Author article MEDengineering

When one is better than many

As medical devices become ever more sophisticated and smaller in size, the challenge for the component manufacturer is how to fit multiple functions into a limited space. Multi-component LSR technology offers a solution to this, that in addition, provides designers with the latitude and flexibility to enhance their applications.

Silicone is ideal for medical devices and equipment, not only because it is inert, biostable and biocompatible with favorable physical and haptic attributes, but also due to the fact that it can be processed in a multitude of ways. This encompasses methods, such as, extrusion, molding, casting, coating and immersion; on its own or in combination with other materials and substrates, including API (Active Pharmaceutical Ingredients).

Multi-component LSR technology is the simultaneous injection of Liquid Silicone Rubber (LSR) in combination with engineered plastics and potentially other substrates. In what is also commonly referred to as 2K, 2shot, 2C LSR, multi-component injection molding, or co-injection, it is used to develop innovative solutions, combining two or more individual materials into one fully bonded component in hard-soft and soft-soft combinations. This is challenging due to the differing process requirements of LSR and other substrates.

One of the primary advantages of this technology is that the complex geometries that can be created mean that multiple separate elements that would have been assembled together can be produced as a single component. This removes the cost and risk associated with assemblies, such as potential leak paths or undesirable spaces for bacterial growth. It also provides the developer with the ability to create considerably more robust and cost-effective solutions that are of higher integrity and which can fit into a smaller design envelope.

In addition, assemblies can be value engineered, something that offers tangible benefits to the device manufacturer in terms of improved performance, prevention of contamination, the opportunity for automating a customer’s production lines, elimination of risk of misassembly, lower inventories and ultimately, reduced total cost of ownership.

For new Multi-component LSR applications, it is important to involve the component manufacturer as early as possible in the development process; from the concept stage so applications can be optimized for market. Trelleborg provides customers with access to specialists in product design and

functional modelling, material selection, as well as manufacturing, quality, and validation engineering, to help accelerate time to market.

Part-function and maximizing performance of an application are primary considerations in the design, but also, right from the earliest point possible Design for Manufacturing (DfM) considerations should be included with solutions for automation, creation of flash-less parts, waste-free production, in-process quality checks, batch by cavity and packaging. This and short cycle times, makes the production of extremely complex Multi-component LSR components possible in the high volumes needed for a medical device, which at full series demand could reach the tens of millions.

Trelleborg's approach to Multi-component LSR processing is unique in its holistic concept. Tooling design, from stage one, is developed not just to optimize the function of a component in the application, but also to maximize the effectiveness of automated operations.

The quality and precision of tooling determines how effective automation can be, not just for molding tools but also for individually designed robotic grippers and handling units that guarantee the feeding of components and removal of finished parts from molds without damage. If needed, this can be directly into customer specific packaging.

At Trelleborg's Multi-component LSR facilities, automation is taken to the ultimate level of process efficiency and quality consistency. Most parts are untouched by human hands until packaged, all in a 24/7 fully automated lights out operation.

For medical devices quality is paramount, and the holy grail of quality is to ensure quality in process rather than have postproduction quality checks. Depending on customer requirements this can be in an 'uncontrolled' or controlled environment of class 100,000, ISO8 or class 10,000, ISO 7 cleanrooms.

Quality is equally considered in the holistic approach, with certified quality systems and process controls built into the production process based on a mindset of producing 100% good quality. The ability to segregate suspect product effectively with minimal disruption in the case of a quality concern, is key to a high-volume, fast pace production process. In line quality checks are electronically recorded allowing full traceability, with products separated by cavity. Any issue can therefore be isolated to just a small number of components and delivered quality from the production line can be checked for that batch in detail.

Fundamental to the disciplines of any high-quality manufacturer involved in supplying 'clean' product, whether from within or outside a classified cleanroom, is a Good Manufacturing Practice (GMP)

discipline firmly rooted in the facility's quality systems. Industry guidelines provide minimum requirements that a manufacturer must meet to assure that products are of high quality and do not pose any risk to the consumer or public.

It is therefore critical for any manufacturer to apply due diligence in the establishment of GMP standards so that they are appropriately set to the specific application concerns and risks of parts produced. Standards for example relating to medical devices may vary depending on whether production relates to a low risk Class 1 device or a long-term implant.

An example of a Multi-component LSR solution is a valve within a medical device. A customer had a control valve with a spring-activated piston in their micro-pump system. This was a three-piece assembly, consisting of the piston that was initially sealed with two silicone O-Rings. They turned to Trelleborg Healthcare & Medical to analyze and resolve a leakage problem, while also aiming to reduce friction within the system.

A thorough analysis of existing components, mating environment, assembly process and application were undertaken to identify the potential sources of leakage and friction. Finite Element Analysis (FEA) simulations gave a better understanding of how the part was reacting within the application.

Key issues were identified as misalignment of the plastic piston as a result of poor quality tooling and process control. This was creating a potential leakage path. Automated O-Ring assembly was not 100% guaranteed, while stack-up of tolerances between the piston, O-Rings and piston housing created increased friction. In addition, mating surfaces and materials were not friction optimized.

A new 2C LSR part was designed to address the root cause of the leakage and friction issues. It consisted of a single component with compressive inner sealing for pressure both sides and deflective outer sealing to reduce contact friction, and for a pressure energized seal. The new design was subjected to FEA simulations to ensure optimum performance. In addition, a DfM analysis was performed including material flow simulation to ensure manufacturing feasibility and proof out the intended tool concept.

Partnership during the design phase led to collaboration on product and component design, materials selection, manufacturing concept development as well as validation. The new LSR part solved leakage and friction issues and provided a fully functional and reliable design. The integration of three individual components into a single one eliminated step in the customer's supply chain and manufacturing process, and thereby led to an increase in the customer's product quality and reliability with reduced production risk and overall lower costs.

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Trelleborg *is a world leader in engineered polymer solutions that seal, damp and protect critical applications in demanding environments. Its innovative solutions accelerate performance for customers in a sustainable way. The Trelleborg Group has annual sales of about SEK 34 billion (EUR 3.32 billion, USD 3.92 billion) and operations in about 50 countries. The Group comprises three business areas: Trelleborg Industrial Solutions, Trelleborg Sealing Solutions and Trelleborg Wheel Systems, and a reporting segment, Businesses under development. The Trelleborg share has been listed on the Stock Exchange since 1964 and is listed on Nasdaq Stockholm, Large Cap. www.trelleborg.com.*

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