Formulated for an Era of New Challenges

ELASTOMER MATERIAL FLEXIBILITY OPTIMIZES PERFORMANCE AND MEETS NEW CHALLENGES

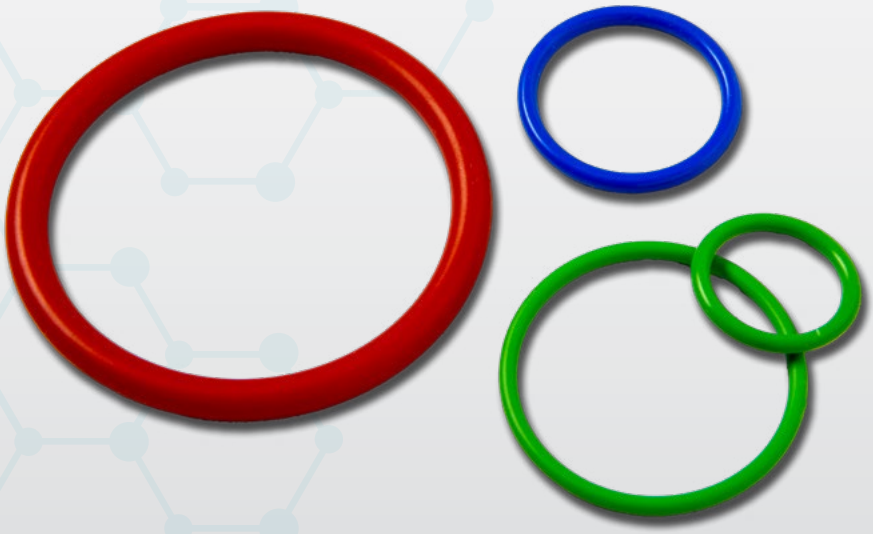
WHITEPAPER

Introduction

The global medical device market offers opportunities for innovation-driven growth. Demand for smart, new life-saving and life-enhancing technologies is perhaps stronger than ever. Manufacturers around the world looking to capitalize on this eager global market face a long list of challenges — some big, some small. Supply chain disruptions, labor shortages, rising materials costs and other headwinds are leading to delays in both engineering and manufacturing processes. Despite these challenges, the world demands medical device manufacturers' best. A surging geriatric population, implications of a global pandemic and the mortality rates for heart disease, cancer, obesity and other conditions are all contributing to strong and sustained market demand. One study predicts a compound annual growth (CAGR) of 5.4% will push global sales of medical devices to nearly $658B (USD) by 2028. Of course, the road to success will be littered with familiar roadblocks — and some that are entirely new.

Worldwide supply chain unpredictability presents perhaps the greatest of these challenges. The availability of raw materials, componentry and sub-assemblies introduces greater volatility for both engineering and manufacturing teams, seriously threatening go-to-market plans. Manufacturers that can respond quickly and nimbly to these challenges will be better able to meet their customers' needs and gain an advantage over competitors.

When specifying a high-performance material for your medical device application, temperature, environment, compatibility, hardness, compression, and certification considerations quickly build stringent material requirements. Expert suppliers consult with OEMs to think creatively, support product development and collaborate to find solutions that will deliver necessary results.



Material Scientists Optimize Performance and Provide More Options

Engineers designing new generations of devices rely heavily on liquid silicone rubber (LSR). It's often a default choice in the medical design and manufacturing process for good reason: it's one of the simplest formulations to provide great stability, temperature tolerance and a low compression set. LSR is one of many elastomers our customers specify for projects requiring unique properties. For example, LSR is a common material choice because of its biocompatibility with body tissue. Even if an engineer knows there are alternatives worth exploring, the pace and pressure of the innovation process typically dismiss any curiosity that could lead to the exploration of alternate materials. However, increasingly demanding applications have prompted further exploration of all elastomeric alternatives to LSR, including large families of customized black rubber. Trelleborg's elastomer specialists can help select the right material out of all potential options (including LSR) to meet the exact specifications of the product design.

Similarities of LSR and Custom Black Rubber

- Excellent electrical insulation
- Good cold temperature flexibility (to -50 °C/-58 °F)
- High temperature tolerance
- Resistance to chemicals
- Strong compression characteristics
- Clean surface finish
- Flame retardance
- Often used in biocompatible applications
- Non-black color options (hydrocarbon-based rubbers)
- Compliance with major regulatory organizations
- Biocompatibility

The Pros and Cons of Using Liquid Silicone Rubber (LSR)

Perhaps the most compelling attribute of LSR for engineers is familiarity. It's a known quantity with a history of aligning with most regulatory requirements and delivering predictable performance on the manufacturing line and in the field. It's a pure and uniform material that's inherently inert and biocompatible — which is especially important for medical applications. It also offers simple formulations that are comprised of just two or three core ingredients.

This reality is magnified as medical device engineers face greater pressure to minimize costs and get products to market faster. As product development schedules are compressed, engineers are more likely to rely on familiar materials like LSR. But, as with most long-time default options, it's not always a perfect fit for new applications. There are many recent cases where new product designs unexpectedly fail during the prototyping stage. Engineering teams typically look to make product design tweaks first, but in many cases, a just-less-than-perfect material can cause these hard-to-detect problems. Reexamining both material and design can save teams from spending time and money trying to solve a core design flaw that may not exist.

A second challenge design teams are facing is supply-chain instability. Silicone shortages have long been a common cause of delays for engineering and manufacturing teams across multiple industries, including healthcare. While this instability can be significantly minimized by experienced supply chain management professionals, a secondary material choice offers even more flexibility when facing supply chain uncertainty.

Unearthing Superior Results Through Custom-Built Formulations

Supply chain uncertainty has prompted engineering teams to explore the full range of elastomeric options. It has also prompted those teams to engage materials science providers earlier in the design process — and led to the discovery of critical-to-function components that deliver superior results in trials, on the manufacturing floor and in the field. Custom black rubber is not new, but customer formulations are offering new opportunities for additional or alternative market value.

Materials scientists at Trelleborg, for example, have access to an ever-expanding portfolio of more than 3,000 proprietary elastomeric compounds (including LSR), giving us the expertise and flexibility to meet the exact specifications for customers' medical device designs. Creating custom black rubber formulations provides engineering teams with greater control — and the ability to select the ideal compound for their products. Most often, custom black rubber compounds include multiple ingredients — compared to just two or three for LSR. This makes the number of formulations almost endless.

Materials flexibility offers an unmistakable source for greater design control, cost savings and improved reliability. Collaborating with materials scientists to modify black rubber formulations allows engineers to manipulate how the material behaves and adjust compression sets, elongation, cure states and other key criteria. Best of all, the core materials used to create custom black rubber formulations have been proven over time to be inherently inert and biocompatible — and safe for use in the human body.

Quick Facts About Custom Black Rubber

- Operating temperatures from -45 °C to +160 °C/-49 °F to +320 °F
- Special grades up to +200 °C/+392 °F
- Exceptional mechanical performance
- Compatible in all sterilization environments, E-beam, EtO and Gamma
- Low long-term compression set with specific compounds
- Biocompatible
- Long life in polar solvents, hot water and steam
- Suitable for contact with alkaline cleaning fluids
- Tested in accordance with ASTM, SIS and FDA
- High wear resistance, minimal creep and permeation
- Compliance with FDA CFR177.2600, 3-A, USP Class VI, Cytotoxicity (USP 87), NSF, KTW, WRAS

Ideal for Medical Devices

A typical challenge in medical devices is to seal against harsh chemicals and fluids. Custom black rubber can offer excellent resistance to polar fluids, polar solvents, alkaline-based cleaners and steam/hot water.

Temperature Resistance

Medical device components typically require the ability to withstand extreme high or low temperatures. Custom black rubber offers temperature stability from -55 °C to 150 °C/ -67 °F to +302 °F.

Exceptional Durability

Custom black rubber can provide outstanding abrasion resistance, which is critical for mitigating detrimental leaks and tears. Components are designed specifically to withstand UV rays, ozone and aging.

Flexibility

Custom black rubber typically allows for 600% elongation and a tensile range of 500-3000 psi to ensure rubber seals can move as needed and avoid creating leak paths.

Taking Time to Customize Can Get Products to Market Faster

Intuitively, the idea of exploring black rubber formulations to create custom component designs seems antithetical to getting products to market faster. The word "custom" in any business is associated with longer development times. However, in most cases, the customization process saves time. Components carefully designed for a particular medical device can improve the success rate in clinical trials — and simplify other aspects of the design process. A proven and versatile material such as LSR offers incredible versatility. It's the right tool for many applications. For other applications, the right tool is a different formulation, one of several thousand potential black rubber combinations. Exploring the world of custom black rubber opens a world of flexibility many manufacturing teams have yet to experience.

Collaborating on Innovations Using Custom Materials

At Trelleborg, we bring experts from a variety of specialties into a collaborative design process from day one. Initial design meetings with our clients typically include materials scientists, design engineers and tooling experts, because better-performing devices are built with thoughtful designs and the right materials. Engaging our experts early in the process means the right questions are asked up front, equipping designers with the right design criteria to ensure components are developed for production success from the start.

Our ability to produce production-intent prototypes from any material in our ever-expanding library saves time, allowing our customers to test fully functional prototypes of critical-to-function components early in the innovation process.

Through our materials science capabilities, our innovation and development processes and our people resources, we find solutions for the toughest projects. Whether your application requires LSR, another compatible material, a turnkey multi-shot part with million-dollar tooling, a complex overmolding, or a system-critical part for a wearable diabetes application, we have the resources and deep bench of expertise to deliver your toughest projects.

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.

Trelleborg Healthcare & Medical develops, manufactures and supplies innovative engineered solutions for demanding medical, biotech and pharmaceutical applications in thermoplastics, silicone and other elastomers. We focus on meeting the most demanding needs of Healthcare & Medical customers with innovative solutions.

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