WHITE PAPER

How to Find Success 3D Printing Medical Devices

In this report, learn how Formlabs Medical helps medical device firms bring digital fabrication in-house, and get inspired through the examples of four companies currently creating groundbreaking devices using 3D printing.

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Introduction

3D printing has been driving innovative solutions and impacting development of medical devices for decades. As 3D printers have become more affordable, and investments in machines and materials accelerate, more companies are gaining access to 3D printing to disrupt the status quo of the healthcare industry.

Formlabs 3D printing brings digital fabrication in-house, minimizing cost and time to enable more nimble product development and more personalized care from R&D all the way through to production.

In this report, we will review the solutions Formlabs Medical offers to medical device firms, discuss four companies currently creating groundbreaking devices, and explain why 3D printing has been vital to their success. By the end of the report, you should have a strong idea of what is possible by bringing Formlabs 3D printing capabilities in-house for medical device design and manufacturing.

In this report, you will meet:

1. restor3D, a company enabling surgeons to repair and reconstruct the human body by uniting 3D printing, biomaterials, biomechanics, and AI.
2. Tension Square, a small business aiming to prevent improper treatment and occlusion of the thoracic catheter, an issue often linked to death in combat and trauma.
3. VO2 Master Health Sensors, a company developing a portable metabolic analyzer that is leaps ahead of traditional stationary devices.
4. Coalesce Product Development, creators of a portfolio of novel and affordable inhalation devices.

Formlabs Medical, Driving Innovative Solutions

A growing number of companies around the world are choosing to invest in Formlabs Medical solutions to help accelerate development of cutting edge medical devices. Let's take a closer look at some of the advantages of Formlabs Medical for medical device firms:

Scales With You

Easily create a large printing fleet with Formlabs 3D printers

Start as small as you like and add printers and capacity as you grow, giving your printing fleet the flexibility it needs to meet demand.

The extensive Formlabs material library means that just one machine can serve multiple purposes at the same time, printing biocompatible devices one day, and paintable representational (looks-like) prototypes the next.

Case Study: Coalesce originally invested in the Form 2 to create looks-like prototypes for generic-branded inhalers. Using Formlabs 3D printers, Coalesce Product Development has shortened lead times for its medical device's casework by 80–90 percent, and achieved 96 percent cost reduction. Over time, they scaled their fleet by investing in the Form 3.

Print end-use medical devices with a Formlabs 3D printer.

Production-Ready Quality

The Formlabs 3D printing ecosystem provides accurate, nonstop printing at a fraction of the cost of the competition. For businesses big and small, it's never been easier or more affordable to bring cutting-edge, professional-quality SLA and SLS 3D printers in-house for medical device development and manufacturing.

Case Study: Mychael Oversteet founded Tension Square, a company dedicated to creating a device which holds a needle decompression secure in place, while preventing damaging kinking, folding, or dislodgement. After years of R&D, he is now printing the final end-use device on his Fuse 1 SLS 3D printer.

Sterilizable & Biocompatible

A range of biocompatible devices printed on a Formlabs 3D printer.

At Formlabs, we develop and manufacture our own sterilizable, biocompatible materials in an ISO 13485 certified facility. These materials empower firms to create biocompatible parts for testing with patients, accelerating the development process by allowing a seamless transition from prototyping to evaluation. Whether it is creating durable, wearable ready devices, or strong devices safe for mucosal membrane contact, the Formlabs biocompatible library was created for medical device firms big and small.

Case Study: Creating the next generation of 3D printed surgical instruments wasn't easy, and restor3D needed access to a range of 3D printing materials, including biocompatible resins. Its surgical tools are a combination of metal and polymer parts, created to replace the fully stainless steel instruments many surgeons have used for their entire careers.

Eliminate Outsourcing For Prototyping

Bring manufacturing in-house with 3D printing.

Rapid prototyping with affordable in-house desktop 3D printers empowers businesses to create prototypes within a day and carry out multiple iterations of design, size, shape, or assembly based on results of real-life testing and analysis, helping you to bring better products to market faster.

Case Study: In order to create a better metabolic analyzer, O'Brien and his team at VO2 Master Health Sensors turned to in-house 3D printing with Formlabs to print end-use parts, create custom tooling, and to rapidly prototyping parts. The result is the VO2 Master Analyzer, a small, lightweight VO2 analyzer that doesn't require cumbersome backpacks, cables, or gas tanks traditionally used in VO2 Max testing.

restor3D: The Next Generation of 3D Printed Surgical Instruments

restor3d is on a mission to empower healthcare providers who repair and reconstruct the human body. It has pursued an approach driven by additive manufacturing due to the design freedom and affordability of 3D printing, which offers a path to disrupt traditional medical markets. The restor3d team drives innovation in precision surgery by changing the way both implants and surgical instruments are developed and delivered. The company was co-founded in 2017 by distinguished entrepreneur, orthopedic surgery professor, and highly-cited materials scientist and engineer Ken Gall.

restor3d leverages 3D printing capabilities to drastically improve surgical care delivery by printing procedure-specific polymer instrumentation that is tailored to cervical spine implants. With over 132,000 anterior cervical discectomy and fusion (ACDF) procedures performed per year in the United States, this massive market traditionally uses stainless steel instruments. These traditional instrumentation systems are slow to evolve, have significant upfront costs, and often present complications in the surgical workflow.

We spoke with Cambre Kelly, VP of Research and Technology at restor3d, to understand how the team tackled this ambitious endeavor, why they invested in Formlabs 3D printers, and understand what is next for restor3d.

restor3d has organically expanded their Formlabs printing fleet over the past three years. Today, restor3D has a fleet of 25 Formlabs printers, with 20 of them qualified for use in production full time, and five available for R&D. Using the same machines and materials for R&D and production established a seamless creation process for the engineering team.

In-House Additive Manufacturing For Healthcare

There have been two major developments in recent years that has enabled restor3D to fundamentally change how spine surgeons operate: clinical interest in additive manufacturing solutions, and expanding 3D printing capabilities. Kelly told us, “I think the overall appetite for education from our surgeon users is growing, and they're excited about this technology. I think that they're starting to see the opportunities and the ability to apply this technology in what they're working on to solve some of the clinical problems.”

The second advancement is evolving 3D printing capabilities. In recent years, in-house 3D printers have become reliable workhorses for medical device firms, with growing material libraries, quality systems, and ability to scale to production level output.

Formlabs printers meet the sweet spot for restor3D for a few reasons. One is the ability to scale on their own terms, adding additional printers to their 3D printing fleet over time. The plug and play nature of the Form 3B allows Restor3D to grow their manufacturing capabilities with demand, instead of having to invest a massive amount of capital upfront with a long return on investment. Second, the flexibility that comes with using the same machine and material during the development process allows the team to move machines into production when needed.

Kelly put it succinctly, saying “the two reasons we have stuck with Formlabs are production flexibility and the ability to incrementally scale. The investment into one of your printers is significantly less than investing half a million dollars to buy one metal printer. So over time we can continue to tack on to our Formlabs fleet as we need to scale incrementally, and do so in a sustainable way that doesn't require a huge capital investment upfront.”

restor3d is comprised of a team of highly skilled biomedical engineers and material scientists who initially focused on 3D printed implants for cervical spine surgeries. But in developing these new implants, the team kept running up against a recurring issue: traditionally manufactured stainless steel instrument systems.

With a fleet of over 25 Formlabs 3D printers in its production line, restor3D is already printing the next generation of surgical tools. This procedure-specific, single packed sterile instrumentation system result in:

- Replacement of large, expensive surgical trays.
- Ability to iterate designs and quickly introduce new tools or features based on surgeon preferences.
- Dramatic reduction of supply chain and sterilization costs for hospitals.

Coalesce Product Development: From Prototyping to Product Development

According to the World Health Organization, an estimated 262 million people around the world suffer from asthma, leading to almost half a million deaths[1]. For sufferers of breathing issues such as asthma or Chronic Obstructive Pulmonary Disease (COPD), an inhalation device is required to make breathing easier. Inhaled medication can control asthma symptoms and allow people with asthma to lead a normal, active life. Unfortunately, access and affordability are barriers for many, especially the uninsured and those in lower income countries. Studies published in the Annals of American Thoracic Society and the Journal of Allergy and Clinical Immunology estimated the annual costs per person for asthma treatment between $1,800 and $4,900 for inhalers and medications prescriptions alone, including direct costs (e.g. medicine and visits to the doctor) -- and indirect costs (e.g. time off from work)[2]. A 2005 Health Costs Survey found that 44% of all people with asthma stopped taking their medicine or visiting the doctor in an effort to save money[3].

UK-based medical device company Coalesce Product Development seeks to address some of these issues. The company develops novel, innovative drug delivery devices including inhalers and injectors, for use in generic inhalation products that offer significantly better value than brand name alternatives that can cost over $380[4] per month.

Inhalers need to be usable by a wide cross-section of society, from adolescents to elderly patients with comorbidities. Therefore, the precise size, shape, and user interface of each new inhaler needs to be very carefully designed and tested. In order to achieve this, the Coalesce

1 https://www.who.int/news-room/fact-sheets/detail/asthma
2 https://www.atsjournals.org/doi/full/10.1513/AnnalsATS.201703-259OC#readcube-epdf
3 https://www.webmd.com/asthma/features/lowering-costs-asthma-treatment
4 https://www.goodrx.com/blog/heres-why-asthma-inhalers-are-so-expensive/

team has turned to using in-house 3D printers to prototype, test, and create various devices in a multitude of different shapes and sizes. To test each product in development, the company also develops its own 3D printed test rigs, jigs, and fixtures.

We talked to Vinnay Chhabildas, Industrial Designer at Coalesce, to learn how the team has expanded its use of 3D printing over the past five years, why they continue to invest in Formlabs to develop their medical devices, and which resins they use for different applications.

Initially, the 3D printed prototypes were used to develop the BPD's exterior architecture. When the design was stable, the printed parts were painted and taken to the Drug Delivery to the Lungs (DDL) conference, an annual gathering of pulmonary and nasal drug delivery specialists. The BPD prototypes looked so realistic that they were often mistaken for a final, end-use product.

Eventually, the same device prototypes were used in a pulmonary function clinical study. The results showed how much variation can occur between different uninstructed inhalation profiles.

Using third party vendors would have cost approximately 20 times more than the raw cost of printing the parts in-house. The caseworks of the BPD cost £11 to produce on the Form 2 compared to around £250 when outsourced. According to Chhabildas, however, the real benefit is the time saved: the parts took only eight hours to print and could be finished and painted within a few days. The same process would take an external contractor a week or two.

INHALER CASEWORK	IN-HOUSE 3D PRINTING	OUTSOURCED 3D PRINTING
Cost	£11	£250
Lead Time	1 - 2 Days	1 - 2 Weeks

Expanding In-House 3D Printing With the Form 3

After bringing most of their 3D printing in-house with the Form 2, and using the machines as workhorses for years, the team upgraded their fleet by purchasing three Form 3s.

Today, the team is running three Form 3s nonstop, five days per week, making them an inseparable part of the development process. Use cases for 3D printing have continued to expand, with the team now printing tooling to help test their devices. An example is printing different mouth pieces in BioMed Clear Resin, a biocompatible, skin safe material, for patient trials. 3D printing allows the team to skip the creation of expensive injection molded plastic parts.

Using Formlabs 3D printers, Coalesce Product Development has shortened lead times for its

medical device's casework by 80–90 percent, and achieved 96 percent cost reduction. Over time they have continued to invest in and expand 3D printing applications, putting them on the leading edge of inhalation product development.

Tension Square: Production Ready Quality

A pneumothorax (noo-moe-THOR-aks), or collapsed lung, occurs when air leaks into the space between the lung and chest wall. The buildup of pressure inside the pleural cavity pushes on the exterior of the lung and causes it to either partially or completely collapse. Often originating from blunt or penetrating chest trauma, tension pneumothorax is a common injury associated with tactical military combat which results in respiratory distress and, if not properly treated, can be fatal. Published literature describes 15% of all wartime injuries as chest-related and, according to Tension Square, PTX is the third leading cause of death during combat and trauma.

Mychael Overstreet, a military veteran, and paramedic has been exposed to such cases regularly while on duty in the US and abroad. Once inserted into the chest wall, the rigid decompression needle is removed and a flexible angiocatheter is left in place, allowing pressure to release from the pleural cavity. Overstreet, like many medical professionals and combat medics before him, found that kinking and dislodging of the flexible catheter was a common problem that decreased the effectiveness of treatment and often proved fatal. Drawing from these experiences, Overstreet founded Tension Square and developed a device designed to hold an angiocath in place during PTX treatment, without the risk of kinking, occlusion, or dislodging. This innovative military veteran saw a need, came up with a solution and after years of R&D, he is now printing the final end-use device on his Fuse 1 SLS 3D printer.

According to Overstreet, “I’ve gone to medical trade shows where people come up to me and ask how I built the Tension Square, because they’ve been trying to solve this problem for a long time. But until recently, the technology wasn’t there. We happened to be working on this at the right time, and had access to the right 3D printers.”

Bringing SLS 3D Printing In-House With the Fuse 1

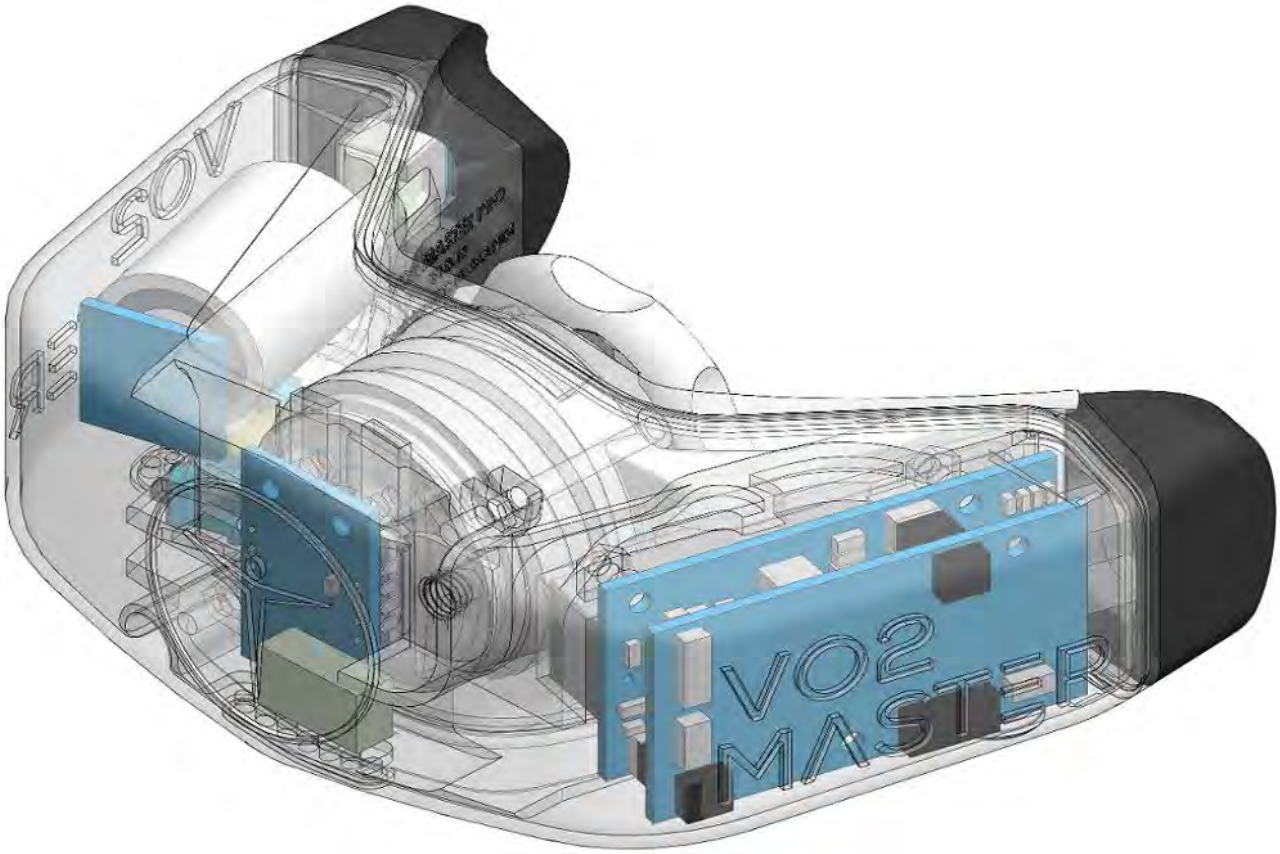
After purchasing the Fuse 1 in early 2021, Overstreet, who did not have engineering experience, was excited to get started, saying “as soon as I got the Fuse 1, I took the stickers off, followed the instructions on the screen, and started printing immediately. It was easy.” He quickly realized that nylon would work better than other 3D printing materials. After a few prints, the design was coming together quickly, saying that “the Fuse 1 was so important for finalizing the design. The ability to print parts in place that move, like the hinges, that changed everything for us. I would not have been able to design that for myself.” With the Fuse 1 on his workbench, Overstreet was able to finalize his design and rapidly move towards production of his medical device. According to him, “we tried multiple resins on the Form 3, but even the Tough 1500 Resin wasn’t meeting our needs. The Nylon 12 material, and the support I could get from the Formlabs team, are really the top two reasons I bought the Fuse 1.”

Having already spent years developing the Tension Square, Overstreet moved to quickly finish his design, saying “since this Fuse 1 design came about, we’ve been moving forward at 200% speed. Things are moving faster now, the post-processing, the printing, everything compared to when we tried to make these on the SLA machines. The design we are going into production with is version V. We almost went through the entire alphabet with prototypes.”

For Overstreet, not only is he launching a new medical device, but also his first small business. Despite the ups and downs, he is excited about the next phase of the company, and getting his device into the hands of medical professionals. He noted that “the first few years, it was a lot of learning, it was difficult, but now we’re here. I’m an airman, a firefighter, a paramedic, but not an engineer.”

After dozens of prototypes, user feedback, and field testing, the team is ready to move into small-batch production. Overstreet said, “our goal is to use the Fuse 1 for production. I don’t like middlemen, we want to cut them out of the process and stop outsourcing. And after all the prototyping we printed in-house, we know we can do production, too.”

Overstreet is printing two end-use parts on the Fuse 1: the base and the housings. The Fuse 1, when properly packed, is able to deliver 125 base-units for the Tension Square per print cycle. For the housings, Overstreet felt comfortable with 90 parts in a single print, which takes approximately 25 hours. This means batches can be started in the morning, and will be finished at the start of the next working day.



VO2 Master: 3D Printing The Next Generation Of Metabolic Analyzers

Peter O'Brien remembers his triathlon coach using a large, clunky machine to measure VO2 levels, which refers to how much oxygen your body can absorb and use. Thinking there must be a better way to measure athletic performance, O'Brien and Dr. Andrew Sellars later founded VO2 Master Health Sensors to create the next generation of metabolic analyzers. After a few years of research, prototyping, and clinical trials, O'Brien tackled the problem of creating a portable metabolic analyzer that was easier to use and more affordable than established machines.

In order to create a better metabolic analyzer, O'Brien and his team turned to in-house 3D printing with Formlabs to print end-use parts, create custom tooling, and to rapidly prototype parts. The result is the VO2 Master Analyzer, a wearable VO2 analyzer; a small, lightweight face worn mask which doesn't require a backpack, cable, or gas tank.

3D Printing End-Use Parts and Tools at Scale

To create and ship the VO2 Master Analyzer, O'Brien deployed 3D printing for end-use production. Originally, the team was making the outside shell of the mask in White Resin. Now, the shells are printed in Tough 1500 and painted white before being fastened to the mask, to improve surface finish, emboss coloration, and durability. Formlabs' material library was a selling point for O'Brien, saying "other companies don't have the material library to compete. Overall, we just feel like Formlabs has the best product on the market."

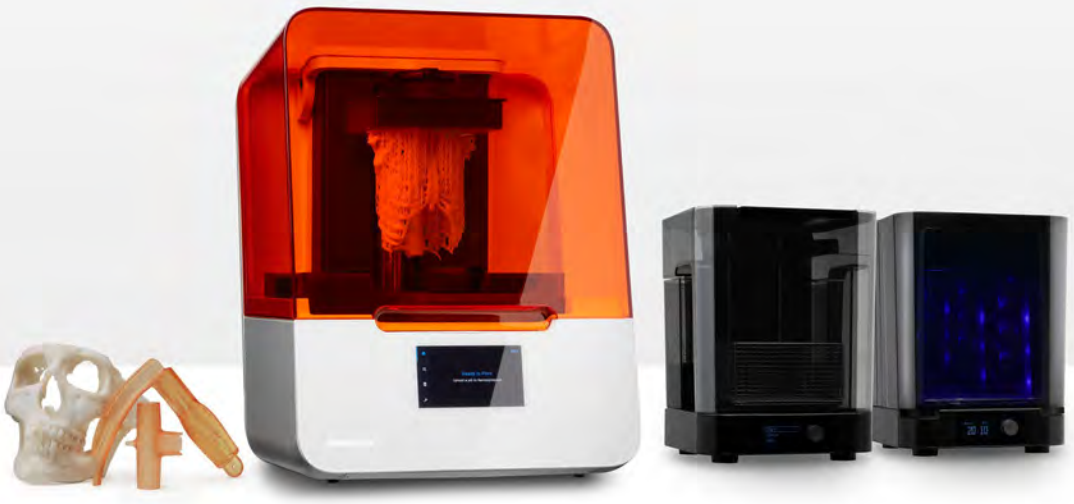
Tough 1500 Resin is a resilient material which simulates the strength and stiffness of polypropylene. According to O'Brien, Tough 1500 Resin is a "robust functional equivalent to injection molding plastics. It meets all of the requirements for this application. We really needed something that had similar properties of standard 3D printing materials, but could also survive drops." And by printing the shell upside down, the team has eliminated the need for support structures on the outer-wall, leaving a smooth finish for them to paint white.

As VO2 Master Health Sensors has scaled, they have ordered additional Form 3s to keep up with production. The company runs a fleet of Form 2 and Form 3s all week in 20 hour cycles, meaning a new batch is ready for employees each and every morning.

For cutting edge applications like the VO2 Master Analyzer, it is often necessary to create custom tools to create or validate a design. During production, the team creates custom jigs to hold the

device level as it is being assembled. This is especially easy with 3D prints, because “we already have the CAD file, so we can create a custom base, and then print it knowing it will fit the device” said O’Brien. This type of tooling may seem small, but it simplifies and speeds up in-house production. Custom made tooling highlights the versatility of equipping engineers and designers with 3D printers.

The VO2 Master team is also building a multitude of silicone molds in Clear Resin, which are used to make batches of clear silicone nubs for the headset. Torque testers are also made in-house, all using the same fleet of printers used for R&D and end-product. O’Brien said, “there are other ways to do some of this testing, but it’s just so easy and convenient to print custom parts. Plus, it’s really cheap”. This type of integration of 3D printing also shields small businesses from supply shocks, meaning they can design and produce their own tooling in-house, reducing reliance on other firms or outsourcing.



Ready To Invest in Formlabs Medical 3D Printing?

For medical device firms, in-house 3D printing allows quick iteration cycles, shortening the product development cycle and creating more time for creative solutions.

Every medical facility should have access to the latest tools to improve care and provide the best patient experience. Get started now or expand your in-house production with Formlabs, a proven, cutting-edge partner in medical 3D printing.

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