

Rising to the challenge of Zero Defect Molding - How to enable high level parametric release and a need for expanded capacity for a complex molded component.

THE CHALLENGE:

Rethinking a complex supply chain issue – A global medical device manufacturer’s challenge to remediate a 6 month backlog for a vascular end-use medical component proved too daunting for conventional thinking. The backlog condition of supply positioned Helix Medical with the opportunity to rethink and innovate a solution to the problematic molding conditions for this strategic customer.

Facing growing demand for volume, the market for the customer’s premiere medical product was becoming a critical issue for this global healthcare company. High demand is normally good news for any company with a cutting edge, first to market product; however, the customer was not confident of their current supplier’s ability to meet the increasing volume requirements for this key plastic component and the client approached Helix Medical – Baldwin Park Operations (formerly APEC) to rectify the situation. The existing platform for production consisted of a 4 cavity mold fitted with a valve gated hot runner system that incorporated slides with complex core pins and sophisticated shut offs to create unique fluid path features in the molded part. These port and flow features were continually compromised during production due to core pin failure and resulted in extensive downtime, scrap, assembly line rejects, excessive need for expensive core pin replacement, and tool repair. All of which exacerbated the backlog supply chain concern for the customer who was facing increasing market demand for their successful device.

SOLUTION PART 1:

Debug, redesign the process, and protect the mold at all costs.

Based on dialogue with Helix Medical, the customer decided to bring the tool to Helix Medical’s Baldwin Park Operations in Southern California seeking a temporary and permanent solution to the consistent backlog situation and a means to organize a long-term plan to support the customer’s market growth objectives.

Baldwin Park’s plastics engineering team went to work immediately. First, the team conducted a PFMEA (Process Failure Modes and Effects Analysis) to develop a roadmap to remediate the current component backlog situation and develop countermeasures to resolve mold tool performance

issues with the 4 cavity production mold. This PFMEA and root-cause analysis project resulted in a calculated plan for quick and deliberate action to repair the tool to full functionality and to then “protect the mold” beyond all doubt in order to maintain a fluid production and quality circumstance. The interim action plan included core pin modifications (all surfaces and shut-offs were fitted and conditioned), infrared sensor curtains were added to ensure no parts were left in harm’s way during the molding process, and secondary safeties were added to machine controller functions to disallow human error. As an additional redundancy for molded part removal safety, an end-of-arm tool (EOAT) was designed and implemented with an above machine robot to extract parts from the mold during each process cycle. The EOAT offered part confirmation assurance coupled with parameter fault-based detection capability for components captured and extracted from the mold. Based on machine controller process set point specifications, the robot controlled EOAT would react to these specifications according to accept or reject criteria. Thereby dispatching parts to a reject collection bin based on machine controller parameter data and eventually stop the machine if necessary.

Once the mold was thoroughly protected and capable, Helix was able to utilize the techniques of Decoupled MoldingSM to improve the quality of the process and cycle time of the component being produced in order to fully optimize production capability. Operating integrity of the mold was increased to the point where the program produced 100% yield and efficiency 24/7.

Full dedicated cavity separation was integrated later adding to the customer quality experience. Cavity separation slimmed the quality exposure margin considerably for the customer offering product segregation with the ability to focus on issue concentration by cavity when and if required. Eventually the backlog situation was eliminated and focus shifted to satisfying the increased market demand for the customer’s part.

CHALLENGE PART 2:

Rising to the Challenge of Zero Defect Molding - How to enable parametric release of produced components on a higher level and with a need for expanded capacity of a complex molded part.

Legacy quality control tools and techniques within the medical device industry rely on detection methods (i.e. compulsory inspection routines in production, Statistical Process Control (SPC), AQL-based lot sample inspection, etc) that do not prevent defects but rather identify them in a way that does not necessarily protect the production population. Helix Medical needed to deploy a process strategy and a means of detection to “measure” out-of-control process circumstances cavity-to-cavity. This was based on a sound fault detection methodology approach that would assure quality shot-to-shot and effectively marginalize false alarm rates. Helix needed a partner to better understand parametric interactions and correlations in a more proactive sense to derive process quality decisions.

SOLUTION PART 2:

The challenge intensifies, increase capacity responsibly and with zero defects without compromising the project.

Helix Medical, in conjunction with the customer, worked with specialized medical mold fabricator Magor Mold to deliver a state-of-the-art 8 cavity mold utilizing lessons learned from the 4 cavity tool experience. In addition to installation of infrared sensors and EOAT with cavity separation, Helix’s engineering team added the RJG eDart System™ to assist and augment the Decoupled Molding process definition. The effort was to provide better control to the tight tolerance / quality requirements of the new 8 cavity molded components. The RJG monitoring system approach was taken to the next level by adding sensor instruments into the mold. This configuration of equipment and instrumentation enables the mold and the injection molding machine to communicate with each other and provide the ultimate in closed-loop process control of the molding conditions. The RJG eDart System now controls and adjusts the process using real-time “at gate” cavity pressure values for each shot. Shot to shot quality of each process cycle is monitored and controlled using “end of fill” cavity pressure values; subsequently sending a signal to the EOAT to accept or reject a part accordingly based on parametric release. This set-up - using a combination of infrared sensors, EOAT, cavity separation, and RJG’s eDart System - enabled Helix Medical to provide uninterrupted supply of this part to all customer division locations worldwide essentially more than doubling their capacity and helping the client to sustain current market share and win additional share virtually overnight. The 8 cavity mold is currently running production at Helix Medical’s Baldwin Park Operations and has been in operation for the last two years without breaking a single core pin and with almost perfect uptime and efficiency. Continued growing global demand for this component has afforded the customer, Magor Mold, and the Helix Medical team the opportunity to design and build a new 16 cavity tool with a similar set up. This new mold has been in production for approximately one year.

RESULTS:

Helix Medical and RJG were able to get the old mold running successfully and the customer was out of their 6 month backlog within 60 days.

A newly designed higher cavitation mold with pressure sensors, high intensity mold protection features, EOAT, and automated cavity separation has delivered continuous processing and consistency effectively isolating suspect parts by fault contributors as required during each process cycle. Without these systems and sound problem solving skills in place, the customer would not have been able to ensure the integrity of the mold, control quality of the components being produced in real-time, and monitor the processing window as accurately as they do today with Helix Medical as their molded and assembled part provider.

The overall savings to the customer and their key project is measured in terms of the elimination of bad parts and delivering 100% yield. This customer has now been running 100% reject-free parts for the past 2 years. The new 16 cavity mold has been running for approximately one year and is on track to offering the customer an additional cost savings.

About Helix Medical – Baldwin Park Operations

The Baldwin Park Operations of Helix Medical, formerly known as APEC, was acquired by Freudenberg-NOK in 2008 and is now part of Helix Medical, LLC. Helix Medical – Baldwin Park Operations, located east of Los Angeles, manufactures high precision medical device components and subassemblies specializing in thermoplastic, silicone (LIM), insert, and two-shot molding. A full service medical component manufacturer, Helix Medical can provide turn-key contract manufacturing services or a single component program based on a client’s needs.

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About Helix Medical, LLC

Founded in 1984, Helix Medical is a global custom manufacturer for the medical device, healthcare, pharmaceutical, IVD, and biotech industries. Medical manufacturing capabilities include silicone and thermoplastic molding and extrusion, assembly, packaging, and complex catheter systems. Headquartered in Carpinteria, CA, Helix Medical operates an FDA-registered medical device facility, certified ISO 13485 with Class 7 & 8 cleanrooms. Additional medical manufacturing operations are located in Baldwin Park, CA; Gloucester, MA; Shenzhen, China; Kaiserslautern, Germany; and Carrick-on-Shannon, Ireland with VistaMed, a Helix Medical joint venture company.

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