Precision Engineering: ProMed Optimizes the LSR Injection Molding Process for Medical Devices

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PLYMOUTH, MN - December 10, 2025 -
ProMed, a contract manufacturer specializing in liquid silicone rubber (LSR) and highly regulated combination products, has announced new process refinements in the LSR injection molding process designed to support the growing demand for precise, reliable, and fully validated medical-grade components. The company has expanded its engineering controls, material handling standards, and cleanroom capabilities to help OEMs and emerging medtech developers meet increasingly complex performance requirements across drug-delivery systems, implantable devices, and minimally invasive technologies.

The updates come at a time when medical device teams continue to face tighter tolerances, more demanding regulatory expectations, and accelerated development cycles. ProMed reports that its refined approach is designed to strengthen production repeatability, reduce variability across high-volume runs, and help customers document compliance from early prototyping through commercial scale.

The optimized process centers on engineered LSR flow control, temperature stability, and metering accuracy. Production teams have implemented expanded in-house testing and more detailed material characterization to ensure predictable curing behavior and dimensional consistency. This includes measuring viscosity ranges, monitoring batch variations, and validating performance against ISO 10993 and FDA biocompatibility requirements. The company has also tightened tool qualification steps, allowing engineers to verify gate design, venting, and part ejection earlier in development. These updates help reduce downstream redesigns and shorten timelines from preliminary samples to validated molds.

In parallel, ProMed has expanded its ISO Class 7 and 8 cleanroom operations. The facilities now support larger custom LSR injection presses, enhanced positive-pressure controls, and more stringent protocols for managing airborne particulates during molding and assembly. For drug-device customers, segregated cleanroom areas allow for controlled material flow during highly sensitive processes such as mixing, filling, and final device assembly involving active pharmaceutical ingredients. According to the manufacturing team, these changes were implemented to help device developers meet rising expectations in combination-product compliance and quality documentation.

Tooling refinements also play a central role in the updated process. ProMed?s in-house tool designers have integrated new simulation software to predict LSR behavior in micro-scale features and complex geometries. The simulations guide mold construction, allowing the team to avoid shear-induced imperfections, minimize flash, and maintain uniform wall thickness in components used for implantable valves, seals, stoppers, and drug-eluting devices. The improved approach also supports shorter lead times by allowing more design decisions to be validated digitally before tool steel is cut.

The updated production framework emphasizes documentation at each stage. Device manufacturers working with ProMed receive structured support during design transfer, including material certifications, molding process sheets, IQ/OQ/PQ documentation, and traceability records. This documentation is particularly valuable for companies preparing for FDA submissions or EU MDR compliance, where detailed evidence of material handling, sterilization compatibility, and manufacturing repeatability is expected.

Alongside LSR improvements, the company continues to offer high-consistency rubber (HCR) molding, micromolding, and insert molding capabilities for hybrid components that combine metals, plastics, and silicones. As more medical devices integrate electronics, sensors, and mechanical subassemblies, LSR encapsulation and overmolding have become more common. The refined injection molding process improves adhesion, reduces stress on sensitive components, and helps protect electronics during sterilization and long-term use.

Industry analysts note a growing emphasis on device miniaturization and active pharmaceutical delivery, creating new challenges in material purity and component uniformity. ProMed?s updated LSR process aims to help engineering teams address these challenges by focusing on consistency from lot to lot. The refinements also support device developers who need to scale from pilot runs to commercial quantities without requalifying materials or altering validated molding conditions.

In addition to production upgrades, the company has also expanded its prototyping services. Development teams can now request rapid-iteration samples using production-grade LSR materials and tooling inserts, allowing earlier functional testing and design confirmation. This reduces the gap between R&D prototypes and commercial-ready components, giving device manufacturers a clearer understanding of performance, durability, and regulatory compatibility earlier in the design cycle.

As regulatory standards and device requirements continue to evolve, the updated LSR injection molding process demonstrates ProMed?s effort to remain aligned with the needs of medical device engineers, procurement teams, and regulatory specialists. The company intends to continue refining its silicone molding technologies as new materials, biocompatible additives, and device designs reach the market.

The enhanced production framework is now active across ProMed?s cleanroom facilities and available to both new and existing customers developing medical-grade silicone components. Engineering teams seeking support with early-stage design, tool development, or high-volume LSR molding can coordinate project reviews through ProMed?s technical staff.

About ProMed:

Since 1989, ProMed has been recognized as a leading Contract Manufacturer of complex, intricately designed molded silicone and plastic components and assemblies for highly regulated industries. ProMed?s expertise extends across applications for short-term and long-term implantable devices, single-use devices, drug-releasing combination devices, and specialized materials and processes for defense applications. They collaboratively work with our customers from prototype through production, providing over 30 years of experience related to design for manufacturability, material selection, tool and fixture design, process development, manufacturing, and other value-added services that result in cost-effective solutions with superior quality.

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