# Replacing Metal Components with Precision Molded Plastic Parts

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**Overview**

Metal parts have been traditionally used for endoscopes because machined metal parts ensure a tight seal at joints in the device. However, use of metal components is costly and drives a need for the product to be sterilized and reused in order to make cost effective. Since endoscopy is an invasive procedure and the cleaning/sterilization process may not remove all body fluids or tissue contaminants, the reuse of endoscopes can pose a contamination risk to patients. A lower cost, single-use precision molded plastics alternative mitigates the risk of patient contamination plus eliminates the need for a washing/autoclave sterilization process following each procedure.

The challenge with this solution has been finding a way to mold plastic parts with enough precision to achieve the same performance properties found in metal components.

Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems, recently designed and molded a plastic valve set which is functionally equivalent to the metal valve set currently used in endoscopes. This paper looks at the challenges the engineering team at Forefront Medical encountered during the design and qualification process. These challenges included:

- Identifying materials with correct level of rigidity and strength to be functionally equivalent to the metal valve set
- Ensuring that the plastic components performed identically and felt similar to their metal counterparts to a doctor performing an endoscopy
- Designing a complex mold that could produce parts with conformance to extremely fine tolerances.

**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.

**Identifying Acceptable Materials**

The valve assembly to be replaced had five separate components: a stem, end cap, snap cap, gasket and spring. Multiple materials were required. The design team began the process with a brainstorming process to determine the likely best materials options. Thermoplastic elastomer (TPE), polypropylene, polycarbonate and acrylonitrile butadiene styrene (ABS) were tested as replacements for the stainless

steel parts. ABS offered the lowest cost and the best level of rigidity. This was important because the ABS part was sliding against a metal component during procedures and the plastic part needed to be able to withstand the friction of the sliding motion. Another benefit was the compatibility of ABS with TPE. Components which would come in contact with the doctor's glove needed to be soft with no sharp edges that could tear the glove. TPE met that criteria and it also provided the best bonding properties with the ABS components.

Materials selection activities were enhanced by the fact that Forefront Medical maintains a database of approved materials which includes a full range of medical-grade polymers. This allowed the team to consider materials which had already gone through biocompatibility testing.

**Addressing the Functional Requirements**

To better understand the functional requirements, the design team closely studied a working unit in their lab. The plastic valve set not only needed to perform functions identical to those performed by the metal part set, it also needed to feel the same to the doctors using the endoscope.

One area of concern was friction. As mentioned earlier, there is an ABS part sliding against a metal part and that operation needed to be as frictionless as possible. The team found that a lubricated ABS would eliminate the friction and was able to work with ABS supplier to specify a material with an oily property that met the requirement.

DoEs were used to fine tune the design of the spring used for a cushioning effect, in order to develop a spring that provided the same "feel" to doctors as the metal spring.

**Designing the Mold**

The most significant challenge involved mold design. The design of plastic components is fundamentally different from that of metal components because the manufacturing process is different. Fabricated metal parts are formed through machining, which supports very tight tolerances, precisely formed groves and sharp corners with 90 degree edges to achieve a tight seal. Conversely, plastic parts are formed via an injection molding process which traditionally has wider tolerances and delivers a less precise cylindrical form.

The tolerance for the components used in the suction valve assembly was 5 microns, which gave a window of +/-2 microns. When a part is injection molded, there is a possibility of non-centering. Additionally, cylindrical molded parts are typically not a perfectly shaped cylinder. The initial parts did not have the required tolerance and as a result, there was leakage in the suction valve.

The team decided to change the mold and the molding concept. The two-cavity mold was redesigned to include a slide-core mechanism for forming the cylindrical portion of the part. The critical dimensions of the part were machined inside of the slide-core mechanism during the injection molding process. A high speed computer numerically-controlled (CNC) electronic discharge machine was used for final machining, since it can control tolerance to less than 3 microns.

The next step in the mold fabrication process was a testing and debugging phase which incorporated a dry run and analysis of product first off the tool. Once parts that met the dimensional specification were molded, key process parameters were identified and logged to define the perfect process window.

Following internal validation and functional testing, the parts were sent to the customer for their evaluation. The cost of the plastic valve set is near parity to the amortized life-time cost of a metal valve set. When the cost of the autoclave/sterilization process following each procedure is considered, the cost of the disposable, single-use valve set is lower than then per procedure cost of using re-useable parts. However, the real value of the use of a single-use, disposable valve set is the contamination risks it mitigates for patients.

The primary challenge in this project wasn't related to resources or technical capabilities. The correct solution utilized equipment and tools already present in Forefront Medical's tool room. Instead the challenge was cognitive. Forefront Medical's team needed to design an innovative approach that utilized existing equipment and tools in ways that eliminated the tolerance constraints found in traditional approaches to tooling design. The tooling design team's software modeling tools helped in this area. Cimatron software is used for tool, hot runner and cooling system designs. Mold-flow software is for mold-flow analysis and to support DoEs to optimize the design and molding parameters. Moldex3D software is utilized for molding process simulations to test assumptions prior to tool fabrication. Use of these tools enabled tool designers to easily demonstrate the likely performance of the tool to the engineering team during the design process.

Integrating design, design analysis, tooling and injection molding expertise enabled the team to develop a viable solution applicable to endoscopes and similar types of invasive medical devices used in surgical and/or diagnostic procedures.

**About Forefront Medical Technology**

*Forefront Medical Technology 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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