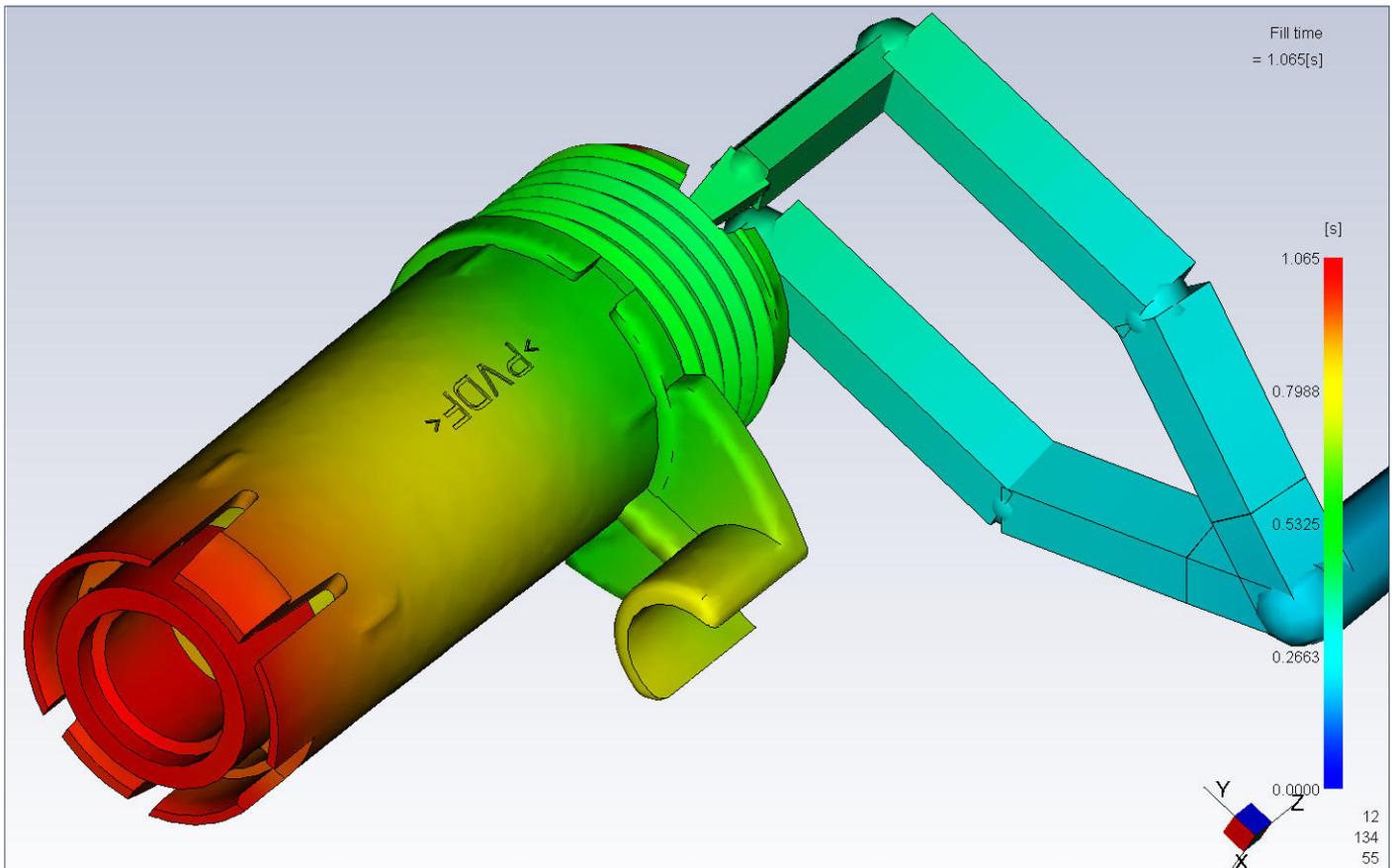


STRENGTHEN REGULATORY COMPLIANCE WITH SCIENTIFIC INJECTION MOLDING (SIM)

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Rheological simulation is used to optimize the design of parts produced by plastic injection.

Dedicated to the life sciences, medical technology, and pharmaceutical sectors, PureLab Plastics has been specializing in the design, development, and manufacturing of plastic injection molding for more than 40 years. To meet the regulatory requirements of this sector, the company has integrated the concept of Scientific Injection Molding into its subcontracting service offerings.

In the field of medical devices, in order for a new application to be brought to market, it must be validated and manufacturers must guarantee its compliance with market regulations. On one hand, they must demonstrate proof of conformity of their product and, on the other hand, prove that the manufacturing process remains reliable and durable throughout the serial life of the product.

Introduced in the 1950s, the plastics processing field, mainly plastic injection, is a new technology developed during the industrial era. Oftentimes, specific key parameters are defined empirically and not with a scientific approach.

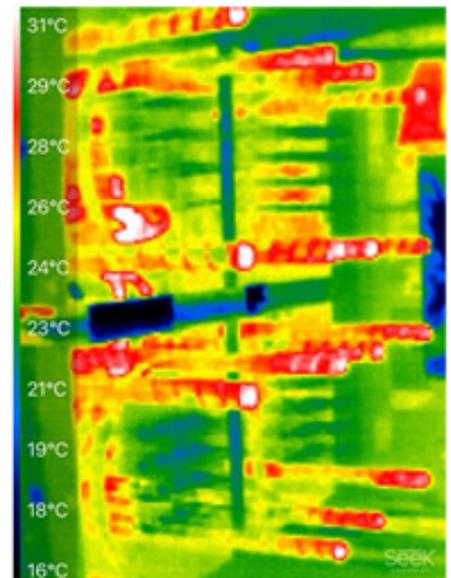
The scope of the SIM applies to the entire product life cycle:

- During product design: material grade characterization studies, rheological studies, material resistance studies, hydraulic studies of tools, ...
- During industrialization: using several tools (viscosity analysis, linearity analysis, cavity balancing, temperature cameras, etc.) and physical measurements (flow rate measurements, cavity pressure measurements, temperature measurements, etc.), it is necessary to monitor the process and ensure that the reality matches the studies done during product design.
- During production: during the industrialization step, the production teams are responsible for maintaining parameters, monitoring any deviations, and taking corrective actions to keep the standard. These parameters are framed by process monitoring through computer interfaces. For example, quality monitoring is carried out through machine data, the presence of sensors in the molds, and by collecting regulation temperatures.

With the goal of better service for customers and remaining a trusted partner in the industry, Purelab Plastics is committed to continuous improvement of their processes, especially when it comes to improving instruments and defining a methodology for injection parameters. These improvements have been proven effective in several «success stories.»

One example of success happened when PureLab Plastics responded to an injection issue where very thin-walled components were needed using rheology simulation. The SIM approach enabled PureLab Plastics to choose a material capable of achieving long flow lengths, with a thickness of only a few tenths of a millimeter. This analysis also revealed that the material's viscosity (and variations) was very influential on the results (the risk of partial filling was very high). As a result, PureLab Plastics decided to control the end of filling via pressure sensors in the footprint.

These learnings have led PureLab Plastics to achieve a level of repeatability that would have been difficult to achieve with a traditional development process. To reinforce this decision, the project team proceeded using both types of analysis. A pilot batch was carried out using the classic molding approach of «switching by the stroke of the injection screw.» The result was conclusive: it turned out that more than 50% of the products had material shortages. Therefore, the team determined that using the SIM approach allowed the project to be completed within the given time frame, and above all, with the level of quality required for this type of Medical Device.



Example of thermic analysis within an injection mold (source PureLab Plastics).

An invaluable tool for winning new markets

According to Romain Bouillet, Head of Research and Development, “At PureLab Plastics, the Scientific Injection Molding approach is a major asset to win new markets. Simulation tools guarantee the project's success and allow the company to be proactive in product design evolution (optimization of material thickness, materials, and cycle times). This allows us to be competitive and reliable because many risks are raised upstream. This approach makes it possible to secure the results expected by customers, optimize their internal validation procedures, and simplify the creation of the technical files required to obtain marketing approvals.”