



Customer Success Story: Medical Device Prototyping for Cogmedix



"The team [Empire Group] continues to impress me with timely responses, lead-time commitments, and unprecedented customer service. I hope this message serves as a note to commit more work to Empire from the engineering team and continued success."

- Engineering Program Manager | Cogmedix

Case Study Overview

Because medical device manufacturers face FDA scrutiny and approval before bringing a medical device to the marketplace, **there is an urgency to start medical device prototyping in end-use materials as swiftly as possible in the product development process.** This can be a challenge for plastic parts that are going to be made using injection molding because of the long lead-times and costs associated with tooling.

The sooner a medical device company can make a leap from traditional prototype materials to production materials, the faster you can discover potential performance issues. That translates into better products getting to market in less time.

Medical device companies are often up against an arduous and time-consuming FDA approval process. If you're not using end-use material, your entire project will be 'frozen' by the FDA for design, material, manufacturing methods, and function.

The goal is to freeze the design as quickly as possible so reapproval won't become necessary. Delays like this are exorbitantly expensive and can be prevented with proper planning.

One way to finalize the design more quickly is by using end-use material earlier in the prototyping stage. Doing so at a much earlier stage enables you to avoid material-related issues during the FDA approval process. However, historically this has been hard to do because making prototypes using production-grade injection molding materials was expensive and time-consuming.

Empire Group worked with Cogmedix to overcome those historical obstacles by using high-strength 3D printed composite injection molded tooling. This breakthrough technology can deliver prototype injection molded parts in days instead of weeks, even using difficult-to-mold materials such as glass-reinforced nylons and Ultem.

Background

The team at Cogmedix brings OEM medical technology to life by providing turnkey manufacturing services to a broad range of medical and dental OEMs. Cogmedix delivers new products to market with dedication to meticulous quality control and full regulatory compliance.

Their company's motto, "Cogmedix = Compliance," amplifies their commitment to safety and full compliance with ISO 13485 and the FDA Quality System Regulation. And the "Compliance, Competence, and Commitment" mantra aligns with the company's constant effort to maximize customer satisfaction and value.

Most of Cogmedix's products include injection molding components. They have a deep understanding of this manufacturing process and believe that validating designs and manufacturing methods means projects will be completed quickly.

The Problem

Cogmedix sought out Empire Group to cut weeks off of each design cycle by using cutting-edge 3D printing and rapid injection molding technologies. **The critical problem they faced was producing a complex injection molded part in end-use materials for compliance and testing on a rapid timeline.**

The parts needed to meet their rigorous standards for quality and tolerance.

Additionally, they would need to be made using the production material and process, in this case, injection molding, to validate the required sterilization protocol.

While Cogmedix did have other options for prototyping these parts, they had major drawbacks. Aluminum injection-molded tooling required longer lead times of 3-6 weeks for each design iteration. And traditional 3D printed tooling could not accommodate difficult to mold design features due to the strength, stiffness, and wear limitations of traditional, non-composite 3D printing materials.



Empire Group Solutions

Empire Group recommended rapid 3D printed tooling using Fortify Flux One machine, a 3D printer with the capability of printing a proprietary ceramic-fiber reinforced resin, which allows for fast lead times coupled with design freedom similar to aluminum tooling. Along the way, some unique challenges were faced. The part required a high aspect ratio thin-walled through-hole, a problematic feature to injection mold without some kind of core inside. Because of Empire Group's full suite of design and manufacturing solutions, we were able to design and fabricate an aluminum pin insert that resolved this complex issue, all under one roof, without extending the timeline.

By combining a high-performance composite 3D printed tool with the precision-machined aluminum core, Empire Group was able to deliver prototype parts made from production material weeks before they could have with traditional tooling.

The Results

Cogmedix was able to quickly prototype a medical device in the end-use material by using Empire Group's rapid injection molding solution with their Fortify expertise, saving time and money. Utilizing Fortify's proprietary composite 3D printing, we delivered injection molded parts in the end-use material on a quick timeline while controlling costs. Typically, timelines for injection molded parts can take up to 4 weeks. What we're doing here is the entire process in one to two weeks.

Using rapid composite 3D printed tooling delivers big wins for medical device product development:

- Prototypes in end-use materials in days instead of weeks
- Prototypes could be used for sterilization testing and FDA product validation
- Quick, cost-effective design iterations to accelerate product development
- Ability to use rapid tooling for low volume production



Cogmedix received injection molded parts in end-use material, which met their uncompromising standards for quality and tolerancing. It also enabled them to use the parts to validate their sterilization process on an accelerated timeline.



Summary

If you're considering using Empire Group's rapid injection molding process, know that it's a complete turnkey solution from design to parts. The massive advantage in partnering with Empire Group to accelerate product development is particularly relevant to companies that are developing products requiring FDA approval. To learn more about how recent advances in 3D printing is changing product development and manufacturing, **check out our webinar: [How New DLP Printing Technologies are Transforming Additive Manufacturing](#)**.

For all intents and purposes, a medical device company can submit a CAD file, have a tool designed and printed in days, and in no time, we'll be shooting parts. Remarkably, you can have an injected molded part in under two weeks - which was previously unimaginable. **Ultimately, speed is the most significant disrupter.**

And while other 3D printed tooling uses inferior technologies that require compromises on material choices, tool life, surface finish, and dimensional control, Empire Group's solution, powered by Fortify's Flux 3D printing platform, gives you design flexibility on par with aluminum tooling. With Empire Group as a partner, intricate design features, tight dimensional controls, and parts made from difficult-to-use engineering-grade materials are entirely achievable. **That means production quality prototype parts in a fraction of the time and cost traditionally available.**

Empire Group's superior manufacturing methods offer turnkey prototype and low-volume production solutions to medical device companies. In fact, there are no rapid injection molding options available that can compete with Empire Group's when it comes to turnaround time, design flexibility, part quality, and cost.

Empire Group can deliver injection molded medical device prototypes previously inconceivable by combining breakthrough 3D printing technologies with rapid tooling solutions. As the only manufacturing company with this capability, the possibilities for medical device prototyping and low-volume production are unrivaled.



Empire Group is changing the competitive landscape for medical device product development by combining breakthrough 3D printing technology with decades of rapid manufacturing experience. As the only manufacturing company with this capability, Empire Group is unrivaled in its ability to help companies iterate faster and get higher quality products to market in less time and at a lower cost.



About Empire Group

Empire Group is a full-service product development and manufacturing company focused on partnering with our customers to create breakthrough products and accelerate their speed to market. Companies on the East Coast, and across the US, that are in the consumer goods, defense, medical device, aerospace/aviation, automotive, juvenile, and toy industries rely on us for our knowledge, experience, and wide range of services.

For questions and inquiries,

[CONTACT US TODAY](#)

