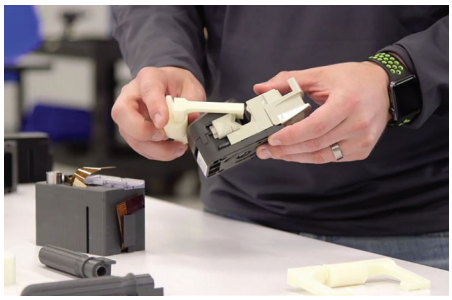
Manufacturing

As CSI projects go through development, product developers collaborate with their manufacturing counterparts to 3D print manufacturing aids to improve production quality and efficiencies. For example, developers and engineers use 3D printing to make sure welding processes for specific tools are optimal through extensive fit testing and iterations.

“[3D printing] helps improve our manufacturing processes by enabling us to test fit everything,” said Curt Miller, a manufacturing engineer. “It gives us the ability to know that when we use these fixtures in production, everything will perform the way we want. 3D printing helps us produce a robust, repeatable process.”

CSI’s innovative drive has expanded their utilization of PolyJet and FDM® 3D printing across all facets of their business, greatly benefiting patients through successful treatment of atherosclerosis.

The coronary training boards CSI uses to help train clinicians on the proper treatment techniques.



Several of CSI’s 3D printed manufacturing aids

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