Case Study – Molded-In Stresses and Superior Optical Clarity in Medical Grade Plastic Products.

Challenge

In August 2005, our client, Genomic Profiling Systems, Inc., currently known as Rapid Micro Biosystems, Inc., was a relatively new comer to industrial microbiology and was working on the development of an exclusive rapid, quantitative, and sensitive microbial testing system. Their unique design would allow their customers to generate significant productivity gains, with cost savings generated from decreased quarantine inventory and reduced product risk.

Our client's Microbiological Enumeration System incorporates proprietary digital imaging technology that automatically enumerates microcolonies days earlier than the traditional visual plate counting methods. The system captures the native fluorescence (auto-fluorescence) that is emitted by all living cells. By detecting microcolonies composed of a small number of cells, the Growth Direct test can automatically report the number of microbes in a sample days earlier than the current visual colony counting method.

The sensitivity and efficiency of the test result from imaging microscopic colonies without magnification using large area CCD (Charge Coupled Device) imaging. Rapid Micro Biosystem's test is accurate and efficient even when the manufacturing sample to be tested contains only a single replicating microbial cell. Because the detection is non-destructive, the system is easier to validate and compatible with all current microbe identification methods.

The problem was that the plastic injection molded optical lid comprised in the custom disposable cassette, designed for their new Microbiological Enumeration System, when exposed to Gamma Irradiation Sterilization resulted in stress concentrations. These stress concentrations are a byproduct of the molded-in stress coupled with the

Corporate Headquarters
770 Main Street
West Warwick, RI 02893
Tel: 401.828.0820
Fax: 401.828.0840

Corporate Offices
New York, NY
Chicago, IL
Dallas, TX
Los Angeles, CA
Hong Kong, China

aforementioned sterilization process, ultimately diminishing the lid's optical clarity and diluting the imaging system's accuracy and effectiveness.

While molded-in stresses are on their own a cause for concern, the symptoms of molded-in stress are typically the "attention getter" because molded-in stresses in plastic components are often undetectable with the naked eye. These stresses can manifest in many different ways, such as deformation and cracking. In clear plastic parts however, where optical clarity is critical, these stresses refract the light and alter the image, which is obviously a serious issue when a core component of your system is imaging.

Solution

While the leading cause for molded-in stress, are just that, they are molded-in, or manufactured into, the plastic injection molding process, there are other factors that one must consider as well, such as material selection, part design, and tooling design or construction, which can also lead to inducing stress into the molded article.

Having identified the symptom as diminished optical clarity following gamma irradiation, we employed a three-pronged approach to solve the problem, and focused our team of plastic engineer's efforts on the following action items:

- **Examine Plastic Product Design**
- **Analyze Plastic Resin**
- **Examine Plastic Tooling Design**
- **Inspect Plastic Injection Molding Tool**
- **Analyze Plastic Injection Molding Processing Parameters**

Our examination of the subject plastic injection molded lid design incorporated a sophisticated 3D CAD solid modeling program designed for plastics, which provided us with the added ability to conduct computer-simulated stress and mold flow analysis of the plastic lid. Our approach allowed us to scrutinize the plastic lid's design in full view of the stresses induced during installation and the molten plastic polymer melt flow during the injection molding process.

There are four modes of plastic failure, material, process, design, and service use. Responsible material identification and selection is a critical component to any viable

product and requires forethought and planning. In order to determine the most suitable plastic resin, one must first create a responsible design, a design that takes into consideration the manufacturing process selected for the manufacture of the product and takes into account foreseeable service use. Following our in-depth analysis, we determined that Polycarbonate would be the most suitable resin. Due to our policy on non-disclosure and dedication to client privilege, we will not disclose the specific grade.

Our evaluation throughout the project encompassed the comprehensive analysis of each of these aforementioned failure modes, both individually and collectively. The leading mistake made by engineers when designing plastic parts is that they simply fail to understand the dynamic relationship between these modes, a critical mistake that often results in an almost immediate or premature failure.

Following our product design review and material identification and selection, we conducted an examination of the plastic injection tooling (mold) used in the manufacture of the subject lid. Our comprehensive analysis included dimensional, construction, cooling, gating, polishing, ejection system, etc.

Result

Based on our thorough research, testing, and analysis of the plastic injection molded lid design, and tooling design, and material identification and selection, and in full view of the product's technical and quality requirements, we recommended changes to each of these areas to improve optical quality and part performance.

We managed and implemented the product and tooling design changes, arranging for the material samples, and onsite inspection of the Massachusetts based medical injection molding facility. We worked with the team at Genomic Profiling Systems engineers to manufacture a plastic lid with excellent optical clarity pre and post gamma irradiation sterilization and that met the medical and quality criteria demanded by Genomic Profiling Systems, Inc.

The successful completion of this product led the successful launch of their Microbiological Enumeration System, on time and on budget. If you would like the experience of plastic experts that have the technical knowledge and real world

experience of working on all-encompassing projects, "call on the experts that those within the industry turn to with their toughest problems" ™, **Toll Free: 866.828.0820.**

For more information, please contact us:

CPC Plastics, Inc.
770 Main Street
West Warwick, RI 02893

Tel: (+011) 401.828.0820
Fax: (+011) 401.828.0840
Toll Free: 1+ 866.828.0820 (U.S. Only)
Online: http://www.cpcplastics.com