

Processes for Rapidly Ensuring a Quality Product

Device companies are always seeking new methods with which to save time and money in the design and manufacturing processes. Two methods associated with prototyping provide a production quality product that can then be tested and appropriate changes made before a full-scale manufacturing run is produced. While it can be used in a variety of device sectors, a cardiovascular example is provided in this article.

By Jeff Hanson

Independent studies conducted by the government and many healthcare associations suggest that between 100,000 and 200,000 deaths in the United States each year are attributed to medical errors. Those errors cost the government nearly \$40 billion, of which almost \$20 billion could be prevented. The Agency of Healthcare Research and Quality claim that medical errors are the eighth ranked cause of death in the country—coming in higher than motor vehicle accidents, breast cancer, and AIDS. Those numbers, coupled with the cuts to healthcare dollars plaguing the industry year after year, present a challenge to medical device designers.



Assortment of medical components built by the FDM process.

The key is to introduce the right product to the right market at the right time. That is simple supply and demand. However, the length of time it takes for the design to get to market can impede that process due to time conflicts, multiple design iterations, and available funding. Many medical device manufacturers are turning to rapid prototyping technology to test the form, fit, and function of their designs

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before moving them to mass production. In fact, some medical device manufacturers—mostly start-up companies—are going one step further by using digital manufacturing technology to produce low volume, production-quality parts to validate the market before investing the insurmountable time and money it takes to mass produce devices.

Choosing the right material is also an imperative part of the production process. Today, thermoplastic materials provide the ability to conduct multiple tests to determine the durability of a product. Many rapid prototyping and direct digital manufacturing companies even offer medical grade plastics, such as ISO 10993-1 and USP Class VI classification in a variety of colors.

Many medical device companies are taking advantage of the benefits rapid prototyping and direct digital manufacturing provide. In fact, a medical device company recently contracted with RedEye RPM to prototype a surgical device that acts as a mini defibrillator during surgery. They wanted to test the market for the product before investing in the more than \$25,000 it costs to build a mold to mass produce it. As an alternative to tooling, they chose to use direct digital manufacturing services to run their first 2,500 units. As a result, they were able to validate its worth in the market, make design iterations to the product during production based on feedback from surgeons (without incurring cost penalties), and finally introduce a product to market that was exactly what surgeons needed. Today, less than a year later, that same company hit the \$1 million mark for successfully manufacturing that product—all due to the flexibility and cost savings provided by rapid prototyping and direct digital manufacturing services.

With the threat of healthcare costs rising and cuts in federal funding for key healthcare programs, hospitals, clinics, and other healthcare establishments will only see tighter budgets and less money to spend on expensive technologies. With the help of rapid prototyping and direct digital manufacturing services, medical device designers have an opportunity to offer products they need at a fraction of the cost—ultimately helping to dramatically decrease the thousands of medical errors occurring each year.

Online

For additional information on the technologies and products discussed in this article, visit Stratsys at www.redeyerpm.com [1].

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