Introduction and Problem Statemen

Cutting Costs, Saving Lives: Our Client's Journey

Introduction

Diabetes is an escalating health crisis that demands innovative and efficient medical solutions. In response, we partnered with a client specializing in medical devices to expedite the development and market introduction of a groundbreaking endoscopic treatment. Our goal was to address the severe complications associated with type 2 diabetes while managing budget constraints and minimizing the project's timeline for completion. This case study illustrates how our expertise in rapid prototyping and additive manufacturing enabled us to overcome significant technical and financial challenges, ultimately facilitating a faster, cost-effective solution to this pressing health concern.

Type 2 Diabetes Context

According to the CDC, approximately 34 million Americans are living with diabetes, with about 90 to 95 percent afflicted by type 2 diabetes. This condition results when the body's cells do not respond correctly to insulin, leading to severe health issues like heart disease, vision loss, and kidney disease. Given the urgency of developing effective treatments, our collaboration aimed to bring a novel endoscopic device to the market efficiently and effectively.



Objective

Our primary objectives were to eliminate the need for the client to raise additional capital and to shorten the traditional timeline required for bringing medical products through the clinical trial phase.

Problem Statement

The project faced substantial obstacles from limited funding that constrained testing and production, as well as technical complexities in creating accurate, operational catheter tips that conform to both functional and aesthetic criteria. Resolving these challenges was essential to ensure the project's success and the development of a quailty product.

Through innovative engineering solutions and advanced materials, we addressed these challenges, demonstrating the power of rapid prototyping and additive manufacturing in streamlining medical device development.

Initial Challenges and Solutions

Rapid Prototyping

To overcome the initial challenges faced by the client, we implemented advanced additive manufacturing techniques. An initial prototype was created in less than 24 hours. This rapid turnaround reduced lead times for testing and iterative improvements. Following the successful creation of the initial prototype, our client granted approval to develop the remaining parts of the device, underscoring the effectiveness and reliability of our rapid prototyping capabilities.

"Working with Aprios allowed us to produce multiple design iterations at a rapid pace, saving vital time—a crucial factor for startups."

Research and Development Engineer ~ Client

Visual

- Traditional Approach (Up to 2 Years)
 - Research and Design Phase: Several months to finalize.
 - Tooling and Prototyping: Over a year due to complexity and necessary iterations.
 - Final Adjustments and Production Ramp-Up: Additional months to perfect.
- Our Additive Manufacturing Approach (Just 2 Weeks)
 - Design to Prototype: Days instead of months.
 - Immediate Manufacturing: Utilizing EPX 82 for superior strength and durability.
 - Rapid Testing and Finalization: Streamlined thanks to the adaptability of additive manufacturing.

This timeline comparison visually underscores the reduction in time, highlighting the efficiency and speed of our innovative approach.

In-Depth Technical Details

Design for Manufacturing Enhancements

Initial Consultation: The engagement began with an initial consultation to understand the specific needs and constraints of the device. We gathered comprehensive requirements related to mechanical properties, safety standards, and performance metrics, ensuring that all critical aspects were considered from the outset.

Iteration Cycles: As design modifications were made, prototypes were rapidly produced for continuous testing and feedback from the client. This approach allowed us to efficiently refine the device, integrating real-time feedback into successive versions. These rapid iteration cycles ensured that improvements were consistently based on practical insights, significantly accelerating the development process.

Feature Improvements: Our team incorporated textured surfaces into the handle components to enhance grip and usability. Ergonomic considerations were also embedded into the design to improve the user interface, making the device more functional and user-friendly. These enhancements were crucial for maximizing the practicality and efficiency of the medical device.

Material Guidance and Selection

We guided the client through selecting from a range of advanced resins to meet various mechanical properties and biocompatibility requirements. The right material choice was pivotal for ensuring the device met stringent standards while performing effectively.

RPU 70 was selected for its high strength, functional toughness, and high ductility, making it ideal for durable handle components. Its biocompatibility features prioritized patient safety and improved comfort, essential factors for medical applications.

SIL 30 was chosen for the nose cone due to its flexibility, biocompatibility, and patient comfort. The material's softness and pliability were crucial for patient-facing components, ensuring the device was both safe and comfortable for use. (Insert image below for a visual)

RPU 130 was used in the cage for its exceptional strength and heat resistance, supporting the device's long-term use. It provided the necessary structural integrity, crucial for the high-performance parts of the device, ensuring durability and reliability over extended periods of use.

Efficiency and Optimization

By utilizing 45-degree angle internal supports/ribs, we eliminated the need for external supports during printing. This not only reduced material usage but also minimized post-processing labor costs. The elimination of external supports also enhanced the aesthetic qualities of the components, reducing marks and imperfections, and improving overall dimensional accuracy.

We further improved cleanability and reduced residue build-up by incorporating vent holes in blind holes. This design choice facilitated easier cleaning and maintenance, extending the device's usability. Enhanced dimensional accuracy was achieved by minimizing potential deformations that could occur during support removal, ensuring high-quality end products. Threaded features were integrated to facilitate easy assembly and disassembly. This ensured secure fastening and ease of maintenance, allowing for straightforward and reliable part interchangeability.





SIL 30



RPU 130

Overall Impact

These technical advancements and material optimizations empowered the client to accelerate product development, save significant costs, and deliver a high-quality, innovative medical device to the market. The rapid prototyping and advanced manufacturing expertise not only met the ambitious objectives but also set new benchmarks in developing medical devices for diabetes care, ultimately benefiting millions of patients worldwide.

Through our collaborative efforts, we demonstrated the power of innovative manufacturing techniques in overcoming complex challenges, achieving both financial and time efficiency while delivering a superior product.

Achievements and Future Outlook

Achievements

Our collaborative efforts with the client resulted in several remarkable achievements, setting new benchmarks in the field of medical device development:

Accelerated Product Development: Through the use of rapid prototyping and additive manufacturing, we drastically reduced the development cycle time. A prototype was created in less than 24 hours, enabling swift iterations and continuous testing.



Cost Efficiency: By optimizing the development and testing phases, we saved millions of dollars. This optimization prevented the need for the client to raise additional capital. Our streamlined process not only conserved financial resources but also expedited the pathway to clinical trials, a critical phase in medical device approval.

Future Outlook

Our commitment to innovation and excellence is poised to continue as we move forward with the following:

Continuous Iteration: We are dedicated to continually iterating the device based on trial feedback. This ongoing process ensures that the device meets the evolving needs of patients and healthcare providers.

Setting New Standards in Diabetes Care: Our long-term impact strives to benefit millions worldwide by offering advanced solutions to manage diabetes, enhancing the quality of life and treatment outcomes.

For further inquiries and detailed information, we invite you to contact us. We are eager to share our expertise and discuss how our innovative solutions can meet and exceed your expectations.

Visit us at: <u>Aprios.com</u>