



Case Study: Redesign to Improve Product Performance

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Overview

A manufacturer of products used for foreign particle management in the esophagus found that the market for its product line was no longer growing. The Company decided that a redesign of the product line was the best way to increase market share.

They turned to Forefront Medical, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems, for a solution. Forefront's team recommended converting the manufacturing process used for the tubing from a dipping process to the combined use of extrusion molding and injection molding. The team also recommended changes in the materials composition for other components used in the product. This paper discusses lessons learned in the redesign and qualification process and the overall results.

Overview of the Design Approach

Forefront Medical's team uses a standardized process in which customer requirements are assessed and a Design Development Plan (DDP) is created. A customer specification is then developed and market inputs are collected. Once the customer specification is approved, 3D CAD models are developed and analyzed. Design reviews which include functional analysis and risk evaluation are completed. After a customer's team approves the design, prototyping and verification began.

The design team is located in Forefront Medical's Singapore headquarters. The Company's tooling fabrication facility and production facilities are located in China. Having a vertically integrated process, that includes design, design analysis, tooling and injection molding, enabled the team to consider a broader range of options, run design of experiences (DOEs) to test assumptions and develop a viable solution to all design challenges.

Disadvantages of the Previous Manufacturing Process

The previously-used dipping process involved dipping the product multiple times to form layers. There were three primary disadvantages of the dipping process. First, it produced a sticky tube, which created a high frictional force during insertion of the endoscope and impaired its key function of serving as a guide for insertion of the endoscope. Second, the sticky tube also was difficult to insert in patients. Finally, it was costly since manufacturing the tubing involved several rounds of dipping.

The dipping process limits the device to a single material type of same shore hardness on the entire device, whereas Forefront's developed process of vertical extrusion molding and injection molding allow the use of different types of material and concomitant shore hardness at different parts of the device, based on the functional requirement.

Understanding the Functional Requirements

The product line included 25-centimeter and 50-centimeter versions of one product plus a third product that was 82 centimeters long. Components included inner tubing, outer tubing with a tapered tip, a distal cuff, and a spring.

Under the redesign for the 25- and 50-centimeter product versions, the wire-reinforced outer tube and the inner tube were extrusion molded and the distal tip and cuff were injection molded. The 82-centimeter product was too long to construct as a single piece, so it was designed in three sections with couplings optimized to provide the right degrees of flexibility and rigidity within different sections of the tubing to enable a physician to easily insert and guide the longer product down the esophagus.

The taper on the tip enables the tube to be inserted without mucosal tearing and/or shearing. To cater this requirement, this distal tip was injection overmolded with a softer PVC resin on the reinforced body. The cuff needed to tightly seal to minimize the risk of body fluid contamination. Finding the right material combination to achieve those functional requirements required several rounds of testing material combination selections.

On the 82-centimeter product, four-to-five different types of materials were selected for the overmolded harnesses that would join the sections. The sections needed a coupling that had the right degree of flexibility for moving through the patient. The product was originally made of PVC. Initially, a polyresin was considered for the couplings. A stainless steel coiling joint with overmolded silicon is now the preferred option.

Manufacturing Considerations

Extrusion with spring reinforcing was selected as preferred process for the outer tube because a normal extruded tube wouldn't work well with the spring. That said, in initial molding tests, the spring wasn't getting into the right pitch. The team had two options: lock the spring into position or have it loose in the inner tube. They chose to use a solvent dipping process to create a groove in the tube for the spring, insert the spring and then overmold.

The longer tube was too long for the molding/solvent dipping process used on the shorter tubes. For this product, the coil is embedded in the mold, since there is no pitch variation. Forefront's electro discharge machining capability enables fabrication of molds with tolerances of 3 microns. One challenge was the gauging inside the mold. The tube needed to have a smoother finish since it would have tissue contact. This meant that only a single point gauge could be used in mold for in-process measurement. Moldflow analysis software was used to optimize the molding parameters to the point where a single point gauge was acceptable.

Forefront's vertical extrusion machine capability was also beneficial. Vertical extrusion improves quality in thin-walled tubing by having easier alignment between the press ram and tools and uniform deformation due to uniform cooling of the billet in the container.

The Result

Both cost and lead-time were reduced. The cost reduction was in the 30-40 percent range, since the production cycle time of the previous process was much longer. Quality improved because the



manufacturing processes became highly automated and the processes were tightly controlled. Functionally and user-friendliness was also improved since friction was no longer a factor with smoother, non-sticky surfaces. Customers also found that the three sections in the longer product provided an instrument that feels soft and flexible on the front, yet more rigid on the back as the tube is inserted further into patient.

The end solution was a result of engineering and materials expertise combined with the range of manufacturing capabilities necessary to fabricate components with very precise specifications and illustrates the value of partnering with a contractor with the in-house resources to address the complexity of this type of product.

About Forefront Medical

Forefront Medical is a global medical device contract manufacturer with five locations. Singapore is Forefront's headquarters, as well as home to our Design Engineering Center and specialty manufacturing. Jiangsu and Xiamen, China, are additional manufacturing locations and are also China FDA Registered. Shanghai, China, Farmington, CT USA and Riel, Netherlands are regional Business Development offices which assure our technical sales teams are close to our customers for local, responsive assistance.

We have developed extensive capabilities with implantable PEEK micro-molded components, laryngeal mask airways, diagnostic devices, drug delivery systems, enteral feeding and multi-lumen catheters, infusion sets, wire reinforced tubes, optically clear components, patient monitoring devices and other specialty products.

Each of our locations has state of the art manufacturing capabilities that include class 100K clean rooms for extrusion and injection molding, complimented by class 10K clean rooms for assembly and packaging. Forefront Medical's integrated technical approach provides customers the total manufacturing solution and global supply chain. Our facilities are TUV ISO 13485, ISO 9001 and FDA Registered. Forefront is a wholly owned subsidiary of VicPlas International Ltd, who is listed on the SGX Main Board, Singapore stock exchange.

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