Case Study: Endotracheal Tube Redesign

April 23, 2015

Overview

Ventilator-associated pneumonia (VAP) is one of most significant healthcare-associated infection (HCAI) risks for patients in long-term intensive care. Traditional endotracheal tube design can contribute to this since oropharyngeal secretions that would normally be swallowed can pool on the top of the cuff of the endotracheal tube and subsequently be passed into the lungs. A number of interventions and prevention strategies are used to minimize the incidence of VAP with varying degrees of success. A least two studies have found that the use of tracheal tubes with subglottic secretion drainage in patients expected to be ventilated for 72 hours or longer, significantly reduces VAP.

In 2013, Forefront Medical, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems, was selected by one of its existing clients to support the development of the single-use portion of new endotracheal tube designed to mitigate the incidence of VAP by maintaining constant pressure within the tube and providing a collection point for oropharyngeal secretions that could easily be drained and cleaned by the hospital's nursing staff.

The Challenge

Forefront's team worked with the customer to develop the single-use components for two models of endotracheal tubes. The complete product combines endotracheal tubes with tracheometry drain tubes made from silicone, along with a tracheal seal monitor which continuously measures the pressure between the cuff and the trachea, enabling it to generate maximum cuff pressure. The resultant optimal tracheal seal significantly helps reduce the risk of aspiration. Key product features included:

- Non-stick coating inside the tube to reduce the formation of biofilm
- An adjustable flange and safety system to prevent any unforeseen extubations
- A silicon spiral tube which can adapt flexibly to airways
- Triple subglottic flushing suction pipes to collect and clear secretions
- A low-volume, low-pressure silicon cuff to provide optimum tracheal sealing and minimize injury to the tracheal mucosa
- A special atraumatic tip for atraumatic intubation and optimum adaptation to airways.

From a design and manufacturing standpoint, the single-use portion of the product required 14 different components which utilized a variety of materials. Achieving the customers' form, functionality and fit goals required an innovative approach to material selection plus use of specialized molding processes with very critical tolerances. The assembly process also included a specialized dipping process.

The Process

The design team started by assessing customer requirements and then created a Design Development Plan (DDP). A customer specification was developed and market inputs were collected. There were several design issues to address.

First, the mouthpiece included a locking nut to lock the tube into position and keep it from moving as the patient moves. Developing the optimum design required a redesign of the original concept.

Second, the device was designed with a multi-lumen tube to facilitate collection and removal of secretions. Silicone was selected as the preferred material. While this is an optimum material for the device in terms of fit and function, it increased the complexity of mold design and fabrication. The cavity design needed to maintain the correct dimensions of the multi-lumen tube and use of liquid silicone resin (LSR) drove a requirement for much tighter mold machining tolerances than required in injection molds for other other materials.

Finally, the tubes needed to be MRI-compatible. The traditional tube design has an outer layer with a wire spring and then an inner layer. These tubes need to be removed during MRI. The team at Forefront recommended nitinol (nickel-titanium) springs, which are MRI-compatible. In the new design there is an outer layer, the nitinol spring and a coating that comprises the inner layer. The non-stick coating also helps reduce the formation of biofilm. The coating requires a dipping process during assembly, which added process development complexity since the pitch of the nitinol spring must be controlled as the inner layer is formed through the dipping process.

Forefront's database of approved materials which have passed biocompatibility and other critical tests helped cut time out of the process. Selecting materials which had previously passed the requisite tests, cut weeks out of the development process plus eliminated the potential issues that could arise if a selected material had failed testing. Another way that Forefront's team cuts time out of the product development process is that its overall design process and design tools are standardized so internal teams collaborating globally have the same frame of reference and can communicate efficiently.

Once the customer specification was approved, 3D CAD models were developed and analyzed. A design review which included functional analysis and risk evaluation was held. After the customer's team approved the design, prototyping and verification began.

The team used a gated design process to enable tooling development to begin as early in the design process as possible. A combination of in-house rapid prototyping capability and in-house tooling design and fabrication capability helped further shorten the product development cycle. The tooling design process included a DFM phase which was followed by development of the mold specification. In this project, the two device models required development of 21 different molds.

Following a design review, mold fabrication began. This was followed by a testing and debugging phase which included a dry run and analysis of product first off the tool. This was a fairly complex process, as the devices used different materials for different components including silicone and polycarbonate. There was also component requiring polypropylene overmolding metal. The LSR molds presented some design and production challenges. A key benefit of LSR molded components is that they are fully cured and pliable after the press cure. This enables the parts to be demolded without the use of ejector pins. However, uncured silicone is a low viscosity polymer that under pressure will flow out any opening greater than 3 microns. As a result, machinability tolerances within the mold are less than three microns. Forefront uses CNC machines for this type of mold fabrication. There are only a limited number of mold fabrication houses capable of fabricating LSR molds.

Production processes underwent a similar development and validation phase with performance qualification to user requirements, operational qualification to functional requirements, installation qualification to design specification and installations. The dipping process for the inner coating required design of experiments (DoEs) to determine the optimum process parameters for correctly pitching the nitinol spring within the tube.

The Result

The product is currently in trials in Cambridge, Harvard, King's Cross, UK and three US hospitals. Forefront is manufacturing its portion of the product entirely in Singapore.

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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