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**History of silicones
in medical devices**

**Unique advantages of silicone
and synthetic polyisoprene rubbers for medical devices**

**Medical silicones
and low volume parts production**

**Use of liquid silicone rubber
in flame retardant rated automotive electrical connectors**

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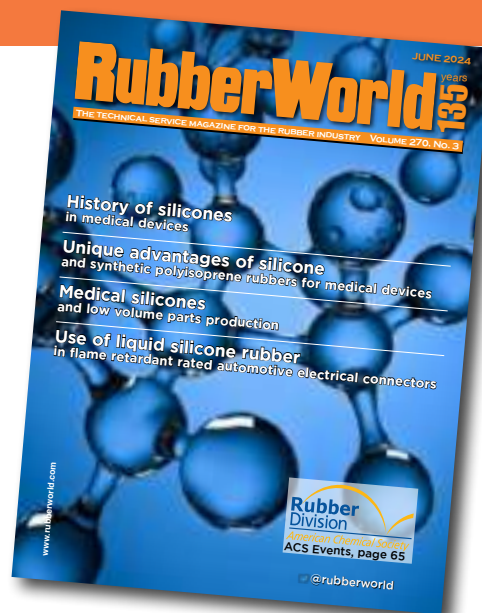
by Michael Goglia and Aneta Clark, *Elkem Silicones*. Selection of silicone type and processing method is crucial in the development and manufacturing of quality medical devices.

38 Unique advantages of silicone and synthetic polyisoprene rubbers for medical devices

by Amalendu Sarkar, *Cirtec Medical*. Distinctive features that make silicone and synthetic polyisoprene rubbers exceptional choices in healthcare contexts are explored and elucidated by the author.

44 Medical silicones and low volume parts production

by Dominic Testo, *Specialty Silicone Products*. USP Class VI medical silicones support low volume parts production, and are available as ready-to-mold compounds, ready-to-cut sheets or rolls, and as finished products. By partnering with a supplier that offers low minimum order quantities and on-time deliveries, designers can get the medical silicone parts they need.



Cover photo: Courtesy of Elkem Silicones

46 Use of liquid silicone rubber in flame retardant rated automotive electrical connectors

by Noel Mower Chang, Yenny Cubides, David Shawl and Dongchan Ahn, *Dow Chemical*. Silastic 9212-50 liquid silicone rubber is a novel formulation that retains mechanical performance, flexibility, thermal range and processability of incumbent materials, while improving dimensional robustness.

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90% of IEC Expo floor is sold

Rubber Division, ACS, will hold its International Elastomer Conference September 9-12 at the David L. Lawrence Convention Center in Pittsburgh, PA, and 90% of the IEC Expo floor is already sold. Exhibiting at the IEC Expo can increase company visibility in the marketplace, and enables firms to find new customers and make new business partners to enhance their growth. More than 3,000 attendees are expected at this year's IEC, which will be co-located with Silicone Expo USA.

Rubber Division, ACS, offers a variety of booth sizes which provide companies with the opportunity to introduce new products, programs and technology; network with industry decision makers, and current and potential clients; support sales efforts with direct, personal on-the-floor contact; obtain a multitude of qualified contacts in just days; reach an international audience (individuals from more than 30 countries are expected to attend the 2024 IEC Expo); and reinforce your company's corporate image with current and potential buyers.

Contact Melanie Avdeyev for more information on exhibiting at the 2024 IEC Expo: (330) 595-5537; ma@rubber.org. Register to attend the IEC Technical Meeting before August 1 for discounted pricing. Visit <https://iec2024.events.rubber.org/registration/pricing>.

Machinery and materials featured

Rubber World's upcoming **July** and **August** editions highlight **Machinery and Equipment** (July) and **Chemicals and Materials** (August). In addition, *Rubber World's* annual Machinery and Equipment Suppliers Directory is published in the July edition. Both the July and August issues include a special Corporate Profile advertising section, where advertisers who schedule a full page ad in either issue earn a free Corporate Profile in the same issue. Corporate Profiles appear opposite the company's advertising to provide the impact of a two-page spread advertisement.

New product press releases, news releases and case studies are invited for these two important issues of *Rubber World*. Please submit your editorial material to my attention (jill@rubberworld.com) at your earliest convenience.

Details on advertising opportunities in *Rubber World* are available from Dennis Kennelly (dennis@rubberworld.com); Mike Dies (mike@rubberworld.com); or Pete McNeil (pete@rubberworld.com). Don't miss out on these excellent opportunities to promote your company's products in two of our biggest issues of the year!



Jill Rohrer

RubberWorld

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The VMI LAT100 tire tread compound tester, accurately simulates road conditions for fast and economical laboratory testing of rubber samples. This way you can save time and money by evaluating tire properties before production starts. The versatile test machine can be employed for typical standard measurements as well as for scientific research, measuring both the abrasion resistance and the friction properties under a wide range of selectable conditions.

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New: dynamic tests

The newly introduced dynamic testing enables a much reduced testing time for any test procedure and can be used for any test surface and condition (dry, wet, ice) as it offers an excellent correlation to the traditional road testing. With the innovative dynamic test functions of the LAT100, the machine can also be used as abrader/tribometer and additionally generate full friction curves.

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A close-up photograph of the yellow VMI LAT100 machine, showing its mechanical components and the 'LAT100' label.

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Business Briefs

R.E. Carroll acquires distributor ChemRep

R.E. Carroll (www.recarroll.com), Ewing, NJ, a specialty chemical distributor primarily serving the adhesives, coatings and rubber industries, announced the acquisition of ChemRep, effective

ACQUISITIONS, EXPANSIONS

June 5. R.E. Carroll is a 99-year-old privately held distributor of raw materials and petroleum products used in the adhesives

and sealants, coatings, rubber and related industries from its four warehouse facilities strategically located in Dalton, GA; Ennis, TX; Ewing, NJ; and Kent, OH. ChemRep, located in Wood Dale, IL, is a regional distributor and manufacturer's representative focusing on products used in the rubber manufacturing industry. ChemRep specializes in activators for sulfur cures, process aids, adhesion promoters, fillers, mold releases and polymers. ChemRep will continue to distribute these products from the Itasca, IL, warehouse. ChemRep will continue to operate as a subsidiary of R.E. Carroll for the immediate future.

Wacker (www.wacker.com), Munich, Germany, has acquired the manufacturing assets and know-how of U.S. based **Bio Med Sciences** to expand its expertise and business in silicone coated healthcare products. A corresponding purchase agreement was signed between Wacker and the Pennsylvania based company. As part of the acquisition, a majority of Bio Med Sciences' workforce will also move to Wacker.

Greene Tweed (www.gtweed.com), Lansdale, PA, a global manufacturer of high performance thermoplastics, composites, seals and engineered components, announced the completion of its manufacturing facility in Ochang, Cheongju-si, Chungcheongbuk-do, Republic of Korea.

Quality registrations

Continental (www.continental-tires.com), Hanover, Germany, announced that its tire plant in Hefei, China, became the company's latest production site to receive the International Sustainability and Carbon Certification (ISCC) Plus sustainability certification.

Lucas Oil (www.lucasoil.com), Indianapolis, IN, announced that its production facility and laboratory in Corydon, IN, has met all the standards for recertification to ISO 9001:2015. The quality management system certification was conducted by the **PRI Registrar Performance Review Institute**, and included both production facilities in Corydon.

Moldex3D (www.moldex3d.com), Zhubei City, Taiwan, announced that its laboratory obtained recertification for ISO 17025, an internationally recognized standard for testing laboratories.

Teijin Carbon Europe (www.tejincarbon.com), Wuppertal, Germany, was awarded ISCC (International Sustainability and Carbon Certification) Plus, covering its Tenax carbon fiber produced at the Heinsberg-Oberbrück plant in Germany.

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Business Briefs

Zochem recognizes Palmer Holland

Zochem (www.zochem.com), Dickson, TN, has awarded **Palmer Holland** its Distributor of the Year Award for 2024. Palmer Holland has been a Zochem distribution partner for many years and has earned this award based on their responsiveness and customer service. This is the second win for Palmer Holland.

CONTRACTS, LICENSES

Bridgestone (www.bridgestoneamericas.com), Nashville, TN, was recognized by **General Motors (GM)** as one of its top global suppliers of 2023. Bridgestone was one of 86 companies out of GM's network of more than 20,000 suppliers to achieve this award, marking Bridgestone's ninth consecutive and 22nd overall recognition from GM.

Bridgestone Americas (www.bridgestoneamericas.com), Nashville, TN, a global provider of premium tires and sustainable mobility solutions, has been chosen by **Maserati** to develop bespoke 20" tires for its first all-electric SUV, the

Maserati Grecale Folgore. After recent collaborations, including fitments for the Maserati MC20 supercar and the Maserati Grecale, Maserati looked to its long term partner for a tire that could enhance the on-road capabilities of its first ever all-electric SUV. Bridgestone responded with custom developed Bridgestone Potenza Sport Enliten tires, its flagship ultra-high performance tire.

Continental (www.continental-tires.com), Hanover, Germany, announced that the U.S. car manufacturer **Chevrolet** is relying on Continental's original equipment expertise for its 2024 Traverse model. The SUV is fitted from the factory with tires from the CrossContact series. The series has been developed especially for good handling qualities on- and off-road. Continental has received worldwide original equipment approval for the CrossContact LX 20 in sizes 20" and 22".

UPM Biochemicals (www.upmbiochemicals.com), Helsinki, Finland, announced that **Artigo**, an international rubber flooring company, will produce its next-generation flooring collections from 2025 with UPM BioMotion renewable functional fillers. UPM BioMotion RFF is said to be a CO₂-negative solution for diverse rubber and plastic applications, containing 100% renewable carbon, certified by **Din Certco**.

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Business Briefs

USTMA launches Tire Recycling Foundation

The U.S. Tire Manufacturers Association (USTMA) (www.ustires.org), Washington, D.C., in partnership with the Tire Industry Association (TIA), announced the formation of

CORPORATE, FINANCIAL NEWS

the Tire Recycling Foundation during its ninth Tire Recycling Conference. This initiative will secure

funding and allocate grants for research, education, intervention and demonstration projects targeting critical knowledge and research gaps within the U.S. tire recycling supply chain. The Tire Recycling Foundation's primary goal is to recycle 100% of end-of-life tires into circular, sustainable markets. "For the past 30 years, USTMA has advocated for sustainable end-of-life tire management, but more work remains with only 71% currently recycled," said Anne Forristall Luke, president and CEO of USTMA. "Through the foundation and collaboration with our newly appointed board of directors, comprised of manufacturers, dealers, recyclers and transportation experts, we are confident we can advance our goal of 100% circularity." The Tire Recycling Foundation board has set ambitious research initiatives to be supported with fundraising targets of \$300,000 in 2025 and \$2-3 million in 2026. A key focus area for the foundation is said to be accelerating the adoption of rubber modified asphalt (RMA), an emerging end-of-life tire market said to have performance, economic and environmental advantages.

Lanxess (www.lanxess.com), Cologne, Germany, a specialty chemicals company, announced an agreement with its utility provider, Entergy Arkansas, to significantly reduce emissions related to powering the company's sites in Arkansas. The agreement reduces Lanxess' Scope 2 emissions (external energy sources) by utilizing a combination of clean and renewable energy produced in Arkansas. The company's three facilities in El Dorado are expected to see an 82% reduction in indirect greenhouse gas emissions associated with the purchase of energy, or Scope 2 emissions; while it is anticipated that the Little Rock facility will achieve a full 100% reduction.

Davis-Standard, LLC (www.davis-standard.com), Pawcatuck, CT, a global designer and manufacturer of extrusion and converting technology, announced that all of its North American facilities are now powered by 100% carbon-free electricity. By transitioning to 100% carbon-free electricity in North America, Davis-Standard is said to have taken a decisive step towards reducing its carbon footprint and mitigating climate change impacts. Davis-Standard achieved this milestone by purchasing Green-e certified Renewable Energy Certificates (RECs) for its Pawcatuck, CT, and Fulton, NY, facilities. These RECs guarantee that the electricity used in these locations is generated from renewable sources, such as wind or solar power.

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Pressure sensitive adhesives to grow 3%

The global pressure sensitive adhesives (PSA) market is projected to grow from \$13.8 billion in 2024 to \$16 billion by 2029, at a compound annual growth rate (CAGR) of 3%, according to a study from Reportsandmarkets.

PSAs represent a critical class of bonding materials that exhibit a permanently tacky nature at room temperature, enabling them to adhere to various surfaces upon the application of slight pressure. This class of adhesives is distinct in its ability to effectively bond a diverse array of materials, including paper, plastic, metal, wood and glass, without the need for a chemical reaction to activate the adhesive properties. The intrinsic balance between adhesion and cohesion within PSAs is paramount; adhesion refers to the ability of the adhesive to bond to external substrates, while cohesion refers to the internal strength of the adhesive's components. The utility of PSAs extends beyond traditional adhesive applications, offering a viable alternative to mechanical fasteners, such as screws, rivets and bolts. This characteristic is particularly advantageous in manufacturing processes where speed and ease of application are critical, making PSAs an optimal choice for point-of-purchase displays and general purpose graphics.

Water based PSAs dominate the mar-

ket due to their environmentally friendly nature, lower cost and safety. These adhesives involve dissolving acrylic polymers and other additives in water, which is then coated onto a substrate. Upon evaporation of the water, a solid adhesive layer remains. Water based PSAs offer performance comparable to solvent based adhesives, while mitigating safety and environmental concerns. They cater to a wide range of applications, including tapes, labels and graphics, and are compatible with rubber, vinyl and acrylic chemistries.

Acrylic PSAs are known for their excellent balance of properties, including high adhesion, durability and resistance to environmental factors. These adhesives are typically used in applications requiring long term performance, such as in the automotive and construction industries. Acrylic PSAs can be formulated to provide excellent ultraviolet (UV) resistance, making them suitable for outdoor use. They also offer good chemical resistance, and can be tailored to adhere to a wide range of substrates, including metals, glass and plastics. The ability to customize acrylic formulations allows manufacturers to create adhesives with specific properties, such as enhanced tack or shear strength.

The Asia Pacific market is expected to experience significant growth during

the forecast period. Economies in this region, including India, China and South Korea, in addition to Brazil and Argentina, are investing heavily in industrial development, driving demand for pressure sensitive adhesives. In contrast, growth in the European market is being constrained by stringent environmental regulations, which are reshaping the PSA market. These regulations are compelling manufacturers to innovate and develop eco-friendly alternatives, impacting market dynamics.

Rubber coatings market expands 6.2%

The global rubber coatings market valuation was estimated at \$6.8 billion for 2022. With a steady compound annual growth rate (CAGR) of 6.2% from 2023 to 2033, this market is expected to reach \$7.2 billion by 2023, and \$13.14 billion by 2033, according to Future Market Insights.

Numerous product types, including polychloroprene, silicone rubber, butyl rubber, EPDM and fluoroelastomers, to mention a few, are available in the form of rubber layers and are used as rubber coatings across various end use industries. The layered medium must be taken into account when choosing a rubber finish material. Rubber coverings are more effective due to their durability in serious environmental issues, as well as their resilience to wear and tear.

According to the study, both synthetic and all natural rubber are used in rubber coatings; however, synthetic rubber is more frequently used. Synthetic polymer finishes are widely used to provide safety coatings on a variety of objects, as well as in caulking and weatherproofing. They also effectively block out noise. Owing to these positive factors, the global rubber coatings market is expected to gain significant traction during the forecast period from 2023 to 2033. the report states.

Malaysian NR production down, exports up

Malaysia's natural rubber (NR) production decreased by 9.2% in March to 26,966 tons as compared to 29,691 tons in February. The Department of Statistics Malaysia (DOSM) said in a statement that year-on-year comparison showed that the production of NR decreased by 0.8% from 27,188 tons in March of 2023. According to the DOSM, total NR stocks fell 3.3% in March to 222,455 tons as compared to February.

Exports of Malaysia's NR amounted to 58,965 tons in March, up 7% over February. China remained the main destination for NR exports, accounting for 48.9% of total exports in March, followed by Germany (9.3%), the United Arab Emirates (9.2%), India (6.9%) and Pakistan (4.5%). The export performance was contributed by natural rubber based products such as gloves, tires, tube and rubber thread. Gloves were the main exports of rubber based products, with a value of 1.14 billion ringgit (\$240 million) in March, an increase of 3.9% compared to February.

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- Zinc Oxide



Air spring technology improves dynamics

Advanced three-chamber air springs from Vibracoustic are said to be redefining comfort and driving dynamics in the Audi e-tron GT. The air springs use a complex design with built-in safety features and silent valve switching for the air chambers, all while securing comfort and driving dynamics.

High performance battery electric vehicles (BEVs) pose a number of significant challenges. To give the vehicle useful range, large batteries must be introduced, and the resulting weight can have a negative impact on driving dynamics. In addition, the quiet running of BEV powertrains means that drivers and occupants can more easily detect mechanical noises and vibrations. Vibracoustic's advanced three-chamber air springs also protect the battery.

The sleek design of performance vehicles often leads to tight packaging, making it difficult to achieve the required volume within the air springs, which is directly related to comfort. Vibracoustic's engineers designed an intricate solution, comprising four plastic components, produced using an innovative hot gas welding process, which is instrumental in enabling complex thermoplastic component manufacturing without compromising component strength or stability. This allowed the solution to achieve the required performance and NVH (noise, vibration and harshness) characteristics. Furthermore, battery safety is another focus area, typical for BEVs, which was supported by the suitable solution design. Through the integration of innovative plugs in the design of the part, the suspension strut is prevented from impacting the battery pack in the event of a crash.

Furthermore, the nearly silent running of electric drivetrains presented another challenge. Engineers had to tackle the more perceivable noises from the switching valves within the air springs, particularly for the rear axle where the spring is closer to the cabin. To address this, the relative position of the valves within the air spring was taken into consideration, with a different solution for the front and rear.

Vibracoustic's three-chamber air spring has three switchable air volumes, allowing it to produce four different stiffness rates, depending on the driving situation, which is directly related to the comfort and driving experiences. The more chambers are activated, the lower the stiffness and the higher the comfort. The air springs can switch between four modes, ranging from a comfortable mode, using all chambers' volume, to a very dynamic mode, using the smallest volume, for which the stiffness more than doubles. The system also utilizes body and wheel

acceleration sensors to enable individual damper control at each axle, adjusting according to driver input, road conditions and the road surface. The suspension can be altered on the fly during cornering, braking and acceleration to minimize roll and pitch movements. The system can also adjust its height based on the driving situation and speed, moving between a total range of 60 mm.

PU foam systems for potting, fixation of EV battery cells

Lightweight, durable polyurethane foam technologies have been added to Huntsman's battery solutions portfolio. The Shokless foam systems were developed for the potting and fixation of cells mounted in electric vehicle (EV) batteries. The range also includes products that can be used as a moldable encapsulant in battery modules or packs.

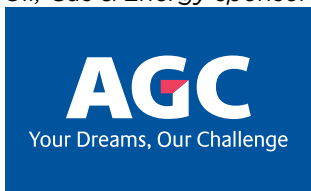
The Shokless foam systems can offer a flexible choice for helping to safeguard the structural integrity of EV batteries in case of impact or a thermal event. The product family includes a range of low to high density foams that can be used via common polyurethane dispensing processes, and can offer a wide processing window for extra handling flexibility.

These new solutions can help provide thermal, as well as structural protection at a cell, module or pack level combined with fast processability compared to non-polyurethane alternatives. The moldable encapsulant version of the Shokless system can further expand design and manufacturing options for EV battery manufacturers and OEMs.

With robust mechanical properties, the systems can offer very good compression and tensile performance with high elongation to failure. Elastic performance can remain stable at different operating temperatures ranging from -35°C to 80°C, based on DMA (dynamic mechanical analysis) tests conducted at Huntsman. The systems have also been developed to be easy to work with thanks to their low viscosity and ability to cure quickly at low temperatures.

Shokless polyurethane systems are generally compatible with a number of different manufacturing methods, such as open- and closed-pour (injection) and cold cure molding. Certain products in the range can also be dispensed with high pressure equipment. Huntsman also offers simulation and modeling capabilities.

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The AGC logo is located in the top left corner. It consists of the letters 'AGC' in a bold, blue, sans-serif font. A small red square is positioned between the 'A' and the 'G'. The logo is set against a white rectangular background.

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Streamlining medical device assembly: The advantages of engineered silicone swelling fluids

In the ever-evolving world of manufacturing and industry, companies are constantly seeking innovative solutions to improve their processes, increase efficiency and reduce costs. One such breakthrough is the advent of engineered swelling fluids, a revolutionary technology that offers a myriad of benefits to various industries, especially medical device manufacturing.

As the demand for smaller and more advanced medical devices continues to rise, manufacturers are faced with the challenge of incorporating complex components into their designs. Tubing plays a crucial role in many medical devices, necessitating the development of state-of-the-art tubing designs (figure 1).

Many medical devices use complex multi-lumen tubes that enable the delivery of fluids, gases, guide wires, cameras and other materials within a single conduit, simplifying the device design and reducing the number of tubes required. However, the assembly of these intricate devices poses significant challenges, particularly when connecting thin or soft tubes to rigid plastic barbed fittings.

The assembly of multi-lumen tubes and their connection to rigid plastic barbed fittings can be a labor-intensive process (figure 2). The delicate nature of the tubes, along with the requirement for precision in aligning and attaching them to the fittings, demands careful attention and considerable manual ef-

fort. This time-consuming task can hinder productivity and potentially lead to errors or inconsistencies during the assembly process.

In this article, the benefits of using swelling fluids to facilitate more efficient and reliable connections, improving the overall medical device assembly process, will be explored by the author.

How engineered swelling fluids work

Engineered silicone swelling fluids simplify the assembly process by swiftly and evenly expanding the silicone tubing (figure 3). By

Figure 1 - tubing plays a crucial role in many medical devices, necessitating the development of state-of-the-art tubing designs



Figure 2 - connecting tubes to rigid fittings can be a labor intensive process in catheter production



Figure 3 - MicroCare Swellex engineered silicone swelling fluids simplify the assembly process by temporarily expanding the silicone tubing



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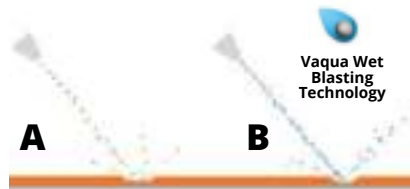
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immersing one end of the tube in the fluid, the tubing quickly swells to the desired dimension. The tube immersion time can be adjusted by the assembler based on the expansion needed, allowing for precise control. For instance, when a minimal tube expansion of 1% to 2% is required for assembly, the entire swelling process can be completed in less than a minute. This expedites the assembly workflow and increases productivity.

After the assembler fits the swelled tube onto the connector, the engineered swelling fluid evaporates rapidly. The tubing returns to its original size, shape, durometer, compression and strength, forming a tight, sealed fit over the fixture, regardless of its geometry. This capability is particularly advantageous for assembling complex multi-lumen tubes. The swift evaporation ensures minimal downtime and allows for immediate use of the assembled device.

Unlike harsh solvents, such as hexane or toluene, engineered silicone swelling fluids are specifically formulated by chemists for the task at hand. They do not alter the physical properties of the tubing, ensuring its integrity and performance remain intact. Moreover, the swelling fluid does not create a permanent bond or weld between the tubing and the fitting, allowing for easy removal, if needed. Some of the benefits of using an engineered swelling fluid for medical device assembly are described.

Simplified connection process

Silicone elastomers are often the material of choice for medical tubing due to their durability, flexibility and resistance to bacterial growth. Connecting silicone tubing to harder materials can pose challenges. Swelling fluids offer a solution by allowing the tubing to easily slide over fittings and connectors. Unlike other methods, such as lubricating with alcohol or oil, swelling fluids provide a reliable and efficient connection process that reduces the risk of leakage and ensures a secure grip.

Improved compatibility

Engineered swelling fluids have excellent materials compatibility, making them suitable for a range of medical tubing materials beyond silicone. Whether it is polyethylene, polyimide, polychloroprene, EPDM (ethylene propylene diene monomer) or molded thermoelastomer tubing, there are engineered swelling agents available to accommodate different material requirements. This versatility enables manufacturers to use a single swelling fluid for diverse types of tubing, simplifying the assembly process and reducing inventory complexity. Overall, swelling fluids are designed by chemists to be safe and effective on most delicate surfaces, preserving the integrity and functionality of the treated materials.

Faster assembly times

Manual insertion of silicone tubing onto rigid plastic or barbed fittings can be time-consuming. Incorporating an engineered swelling fluid into the assembly process significantly speeds up

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the process. The tubing swells uniformly upon contact with the fluid, making it easier to slide onto fittings. This accelerated assembly time translates into increased throughput and improved overall productivity.

Enhanced worker safety

Engineered swelling fluids contribute to worker safety by reducing the amount of force required to insert tubing onto connectors. This is especially beneficial when dealing with thin-wall tubing that lacks structural rigidity and is prone to folding or collapsing during assembly. By minimizing the risk of workplace related injuries, such as carpal tunnel syndrome or wrist problems, engineered swelling fluids promote a safer working environment.

Reduced waste and improved validation

Engineered swelling fluids help prevent tubing damage, such as stress cracks, during the manufacturing process. By minimizing scrap parts and waste, medical device manufacturers can optimize their resources and improve cost-efficiency. Furthermore, the use of swelling fluids simplifies the validation process, as the engineered swelling fluids do not introduce heat, adhesives or other substances that could compromise the integrity of the tube, fitting or device. This facilitates qualification and validation efforts, and helps ensure compliance with industry standards.

Environmentally friendly solution

Many modern engineered swelling fluids are environmentally friendly and sustainable alternatives to aggressive solvents like hexane. They have low global warming potential (GWP) and do not contribute to ground or air quality issues. By opting for engineered swelling fluids, medical device manufacturers can more easily adhere to strict environmental regulations, reduce their carbon footprint, and contribute to a greener and more sustainable future.

Conclusion

Engineered swelling fluids offer numerous advantages in medical device assembly, simplifying the tube connection process, improving compatibility, reducing assembly time, enhancing worker safety, minimizing waste, and supporting environmental sustainability. These fluids provide a reliable and efficient means of connecting tubing to fittings and molded parts, ensuring leak-free and secure connections. By leveraging the benefits of engineered swelling fluids, manufacturers can streamline their assembly processes, increase productivity, and deliver high quality medical devices to meet the evolving needs of patients and healthcare providers.

When selecting an engineered swelling fluid, it is important to consult with a company that specializes in medical lubricating and coating technology to determine the best fluid for each individual application. They can recommend which engineered swelling fluid and process will work best.

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Choosing the right silicone adhesives for medical device assembly can be simple

Medical device assembly can be a daunting task when considering various substrates must be joined together or sealed to function properly in life saving or life sustaining medical devices, in addition to making sure the device meets biocompatibility, device durability and safety criteria. Choosing the right silicone adhesive for medical device assembly does not have to be a complex task, and in doing so, can help increase adhesion and improve device performance. By answering some simple questions about a medical device, manufacturers can identify the right silicone adhesives needed for a device assembly.

What type of application?

For medical device assembly, determining the end-use application early in the design process can help with selection of the right material grade adhesive. Device manufacturers should first consider whether the device will be short term (≤ 29 days) or long term (>29 days) implantable, or if the device requires permanent adhesion (e.g., catheters, pacemakers and cochlear implants), or whether the device will be wearable, where temporary adhesion is needed. Identifying the specific end use of the end application will help manufacturers select the appropriate grade of silicone adhesives.

What kind of substrates?

Whether the device is made of one or more materials, such as plastics, metals or silicones, it is important to understand the substrate compatibility with the selected adhesive, because certain substrates may require additional surface preparation for the silicone adhesive to bond well. Manufacturers need to understand the type of surface preparation (e.g., substrate cleaning, surface treatments like plasma and corona, and adhesive primers) needed to increase the surface energy and ensure proper adhesive application.

Can heat be applied to increase cure rate?

Understanding temperature limitations with the substrates used in medical device assembly can help identify the type of silicone adhesive needed and better define the device assembly process. Typically, when adhering to substrates that can tolerate heat greater than 60°C , device manufacturers can use two-part adhesives. If the substrates have limited temperature tolerance of less than 60°C , manufacturers should consider using a one-part adhesive; however, a two-part adhesive can be used for substrates with limited temperature tolerance, in some instances.

Other considerations for assembling medical devices

Medical device manufacturers should understand silicone adhesive properties needed for device assembly. Understanding the

adhesive viscosity or rheology can help to identify the appropriate silicone adhesive needed if the assembly requires a self-leveling, low viscosity adhesive, or an adhesive designed with thixotropic characteristics. Additionally, it is important to understand the effect of the sterilization method on the long term performance of the adhesive, since some sterilization methods have the potential to impact adhesion. Radiation sterilization (e.g., gamma or e-beam) may change the mechanical properties of the adhesive through additional crosslinking that may affect device performance characteristics (refs. 1 and 5). A thorough evaluation of the device's critical to quality criteria should be a primary goal (figure 1).

One-part condensation cure silicone adhesives

Traditional one-part condensation cure silicone adhesives are tin catalyzed and cure by exposure to atmospheric moisture, so they do not require mixing and can be dispensed directly from the packaging. One-part silicone adhesives are well suited for applications that require bonding silicone to other silicones, glass, metals and plastics. Condensation cure adhesives can be used in various applications, whether the assembly requires shape retaining (thixotropic) characteristics or self-leveling properties (e.g., adhering a silicone balloon at the distal end of a urinary catheter where narrow bond line thickness is desired). Because condensation cure adhesives do not need heat to cure, they are ideal for use where devices have temperature sensitive components.

During the curing process, condensation cure adhesives release reaction byproducts such as mild acids, alcohols or other volatile substances which can cause shrinkage from the original dispensed volume. Proper ventilation or exhaust systems should be used to remove cure byproducts from the manufacturing area when using condensation cure adhesives.

Furthermore, condensation cure adhesives have shorter work time, slower cure time, and may be limited by cross-sectional thickness and surface area exposed to air to cure when compared to two-part addition cure silicone adhesives.

Two-part addition cure silicone adhesives

Two-part addition cure silicone adhesives are platinum catalyzed systems offering a broad range of curing options. Addition cure silicone adhesives are versatile because they can be designed to cure at room temperature, yet cure can be accelerated by exposure to elevated temperatures. Like condensation cure systems, addition cure silicone adhesives adhere to a broad range of substrates, and manufacturers can use them for applications like bonding dissimilar substrates, encapsulating or sealing.



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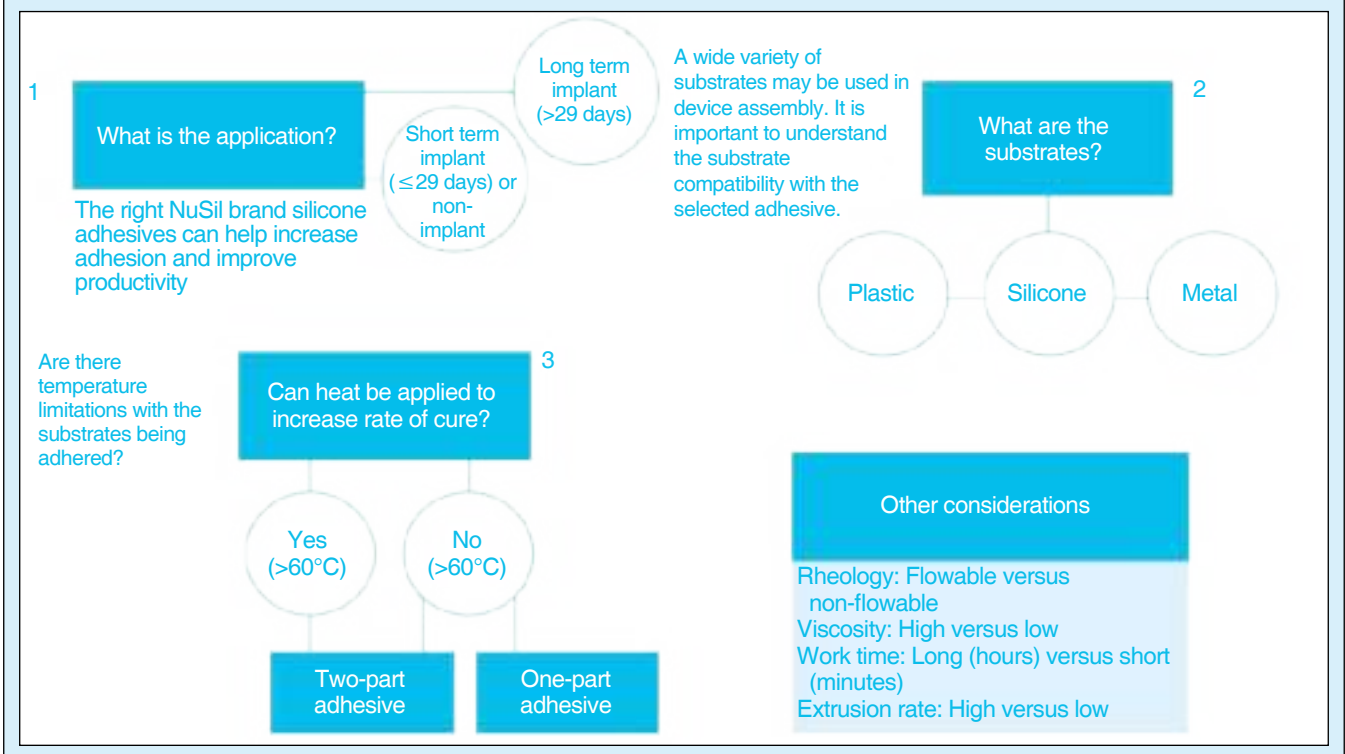


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Perspective

Figure 1 - thorough evaluation of devices critical to quality criteria should be a primary goal



Unlike condensation cure systems, there are no cure byproducts released during the vulcanization process; therefore, post-cure is not required, but could be beneficial to stabilize the material properties (ref. 2). No cure byproducts also mean less shrinkage. Since moisture permeation is not needed for addition cure systems to vulcanize, cross-sectional thickness and enclosed environment are not process limitations.

Careful planning must be considered when choosing addition cure silicone adhesives, since they require mixing of the two components together in a prescribed mix ratio. Air entrapped during mixing should be removed by vacuum prior to use. Addition cure silicone adhesives can also be packaged in a ready to use, dual cartridge configuration, and dispensed through a static mix element directly into a mold without additional equipment for mixing or vacuum to remove entrapped air.

A typical drawback to addition cure silicones is that it can be susceptible to cure “poisons,” where the catalyst can be easily inhibited or poisoned by incompatible substances like sulfur containing (e.g., natural rubber, latex or polychloroprene), nitrogen containing (e.g., amines) or organotin containing (e.g., condensation cure silicones) substances. Other platinum catalyzed silicone system inhibitors include some pharmaceutical drugs and conductive fillers (ref. 3).

Other silicone adhesive options

In other cases where an adhesive needs to bond and encapsulate

or coat a device component, manufacturers should consider an adhesive dispersed in solvent. Both one-part condensation cure and two-part addition cure silicone adhesives can be dispersed in solvent without limitation or sacrificing their adhesive properties. The dispersed adhesive’s low viscosity allows for it to be sprayed, dipped or brushed to a very thin film. A silicone film adhesive should be considered if an assembly application may require prefabricated adhesive with specific geometry and bond line tolerance. Silicone film adhesives are commonly used in place of liquid adhesives for general applications (e.g., bonding electronic components to flat vertical surfaces or stack-ups for adhering layers of composites); but in medical device applications, they can be used to adhere balloons and other device assemblies (ref. 4). Silicone adhesives, whether one-part or two-part systems, are versatile enough that they can be customized for applications requiring incorporation of radiopaque filler for x-ray visibility or colored pigments for parts differentiation.

Product support

A silicone adhesives manufacturer with deep medical device expertise can help early in the medical device design process. It is important to partner with an experienced silicone adhesives manufacturer who can offer manufacturing and purity qualifications, as well as provide support during the regulatory filing process, such as access to material master access files (MAFs)

(continued on page 52)

Patent News

Rubber composition and a rubber product

U.S. patent: 11,834,569

Issued: December 5, 2023

Inventors: Marc Weydert, Suzanne Michelle, Laura Puchot, Acerina Trejo Machin and Pierre Verge

Assigned: Goodyear Tire & Rubber

Key statement: The present invention is directed to a rubber composition comprising 100 phr of one or more diene based elastomers, 30 phr to 200 phr of a filler and a benzoxazine which is the reaction of (i) a diphenol comprising two phenol groups and a bridge covalently connecting the two phenol groups, (ii) an aldehyde derivative and (iii) an amine, wherein the bridge is connected to at least one of the phenol groups at a meta position of said at least one phenol group. The present invention is also directed to a rubber product comprising

such a rubber composition and the use of such rubber products in tire components.

Surface modification of elastomers via encapsulated glass (SiO₂)

U.S. patent: 11,833,769

Issued: December 5, 2023

Inventors: Scott W. Slabaugh, Liliya Lyandres and Warren Taylor

Assigned: Apple

Key statement: A composite is provided to include an elastomer substrate comprising methyl groups. The composite may also include a layer of glass comprising SiO₂ formed over the elastomer substrate. A method of fabricating the composite is provided. The method may include diffusing an ozone-rich gas into the substrate of an elastomer substrate comprising methyl groups. The method may also include exposing the elastomer substrate to UV radiation for a period of time. The method may further

include converting a surface portion of the elastomer substrate into a layer of glass formed over the elastomer substrate.

Crosslinked elastomers as a replacement for rubber

U.S. patent: 11,845,836

Issued: December 19, 2023

Inventors: Jari-Jussi Ruskeeniemi, Jeroen Oederkerk, Oscar Prieto, Stefan Hellström, Tanja Piel, Daniela Mileva and Floran Prades
Assigned: Borealis AG

Key statement: Articles comprising a polymer composition, wherein the polymer composition is obtainable by grafting an ethylene copolymer with comonomer units comprising hydrolyzable silane groups, wherein the polymer composition shows high gel content and low compression set at -25°C. These articles have applications in automotive weatherstripping, such as sealing systems for doors, trunks and hoods.

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Patent News

Tire guard device

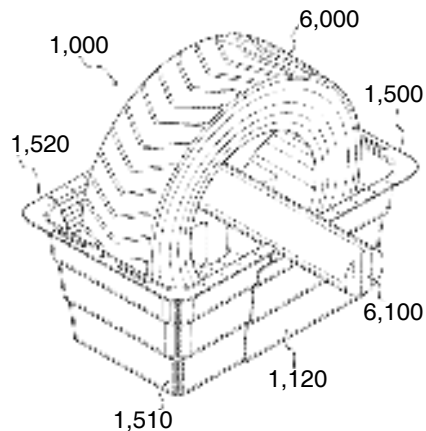
U.S. patent: 11,807,081

Issued: November 7, 2023

Inventors: Davy Russ Bingman

Key statement: A device for protecting a tire affixed to a vehicle. The tire guard device includes an interlocking U-shaped guard member that forms a housing with an interior volume when connected with a second U-shaped guard member. Each guard member includes a sidewall and an open end with an exposed interface edge disposed along the sidewall, wherein the interface edges overlap to secure to enclose around the tire. An upper edge of the sidewall includes a lip that protrudes outward from the interior volume to prevent mice and other pests from accessing the tire. The sidewall includes a cutaway region on an interior side that can receive an axle extending from the tire. The cut-

away region is sizable to the vehicle and allows for coverage of various vehicle and tire/wheel makes and models.



Pneumatic tire comprising a rubber composition containing a thermoplastic polyurethane

U.S. patent: 11,814,515

Issued: November 14, 2023

Inventors: Cyrille Guery and Jose-Carlos Araujo Da Silva

Assigned: Michelin

Key statement: A tire which has improved mechanical properties comprises a rubber composition based on at least one diene elastomer, at least one thermoplastic polyurethane and a cross-linking system; the composition does not comprise any reinforcing filler or comprises less than 25 parts by weight thereof per hundred parts by weight of elastomer, phr, the carbon black content in the composition being less than 20 phr.

Tire dressing composition and methods of making thereof

U.S. patent: 11,820,907

Issued: November 21, 2023

Inventors: Tsao-Chin Clarence Huang and Ali Alwattari

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Patent News

Assigned: Illinois Tool Works

Key statement: A tire dressing composition is provided that includes petroleum distillates in which a polybutene or isobutene/butene copolymer is dissolved to form a clear solution. In the water-based approach, the polybutene or isobutene/butene copolymer was emulsified by a surfactant. A wetting agent is also present in the composition to render the composition self-leveling. The sprayable tire dressing composition provides a high gloss and good wettability to a tire surface that develops a uniform coating on the treated tire surface.

Rubber composition for covering electromagnetic tag and electromagnetic tag module

U.S. patent: 11,827,783

Issued: November 28, 2023

Inventor: Kyung Hoon Chung

Assigned: Nexen Tire

Key statement: A rubber composition for covering an electromagnetic tag is proposed. The rubber composition may include a base rubber and a reinforcing filler comprising carbon black or boron nitride. The rubber composition may also include an insulating filler comprising at least one selected from silica, titanium dioxide, talc and calcium carbonate. The rubber composition may further include a reinforcing resin comprising an alkyl phenol formaldehyde resin or a resorcinol formaldehyde resin. Based on 100 parts by weight of the base rubber, the total amount of the reinforcing filler and the insulating filler may be 40 parts by weight or more, the amount of the insulating filler may be 10 parts by weight or more and the amount of the reinforcing resin may be 0.5 parts by weight to 5 parts by weight.

Rubber composition and a tire

U.S. patent: 11,827,791

Issued: November 28, 2023

Inventors: Virginie Elyane Michelle Catherine Picard, Jérôme Joel Daniel Delville, Pascal Patrick Steiner and Malik Djelloul-Mazouz

Assigned: Goodyear Tire & Rubber

Key statement: In a first aspect, the present invention is directed to a rubber composition comprising 70 phr to 90 phr of styrene butadiene rubber, wherein said styrene butadiene rubber comprises a first styrene butadiene rubber having a glass transition temperature within a range of -49°C to -15°C , and a second styrene butadiene rubber having a glass transition temperature within a range of -50°C to -89°C . Furthermore, the rubber composition comprises from 10 phr to 30 phr of one or more of natural rubber

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Patent News

and synthetic polyisoprene rubber, 100 phr to 200 phr of silica and at least 25 phr of at least one terpene resin having a weight average molecular weight (Mw) of at most 1,000 g/mol. Moreover, the invention is directed to a tire comprising such a rubber composition, in particular in the tread of the tire.

Reinforcement of elastomers by reactive ionic surfactant

U.S. patent: 11,827,769

Issued: November 28, 2023

Inventors: Li Jia and Mengsha Qian

Assigned: The University of Akron

Key statement: Curable rubber compositions that include reactive ionic surfactants as reinforcing fillers are described, as well as methods for preparing composite rubber compounds by direct addition of ionic surfactant solutions into rubber latex.

Golf ball rubber composition and golf ball using the same

U.S. patent: 11,826,615

Issued: November 28, 2023

Inventors: Kai Hayashi, Kazuyoshi Shiga, Hikaru Nagakura and Takahiro Shigemitsu

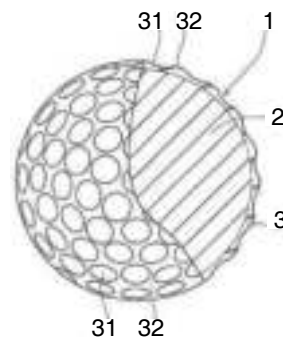
Assigned: Sumitomo Rubber Industries

Key statement: An object of the present invention is to provide a cured product of a golf ball rubber composition imparting excellent durability. The present invention provides a cured product of a golf ball rubber composition cured from a golf ball rubber composition containing (a) a base rubber, (b) an α,β -unsaturated carboxylic acid having 3 to 8 carbon atoms and/or a metal salt thereof as a co-crosslinking agent and (c) a crosslinking initiator, wherein the cured product of the golf ball rubber composition satisfies the following mathematical

formula (1):

$$Y < (0.1 \times X) - 1.30 \quad (1)$$

In the formula (1), Y represents an effective crosslinking density of the cured product of the rubber composition (mmol/cc) and X represents an amount of the component (b) with respect to 100 parts by mass of (a) the base rubber (parts by mass).



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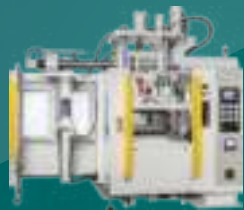
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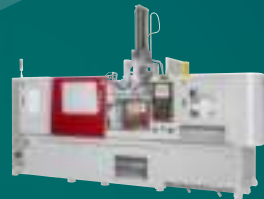
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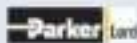


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History of silicones in medical devices

by Michael Goglia and Aneta Clark, Elkem Silicones

Silicones are considered a highly versatile family of synthetic polymers. They have played a pivotal role in the advancement of medical technology, both past and present. The usage of silicones in medical applications began shortly after their commercial availability in the mid-20th century. Chemists first discovered silicon, the element that forms the basis for silicone, in the early 1800s. However, it was not until the mid-1940s that silicone materials became readily available. This new chemistry was first used during World War II to protect electrical components on Allied airplanes.

Chemical structure

The basic structure of silicones is made up of polyorganosiloxanes, where silicon atoms are linked to oxygen to create the «siloxane» bond. The remaining valences of silicon are linked to organic groups, mainly methyl groups (CH₃): phenyl, vinyl or hydrogen (figure 1).

One of the earliest medical uses of silicone was by Dr. F. Lahey, who implanted a silicone elastomer tube for duct repair in biliary surgery. Since that first surgery, advanced usage continued; and by the 1960s, silicone became an integral material in medical device design.

Leveraging silicone's unique properties, such as biocompatibility, resistance to temperature extremes and flexibility, it became suitable for a broad range of components, supporting both patient comfort and life sustaining devices such as valves and pacemakers.

Other common uses of silicone across the medical device industry include orthotic liners, where silicone can offer superior comfort to patients compared to alternate materials. Extruded silicone tubing is used for fluid delivery where extractables and leachables are extremely important to ensuring patient health. Lastly, silicone foley catheters play an important role in easing discomfort, and are highly sterilizable to ensure infection

will be at a minimum (figure 2).

In recent years, the medical industry has continued to innovate with silicone materials, developing advanced implantable devices, such as neurostimulation pulse generators for pain and seizure treatment. Advanced usage in wearable devices is becoming more mainstream, as well, with the introduction of biosensors that can use a conductive silicone to read vitals on the body and offer adhesive properties to adhere the device. The bio-

compatibility of silicones, defined as the ability of a material to perform with an appropriate host response in a specific situation, has been a key factor in their widespread adoption in medical devices, and silicone is superior to other materials in this situation (figure 3).

Overall, the history of silicones in medical devices is a testament to the material's enduring utility and the medical field's commitment to finding solutions that enhance patient care and treatment outcomes. As technology advances, silicones are likely to remain at the forefront of medical device innovation, adapting to new challenges and opportunities.

Megatrends supporting growth of silicones in medical devices

Industry megatrends that are shaping the industry include the aging global population, the rise in chronic conditions, the shift towards patient managed health and fitness, and the imperative to reduce healthcare costs.

- **Aging population:** The world is experiencing a significant increase in the senior demographic, which is expected to double by 2060. This population typically requires more medical attention, and wearable medical devices offer a convenient solution for remote monitoring and treatment, enhancing the quality of life for seniors.
- **Chronic conditions:** Chronic diseases such as heart disease, stroke, cancer, diabetes, obesity and arthritis are prevalent and require continuous monitoring. Wearable medical devices equipped with silicone adhesives can provide critical data to clinicians and deliver medication as needed.
- **Patient managed health:** There is a growing trend of individuals taking an active role in managing their own health and fitness. Silicones play a crucial role in the development of skin-adhered devices that assist in self-management, from monitoring ambulation to aiding in smoking cessation.
- **Cost reduction:** The healthcare industry is under pressure to reduce costs. At home monitoring enabled by silicone devices can decrease the need for inpatient and outpatient clinical care, thus controlling expenses. Also, advancing automation techniques used in silicone molding and reduction in cycle times with innovative, faster curing materials reduce component costs.

Figure 1 - polydimethylsiloxane (FLD 47)

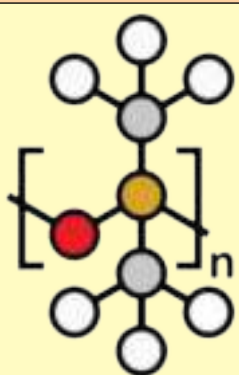
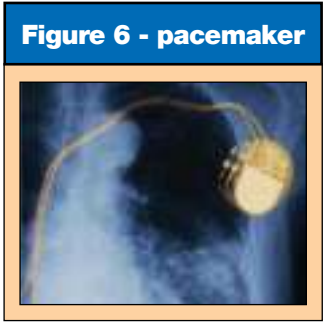
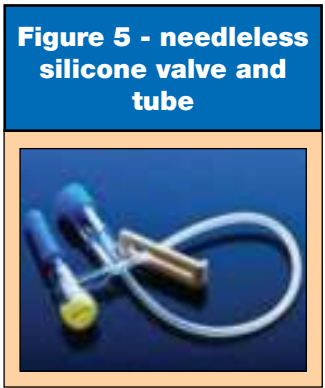


Figure 2 - silicone hose, valves and catheters



Figure 3 - printed circuit board for wearable electronics





Advancements in silicone technology

New silicone elastomers have been developed to allow the incorporation of certain active pharmaceutical ingredients (API) into the matrix that can offer targeted release to specific patient areas via a small implant. Traditional technologies using addition curing of silicone elastomers would bond the API into the silicone matrix and not allow its release. Today, silicone excipients can effectively deliver medication at lower doses directly to a treatment site. This allows for faster innovation, as pharmaceutical development is extremely lengthy, and takes advantage of better delivery systems for existing medications (figure 4).

Silicones will continue to be an integral part of addressing these existing megatrends and supporting new ones as they arise, driven by the need to address the challenges posed by demographic shifts and economic pressures. Their unique properties make them indispensable in the creation of medical devices that are not only effective, but also improve patient experience and adherence to treatment protocols. The future of medical devices will likely see even greater integration of silicone based materials, as these megatrends continue to influence the industry.

Types of medical devices and the silicones used

Some specific medical devices that incorporate silicone include:

- Catheters: Silicone high consistency rubber is typically used for the tubing, and liquid silicone rubber would be used for the balloon which when inserted in the bladder is filled with air to hold the device in place.
- Tubing: Medical tubing for feeding, drainage and use with peristaltic pumps is commonly made from silicone because of its non-reactivity, flexibility and compression set,

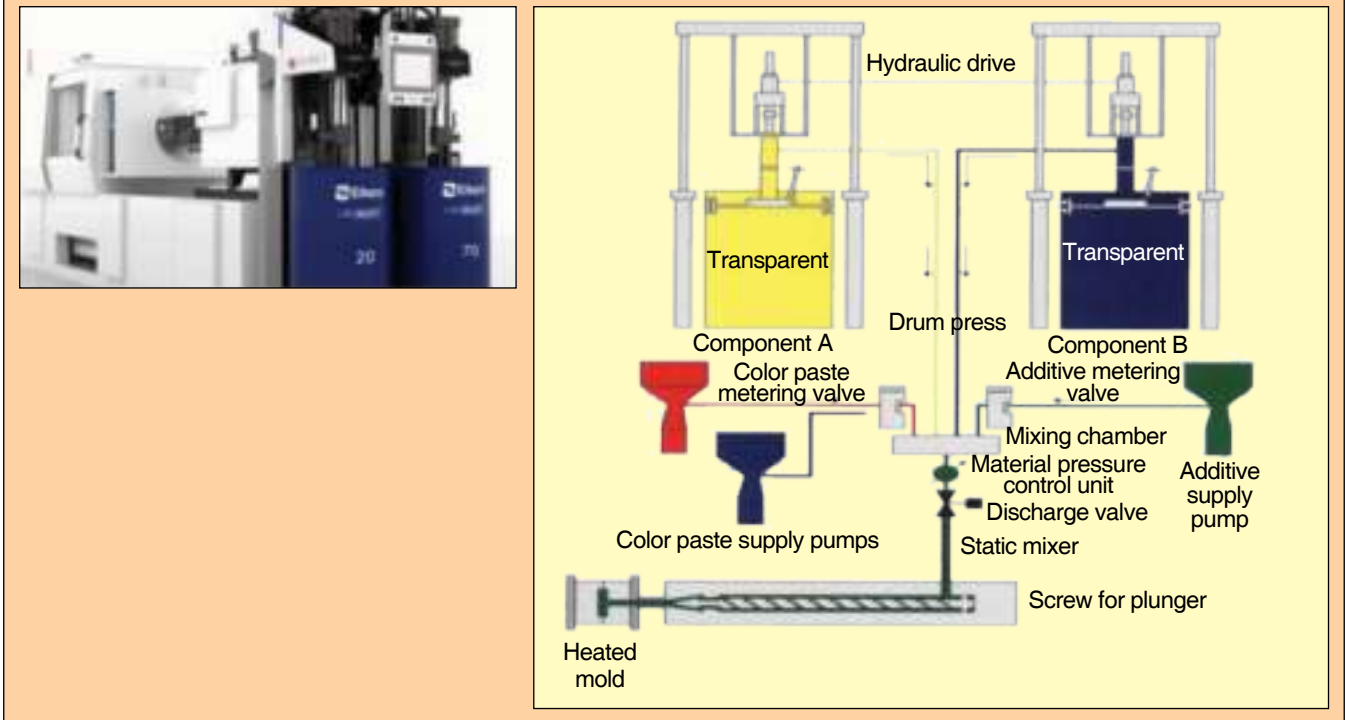
allowing it to handle multiple cycles without deformation (figure 5).

- Implantable devices: Silicone’s stability, nontoxicity and insolubility in bodily fluids make it suitable for long term implantable devices, such as pacemakers, shunts and joint replacements (figure 6).
- Prosthetics: Silicone is used in prosthetic devices due to its ability to mimic the texture and flexibility of human skin and tissue.
- Surgical tools and equipment: Silicone rubbers are applied to handles and grips of surgical tools to provide better handling and control, and will not degrade after many rounds of sterilization. Also, thin layers of silicone can be applied to surgical blades and needles to provide better slip when entering the skin.
- Hearing aids: The soft and flexible nature of silicone makes it ideal for use in hearing aids, giving comfort to the user.
- Seals, gaskets and o-rings: Silicone seals and gaskets are used in various medical devices to ensure airtight and fluid-tight seals.
- Medical wearables: Silicone is used in wearable medical devices due to its skin-friendly properties and durability.
- Breathing masks and respiratory devices: Silicone’s flexibility and non-toxicity are crucial for masks and devices that assist with breathing.
- Infusion pumps and valves: These devices often contain silicone components due to silicone’s chemical inertness and compatibility with various drugs and solutions. Also, the valves play a key role in fluid delivery to the body.

Table 1 - types of silicones and processing methods used in medical devices

	<i>RTV-2</i>	<i>LSR</i>	<i>HCR</i>
Mix A/B ratio	Two components 10/1 and 1/1 are typical	Two components 1/1	Mono and multiple components 2 to 4
Specific gravity (g/cm ³)	1 to 1.15	1 to 1.3	1 to 1.6
Hardness (durometer A)	25 to 50	1 to 80	20 to 80
Tensile strength (MPa)	3 to 6	1 to 11	5 to 11
Tear strength (kN/m)	15 to 30	12 to 50	15 to 40
Elongation at break (%)	200 to 450	250 to 900	200 to 800
Curing reaction	Polyaddition and polycondensation	Polyaddition	Peroxide and polyaddition
Viscosity (Pa.s)	10 to 50	50 to 1,000	High consistency (gum stock)
Processing technology	Casting	Injection molding	Injection/compression and transfer molding
Process temperature	Room temperature or 50°C to 150°C	>150°C	>150°C

Figure 7 - LSR Select pump and press (left) and LSR injection setup (right)



Types of silicones and processing methods used in medical devices

The types of silicones and processing methods used in medical devices include the following (table 1):

- Room temperature vulcanizing (RTV): RTV silicones are used for their ease of use and ability to cure at room temperature. They are often utilized for making molds, adhesives and coatings for medical devices. They can be both two-part and one-part systems, and use various catalyst systems to cure.
- Liquid silicone rubber (LSR): LSR is known for its purity, clarity and consistency. LSRs are typically a 1:1 mix ratio and use a platinum catalyst that requires heat to cure. LSR is considered the go-to material when possible for complex part design and production efficiency.
- High consistency rubber (HCR): HCR silicones are used to manufacture solid silicone rubber into rolled sheets or extruded profiles, such as tubing and hose. These are then cured using either platinum or peroxide catalyst additives. This material is mixed on a two-roll mill to incorporate the catalyst and ensure proper mix, and then calendered or extruded. HCR offers high physical properties, but is difficult to process.

The processing methods for these silicones vary, depending on the type of silicone and the intended application of the medical device:

- Injection molding or LIM (liquid injection molding): This process is highly efficient for manufacturing complex parts, and is commonly used with LSR. It involves injecting the silicone into a heated mold, where it cures into the desired shape. LSR can also be used in two-shot

molding processes where a thermoplastic component can be incorporated with the soft silicone portion (figure 7).

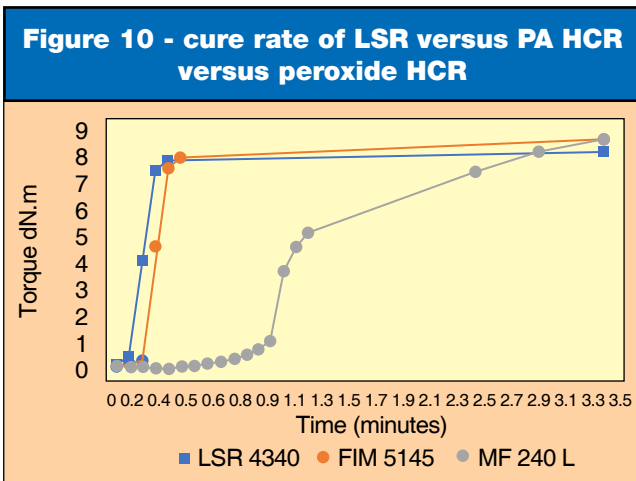
- Extrusion: Used with HCR, extrusion involves pushing the silicone through a die to create long continuous shapes like tubing, which are then cured (figure 8). Typically, cure occurs through infrared ovens or a hot salt bath.
- Compression molding: This method involves placing the silicone material into a heated mold cavity and applying pressure to form the part. It is suitable for both LSR and HCR silicones.
- Transfer molding: Similar to compression molding, transfer molding involves transferring the silicone material from one part of the mold to another, where it is then cured under pressure.
- Calendering: Primarily used with HCR, calendering involves passing the silicone through a series of rollers to form thin sheets, which are then cured.
- 3D printing: A relatively new method, 3D printing with silicone allows for the creation of complex

Figure 8 - silicone tubing



Figure 9 - 3D printed silicone





geometries that are difficult to achieve with traditional molding techniques (figure 9).

Each of these processing methods has its own set of advantages and challenges, and the choice of method will depend on factors such as the complexity of the design, the properties required of the final product and the production volume. All aspects are critical to ensure a quality medical device can be produced cost-effectively.

Lastly, for the final step of device production following one of the methods above, there is a need to sterilize the component or medical device. For sterilization, several methods can be used on silicone materials. The most common methods include ethylene oxide (EtO), electron beam, gamma radiation, steam autoclave and dry heat. The choice of sterilization method depends on the silicone type, the device's design and its intended use.

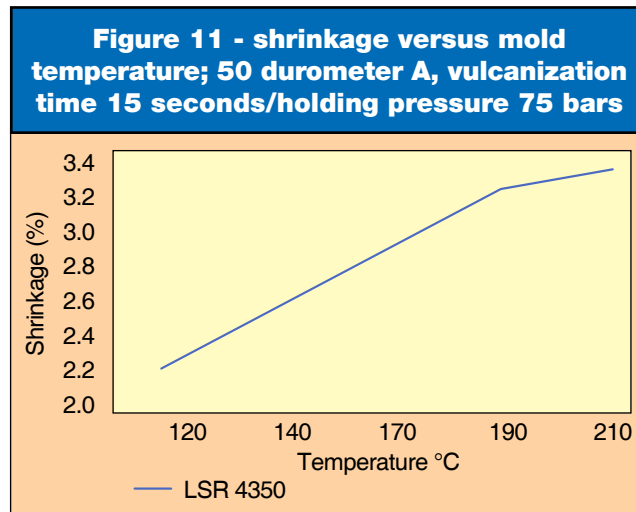
In conclusion, the selection of silicone type and processing method is crucial in the development and manufacturing of medical devices. Each of these processing methods and materials has its own set of advantages and challenges; the choice of method will depend on factors such as the complexity of the design, the properties required of the final product and the production volume. All aspects are critical to ensure a quality medical device can be produced cost-effectively. It requires a thorough understanding of the material properties, the device's requirements and the regulatory standards governing medical devices. The versatility of silicones and the variety of processing methods available make them an indispensable material in the healthcare industry.

LSR becoming the primary molded material for medical technology

Liquid silicone rubber (LSR) has increasingly replaced high consistency rubber (HCR) in various applications due to several advantages that LSR offers over HCR. The following is a detailed comparison based on the information gathered:

Crosslinking and mechanical properties

Both LSR and HCR obtain their properties through crosslinking, which is a chemical reaction that interconnects polymer chains. This process is crucial, as it affects the mechanical prop-



erties, such as elongation at break, strain recovery and compression set. LSR tends to have a more regular network of crosslinks compared to HCR, which contributes to its greater elasticity and absence of molecular byproducts that could restrict its use in medical and biomedical applications (figure 10).

Processing and manufacturing

LSR can be processed through various methods, such as casting, extrusion or injection molding, and hardens with the application of heat. It has a lower viscosity than HCR, which makes it easier to handle and ideal for manufacturing complex geometries and intricate products. The lower viscosity of LSR also allows for more efficient processing via injection molding, making it a preferred choice for large scale production and automation (figure 11).

Material properties

LSR is compatible with a wide spectrum of temperatures, from -60°C to +250°C, maintaining its high performance mechanical properties at all times. Second, it is also highly biocompatible due to the nature of its composition and the Si-O bond. Third, it is very durable, and therefore ensures long term stability and chemical resistance. Fourth, its electrical properties make it ideal for insulation and precise conductivity protection. Lastly, it is transparent, and can be pigmented to harmonize with all color needs, including human skin tones (figure 12).

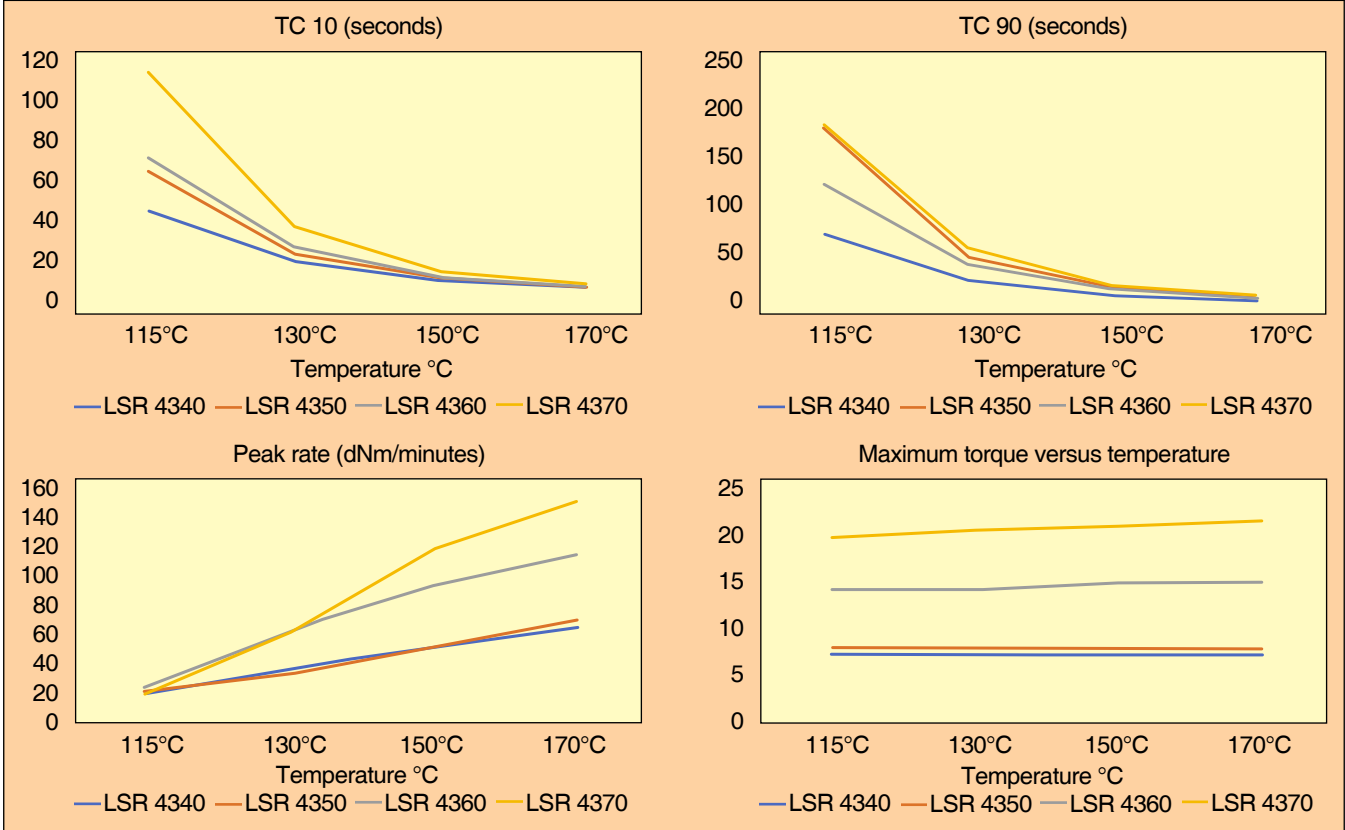
In summary, LSR has replaced HCR in many applications due to its superior crosslinking network, ease of processing, suitability for complex geometries, cost-effectiveness in manufacturing and robust material properties that are crucial for high performance industries. The choice between LSR and HCR will depend on the specific requirements of the application, but the trend towards LSR is evident in industries that prioritize efficiency and precision.

Sustainability of silicones

The sustainability of silicones in medical devices is multifaceted, involving environmental, economic and social responsibilities.

From an environmental perspective, silicones are durable and resistant to extreme temperatures and sterilization process-

Figure 12 - material properties of liquid silicone rubber (LSR)



es, which can reduce the need for frequent replacement and minimize waste. Additionally, the possibility of recycling silicone materials is being explored, which could further enhance their sustainability profile. Prior to full scale recycling of silicones, the best short term solutions involve reducing CO₂ emissions using sustainable energy, whether it be solar or hydroelectric. Silicones are energy intensive to produce, and in the past, fossil fuels were widely used. Also, responsible water management and waste management in circularity provide high levels of short term improvements.

Economically, silicones offer cost-effectiveness in the manufacturing process due to their ease of processing via automation, and the ability to be molded into multiple shapes and sizes. This versatility can lead to reduced production costs and, consequently, more affordable medical devices, making it financially viable for years to come.

Socially, the use of silicones in medical devices has a significant impact on patient care. Their hypoallergenic properties and comfort in use contribute to better patient outcomes and experiences. Moreover, the longevity and reliability of silicone based devices can lead to improved quality of life for patients with chronic conditions who rely on medical devices for daily living.

Furthermore, the medical industry is increasingly focusing on the development of sustainable materials. Historically used petroleum based plastics and elastomers will see a decline in usage with new device development. Silicones, with their long history of safe use and continual innovation, are well-positioned to meet these evolving demands. As research continues, one can

anticipate that medical grade silicones will play a pivotal role in the future of healthcare, balancing the needs for performance, patient safety and environmental responsibility.

Regulatory landscape for medical grade silicones

The regulatory landscape for medical grade silicones is defined by a complex framework that ensures the safety and efficacy of these materials when used in medical applications. The United States Food and Drug Administration (FDA) plays a pivotal role in this process, setting forth regulations that manufacturers must comply with to market their silicone based products.

Medical grade silicones are primarily regulated under several key standards and regulations:

- 21 CFR Part 177: This regulation specifies the requirements for polymers, including silicones, intended for use in contact with food. It outlines permissible additives, maximum extractable levels and overall safety criteria to prevent the migration of harmful substances into food. While this is generally linked to food, there can be some crossover with medical device demands.
- USP Class VI: The United States Pharmacopeia (USP) Class VI standard is crucial for materials used in medical and pharmaceutical devices. It requires that silicone products undergo cytotoxicity, sensitization and systemic toxicity assessments to ensure safety for medical use.
- ISO 10993: This international standard provides guidelines for evaluating the biological safety of medical devices, including silicone based components. It encompasses

Table 2 - medical device classification per the Food and Drug Administration (FDA)

Classification	% of medical devices	Examples	Potential risk level	Subject to
Class I	47%	Toothbrushes, oxygen masks, elastic bandages	Minimal	General controls to ensure device safety and effectiveness once manufactured
Class II	43%	Orthopedic and spine implants, IV pumps, ultrasound equipment	Medium	General controls Special controls (510K) (includes labeling, testing and performance standards)
Class III (life supporting/ sustaining)	10%	Cardiac pacemakers, implantable defibrillators, coronary stents	High	General controls and PMA Most require clinical data (due to the life support/sustaining purpose and/or being implanted into the body long term)

PMA: premarket approval
Source: <https://healthtrustpg.com/thesource/clinical-connection/checks-and-balances>

various tests such as irritation, genotoxicity and implantation tests to assess the compatibility of silicone materials with the human body.

The FDA categorizes medical devices into three classes based on the device’s risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. Class I includes devices with the lowest risk, and Class III includes those with the greatest risk. The device classification determines the regulatory pathway required for FDA clearance and/or approval to market the product (table 2).

The two primary regulatory pathways in the United States are:

- 510(k) premarket notification: This is a process that allows a device to be marketed if it is demonstrated to be substantially equivalent to a legally marketed device that is not subject to premarket approval.
- Premarket approval (PMA): This is a more rigorous process that requires the submission of clinical data to support claims of safety and effectiveness for Class III devices.

It is important to note that there is currently no regulatory definition of a medical grade polymer, and no prescriptive regulatory requirements for raw materials used in medical devices. Therefore, material suppliers and others in the medical device industry have assigned their own meaning to a “medical grade polymer or silicone.”

Manufacturers and initial distributors of medical devices must register their establishments with the FDA, and all organizations intending to market a medical device in the United States need to officially list their product with the FDA. Typically, the silicone raw material manufacturers are not registered with the FDA unless the end product as is would be considered a medical device and not a raw material.

The regulatory landscape for medical grade silicones is continually evolving, with ongoing monitoring by regulatory bodies like the FDA to ensure the highest standards of patient safety and product efficacy. Manufacturers must stay abreast of these changes to maintain compliance and ensure the continued success of their products in the market.

EU MDR information

The European Union’s Medical Device Regulation (MDR),

specifically Regulation (EU) 2017/745, is a comprehensive set of rules governing the production and distribution of medical devices within the EU, including medical grade silicones. This regulation, which came into effect on May 26, 2021, replaces the previous Medical Device Directive (MDD), and aims to enhance patient safety and ensure the highest quality of medical devices.

Medical grade silicones must comply with the stringent requirements set forth by the MDR. The regulation outlines the obligations of manufacturers, importers and distributors, emphasizing the need for a transparent supply chain and rigorous clinical evaluations.

Key aspects of the MDR that affect medical grade silicones include:

- Enhanced traceability: The MDR introduces a unique device identification (UDI) system which facilitates the traceability of medical devices throughout their lifecycle.
- Clinical evaluation and investigation: Manufacturers must conduct clinical evaluations and investigations to demonstrate the safety and performance of their medical devices, including those made with medical grade silicones.
- Post-market surveillance: The MDR requires a proactive post-market surveillance system to monitor the ongoing safety and performance of medical devices after they have been released to the market.
- Risk management: Manufacturers must implement a thorough risk management system, assessing and mitigating risks associated with the use of medical grade silicones in their devices.
- Quality management system: A quality management system (QMS) compliant with the MDR is mandatory for all manufacturers, ensuring consistent quality and safety of medical devices.
- Notified bodies: The role of notified bodies has been strengthened under the MDR, with increased oversight and stricter requirements for certification of medical devices.
- Economic operators: The MDR defines specific responsibilities for economic operators, including manufacturers, authorized representatives, importers and distributors, to ensure compliance with the regulation.

- **Transparency and information sharing:** The MDR enhances the transparency of information, requiring manufacturers to provide more detailed documentation and making information more accessible to the public.

For manufacturers and suppliers of medical grade silicones, understanding and adhering to the MDR is crucial for market access and the continued success of their products within the EU. It is recommended that they stay informed about the latest guidance documents and implement the necessary changes to their processes and products to maintain compliance with the MDR.

For further detailed information, the full text of Regulation (EU) 2017/745 can be accessed, providing an in-depth understanding of all the requirements and stipulations of the MDR. Additionally, guidance on the classification of medical devices, which may include those made with medical grade silicones, is available to assist manufacturers in correctly classifying their products according to the MDR.

From proven, widely adapted material technologies, such as liquid silicone rubber for injection molding, to regulatory trends in support of device safety, the medical market continues to evolve. At the core of it, driving the developments are emerging needs for new technologies and devices.

The COVID-19 pandemic has pushed to the forefront the needs for improvements in existing medical technologies and development of new ones. From faster drug discovery to more robust testing and efficiencies in product launches, many opportunities have surfaced to pave the way to the transformational changes in the industry.

One of the key areas of the technology which experienced a significant boost as a result of the pandemic was diagnostics. As the world changed seemingly overnight, new solutions were expedited to meet critical demands for accurate and easily scalable virus detection. Silicones certainly played a role in getting such tests to the market.

Within other areas of diagnostics, and outside of infectious diseases, such as drug discovery and drug toxicity testing, for example, a significant transformation is underway. With such a change in approach and disruptive technologies emerging, next generation silicone materials are necessary to meet the functional performance criteria of tomorrow's applications. The widespread adoption of silicones in the healthcare market to date and their longstanding biocompatibility record provide a solid baseline for new, innovative material developments to serve the industry's future needs.

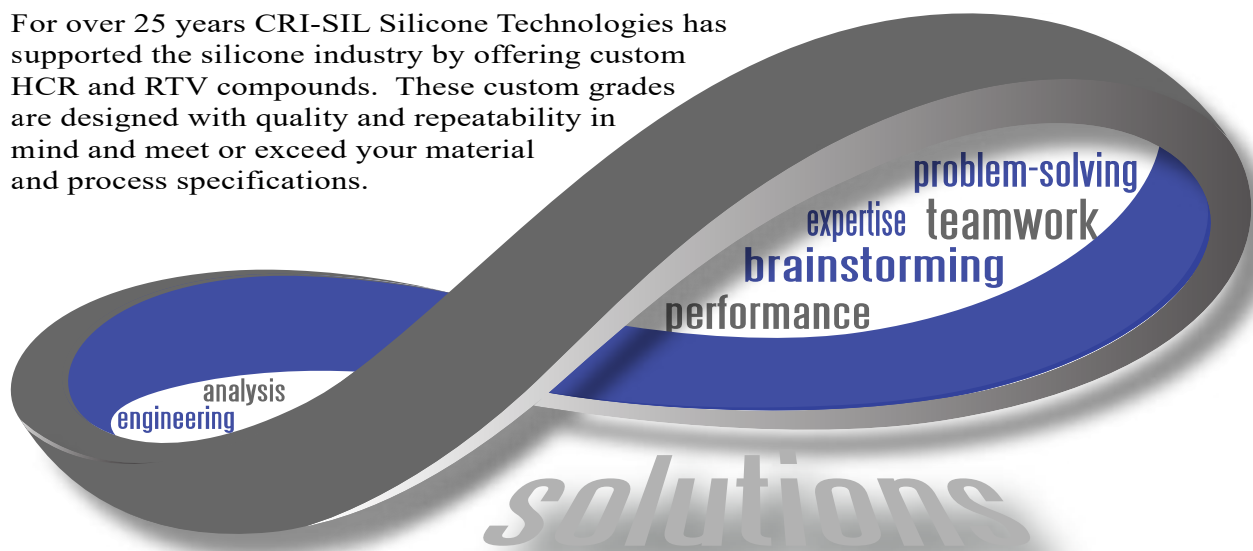
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Unique advantages of silicone and synthetic polyisoprene rubbers for medical devices

by Amalendu Sarkar, Cirtec Medical

The demand for advanced materials is paramount in the rapidly evolving landscape of healthcare industries. Silicone and synthetic polyisoprene rubbers have emerged as standout options, offering diverse characteristics ideal for enhancing medical and surgical device applications.

Material selection plays a pivotal role in the success or failure of medical devices, with rubbers posing unique challenges due to their complexity and variability. Future medical device designs require fresh, innovative solutions to address better patient safety and outcomes, and to lower costs.

By comprehensively understanding the advantages and limitations of silicone and synthetic polyisoprene rubbers, design engineers can make informed decisions to optimize the performance and reliability of their innovative medical devices. This article aims to explore and elucidate the distinctive features that make silicone and synthetic polyisoprene rubbers exceptional choices in healthcare contexts. It serves as a valuable resource for design engineers and product development teams seeking to select the most suitable rubbery materials for their next-generation medical and surgical devices, as well as drug delivery systems.

Unique qualities of silicone and synthetic polyisoprene rubber

Silicone rubber

Silicone rubber is intricately associated with numerous medical devices. Its robust silicone-oxygen bonds in the main chain backbone distinguish it from polyisoprene and other organic rubbers reliant on carbon-carbon bonds. This molecular structure grants silicone rubber exceptional stability, flexibility and biological inertness; qualities paramount in healthcare applications.

- **Unrivaled biocompatibility:** Silicone rubber offers unparalleled biocompatibility, making it well-suited for direct and prolonged contact with bodily tissues and fluids, ensuring patient safety and minimizing the risk of adverse reactions.
- **Extensive operational range:** With an extensive operational temperature range, silicone rubber remains stable and functional across various environmental conditions, from extreme heat to sub-zero temperatures.
- **Compatibility with sterilization:** Silicone rubber's compatibility with various sterilization processes ensures the maintenance of product integrity and safety, which is critical for medical applications.
- **Remarkable flexibility and softness:** Silicone rubber exhibits remarkable flexibility and softness, enhancing patient comfort and facilitating ease of use in medical devices and implants.
- **Extended shelf life:** Silicone rubber's inherent durability and stability contribute to an extended shelf life, ensuring product efficacy over time.

These distinctive attributes collectively position silicone rub-

ber as a material of choice for a wide array of medical applications, embodying innovation, reliability and excellence in healthcare technology.

Synthetic polyisoprene rubber (IR)

Synthetic polyisoprene (IR) distinguishes itself from other rubber materials through its exceptional combination of properties and characteristics. Widely utilized across industries ranging from automotive to medical, its versatility, reliability and performance are unparalleled. By replicating the molecular structure of natural rubber (NR), while eliminating organic proteins and impurities, synthetic polyisoprene inherits the desirable physical and mechanical traits of NR without allergens.

- **Elastic recovery:** Similar to NR, synthetic IR formulations with higher cis-1,4 content demonstrate strain-induced crystallization (SIC), reinforcing strength under tension. This unique attribute endows synthetic cis-1,4 polyisoprene with superior tensile and tear strength, making it an ideal choice for applications requiring exceptional durability.
- **Barrier properties:** Synthetic polyisoprene is highly regarded within the medical industry for its remarkable resealability. This feature enables it to maintain critical barrier properties in septum, stopper or closure applications, even after repeated needle punctures. Additionally, properly formulated polyisoprene septa or stoppers remain free from coring (material shedding) following punctures. These attributes render synthetic polyisoprene unmatched for various fluid management applications in medical settings.

Applications in the medical field

Silicone rubber products

Silicone rubber products (figure 1) have gained significant traction in the healthcare industry, owing to their remarkable properties that render them suitable for various medical applications, including the following:

- **Medical implants:** Silicone rubber is utilized in the fabrication of medical implants, such as breast implants, cochlear implants, intraocular lenses and integral components of implantable pulse generators (IPGs).
- **Surgical instruments and tools:** Silicone rubber is employed

Figure 1 - silicone rubber products



to manufacture ergonomic grips and handles for surgical instruments, enhancing precision and comfort during surgical procedures.

- Medical tubing and catheters: Silicone rubber's flexibility, biocompatibility, low extractables and leachability, and minimal reactivity to bodily fluids make it an ideal material for medical tubing and catheters. It finds applications in intravenous (IV) lines, urinary catheters, breast pumps, enteral tubes, peristaltic pumps and drainage tubes.
- Medical seals and gaskets: Silicone rubber seals and gaskets ensure the proper functioning and sterility maintenance of medical devices and equipment commonly utilized in pumps, valves and respiratory devices.
- Wound dressing and adhesives: Silicone rubber wound dressings and adhesive products provide gentle, protective barriers for wounds, preventing adherence during healing.
- Respiratory equipment: Silicone rubber components for respiratory equipment, including masks, tubing and valves, offer critical biocompatibility and resistance to sterilization processes, ensuring patient safety.
- Medical balloons: Silicone rubber medical balloons used in angioplasty, catheterization and dilation procedures expand, while maintaining surgical integrity.
- Prosthetics and orthotics: Silicone rubber's flexibility, durability and softness make it suitable for prosthetics, orthotics and custom medical devices, providing comfortable solutions for patients with mobility challenges.
- Dental applications: Silicone rubber is employed in dental impression materials, bite guards, dental molds and orthodontic devices, offering accuracy and stability during dental procedures.
- Dialysis equipment: Silicone rubber components in dialysis equipment are compatible with blood contact applications and resistant to dialysis chemicals.

Synthetic polyisoprene rubber products

Synthetic polyisoprene rubber products (figure 2) are utilized across a wide array of medical applications, demonstrating their versatility and reliability in ensuring patient safety and efficacy. These applications include:

- Seals and o-rings
- Duckbills and slitted valves
- Bellows

Figure 2 - synthetic polyisoprene rubber products



- Plunger tips
- Rubber stoppers
- Septa for IV systems
- Valve components
- Diaphragms
- Needle shields
- Resealable components in surgical settings
- Drug delivery and fluids management systems

Both silicone rubber and synthetic polyisoprene rubber contribute significantly to enhancing patient care, improving medical device performance and fostering innovation in healthcare solutions.

Advantages for medical device manufacturers

Both silicone and synthetic polyisoprene rubbers offer a multitude of benefits to medical device manufacturers, positioning them as preferred materials across various applications in the healthcare industry.

Silicone rubber

Silicone rubber offers a plethora of advantages that make it indispensable for medical device manufacturers, including:

- Biocompatibility: Silicone rubber is highly biocompatible, making it well-tolerated by the human body and minimizing the risk of adverse reactions. This crucial property is essential for medical products that directly contact bodily tissues and fluids, ensuring patient safety.
- Stability and durability: Silicone rubber is inherently stable and durable, withstanding the rigors of medical device applications and maintaining its performance over time.
- Sterilizability: Silicone rubber can be easily sterilized using various techniques such as ethylene oxide (EtO), gamma radiation, electron beam (e-beam) radiation, steam and ozone, ensuring the safety and sterility of medical devices.
- UV resistance: Silicone rubber exhibits excellent resistance to UV light, making it suitable for medical devices exposed to sunlight or other sources of UV radiation.
- Versatility: Silicone rubber's versatility allows for the fabrication of a wide range of medical devices, including implants, tubing, seals and adhesives, catering to diverse healthcare needs.

Synthetic polyisoprene rubber (IR)

Synthetic polyisoprene rubber (IR) boasts several advantageous properties that cater to the needs of medical device manufacturers, including:

- High green strength and good hysteresis: Synthetic IR exhibits robust green strength and hysteresis properties, ensuring resilience and durability in medical device applications.
- Elastic recovery and dynamic properties: Synthetic IR's excellent elastic recovery and dynamic properties enable it to maintain its shape and performance over time, enhancing the longevity of medical devices.
- Strain-induced crystallization (SIC): The phenomenon of SIC in synthetic IR material provides resistance against crack initiation and propagation, contributing to its

exceptional tensile and tear strength properties.

- **Resealability:** Properly formulated synthetic polyisoprene demonstrates high resealability characteristics, minimizing the risk of leakage and contamination in medical devices.
- **Gas permeability:** Synthetic polyisoprene exhibits relatively low permeability to various gases, ensuring the integrity and efficacy of medical devices in gas sensitive applications.

The combination of these properties makes silicone rubber and synthetic polyisoprene invaluable materials for medical device manufacturers, enabling the development of safe, reliable and effective healthcare solutions.

Overcoming challenges in medical device applications

While silicone and synthetic polyisoprene rubbers offer compelling advantages for medical device applications, they also present unique challenges that require careful consideration and mitigation strategies.

Challenges with silicone rubbers

Silicone rubbers are said to present the following challenges:

- **Cost considerations:** Silicone rubbers can be relatively more expensive than other rubbery materials, posing cost challenges for medical device manufacturers. To address this, manufacturers may explore alternative formulations or manufacturing processes to optimize costs without compromising on quality or performance.
- **Protein absorption:** In some specialized applications, silicone rubbers have been reported to absorb proteins and antioxidants, potentially affecting the performance of drug solutions or biological samples. Manufacturers must carefully evaluate the compatibility of silicone rubbers with specific drug formulations and implement appropriate surface treatments or barrier coatings to mitigate protein absorption issues.

Challenges with synthetic polyisoprene rubbers

Synthetic polyisoprene rubbers are said to present the following challenges:

- **Additives in compounding:** Synthetic polyisoprene rubbers require the incorporation of additives such as antioxidants and curatives during compounding to achieve desired properties. However, selecting and optimizing these additives is critical to ensure optimal performance and safety. Manufacturers must carefully choose additives free from polynuclear aromatics (PNAs) and nitrosamines to minimize potential health risks.
- **Compatibility considerations:** Synthetic polyisoprene materials may exhibit compatibility issues with certain drugs or chemicals used in medical applications. Manufacturers must conduct thorough compatibility testing to ensure that the material does not interact adversely with drug solutions or other substances, maintaining the medical device's efficacy and safety.

Overcoming challenges

Methods to overcome challenges presented by silicone and

synthetic polyisoprene include the following:

- **Rigorous testing and quality control:** Manufacturers should conduct comprehensive testing to evaluate silicone and synthetic polyisoprene rubbers' performance, biocompatibility and chemical resistance in medical device applications. This includes material characterization, accelerated aging studies and compatibility testing with relevant drugs and fluids.
- **Collaboration with experts:** Collaboration with material scientists, regulatory experts and experienced manufacturers specializing in rubber materials can provide valuable insights and guidance in overcoming challenges associated with silicone and synthetic polyisoprene rubbers. Leveraging the expertise of industry professionals can help identify potential issues early in the development process and implement effective solutions.
- **Adherence to regulatory guidelines:** Medical device manufacturers may need to adhere to regulatory guidelines and standards, such as ISO 10993 for biocompatibility testing and USP Class VI for material safety when selecting and using silicone and synthetic polyisoprene rubbers in medical devices. Compliance with regulatory requirements ensures the safety and efficacy of the final product and facilitates market approval and commercialization.

By addressing these challenges through rigorous testing, collaboration with experts and adherence to regulatory standards, medical device manufacturers can harness the unique advantages of silicone and synthetic polyisoprene rubbers, while mitigating potential risks, ensuring the development of safe, reliable and effective medical devices.

Exploring growth opportunities and innovative applications

Silicone and synthetic polyisoprene materials are experiencing significant growth trajectories and are being increasingly explored for innovative applications beyond traditional use cases within medical device manufacturing.

Silicone products

Silicone products are experiencing widespread adoption across numerous medical specialties and industries. Growth areas for silicone materials within medical device manufacturing include:

- General surgery
- Cardiology
- Oncology
- Ophthalmology
- Orthopedics
- Enteral feeding
- Overmolded surgical products
- Duckbill valves
- Catheter tubes
- Medical tubing
- Pump tubing
- Medical cables
- Dental impression segments
- Respiratory device industries
- Implantable products
- Plunger tips

- O-rings
- Radiopaque molded and extruded products
- Self-lubricated products
- Wound drains
- Stoppers and valves

The versatility and biocompatibility of silicone make it particularly well suited for these diverse applications, enabling the development of innovative medical devices and solutions.

Synthetic polyisoprene materials

Similarly, in the realm of medical device manufacturing, synthetic polyisoprene materials are witnessing remarkable growth in various application segments, including:

- Oncology
- Cardiology
- Drug delivery
- Surgical
- Orthopedic surgery
- Wound care products
- Septa
- Slitted and unslitted valves
- Seals and o-rings
- Thin wall bellows
- Stoppers
- Diaphragms
- IV components
- Needle shields
- Resealable insulin plugs

These diverse applications highlight the versatility and utility of synthetic polyisoprene materials in addressing a wide range of medical needs and challenges.

Expanding horizons

The continuous expansion of silicone and synthetic polyisoprene materials into new and unconventional medical applications underscores their adaptability and versatility. As the healthcare landscape evolves and new challenges emerge, these materials offer a robust foundation for driving innovation and addressing unmet medical needs. By exploring growth opportunities and embracing innovative use cases, medical device manufacturers can leverage the unique properties of silicone and synthetic polyisoprene materials to develop cutting edge solutions that enhance patient care and improve clinical outcomes.

Addressing general misconceptions surrounding silicone and synthetic polyisoprene and rubbers

Misconceptions about silicone and synthetic polyisoprene rubbers can often stem from incomplete information or misunderstandings. Here are some common misconceptions that require clarification:

Safety of silicone

There is a belief that silicone is toxic and harmful to the body, leading to concerns about its use in medical devices. High quality, medical grade silicone rubber undergoes rigorous testing and meets stringent regulatory standards for medical device applications. It is biocompatible, inert and hypoallergenic, making it

safe for use in medical implants and devices. Silicone materials have a long history of safe use and have been proven suitable for both short term and long term implantable products.

Cost of silicone rubbers

There is a perception that silicone rubber materials are inherently expensive, leading to reluctance in their adoption. While high quality silicone materials may have a higher initial cost, their overall value, including biocompatibility, durability and performance, often outweighs the initial investment. The value proposition of silicone rubbers becomes evident when considering the criticality of the end application and the potential cost of failure.

Synthetic polyisoprene versus natural rubber latex (NRL)

Synthetic polyisoprene is often mistaken for natural rubber latex (NRL) and assumed to carry the same allergenic risks.

Synthetic polyisoprene is a distinct material synthesized from petroleum sources to mimic the properties of natural rubber, while reducing allergenic potential. Unlike NRL, synthetic polyisoprene offers enhanced biocompatibility and consistency.

By addressing these misconceptions and providing accurate information, manufacturers can make informed decisions about the selection and use of synthetic polyisoprene and silicone rubbers in medical device applications, ultimately ensuring their products' safety, efficacy and quality.

Additional insights/advice for medical device manufacturers

Key takeaways for materials selection

One of the major reasons for the success or failure of a new medical device can depend on material selection. When choosing between synthetic polyisoprene and silicone rubbers, it is crucial to consider the specific requirements of the device. Factors such as biocompatibility, mechanical properties, resealability characteristics, sterilization compatibility and long term performance in real world conditions should all be taken into consideration. A summary of the performance properties of silicone versus synthetic polyisoprene rubbers is shown in table 1.

It is also important to collaborate with material experts, interdisciplinary teams and design engineers to ensure that one is utilizing the most suitable material for an application. It is essential to keep the patient at the forefront of the device development efforts. Additionally, consider the environmental impact of the devices and materials, and explore opportunities to minimize waste and energy consumption, while adopting sustainable practices.

In the rapidly evolving field of medical device manufacturing, staying informed, collaborative and adaptable is key. By leveraging the unique properties of silicone and synthetic polyisoprene rubbers, and by fostering innovation and patient centricity, manufacturers can drive transformative advancements in healthcare technology, and ultimately enhance patient outcomes.

- **Innovation:** Embrace innovation and think beyond traditional applications. Both silicone and synthetic polyisoprene rubbers offer versatile properties that can be harnessed for groundbreaking medical device solutions. Collaborate with interdisciplinary teams, and research

Table 1 - general performance properties of silicone versus polyisoprene

Properties	Silicone	Polyisoprene
Excellent	Green	Yellow
Moderate/good*	Yellow	Green
Poor	Red	Yellow
Biocompatibility**	Green	Yellow
Temperature, chemical, UV light and microbial resistance	Green	Yellow
Tensile and tear strength	Yellow	Green
Elastic recovery	Red	Green
Dynamic properties	Red	Green
Coring	Red	Green
Resealability	Green	Yellow
Shelf life	Yellow	Green
Permeability	Yellow	Green
Clarity, translucence	Green	Yellow
Pigmentability	Green	Yellow
Low temperature flexibility	Red	Green
Green strength	Red	Green
Bloom	Green	Yellow

* Utility may be acceptable or limited, depending on application
 ** All medical elastomers must have a certain degree of biocompatibility, depending on the criticality of the end applications

Table 2 - typical business and manufacturing considerations

	Silicone	Polyisoprene
Material expense	More expensive (typically)	Less expensive (typically)
Development time/expense*	LSR and HCR (minimum development time through use of standard materials)	More time typically needed for materials development**
Material options	HCR, LSR	HCR gum, liquid latex
Curing methods	Peroxide, platinum	Sulfur, peroxide
Typical processing methods	LSR injection and often valve-gated cold runners HCR (transfer mold or injection)	Transfer molded (wasteless flashless); Compression molded die cut Injection transfer/compression
Assembly, tackiness	Tackiness can inhibit automatic assembly with softer durometer materials; LCF** coating can reduce tack	Inherently tacky; reduced surface coefficient of friction by chlorination enables use of automated assembly
Sterilization	EO, gamma, E-beam, steam, ozone	EO, gamma, E-beam, steam

* Includes materials development, prototyping, testing
 ** LCF stands for low coefficient of friction

institutions and startups to explore new use cases and drive healthcare technology forward.

- **Regulatory compliance:** Regulatory compliance is non-negotiable in the medical device industry. Ensure that any material modifications, formulations or designs adhere to the relevant regulations and standards. Conduct comprehensive biocompatibility testing, material characterization and performance evaluations to support regulatory submissions.
- **Collaboration:** Collaboration is key to success. Engage with material suppliers, researchers, regulatory experts and clinicians early in the development process. Their insights can guide material selection, design optimization and validation strategies, ultimately leading to more effective and reliable medical devices.
- **Continuous learning:** Stay informed about the latest advancements in materials science, manufacturing techniques and healthcare technology. Regularly attend conferences, webinars and workshops to gain insights into emerging trends and best practices in medical device manufacturing.
- **Patient-centric approach:** Keep the patient at the center of device development efforts. Understand the unmet needs of healthcare professionals and patients to design devices that offer improved outcomes, enhanced comfort and better quality of life.
- **Sustainability:** As the industry evolves, consider the environmental impact of devices and materials. Explore ways to minimize waste, reduce energy consumption, and choose materials that align with sustainable practices.
- **Risk management:** Implement a robust risk management

strategy throughout the device development lifecycle. Identify potential failure modes, assess their impact and develop mitigation plans to ensure patient safety and device reliability.

- **Validation and testing:** Rigorous validation and testing are essential to confirm the safety and performance of devices. Conduct real world testing whenever possible to simulate actual clinical conditions and gather valuable feedback for refinement.
- **Long term commitment:** The medical device industry requires a long term commitment to quality, safety and continuous improvement. Stay dedicated to post-market surveillance, ongoing product enhancements and maintaining strong relationships with healthcare professionals and end users.

Both silicone and synthetic polyisoprene based materials are closely associated with medical devices. In the case of silicone, the strong, highly stable silicon-oxygen bonds in its main chain backbone make this elastomer more stable, flexible and chemi-

cally inert than elastomers such as polyisoprene, which have carbon-carbon bonds. This gives silicone unique performance properties that can be highly desirable for healthcare applications, including unmatched biocompatibility, excellent temperature and chemical resistance, and long shelf life.

But for some medical devices, silicone's strengths can be a drawback. Silicone rubber lacks IR's strength, elastic recovery, resealability and resistance to coring. Since silicone is generally more expensive than polyisoprene, understanding the performance properties (table 1) and business and manufacturing requirements (table 2) of both elastomers is important to making informed decisions on product design and cost.

Conclusion

Elastomer material selection and optimization has a major impact on a medical device's performance, cost, durability and time to market. Silicone is widely used in the healthcare industry for its exceptional stability, flexibility and biological inertness. Polyisoprene is widely used in the healthcare industry for its resilience, abrasion resistance, ability to reseal and relatively low cost.

Choosing a medical elastomer partner with in-depth experience and knowledge in both silicone and polyisoprene materials development, processing and manufacturing, and involving them early in product development, is critical to meeting product design, cost and commercialization goals for medical devices.



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Medical silicones and low volume parts production

by Dominic Testo, Specialty Silicone Products

Medical silicones that meet USP Class VI requirements are used in many healthcare and infant care applications. Examples include parts like washers, gaskets and valves for medical devices, and products such as nursing pads, neonatal pacifiers and orthotic foot cushions. USP Class VI medical silicones are also used to overmold the handles of surgical tools and infant toothbrushes. Designers need to select materials with proven histories of biocompatibility, but it is also essential to choose a fabrication method that is cost-effective for the quantities required.

Typically, USP Class VI medical silicones are used in high volume parts production. Injection molding and rotary die cutting can produce tens of thousands of parts, but both require tooling that is too expensive for lower part volumes. These processes support complex part geometries and a high degree of precision, but it is difficult to justify the cost of a die or mold that costs tens of thousands of dollars for when only tens or hundreds of components are required. Economically, neither fabrication method is practical for a handful of prototypes either.

For low volume parts production, designers can choose other

molding or cutting techniques instead. There are design for manufacturing (DFM) issues to consider with each, but these options are cost-effective. Whether designers need ready-to-mold compounds, ready-to-cut sheets and rolls, or finished products, low volume parts production is possible with USP Class VI medical silicones. It is also economically practical, including for prototypes.

Compression molding

Compression molding cannot match injection molding's part tolerances, but the molds are considerably less expensive. That is because compression molds are simpler, require less machining, and generally do not require release mechanisms like sliders, since molded parts are removed from the tool by hand. With USP Class VI silicones, compression molding applications include parts that are flat, thin-walled, or have smooth contours and simple geometries. The cycle times are longer than with injection molding, but compression molds can have multiple cavities (figure 1).

Like injection molding, compression molding supports overmolding. The first material (the substrate) is partially or fully covered by the second material (the overmold). Because USP Class VI silicones are available in lower durometers, a softer medical silicone can be used to overmold a harder handle and make it easier and more comfortable to grip (table 1). Of course, USP Class VI silicones are also used as an overmold so that the material that contacts human skin will not cause irritation.

Compression molding is also used for the cost-effective prototyping of medical silicone parts. Often, it is before an investment in a larger and more expensive injection mold is made. Compression molding can produce medical parts in a range of sizes, including small valves and components with threads, holes and grooves. If flash is a concern, a skilled compression molder can trim away any excess material that escapes between the tool's parting line. Cryogenic deflashing is also an option for batches of medical silicone parts.

Flash cutting and flatbed die cutting

Flash cutting is a low volume alternative to rotary die cutting that uses a multi-tool head with oscillating blades, drag knives and other instruments for cutting or punching sheet materials. Unlike rotary die cutting, which can cost-effectively produce tens of

Figure 1 - compression molding can produce low volumes of USP Class VI silicone parts



Table 1 - USP Class VI silicones come in a range of durometers, including very soft materials

USP Class VI silicone	Durometer A	Tensile strength (psi)	Elongation %	Tear strength, type B (ppi)	Specific gravity
SSP2390-10D	11	370	990	90	1.09
SSP2390-20D	21	640	910	135	1.09
SSP2390-30D	30	950	890	150	1.10
SSP2390-40D	39	1,310	840	165	1.12
SSP2390-50D	48	1,510	770	165	1.14
SSP2390-60D	59	1,500	770	215	1.17
SSP2390-70D	72	1,390	720	220	1.19
SSP2390-80D	79	1,310	670	160	1.21

Figure 2 - calendaring is used to produce rolls of USP Class VI medical silicones



thousands of parts, flash cutting is economical with tens or hundreds of parts. The cuts are smooth and precise, and flash cut parts made of USP Class VI silicones can be nested for higher material yields. Parts in smaller sizes are readily achievable.

Flatbed die cutting is also used with USP Class VI medical silicones. Custom tooling is required, but the steel rule dies that this process requires cost less than rotary dies. The cycle times are slower and the setup times are longer, but flatbed die cutting can more closely nest parts to help reduce material waste. Sometimes, automated flatbed die cutting is used for part volumes that are too high for flash cutting, but too low for rotary die cutting. Manual flatbed die cutting can also be used with USP Class VI silicones, but an operator must feed sheets of material by hand.

Automated flatbed die cutting supports the use of both sheet and roll materials. With USP Class VI silicones, sheet stock is compression molded and roll stock is calendared. Calendaring (the process of smoothing and compressing a continuous sheet by passing it through heated rolls) can achieve tight thickness tolerances, even with very thin grades (figure 2). The calendaring process at Specialty Silicone Products can achieve thickness tolerances down to ± 0.002 " (.00508 cm) for USP Class VI silicones.

Other molding and cutting techniques

Compression molding, flash cutting and flatbed die cutting are not the only techniques that support low volume parts production with USP Class VI medical silicones. Transfer molding can also be used to overmold medical devices and surgical instruments. Because it allows for precise control over the amount of material in the tool, this molding process can create quality medical components, while minimizing material waste and reducing the need for post-production trimming.

Waterjet cutting is a toolless process in which a stream of highly pressurized water provides the cutting action. Although water jet equipment can also cut extrusions, it is often used to convert sheets or rolls of USP Class VI medical silicones into flat parts. Examples include washer-like gaskets that are used in the handles of medical devices in ambulances, and flat gaskets that are slit to hold tubes or valves in medical equipment. Parts nesting and intricate cuts are achievable.

Table 2 - durometer, time and temperature all affect compression set percentages

Material	Compression set (%)		
	22 hours at 175° C	70 hours at 100° C	70 hours at 150° C
SSP2390-10D	22.5	49.2	44.2
SSP2390-20D	15.0	32.2	34.2
SSP2390-30D	13.2	25.0	27.3
SSP2390-40D	12.4	25.0	30.6
SSP2390-50D	14.0	33.9	38.8
SSP2390-60D	63.9	27.9	66.9
SSP2390-70D	78.7	32.8	83.6
SSP2390-80D	44.7	87.8	90.2

Additional considerations

When selecting medical silicones, designers also need to consider compression set percentage because of its relationship to sealing. Otherwise, a medical gasket that compresses by an excessive amount may not “bounce back” after a compressive stress is removed. Durometer affects compression, but it is not the only factor. Because USP Class VI medical silicones may be used in long duration, high heat applications, it is important to account for time and temperature (table 2). For example, a surgical or dental tool with an overmolded silicone grip may be steam sterilized.

Designers also need to select medical silicones that can meet application specific requirements. At high temperatures and low pressures, elastomers that pass ASTM E595 outgas testing offer greater resistance to a loss in material properties. In medical applications, steam sterilization for surgical tools and vacuum chambers for blood products may expose silicones to conditions where excessive outgassing can occur. USP Class VI medical silicones that are independently tested to ASTM E595 can address these concerns.

Medical silicones that are platinum cured offer several advantages over peroxide cured materials. For starters, the peroxide system requires post curing to remove byproducts such as volatile organic acids. Platinum cured silicones do not require post-curing, and have higher physical properties and lower shrinkage values. Platinum curing also offers greater control over cure rates for medical silicones with a more consistent appearance. Normally, USP Class VI medical silicones are translucent. They are also available in colors such as red, black, white or gray; but pigmented grades need separate testing per color by the end user to ensure biocompatibility.

Conclusion

USP Class VI medical silicones support low volume parts production, and are available as ready-to-mold compounds, ready-to-cut sheets or rolls, and as finished products. Although the tooling costs of injection molding and rotary die cutting do not warrant low volume production, designers can specify compression molding, flash cutting or flatbed die cutting instead. Transfer molding and waterjet cutting are also options, even with prototyping. By partnering with a supplier that offers low minimum order quantities (MOQs) and on-time deliveries, designers can get the medical silicone parts they need.

Use of liquid silicone rubber in flame retardant rated automotive electrical connectors

by Noel Mower Chang, Yenny Cubides, David Shawl and Dongchan Ahn, Dow Chemical

Automotive connectors serve the critical function of providing electrical power and control to the various modules in a vehicle. With increasing demands on vehicle performance, fuel efficiency, safety requirements and quality-of-life functionalities, these connector designs are also proportionally becoming more sophisticated. Connector seals are elastomeric parts that work in conjunction with a larger housing to provide both electrical and environmental isolation to the connector junctions. Silicone elastomers have been broadly utilized in this area due to an excellent balance of mechanical properties, chemical and thermal stabilities, processing ease and self-lubricating properties.

The density of electrical components in vehicles continues to increase dramatically with the evolution of automotive design. The rapid adaptation of electric vehicle (EV) technologies also leads to increasingly stringent fire safety requirements for vehicle components and modules alike. To meet these requirements, fire retardant (FR) grade filled engineering thermoplastics are increasingly used in place of conventional structural grades, with use of halogen-free FR (HFFR) additives at the forefront of this effort. This seemingly simple component upgrade has led to unintended secondary interactions with surrounding materials, such as silicone elastomer seals. Recently, there have been increasing reports on the apparent early degradation of connector seals during parts testing when a FR plastic is used in the housing, while non-silicone materials, such as ethylene acrylic elastomers (AEM), remain relatively unaffected (refs. 1 and 2). This article describes the mechanical and analytical evaluations of silicone elastomers in direct contact with various FR engineered thermoplastics, and the formulation efforts towards minimizing the apparent chemical incompatibility between the two materials.

Experimental

Preparation and characterization of LSR formulations

A two-part, platinum cure, 50 A durometer LSR, along with additional components as applicable, was prepared and cured according to standard methods. Standard ASTM plaques (10" x 10" x 0.075") were press cured at 120°C for 10 minutes, and as-molded material was tested for mechanical properties. Durometer A hardness (D2240), tensile properties (D412), tear die B strength (D624) and specific gravity (D792) were measured using ASTM standards as specified. All rheological measurements were performed at 25°C on a TA Instruments AR 2000 rheometer (0.1 to 10 s⁻¹) and Nitzsch Rosand RH2000 capillary rheometer (100 to 10,000 s⁻¹). Curing measurements of the LSR mixture were conducted using a Premier MDR from Alpha Technologies for 6 minutes at 120°C. Attenuated total reflectance infrared spectrometry (ATR-IR) of plastic surfaces was carried out using a Nicolet 6700 FTIR spectrometer with a single bounce ATR-IR accessory (SmartMiracle) with a ZnSe crystal. LSR materials were evalu-

ated in ASTM test specimen injection molds using a LIMWorks ProChanger H1 injection molding machine.

Compression set in direct contact with thermoplastics

Compression set results were undertaken in accordance with ASTM D395 (18 Standard Test Methods for Rubber Property, Compression Set), method B, in which a cylindrical disc of diameter 29.0 mm ± 0.5 mm and thickness 12.5 mm ± 0.5 mm was compressed by 25% to about 9.38 mm thickness. Under compression, the LSR buttons were sandwiched on both the top and bottom with a substrate (aluminum [Al] or thermoplastic) and placed in the compression fixture, as shown in figure 1. The fixture was then placed in a convection oven for the specified temperature and durations. Subsequently, compression was released, and the test pieces were allowed to rest for 30 minutes prior to taking measurements.

Results and discussion

Materials selection

There are many ways to describe FR characteristics of a material, such as its UL-94 rating. However, this type of designation lacks chemical descriptors that enable mechanistic insights. The FR components can be divided into chemical categories based on ISO 1043.4 designations to better investigate the interactions between silicone elastomer and the FR thermoplastic. The four main relevant categories in these applications are shown in figure 2, which includes: FR(17), FR(40), FR(5X) and FR(30), with the latter two usually used together (i.e., FR[30 + 5X]).

While all the classes mentioned above are used today in automotive connector housings, it is expected that phosphate type FRs (mainly FR[40]) will continue to gain prevalence due to environmental concerns of brominated components.

Correlation of hardness and compression set increase

In the initial experiments, the compression set of the control LSR material was measured in direct contact with a variety of PA66

Figure 1 - modified compression set setup of LSR button sandwiched with substrate (Al/thermoplastic)

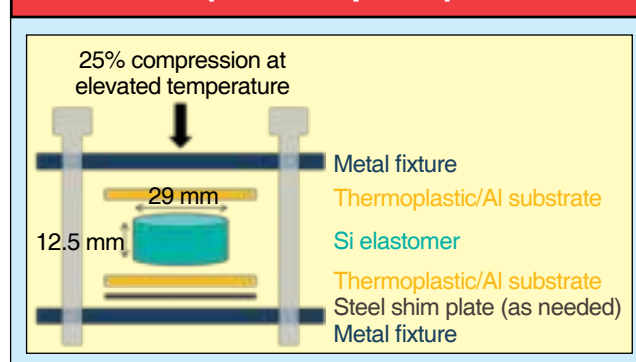
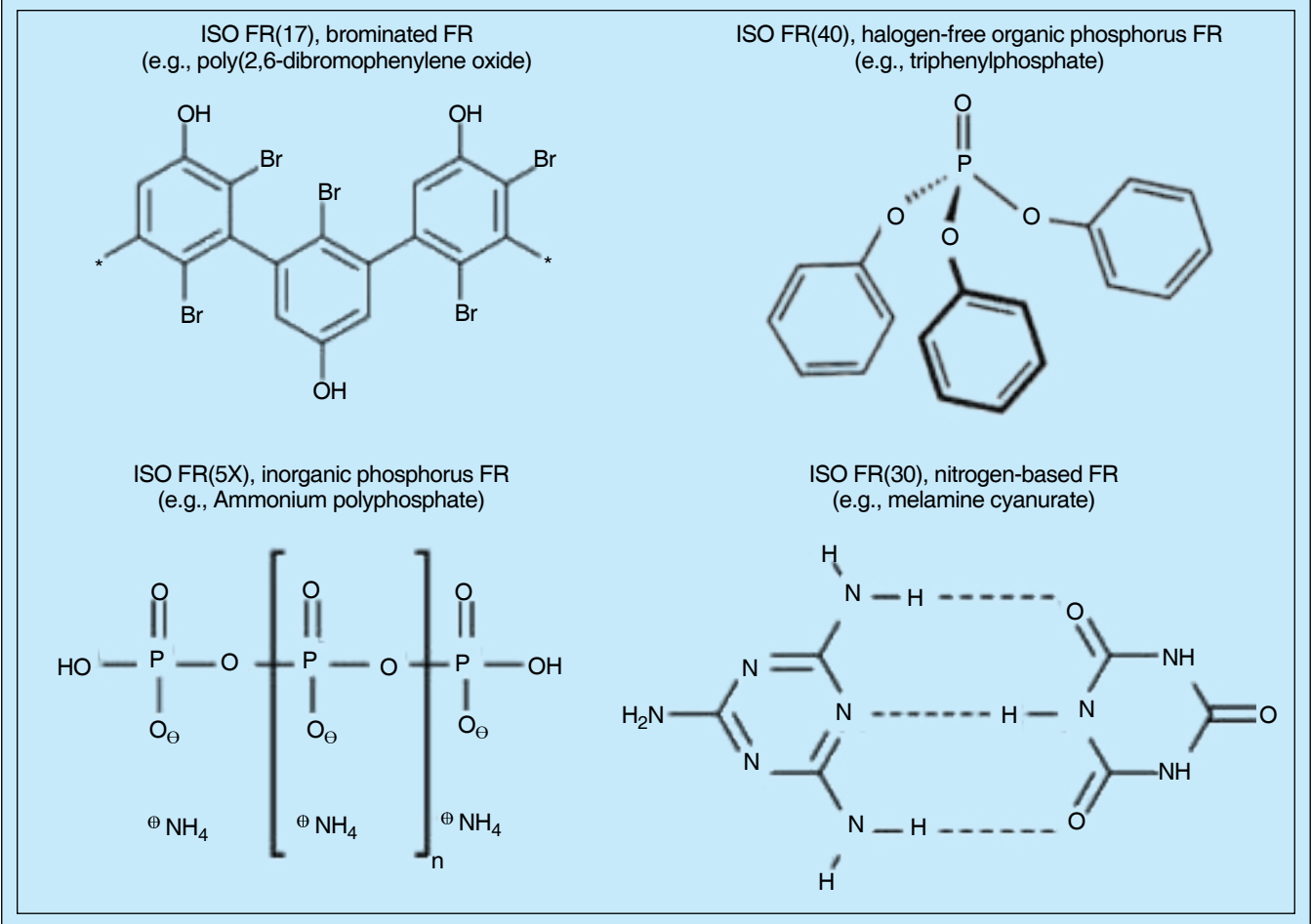


Figure 2 - ISO 1043-4 classification and examples of flame retardant (FR) compounds used in plastic for connector housings



and PBT substrates (figure 3). Consistent with previous reports, thermoplastics containing organophosphates (FR[40]) appeared

to have the worst deterioration in compression set. There was also an inverse correlation between compression set and hardness in

Figure 3 - compression set versus hardness of control LSR in contact with a) PA and b) PBT substrates after heat aging for 168 hours at 175°C

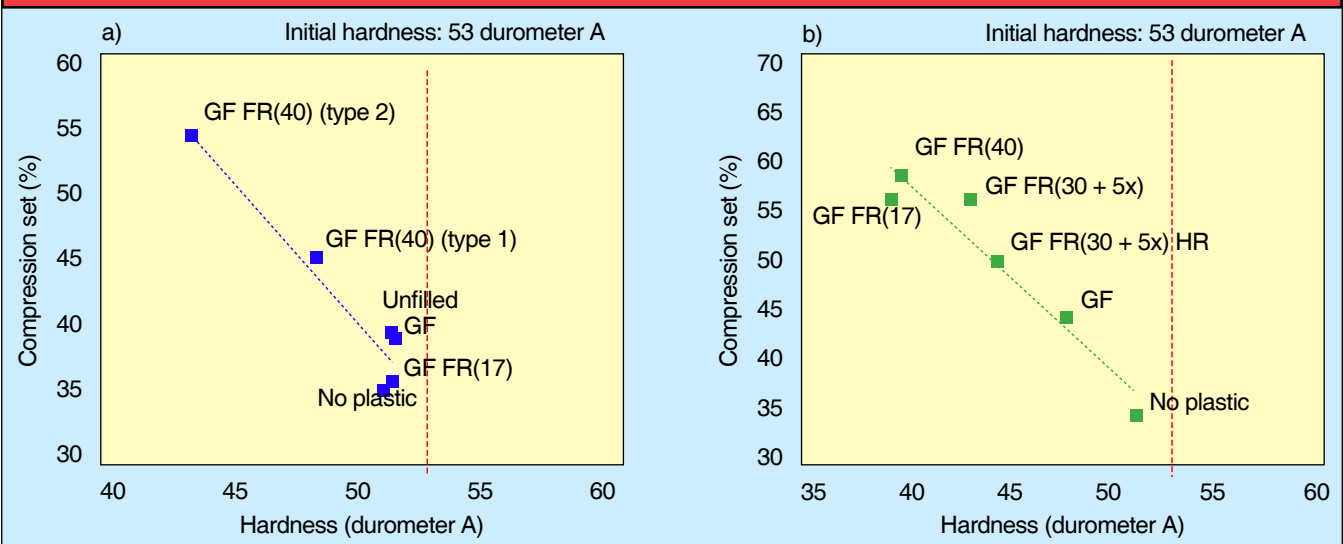
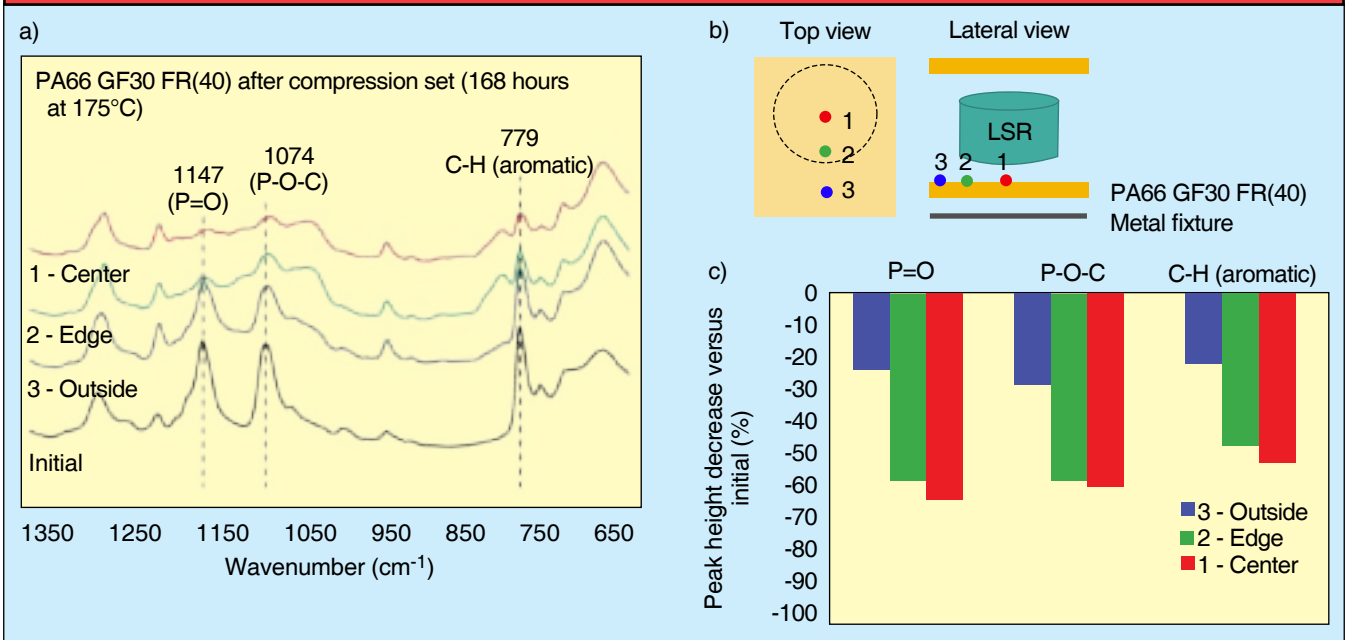


Figure 4 - a) ATR-IR spectra of PA66 GF25 FR(40) plastic surface before and after compression aging for 168 hours at 175°C at various regions in relation to the LSR specimen; b) schematic representation of the top and lateral view of PA66 GF30 FR(40) plastic where ATR-IR spectra were collected; c) peak intensity change of P=O, P-O-C and C-H absorption peaks with respect to initial condition at different regions



each data set.

Compression set of silicone elastomers is caused by a combination of physical, viscoelastic relaxation of the material under

deformation and chemical reactions during aging under compression that can cause restructuring of the silicone network to hinder elastic recovery. One possible mechanism leading to compression

Figure 5 - compression set of LSR formulations containing different additives in contact with aluminum, unfilled PA66 and PA66/6T GF25 FR(40) substrates for 168 hours at 175°C; typical values, not to be construed as specifications; users should confirm results by their own tests

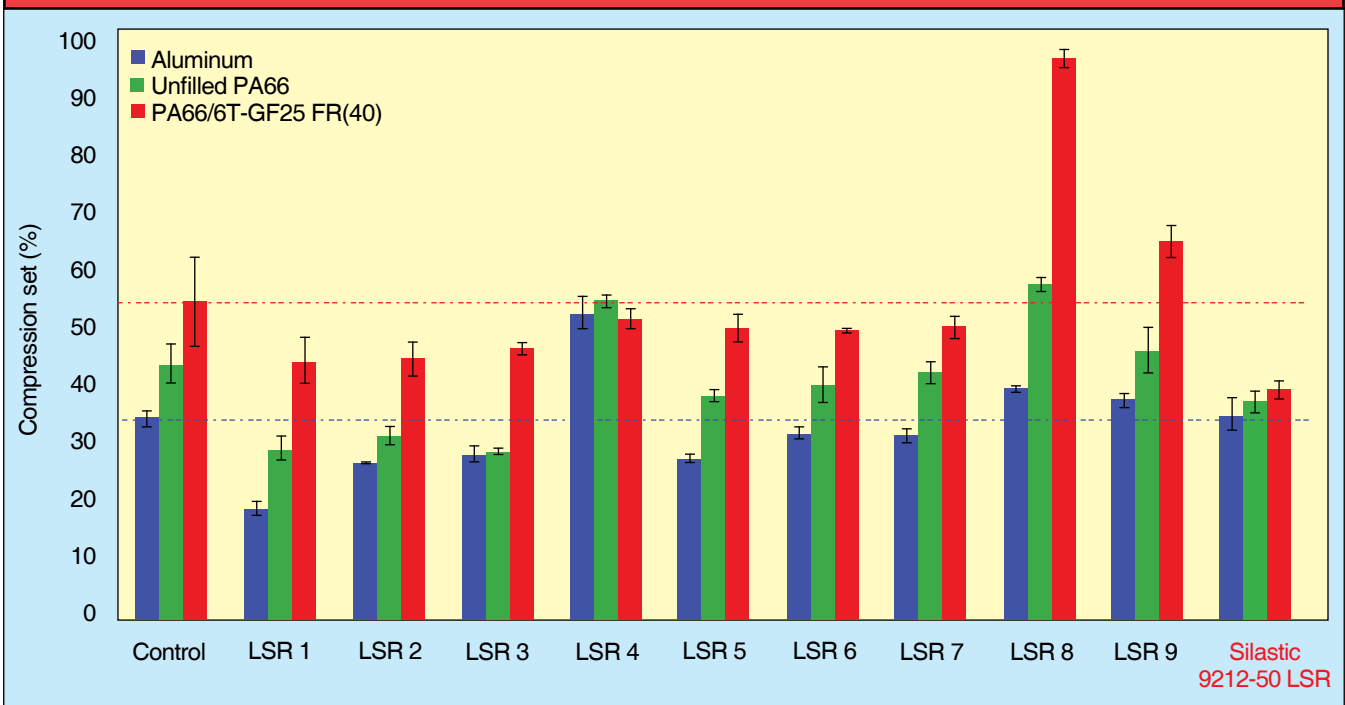
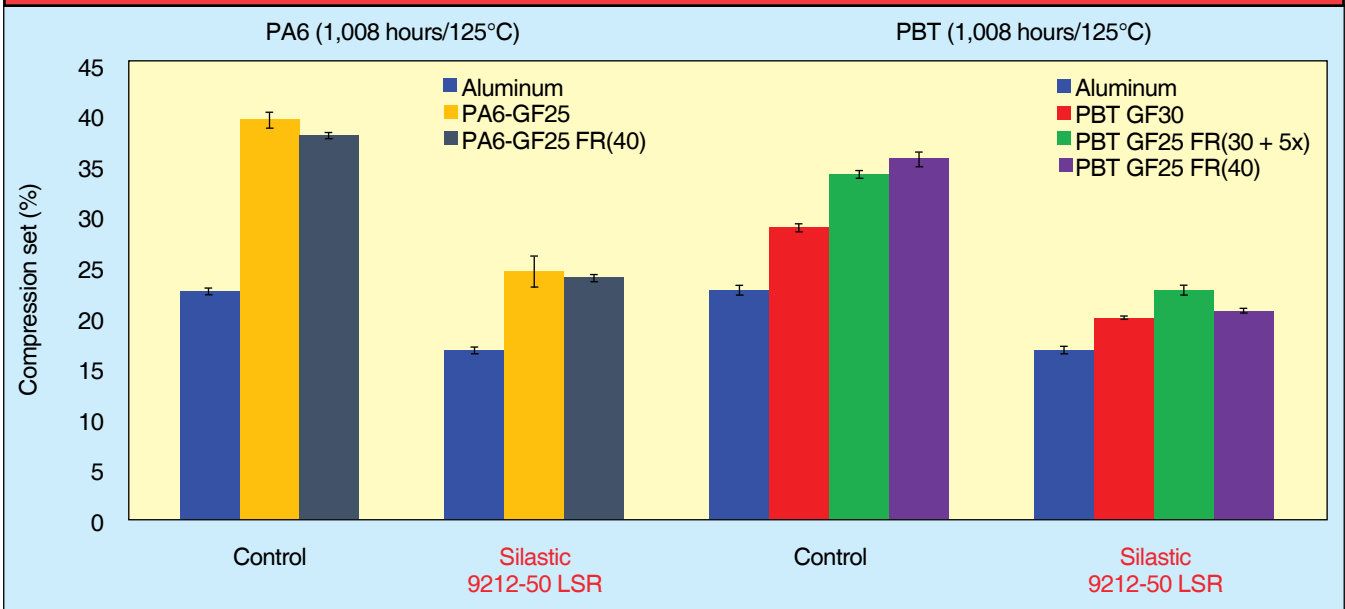


Figure 6 - compression of control and Silastic 9212-50 LSR formulations in contact with a) PA6 and b) PBT substrates for 1,008 hours at 125°C; typical values, not to be construed as specifications; users should confirm results by their own tests



set is due to post-cure crosslinking reactions, which typically translates into stiffening of the silicone network. Without external influences, one can conventionally expect a direct correlation between surface hardness and compression set. This unexpected inverse relationship hints that another mechanism is at play that counteracts the effect of crosslinking under compressive aging.

Infrared (IR) analysis of plastic substrates

A surface ATR-IR spectroscopic analysis was conducted on the plastic substrates before and after the compression set experiments to elucidate chemical changes on the interface. Figure 4a shows the IR spectra of a PA66 substrate used in compression set aging corresponding to the positions shown in figure 4b. The three peaks corresponding to characteristic absorption peaks of phosphorus based FR are highlighted. While the data do not distinguish between degradation or migration of FR species, the IR spectra show direct evidence of a compositional change at the silicone-plastic interface that is directly correlated to the degree of contact between the two materials (figure 4c). This observation is consistent with the hypothesis that the compression set of a silicone elastomer is influenced by the lability of these phosphate FR components.

Improving compression set stability with additives

As a material commonly used in challenging environments, there is a plethora of thermal stabilizers, acid neutralizers, cure accelerators and many other material options available to extend the already favorable inherent stabilities of silicone elastomers (refs. 3-8). Using a variety of conventional additives, a selection of compression set results for LSR formulations in contact with a variety of substrates is summarized in figure 5.

The majority of the formulations still present the staircase increase across the three substrates. While some heat stabilizing

Table 1 - physical properties of control and Silastic 9212-50 LSR

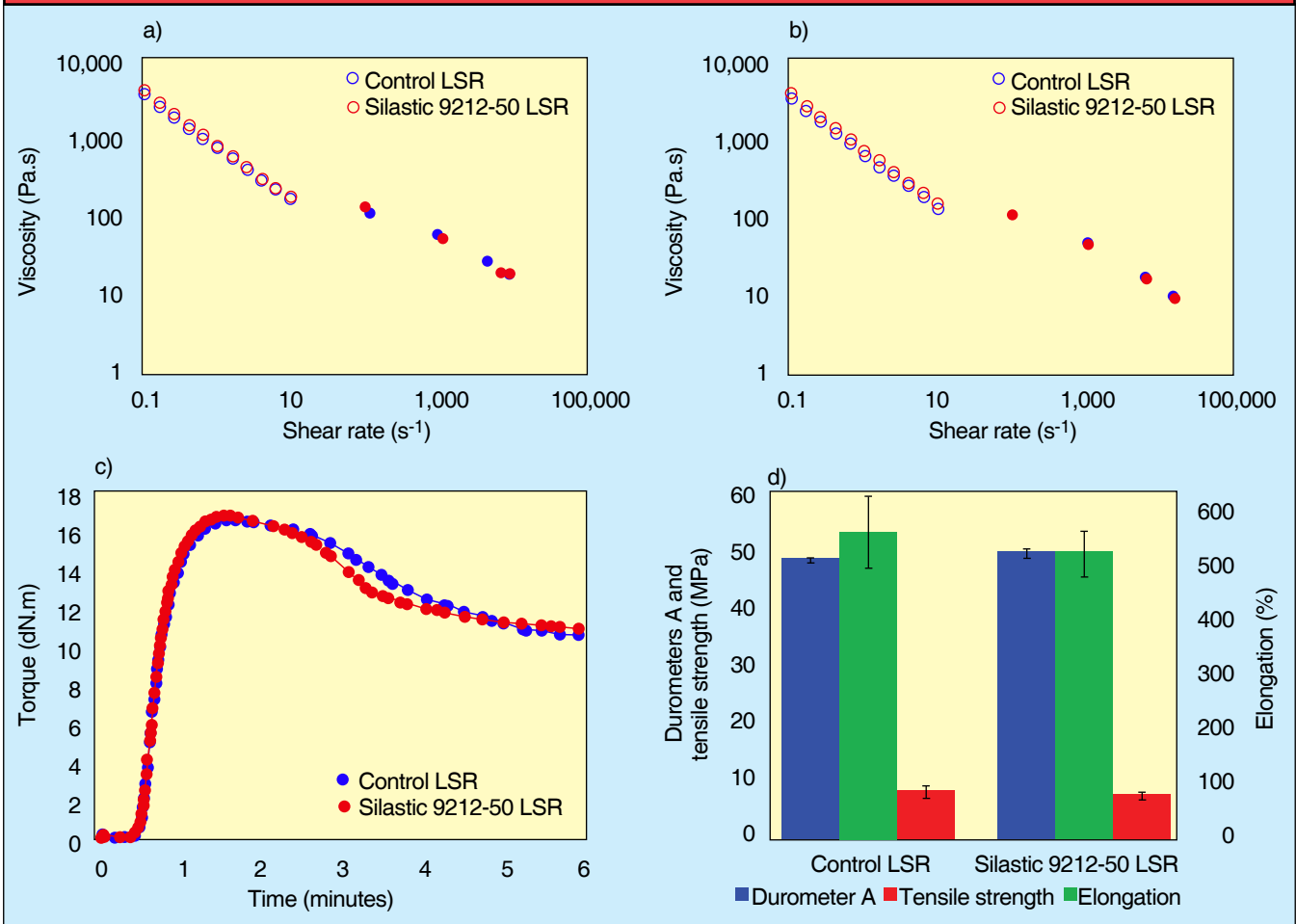
Method	Expected values	Silastic 9212-50 LSR
Rheological properties		
Viscosity at 10 s ⁻¹ , part A (Pa.s)	100-400	187
Viscosity at 10 s ⁻¹ , part B (Pa.s)	100-400	155
Curing properties¹		
S' max (lb.-in.)	-	16.8
T2 (s)	-	26.6
T20 (s)	-	34.1
T90 (s)	-	62.6
Physical and mechanical properties²		
Durometer (A)	50	53
Tensile (MPa)	7.0	8.6
Elongation (%)	450	516
100% modulus (MPa)	-	2.2
Tear die B (KN/m)	35-40	43
Specific gravity	1.13	1.13
Compression set (22 hours/177°C) (%) ³	20	20.9
Heat aging, 70 hours/200°C²		
Change in hardness, durometer A (point)	-	4
Change in tensile (%)	-	-2.3
Change in elongation (%)	-	-15
Fluid immersion, IRM 903, 70 hours/150°C²		
Change in hardness, durometer A (point)	-	-10
Change in tensile (%)	-	-37
Change in elongation (%)	-	-46
Volume swell (%)	-	41

¹MDR condition: 6 minutes at 120°C

²Cure conditions: 10 minutes at 120°C, no post cure

³ASTM D395, type 1, cured for 15 minutes at 171°C

Figure 7 - rheology of a) part A and b) part B of the control LSR and Silastic 9212-50 LSR (unfilled markers measured with parallel plate rheometer and filled markers measured with capillary rheometer); c) MDR cure profile and d) mechanical properties of control LSR and Silastic 9212-50 LSR; typical values, not to be construed as specifications; users should confirm results by their own tests



additives were able to decrease compression set on an inert (i.e., aluminum) surface, they were unable to suppress the degradation caused by contacting the LSR with the FR plastic. In the end, there was only one LSR formulation showing good compression set stability across this substrate scope.

The resulting data from this extensive study, combined with other formulation knowhow, were used to generate the end formulation for Silastic 9212-50 LSR.

It is worth noting that much of the compression set evaluation has been done by deviating from a standardized test method, and is still a bulk property of the material. Correlation to end article performance and an addendum to industrial specifications would be key to implementing a system solution.

Compression set of Silastic 9212-50 LSR on PA6 and PBT

After formulation optimization, Silastic 9212-50 LSR was tested against an expanded scope of substrates. Due to the inherent lower thermal stabilities of PA6 and PBT compared to PA66, the testing was conducted at lower temperature (125°C) for a longer duration (1,008 hours). The resulting compression set values and their re-

spective control samples are shown in figure 6. Overall, Silastic 9212-50 LSR performed significantly better than the control formulation when in contact with FR-free and FR containing plastics. The PBT example showed the first indication that Silastic 9212-50 LSR is also effective in stabilizing inorganic polyphosphate additives (i.e., FR[5X]).

Mechanical properties

While compression set stability is a key material property requirement, all other mechanical, physical and reactive properties favorably associated with incumbent LSRs must be retained to enable a drop-in material solution. Some of the key properties of Silastic 9212-50 LSR are summarized in table 1 compared to a standard range of properties for a typical material in this application (typical values, not to be construed as specifications; users should confirm results by their own tests).

Rheology and injection molding

Outside of the physical properties, the final practical consideration for a drop-in material solution is the processability of the new

Figure 8 - compression set of Silastic 9212-50 LSR compared to standard LSRs and AEM materials in contact with PA66 substrates for 168 hours at 175°C; typical values, not to be construed as specifications; users should confirm results by their own tests

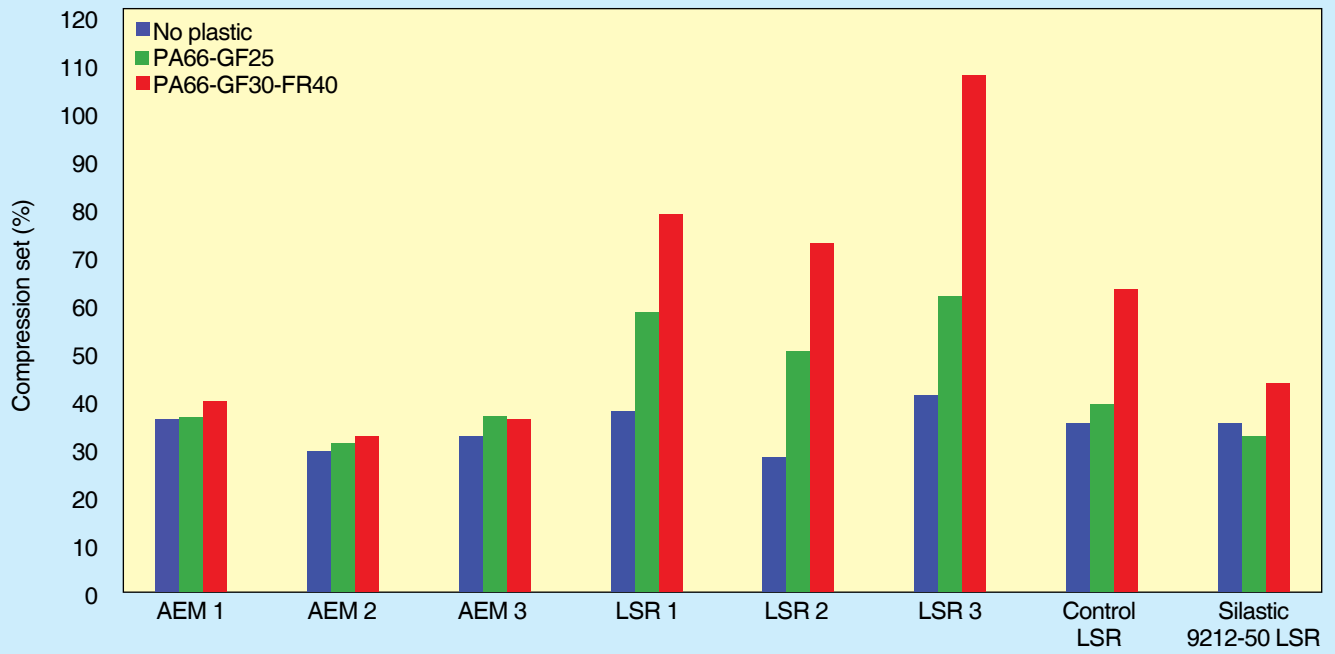


Table 2 - physical properties and features of Silastic 9212-50 LSR compared to standard LSR and AEM

	Unit	AEM	Standard LSR	Silastic 9212-50 LSR
Processing	-	Compression molding	LIMS	LIMS
Hardness range	Durometer A	50+	20-70	20-70
FR compatible	-	Yes	No	Yes
Self-lubricating	-	No	Yes	Yes
Pigmentable	-	No	Yes	Yes

formulations. Figure 7 shows a summary of the various aspects of material properties that may influence injection molding. The top two figures (7a and 7b) show the classic power law shear rate dependence viscosity of Parts A and B. Figure 7c shows the cure profile of Silastic 9212-50 LSR and control LSR. Both curves show a steep onset of cure characteristic of a balanced platinum cure system and the same slight drop off after reaching maximum torque due to the slippery nature of a self-lubricating formulation. Finally, a small injection molding trial was conducted to show comparable mold flow behavior. The resulting mechanical properties of the injection molded tensile bars are comparable for both formulations (figure 7d).

Benchmarking against competitive materials

Compression set values of Silastic 9212-50 LSR and the control material were plotted in line with the results from the competitive AEM materials and standard grade LSR materials in figure 8 that were reported in prior literature (ref. 2). Silastic 9212-50 LSR was able to achieve compression set stabilization that is comparable to the AEM counterpart on the FR40 filled PA66. In addition, table 2 summarizes the key attributes of each of the material categories

when selecting a sealing material for the FR connector housing. Silastic 9212-50 LSR is able to meet the properties and processing expectations, while maintaining compression set stability across a variety of relevant FR thermoplastics, and can be a suitable drop-in material solution where conventional LSRs fall short.

Conclusions

Chemical compatibility between silicone elastomers and fire retardant filled engineered thermoplastic has become a topic of interest with increasing scrutiny of the fire safety of automotive components. An accelerated increase in compression set has been observed when silicone elastomers are heat aged in direct contact with FR thermoplastics, especially in the case of organic phosphate additives. These compression set increases are correlated to a decrease in surface hardness and the loss of phosphate species from the plastic on the silicone-plastic interface.

Introduction of targeted stabilizing additives, in combination with adjustment of existing components in a curable silicone formulation, led to the development of Silastic 9212-50 LSR, which enables improved compression set stabilization in contact with a wide variety of FR engineered thermoplastic formulations com-

monly used as automotive connector housings. Additionally, Silastic 9212-50 LSR can achieve comparable properties and processability compared to the incumbent materials, enabling a drop-in solution in applications where conventional LSRs fall short.

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Perspective

(continued from page 20)

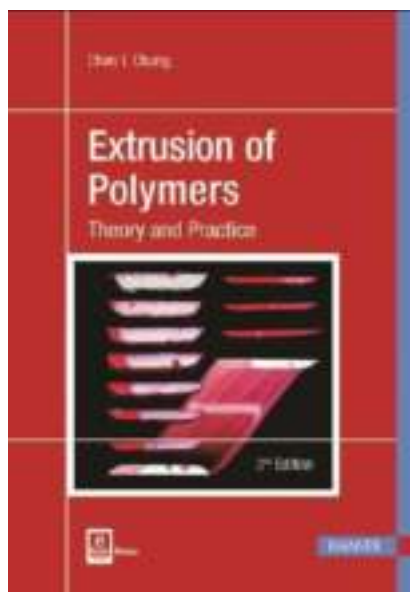
filed with the U.S. Food and Drug Administration (FDA). Material selection is critical to unlocking the next-generation medical device's potential, but the silicone adhesive selection process can be simplified by collaborating with the right silicone adhesives manufacturer.

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Meetings

Liquid Silicone Rubber 2024 organized

The seventh annual liquid silicone rubber conference, LSR 2024, will take place in Minneapolis, MN, October 14-15. The date and location for this year's conference

were strategically chosen to complement attending the MD&M (Medical Design & Manufacturing) show in Minneapolis on October 16-17, with the LSR confer-

ence hotel in convenient walking distance to the Minneapolis Convention Center, according to the LSR 2024 conference chair, Amos Golovoy.

LSR 2024 brings together professionals from various industries to discuss timely topics in LSR, including new chemistry, novel processing and manufacturing techniques, and emerging technologies. More than 20 professionals from around the world will be presenting at the conference, with topics ranging from research on LSR in EVs, to increasing functionality in medical device componentry, to technology and methods for improving OEE (overall equipment effectiveness).

The LSR conference will also include a panel discussion featuring representatives from Elkem, Momentive, Shin-Etsu and Dow. The entire agenda can be viewed at www.LSRConference.com.

"Our annual LSR conference is the one I most look forward to each year," commented Golovoy, retired Ford engineer and conference chair. "The attendees bring such an energy and enthusiasm to each day's agenda, and the intermixing of the various industries, from automotive to

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Registration for LSR 2024 and the exhibit is now open. Sponsorships are also available for those looking for additional visibility.

For more information or to register, visit www.LSRConference.com. Questions about attending or sponsoring LSR 2024 can be directed to Heather Dib, business manager for Executive Conference Management (ecm@executive-conference.com).

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Rubber Group News

The **Chicago Rubber Group** will hold a golf outing July 18 at the Village Links of Glen Ellyn in Glen Ellyn, IL. Details are available at www.chicagorubbergroup.org.

The **Detroit Rubber Group** will hold a fishing outing July 11 at the Toledo Beach Marina in LaSalle, MI. The DRG will hold a golf outing August 20 at Northville Hills Golf Club in Northville, MI. Details are available at www.rubber.org/detroit-rubber-group-inc.

The **Mexico Rubber Group** will hold the Processing Aids for Rubber Compounds course, instructed by Jose Gazano, July 25 in the Rubber Chamber Auditorium in Mexico City, Mexico. Details are available at www.rubber.org/mexico-rubber-group.

The **Michigan Rubber Group** will hold a fishing outing August 8 in Ludington, MI. Further information is available at www.michiganrubbergroup.com.

The **New England Rubber & Plastics Group** will hold a golf outing August 20 at Blackstone National Golf Club in Sutton, MA. Details are available at www.nerpg.org.

The **Ohio Rubber Group** will hold a golf outing August 26 at Silver Lake Country Club in Stow, OH. Further information is available at www.ohiorubbergroup.org.

The **Twin Cities Rubber Group** will hold a golf outing August 1 at Willingers Golf Club in Northfield, MN. Visit www.twincitiesrubbergroup.org for details.



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Calendar



Future Meetings/ Expos

2024	September 9-12
Pittsburgh	
2025	March 4-6
Orlando	
Cleveland	September 8-11

www.rubber.org

Active Communications International, The European Carbon Black Summit 2024, Amsterdam, The Netherlands, www.wplgroup.com/aci/event/carbon-black-summit - June 19-20.

Society of Plastics Engineers, Extrusion Division, Screw Design Conference-Topcon, UMass Lowell, Lowell, MA, www.4spe.org - June 19-20.

Rubber Division, ACS, Elastomers for Selective Gas Separation, Including Carbon Capture webinar, www.rubber.org/training/ - June 20.

Rubber Division, American Chemical Society, Manufacturing Mondays Webinar Series: Tire Building, www.rubber.org/training/ - June 24.

Smarter Shows (Tarsus) Ltd., Foam Expo North America, Novi, MI, www.foam-expo.com - June 25-27.

Rubber Division, ACS, Sustainability in the Rubber Industry course, ACE Laboratories, Ravenna, OH, www.rubber.org/training/ - June 26.

Brazil Rubber Group, 20th Brazilian Congress of Rubber Technology, Expo Center Norte, Sao Paulo, Brazil, <https://abtb.com.br/congresso2024/index.php> - June 26-27.

Brazil Rubber Group, EXPOBOR 15th International Technology Fair, Expo Center Norte, Sao Paulo, Brazil, <https://expobor.com.br/> - June 26-28.

July

Rubber Division, ACS, Manufacturing Mondays Webinar Series: Curing, www.rubber.org/training/ - July 1.

German Rubber Society (DKG), DKT 2024 German rubber conference and trade exhibition, Nuremberg, Germany, www.dkt2024.de - July 1-4.

University of Akron, Akron Polymer Training Services, An Introduction to Continuous Vulcanization and CV Processes online course, www.uakron.edu/apts/ - July 5.

Rubber Division, ACS, Manufacturing Mondays Webinar Series: Final Inspection and Quality Assurance, www.rubber.org/training/ - July 8.

Detroit Rubber Group, fishing outing, Toledo Beach Marina, LaSalle, MI, www.rubber.org/detroit-rubber-group-inc - July 11.

Association for Rubber Products Manufacturers, Seals Product Design and Manufacturing training, Columbus, OH, www.arpminc.com - July 15.

Rubber Division, American Chemical Society, Manufacturing Mondays Webinar Series: Tire Testing, www.rubber.org/training/ - July 15.

University of Akron, Akron Polymer Training Services, Advanced Injection Molding online course, www.uakron.edu/apts/ - July 16-19.

Chicago Rubber Group, golf outing, Village Links of Glen Ellyn, Glen Ellyn, IL, www.chicagorubbergroup.org - July 18.

Rubber Division, ACS, Manufacturing Mondays Webinar Series: Future Trends and Summary, www.rubber.org/training/ - July 22.

Rubber Division, ACS, Women of Rubber Division (WORD) Conversation via Zoom, www.rubber.org/upcoming-events/ - July 23.

University of Akron, Akron Polymer Training Services, Complete Injection Molding online course, www.uakron.edu/apts/ - July 24-26.

Mexico Rubber Group, Course: Processing Aids for Rubber Compounds, Rubber Chamber Auditorium, Mexico City, Mexico, www.rubber.org/mexico-rubber-grooup - July 25.

University of Akron, Akron Polymer Training Services, RPA Testing of Rubber Processability online course, www.uakron.edu/apts/ - July 25-26.

University of Akron, Akron Polymer Training Services, Injection Molding Certificate Program online course, www.uakron.edu/apts/ - July 29 - August 2.

Latin Expo Group, Latin Tire and Automotive Parts Expo, Panama Convention Center, Panama, www.latinexpo-group.com - July 31 - August 2.

August

Twin Cities Rubber Group, golf outing, Willingers Golf Club, Northfield, MN, www.twincitiesrubbergroup.org - August 1.

Latin American Association of Rubber Technology and Queretaro Automotive Cluster, Third Rubber Technology Symposium, Hacienda Jurica Hotel, Queretaro, Mexico, Lucian Jimenez (gerencia@sltcaucho.org) - August 7-8.

Michigan Rubber Group, fishing outing, Ludington, MI, www.michiganrubbergroup.com - August 8.

University of Akron, Akron Polymer Training Services, Tire Safety and Durability online course, www.uakron.edu/apts/ - August 13.

Detroit Rubber Group, golf outing, Northville Hills Golf Club, Northville, MI, www.rubber.org/detroit-rubber-group-inc - August 20.

New England Rubber and Plastics Group, golf outing, Blackstone National Golf Club, Sutton, MA, www.nerpg.org - August 20.

Ohio Rubber Group, golf outing, Silver Lake Country Club, Stow, OH, www.ohiorubbergroup.org - August 26.

September

Mexico Rubber Group, Course: Rubber Compounding Part II: Basic Reverse Engineering, Rubber Chamber Auditorium, Mexico City, Mexico, www.rubber.org/mexico-rubber-grooup - September 5.

University of Akron, Akron Polymer Training Services, Dynamic Viscoelastic Behavior of Rubber and its Products online course, www.uakron.edu/apts/ - September 5-6.

Rubber Division, ACS, International Elastomer Conference co-located with Silicone Expo USA, David L. Lawrence Convention Center, Pittsburgh, PA, www.rubber.org - September 9-12.

University of Akron, Akron Polymer Training Services, Polymer Science Based Product Development for Engineers and Scientists online course, www.uakron.edu/apts/ - September 18-20.

University of Akron, Akron Polymer Training Services, Rubber Molding Processes, Principles, Troubleshooting and Mold Design online course, www.uakron.edu/apts/ - September 18-20.

Twin Cities Rubber Group, fall technical meeting, Cowboy Jack's, Bloomington, MN, www.twincitiesrubbergroup.org - September 19.

Ohio Rubber Group, fall technical meeting, Hilton Garden Inn, Twinsburg, OH, www.ohiorubbergroup.org - September 24.

University of Akron, Akron Polymer Training Services, Understanding Dynamic Properties of Rubber and Rubber Products online course, www.uakron.edu/apts/ - September 25-26.

American Chemistry Council's Center for the Polyurethanes Industry (CPI), 2024 Polyurethanes Technical Conference, Omni Hotel at Centennial Park, Atlanta, GA, <https://www.americanchemistry.com/industry-groups/center-for-the-polyurethanes-industry-cpi/polyurethanes-technical-conference> - September 30 - October 2.

Silicone extrusion line for microtubing

The EEK 32.12 extruder with a horizontal infrared tunnel is offered for processing silicones. The silicone extruder is equipped with a KF1-7000 piston feeder, which makes it easy to feed entire silicone blocks of around 6 kg. The piston pushes the silicone through a changeable die to form a thin strand, which is continuously fed into the extruder. The variability of the die makes it possible to adjust the diameter of the strand.

The horizontal infrared vulcanization tunnel H-IRT 21/0.5 allows for the curing of peroxide or addition cured silicones. The company has developed a tunnel with a variable vulcanization channel, which allows adaptation to the respective product dimensions, said to result in an enormous increase in efficiency, even with extremely small product dimensions, without loss of energy.

Thanks to the high quality and precision, silicone tubing produced on the cleanroom extrusion lines is said to meet the requirements for products in medical applications perfectly.



Water cooled motors and control cabinets,, as well as the use of a complete stainless steel variant, ensure compliance with all required cleanroom conditions, according to the company.

Typical products from these silicone extrusion lines used in the medical sector are catheter, multi-lumen, drainage and breathing tubes; but also milk and potable water tubing.

The key components of these production lines include the universal silicone extruders, said to form the centerpiece of the line. The compact design is said to allow optimal integration into coextrusion lines.

Thanks to the special screw and barrel geometries, they are perfectly adapted to the processing of silicone, according to the company. The unique design of the feed section is said to simplify cleaning and minimize downtimes during material changes, even with very soft and sticky compounds. (*Rubicon Gummitechnik und Maschinenbau GmbH*)

www.rubicon-halle.de

Medical tubing extrusion

A global provider of extrusion tooling for medical tubing and other products is said to have achieved a series of successes in the areas of multi-layer dies and, most recently, a reciprocal tubing die for wound draining that reconfigures the internal chambers of the tubing to accommodate drainage. Drain tubes can be inserted prophylactically to prevent or remove the accumulation of fluid in a wound. Alternatively, such tubing can also be therapeutically inserted to evacuate an existing collection of fluid in a wound. The company's design is said to have unique features that eliminate the need to weld or otherwise join sections with different profiles together. The traditional tip and die assembly is replaced with a linear reciprocating assembly that changes the tube's profile within a given length. This process is repeated throughout a single extrusion run without interruption. (*Guill Tool & Engineering*)



www.guill.com

Silicone technology

High precision liquid silicone rubber (LSR) molded and multi-component parts are developed using precision processing tools to produce high-consistency silicone rubber solutions, including components with complex geometries. These parts are manufactured at strategically positioned global production sites, all run in a consistent manner worldwide using the same processes and materials, according to the company. (*Trelleborg Sealing Solutions*)

www.trelleborg.com/seals

Heat stabilizer additives

W-series (including W0/W3/W6) products are ready-to-use additives comprised of heat stabilizing filler and reactive silicone polymer, which are said to ensure no migration of filler during the vulcanization as the filler is incorporated into the elastomer network. No negative impact on silicone rubber properties is reported when dosage recommendations are observed, according to the company. The products are compatible with peroxide and platinum curing systems, and could be used to extend the service life of silicone elastomers at temperatures above 170°C. The maximum recommended service temperature is 250°C for W0, 280°C for W6 and 300°C for W3. The products should be incorporated into silicone rubbers using standard mixing techniques. Good results are said to be obtained by incorporating the curing agent at the same time. The recommended dosage is 2% to ~4%. (*Wynca USA*)

www.wynca-usa.com

Ready-to-use silicones

An extensive range of ready-to-use (RTU) silicones includes the company's heat curable rubber silicones sold under the Bluesil tradename, designed for high performance applications in a variety of industries. Whether the need is for silicone solutions for high voltage cables and wires, power insulators, extreme temperatures, fire resistance or weather durability, Bluesil silicones are said to be the solution. This company is a global supplier of key raw materials such as silicon metals, gums, bases and various performance additives said to ensure consistency, reliability and security of supply. (*Elkem*)

www.elkem.com

Non-post-cure LSR grades

Silicone rubber grades that do not need to be post-cured after processing include Elastosil LR 5003 liquid silicone rubber, said to be suitable for applications in the food industry and other sensitive areas. A novel solution for marking silicone rubber is also provided. Elastosil color pastes are said to ensure that such silicones can be permanently and precisely labeled by laser. Elastosil Eco silicone rubber grades are said to be manufactured in a resource efficient manner using non-fossil methanol. Silicone rubber is said to frequently undergo post-curing after processing. During this post-curing procedure, the cured silicone elastomer is heated in a well ventilated oven for several hours to temperatures of up to 200°C. This is said to eliminate volatile components, while enhancing the strength of the silicone rubber. However, this is an expensive step in production that not only consumes a lot of time and energy, but also interrupts the flow of a highly automated production process, according to the company. This line of non-post-curing silicone rubber grades under the name Elastosil LR 5003 is said to be particularly suitable for the large scale manufacture of products in the food industry and other sensitive areas. (*Wacker Chemie AG*)

www.wacker.com

Low outgassing silicone

SSP502-55LT is an EMI/RFI silicone that meets ASTM E595 low outgassing test requirements and withstands temperatures as low as -70°C, according to the manufacturer. Applications for this shielding elastomer include the high vacuum, low temperature environment of outer space, where released gases from EMI gaskets can condense upon and cloud sensitive optics. SSP502-55LT is a 55 durometer, nickel-graphite filled silicone that joins a growing family of low outgassing compounds from the company, including offsets to Parker Chomerics Cho-Seal materials and replacements for discontinued Gore EMI gasketing, according to the company. The SSP502-55LT material is said to withstand colder temperatures than its offsets to Gore GS2100 and Gore GS5200, both of which are also medium durometer, nickel-graphite compounds. In addition to ready-to-fabricate materials, the company offers finished gaskets made from SSP502-55LT. On-site flash cutting and die cutting are used for flat gasket fabrication, and the company's toolroom is equipped with CNC machines and staffed by machinists. In addition to dies, jigs and fixtures, the company cuts the molds for the compression molded EMI gaskets. (*Specialty Silicone Products*)

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Answering the Call



LSR injection molding

An electric Allrounder 470 E Golden Electric with a clamping force of 1,000 kN, liquid silicone rubber (LSR) cylinder and vacuum equipment can produce valves made of liquid silicone for use in cars. The Elastosil material (durometer hardness 50 A) from Wacker is resistant to heat and media, and is also known for its good resilience and consistently high performance, according to the company. Using an eight-cavity mold, eight LSR components weighing 0.8 grams each can be produced in a cycle time of around 55 seconds. Injection is sprueless and takes place directly via a pneumatic cold runner system. A Flexlift 10 linear robotic system gently removes the molded parts from the mold and sets them down on a conveyor belt. Linear robotic systems were launched in the Flexlift series. Thanks to their low height and telescopic design, they are said to be suitable for confined spaces. (Arburg)



www.arburg.com

Silicone rubber processing

Technologies for mixing, extruding and fine mesh straining of silicone rubber compounds are developed and applied by the company. Silicone rubber compounds are said to be in demand in many industrial sectors, especially in the technical, sealing and medical industry, where high standards of product quality and performance are required. To meet these demands, sustainable and automated production processes are needed, which enable a gentle but process-reliable material processing, and at the same time conserve resources, according to the company. The basic processes of mixing, extruding and fine mesh straining of silicone rubber compounds are said to be crucial steps to achieve the desired properties and surface qualities of the final product. However, the processing temperature, as well as sensitive compounds or those containing abrasive fillers, pose significant challenges to machinery in the silicone elastomer industry. This company is said to provide innovative technologies for mixing, extruding and fine mesh straining of silicone rubber compounds. The firm offers machine configurations that are specifically tailored to the requirements of the respective application, such as conical twin-screw extruders or a combination of conical twin-screw and single-screw extruders. This technology is said to enable improved processing of temperature-sensitive and abrasive compounds by ensuring both the process reliability and the material homogeneity. In addition, they are said to contribute to a reduction of energy consumption and waste generation, which leads to a sustainable way of doing business. (Uth GmbH)



www.uth-gmbh.com

LSR integrated processing

The focus of liquid silicone rubber (LSR) processing includes the production of a highly precise infusion valve on a fully electric E-mac 465/130 injection molding machine, according to the company, realized in cooperation with the companies Nexus, Psilikon GmbH & Co. KG and ShinEtsu. The challenges of LSR processing, such as high precision and strict tolerance requirements, are said to be met by combining this company's machine technology, injection molding tool, automation and the Nexus X20 dosing system with a high quality LSR material from ShinEtsu. A particular highlight of this application is said to be the efficient in-process inline slitting, which reduces cycle time, and thus energy and manufacturing costs, according to the company. The firm also offers a production cell for processing EPDM rubber, highlighting the advantages of the tie-bar-less Victory 460/120 Tech injection molding machine. Its compact and tie-bar-less design is said to allow for efficient use of production space, and optimizes overall production workflows. In a single-cavity mold, flash-free sieve stars can be produced in a 60 second cycle. (Engel)

www.engelglobal.com



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Circulation attritors

This manufacturer of grinding and dispersing equipment for a broad range of industrial applications recently shipped four QL-100 circulation attritors. These production grinding mills are said to be distinguished by their ability to achieve results in a faster grind and a narrower particle size distribution. The attritor circulation system typically includes a separate holding or premix tank that can be ten times larger than the size of the mill. The entire contents of the holding tank will pass through the grinding chamber approximately eight times an hour. Attritor circulation milling is said to improve efficiency by passing material through the mill multiple times, lowers costs by using less grinding media and achieves higher throughput capacity than a similar sized batch machine, according to the manufacturer. Each mill has a gross tank volume of approximately 122 gallons, and is powered by a 150 hp inverter duty, explosion-proof motor. The mills can also be mounted on 44-1/2" custom designed frame risers. (Union Process)



www.unionprocess.com

Injection molding system

The 968.560 ZO Benchmark features 6,300 kN clamping pressure, a 6,600 cm³ FIFO-A injection unit and silicone tamper. Thanks to the Benchmark clamping system and the demolding table, this machine is said to offer optimum ergonomics for the operator and ideal accessibility for handling systems, robots or other automation systems, according to the manufacturer. The areas of application for this series are said to be wide ranging, from large volume seals, insulators, cable sleeves and rubber-metal parts to respiratory masks, vibrating screens and membranes. The patented FlowControl cold runner technology for sprue-free and waste-free injection molding is also available from the company. This machine is also equipped with all available energy saving options. In addition to the savings achieved using the company's ServoGear hydraulics and EcoSilence temperature control units, EnergyControl+, Iso+, HeatShield and IsoMold are said to contribute to a significant reduction in energy consumption, according to the company. The firm also provides cold runner technology, digitalization, automation solutions, traceability, sustainable solutions, silicone processing, and more. (Klockner Desma Elastomertechnik GmbH)

www.desma.biz



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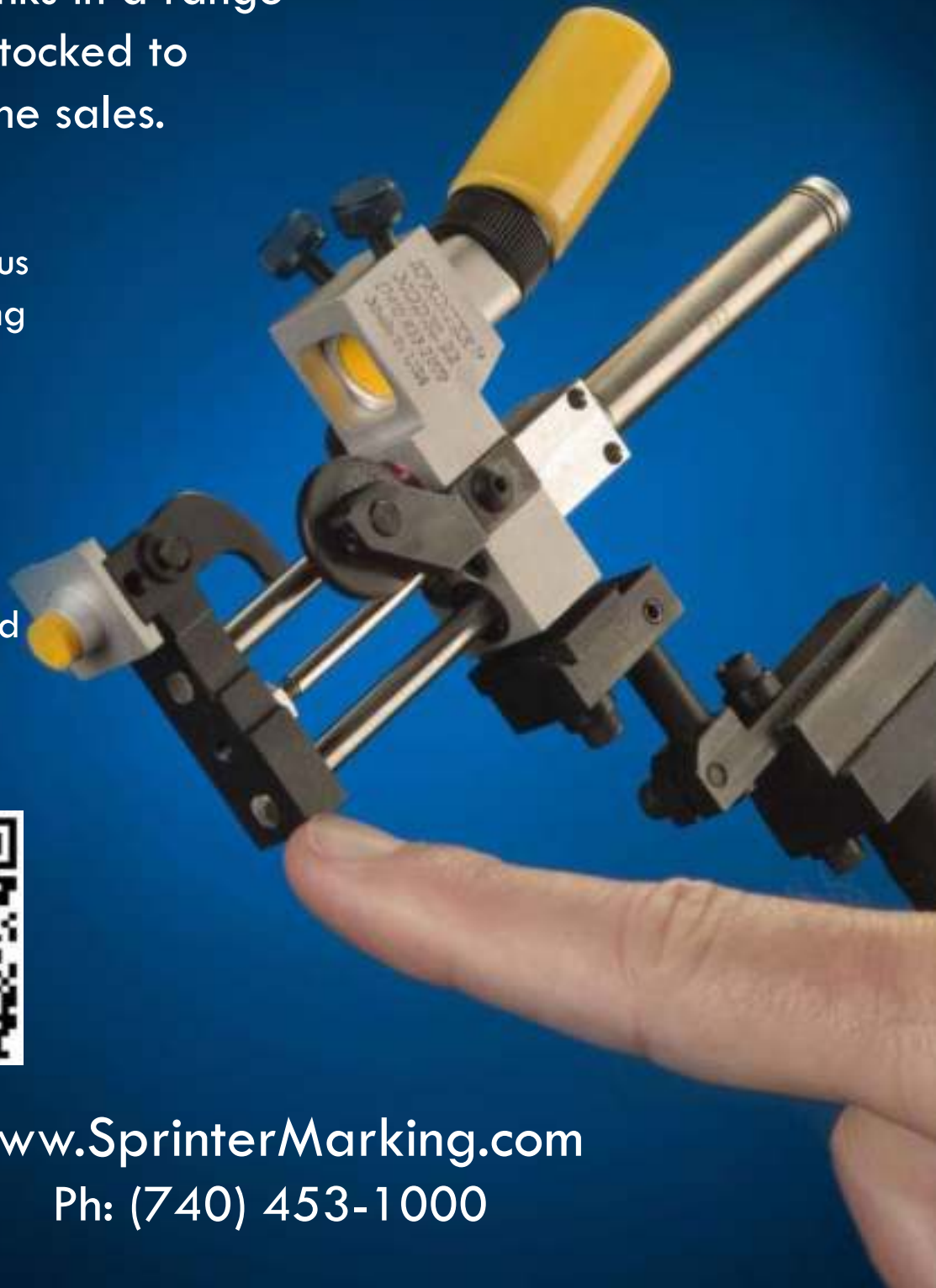
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Mass spectrometers

The Maldi EasyCare solution is said to provide a convenient way for users of the Maldi-8000 Series TOF mass spectrometers to perform routine upkeep on the system. The Maldi EasyCare solution increases uptime and reduces costs because it enables operators to care for the system themselves without the need for service engineer maintenance calls, according to the company. The Maldi EasyCare solution specifically addresses the challenge of Maldi-TOF ion optics contamination, which reduces instrument performance. With the Maldi EasyCare solution, operators can easily remove, clean and refit ion optics, according to the manufacturer. The software wizard automatically tunes deflectors and the detector to optimize instrument performance. Benchtop Maldi instruments updated with the Maldi EasyCare solution are said to retain the same performance as the previous models, ensuring an outstanding combination of mass resolution and sensitivity. Operators are said to easily upgrade EasyCare-ready versions of the Maldi-8020 and the dual-polarity Maldi-8030 through a software license activation. The Maldi EasyCare solution is said to be ideal for running high shot number applications. (*Shimadzu Scientific Instruments*)

www.ssi.shimadzu.com

Capillary rheometer

The Rheograph is said to be an innovative high pressure capillary rheometer according to DIN 54811 for determining the flow behavior and viscosity of thermoplastics and rubbers. This device is the result of more than 40 years of experience gained from numerous generations of rheological capillary rheometry, according to the company. The device is used to determine the flow behavior and viscosity of thermoplastics and rubbers. In the process, plastic granulate or powder is melted in the heated test cylinder and pressed out of the capillary with a test piston and a constant force or speed. The Rheograph is used in research and development, as well as in quality and incoming goods control. The test chamber temperature is controlled by a special temperature control algorithm. The setpoint temperature can be specified with a resolution of 0.1°C. The actual value is displayed on the screen with a resolution of 0.01°C. The unit is controlled by a panel PC with an optimized real-time operating system. Display and command input is via a 14.48 cm (5.7") color QVGA touchscreen. The connection to the PC is made via an Ethernet interface. The test piston is advanced by a ball screw, which is driven by a servo motor via a toothed belt drive. (*Goettfert*)

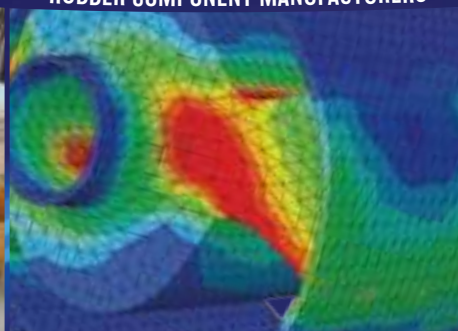
www.goettfert.com

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PFAS-free parts coating

An eco-friendly solution is offered for the coating of mass produced small parts made from elastomers. The coating material, for the first time PFAS-free, has been specifically adapted to Rotamat systems. PFAS (per- and polyfluoroalkyl substances), which until today are part of many coating materials, decay very slowly in the environment or do not decay at all. They are also suspected of causing cancer. It is highly likely that the EU will completely prohibit the use of PFAS in the near future, according to the company. The PFAS-free anti-friction lacquers CSIP13 and CSIPN18 are offered for sealing components made from elastomers or plastic; for example, o-rings or flat seals. Even though the lacquers contain no PFAS, they are said to have the same low friction coefficient as PTFE based coating materials and offer the same life expectancy, according to the company. The lacquer was specifically developed for Rotamat coaters. The Rotamat R 100 with its high volume drum capacity is increasingly used by customers who coat large components; for example, pleated protective covers. Coating of parts for the automotive industry is said to demand high process stability and consistency of results. *(Walther Trowal)*

www.walthertrawal.com

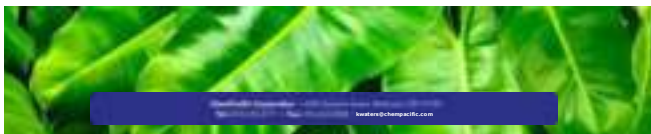


ChemPacific offers a number of Eco-Friendly Latex Rubber Emulsion products for a variety of industrial manufacturing applications. Currently, these products are widely used in the production of latex gloves. These emulsions provide improvements to process & performance of finished products such as enhanced barrier properties, improved fabric strength, increased handling features, and elasticity & viscosity of many anionic emulsions.

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Paints, Coatings & Adhesives
 Food Packaging Paper Coating
 Water-based Latex Paint
 Glue Manufacturing



Renewable functional fillers

BioMotion renewable functional fillers (RFF) are said to open up a new innovative product category that can be used in a wide range of rubber and plastic applications and has a significantly lower CO₂ footprint than conventional petroleum based products, according to the manufacturer. The company is said to have opened the world's first industrial scale biorefinery in Leuna, Germany, which turns wood into next generation biochemicals. Lignin based renewable functional fillers are said to offer a sustainable alternative to carbon black and precipitated silica in a broad range of rubber and plastic applications. *(UPM Biochemicals)*

www.upm.com

HSBR and TPE solutions

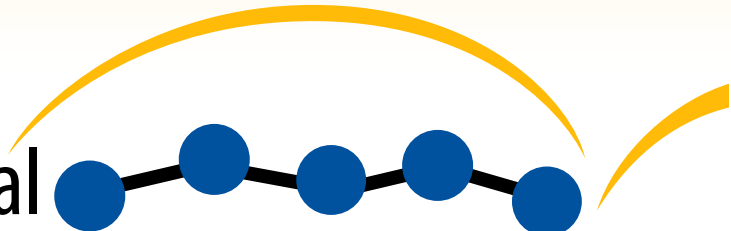
By applying selective hydrogenation, the company's hydrogenated solution styrene butadiene rubber (HSBR) material is said to offer a remarkable combination of characteristics, as it retains some of the desirable properties of an SBR, such as good processability and compatibility, while also benefiting from an improved resistance to heat, aging and chemicals due to the hydrogenation process. In addition, recent studies show that the functionalized HSBR has the possibility of contributing to reducing the usage of 6PPD, an antioxidant used to protect the polymer from rapid aging, according to the company. Recent studies are said to have shown that 6PPD can break down into a harmful substance called 6PPD-quinone, and upon contact with water, the quinone compound becomes toxic for the environment. Furthermore, hydrogenation also is said to increase the hardness of the rubber, potentially reducing the need for filler materials such as silica or carbon black. Functionalized and selectively hydrogenated SBR is said to open a horizon with applications ranging from performance tires to non-tire applications such as belts, hoses and rubber products that require enhanced durability and performance. The company also offers an innovative approach utilizing a tailor designed thermoplastic styrene block copolymer (SEBS) grade for automotive interior surfaces which require good haptics and soft touch. *(Asahi Kasei)*

www.asahi-kasei.com

Rubber additive solutions

A complete line of additives that function individually or in combination in both natural and synthetic rubber is offered by the company. By providing a full range of material enhancing products, i.e., dispersants, homogenizers, lubricants, peptizers, plasticizers and tackifiers, the incorporation of the company's additives is said to significantly improve processability for all stages of rubber production. The firm is said to be a flexible innovation partner, producing additives in accordance with the demanding specifications of customers and reacting swiftly to market needs, adapting new technologies quickly to ensure customer satisfaction and loyalty. *(Struktol Company of America)*

www.struktol.com



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Wynca USA (www.wynca-usa.com) is a wholly owned subsidiary of Wynca International, and has a focus on silicones. Wynca USA was founded in 2014. The company provides knowledge and understanding of the U.S. silicone market, coupled with a dedication to its customers. Silicone products offered by Wynca USA include silicone intermediates, solid silicone rubber, liquid silicone rubber and silicone oil.

Wynca USA has developed a strong understanding of its customers' business in an effort to strengthen its relationships with customers. Wynca USA teams with its parent company, Wynca International, to focus on reliable supply and quality assurance, while effectively competing in the U.S. marketplace.

Since entering the U.S market, Wynca USA has continued to grow due to its strong, profitable business relationship with its customer base. Wynca USA's culture is focused on being a best in class supplier focused on growing its customer relationships. Wynca USA is said to

couple Chinese efficiency and global expertise with U.S. market knowledge in order to be its customers' best choice.

Wynca International entered the silicone market in 1985, and is said to be the most integrated manufacturer of silicone products in China. Wynca is 100% self-sufficient for its silicone metal requirements. Wynca produces approximately 2,000 different silicone products to serve the market. Wynca International is qualified to the following standards for silicone products to ensure product quality and compliance: ISO 9001:2015 QMS; ISO 14001:2015 EMS; IATF 16949 QMS; GB/T 45001 (Occupational Health and Safety); and GB/T 29490 (Intellectual Property Management). Wynca employs over 6,000 associates, with over 250 involved in research and development around the world. The company owns more than 182 patents and over 3,000 registration certificates in 113 countries.

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Goldsmith & Eggleton
H&R Group
HallStar Company
Harwick Standard
Infinity Rubber
Kayton Industry Co., Ltd.
Kenrich Pertochemicals
Kumyang
Monolith Materials
Polymer Solutions Group
Polymer Valley Chemicals, Inc.
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Renkert Oil
Soucy
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Eagle Elastomer
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Elmet (www.elmet.com) is a specialist in the development and manufacture of high quality equipment for the production of silicone and rubber components. Constant advancement of the range of products and of technologies has turned Elmet into a full system supplier.

As a small and committed team with a lot of experience in the areas of tool making and the automation of the LIM (liquid injection molding) process, the founders' dreams of being independent one day came true. Elmet customers were thrilled from the beginning with the company's open and direct communication, extensive know-how and tireless drive to expand the existing knowledge and

try out new things. The knowledge that could be gained from striking an increasing number of new paths has currently materialized in the form of sophisticated and high quality products that are implemented on a daily basis by very well trained and motivated staff. Due to the permanent development cycle that is constantly applied to products, production processes and staff, Elmet assures its global customers will meet the highest demand of full system solutions in the production of silicone and rubber components now and in the future. This makes Elmet a specialist and leading partner for the production of high grade LSR elastomer parts, dosing systems and parts production worldwide.

Twenty-five years of experience, continuous learning and development, a comprehensive product portfolio of high precision tools to proprietary developed dosing systems and cold runner technology make Elmet a reliable and competent full system supplier for the series and mass production of complex assemblies, Elmet, as a full service supplier, constantly focuses on the success of its customers.

Elmet is certified to ISO 9001:2015 and IATF 16949:2016, and is constantly working to improve the processes and to guarantee security of supply for customers.



Wacker (www.wacker.com) is a technological leader in the chemical industry and manufactures products for all key global industries. It is active in the silicone, polymer, life sciences and polysilicon markets. With a range of more than 2,800 silicone products, Wacker ranks among the world's largest manufacturers of silanes and silicones. Wacker is also the market leader in key subsegments, with a product portfolio ranging from silanes through silicone fluids, emulsions, elastomers, sealants and resins to pyrogenic silicas. Thanks to their highly diverse properties, silicones offer virtually unlimited potential for intelligent, customizable solutions to numerous sectors. Key application areas include engineering, electronics, chemicals, cosmetics, textiles and paper.

Wacker's wealth of products, experience and expertise enables the firm to offer complete, customized solutions. Cooperating closely with customers, Wacker develops new products and innovative production processes to help customers cut costs and optimize their business. To this end, Wacker provides laboratory support for product formulation and approval, and for scale-up to full production. Wacker also assists customers with the development of supply chain and packaging strategies.

Non-vulcanized silicone rubber consists of polymers of different chain lengths. These so-called polysiloxane chains always contain a silicone-oxygen backbone, with two organic side groups, usually methyl groups, bound to each silicon atom. These polysiloxane chains determine the key material properties common to all silicone rubbers, such as heat resistance and electrical characteristics. The choice of additive determines the particular processing and material properties of Wacker's silicone rubber portfolio, extending the approximately 1,000 products. Crosslinkers, fillers and catalysts are among the most important additives. Wacker offers a wide range of different silicone rubber grades marketed under the trade names Elastosil, Geniosil, Powersil, Semicosil, Silmix, Silpuran and Wacker.

Wacker's integrated management systems represent the company's most comprehensive management tool to maintain sustainable business practices.

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People in the News

Goodyear names Nicole Gray chief HR officer

Nicole Gray was appointed senior vice president and chief human resources officer for Goodyear Tire & Rubber. Gray replaces **Gary VanderLind** who is retiring as senior vice president and chief human resources officer, effective July 1. VanderLind worked for Goodyear for nearly 40 years.



Nicole Gray
Goodyear



Anne W. Baarup
Continental



Ching Gettman
Davis-Standard



Daniel Polster
Simtec Silicone Parts

MANAGEMENT

Anne Windberg Baarup took over management of the sustainability department for Continental's group sector ContiTech. She is now responsible for the strategic direction and global management of sustainability activities for the company's industrial business, with a focus on using recycled and bio-based materials.

Ching Gettman has joined Davis-Standard, a global designer and manufacturer of extrusion and converting technology, as president of the Davis-Standard Global Services team.

Daniel Polster was named managing director of Simtec Silicone Parts, LLC, replacing **Roland Keller**.

Bryan Shields was promoted to senior product manager for Harwick Standard Distribution.

Darren Schulz was appointed president of Duro-Last, a member of the Holcim Building Envelope.

Ecore International appointed **Shweta Srikanth** as chief circularity officer.

International Institute of Synthetic Rubber Producers (IISRP) elects president international

Zhuang Yi was elected as the IISRP's president international for the year 2024-2025 at the association's 64th Annual General Meeting on May 8. In this role, Zhuang replaces **Kazuyoshi Matsuura** of Zeon Elastomers, who became the IISRP's past president international.

Yi is said to have a well-recognized and extensive professional background in the polymer industry. He is currently the chief specialist in synthetic materials for China Petroleum and Chemical Group (Sinopec). Yi has been engaged in scientific research and management in the field of petrochemical and synthetic polymer materials.

In 1988, Yi joined the Liaoyang Branch of PetroChina Company Limited. In 1997, he joined Sinopec and worked in the Science and Technology Department. In 2022, he was appointed as Sinopec's chief specialist in the field of synthetic materials.

Yi currently serves as vice presi-



dent of the China Synthetic Rubber Industry Association and director of the Chemical New Materials Professional Committee of the China Petroleum and Chemical Industry Federation.

In addition to Matsuura, who is now the past president international, other members elected to the Institute's Executive Committee for the year

2024-2025 are:

- **Kevin Liu** of TSRC, president of the Asia Pacific Section and member of the FPAC.
- **Giovanni Cassuti** of Versalis, EMEA section vice president.
- **Brian Chapman** of Kuraray Americas, member of the FPAC
- **Masayoshi Iwasa** of Asahi Kasei, vice president of the Asia Pacific section.
- **Robert Rikhoff** of Lion Elastomers, president of the Americas section
- **Juan Ramon Salinas** of IISRP, managing director, assistant treasurer and recording secretary

The IISRP is an international not-for-profit trade association with corporate members domiciled in more than 20 countries, who produce more than 75% of the world's supply of synthetic rubber. Headquartered in Houston, TX, the Institute supports Milan, Tokyo and Beijing regional offices.

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