Improving an innovative medical device through additive manufacturing

At Fast Radius, we like to say that manufacturing is important, because we know that the physical things manufacturing creates can advance the human condition by making it healthier, safer and more productive. There is probably no better embodiment of this idea than Coapt, a Chicago-based company that produces myoelectric pattern recognition systems for upper limb prostheses.

But what is a myoelectric pattern recognition system, exactly? When explained in laymen's terms, it's easy to understand – but still incredible to comprehend. The Coapt COMPLETE CONTROL system is an FDA class II medical device that enables people who have lost their upper limbs to fully control movement in their prosthetic arms. It does this through an electrical pattern recognition system that captures coordinated muscle signals sent through the brain, decodes the patterns in real time, and translates those patterns into the wearer's intended movement – such as picking up an object, or waving a hand.

Coapt has been producing this incredible product for five years. In 2018, the company had gathered enough optimization feedback from its users to begin production on the second generation of COMPLETE CONTROL. This meant not only retooling the system's software, but redesigning the hardware components, too. Coapt needed a manufacturing partner that moves with the speed required to hit their product release timeline. They turned to the team at Fast Radius to help them meet their goals. Fast Radius was able to provide three key benefits for Coapt:

1. **Rapid prototyping and development**
2. **Additive technology and materials expertise**
3. **Additive production supply for end-use parts**

Rapid prototyping and development

Over the course of twelve weeks, Fast Radius was able to print 36 unique designs yielding 195 parts for the Coapt team to evaluate.

There were many parts that Coapt wanted to test and make differently in the next wave of COMPLETE CONTROL. And it wasn't just the geometries that Coapt wanted to iterate, it was also the textures and aesthetics of the parts. With so many variables to consider, it didn't make sense for Coapt's engineering team to prototype using legacy processes like injection molding. Instead, the team opted to use additive processes– specifically Carbon® Digital Light Synthesis (DLS) and HP Multi Jet Fusion (MJF). Over the course of twelve weeks, Fast Radius was able to print 36 unique designs yielding 195 parts for the Coapt team to evaluate. Producing this volume of prototypes so quickly not only helped Coapt get to an end-product much faster than they anticipated, but it also gave them the opportunity to test a wide variety of factors at a rapid pace.

Additive technology and materials expertise

Coapt was familiar with additive manufacturing technology, but 3D printing wasn't necessarily a core discipline for their engineers. Blair Lock, founder and CEO of Coapt, said that his team had previously worked with service bureaus to print prototypes, but the overall experience was lacking. "Service bureaus were happy to take our designs and print them, but they would expect us to specify the exact technology or materials to use, and we weren't sure," said Lock. Fast Radius's full-spectrum service model proved to be a much better fit for Coapt's needs.

"Fast Radius helped us understand all of the additive technologies and materials that were available to us for this project," said Lock. "They guided us in the right direction based on our requirements and were able to give us feedback on how to improve our designs to manufacture them with 3D printing."

Being able to lean into Fast Radius's additive engineering and design expertise significantly bolstered Coapt's own engineering chops. But utilizing Fast Radius's globally-recognized factory gave the company an extra edge. Instead of heavily investing in on-site 3D printing technology for prototyping, Coapt tapped into Fast Radius's technology infrastructure to make rapid iterations as needed.

This fabrication dummy was made using HP MJF and PA 12 material.

Additive production supply for end-use parts

There are nearly a dozen core hardware components that make up the second generation of the COMPLETE CONTROL system, with each one manufactured using the most efficient process for that part – that includes additively manufactured parts, made in Fast Radius's factory.

Two of those parts are the calibration button and can plugs. Each of these pieces are very small with fine details. The button in particular needed to attain a certain textural finish since the user will interact with it often. Because of the size and aesthetic requirements, both parts are manufactured using Carbon® DLS technology and EPU 40 material. The Carbon® M2 printer enables a large throughput for these parts; see the table below for a full breakdown of the build.

PART		DIMENSIONS (MM)	PARTS PER PRINT	PRINT TIME
BUTTON		11 x 11 x 5.5	135	35 MINUTES
CAN PLUG		1.75 x 5.2 x 3.2	848	23 MINUTES

Coapt chose to make one more critical part using additive manufacturing: the fabrication dummy. While the fabrication dummy isn't on the final prosthetic, it is part of the kit that the prosthetist uses to ensure that COMPLETE CONTROL's electronic circuit board housing will fit correctly within the wearer's prosthetic. This part is made using PA 12 material with HP MJF technology – a perfect fit based on the part's need for rigidity and light weight.

End-to-end manufacturing partnership

In the case of Coapt, Fast Radius provided a strategic manufacturing partnership over the full lifecycle of the product – from design optimization, to prototyping, all the way to production. If you're looking to produce a complex product and want to see how additive manufacturing can speed up or improve your development cycle, talk to the team at Fast Radius today.

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