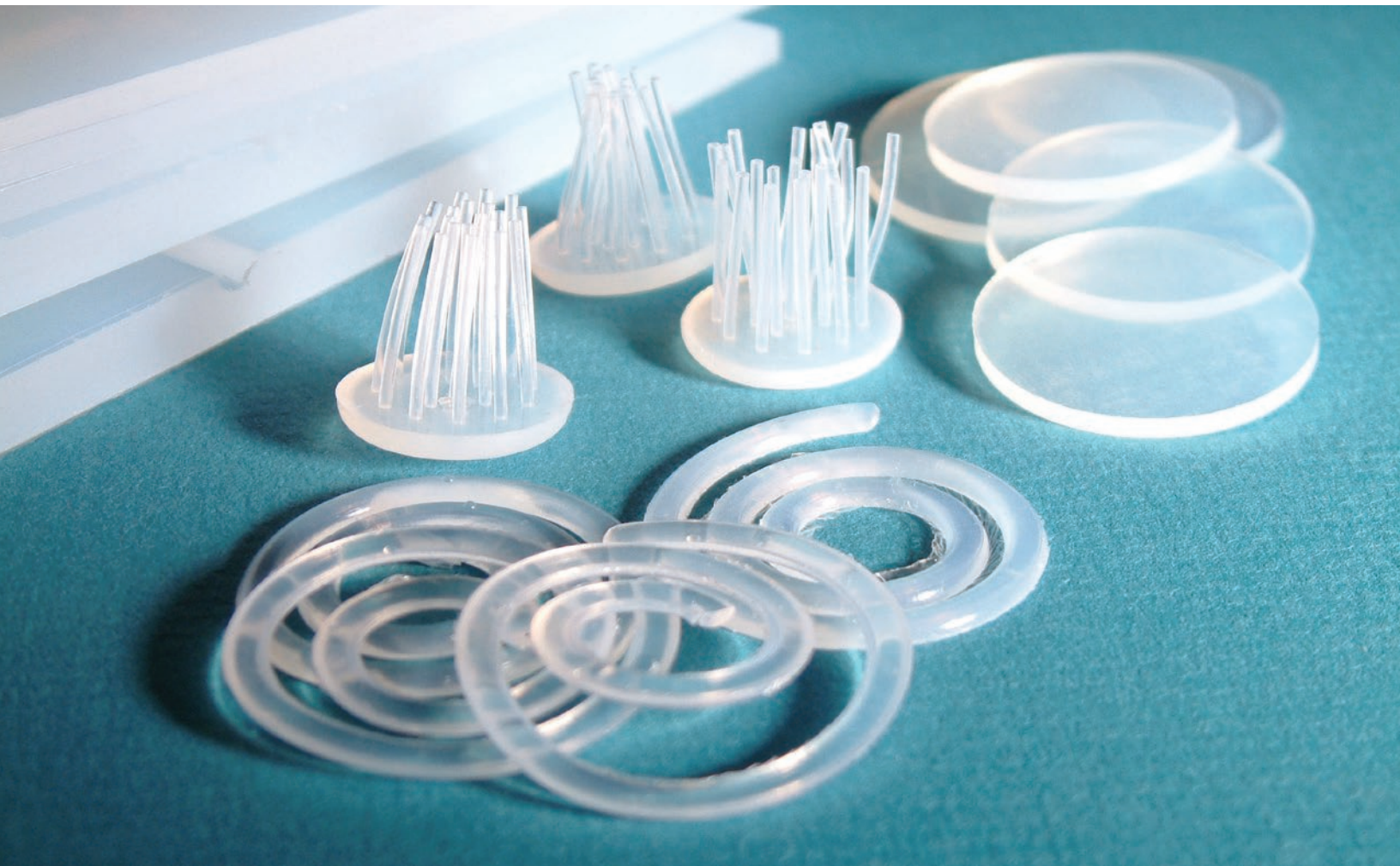


# Silicone elastomers for medical device applications

Application and product overview



# Expertise meets innovation

The past few decades have brought extensive advances in medical care. New and innovative technologies have helped find unprecedented ways to fight disease. Many of these technologies are the result of a visionary expansion in materials.

The diversity and versatility of DuPont™ Liveo™ healthcare silicone elastomers help manufacturers of medical implants and devices around the world create innovative products to address critical medical needs. These silicone elastomers are suitable for a wide variety of medical device applications:

- Short-term and long-term implanted devices
- Medical/diagnostic devices and components
- Non-implant external devices

Liveo™ silicone elastomers can help meet your need for quality, reliability and dependable performance:

- Biocompatible, and FDA food grade compliant
- Consistent from batch to batch
- Available in a broad range of Shore A hardnesses
- Sterilizable (e.g., autoclave, gamma irradiation)
- Do not contain organic plasticizers, phthalates or latex additives
- Solventless, pigmentable and non-blooming in platinum catalyzed system, with high gas permeability compared to most other thermoset elastomers and thermoplastics

## The right material for the right application

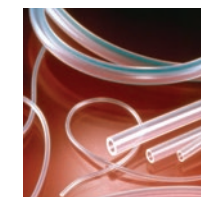
DuPont offers a broad range of uncatalyzed and platinum catalyzed silicones designed for the fabrication of medical devices and device components.

Use this overview as one of the first steps to help you find the most suitable material for your application.



**Liquid silicone rubber (LSR)** products are pumpable thermoset silicone elastomers that can be processed by molding equipment. Their relatively low viscosity makes them ideal for intricate designs and close-tolerance parts.

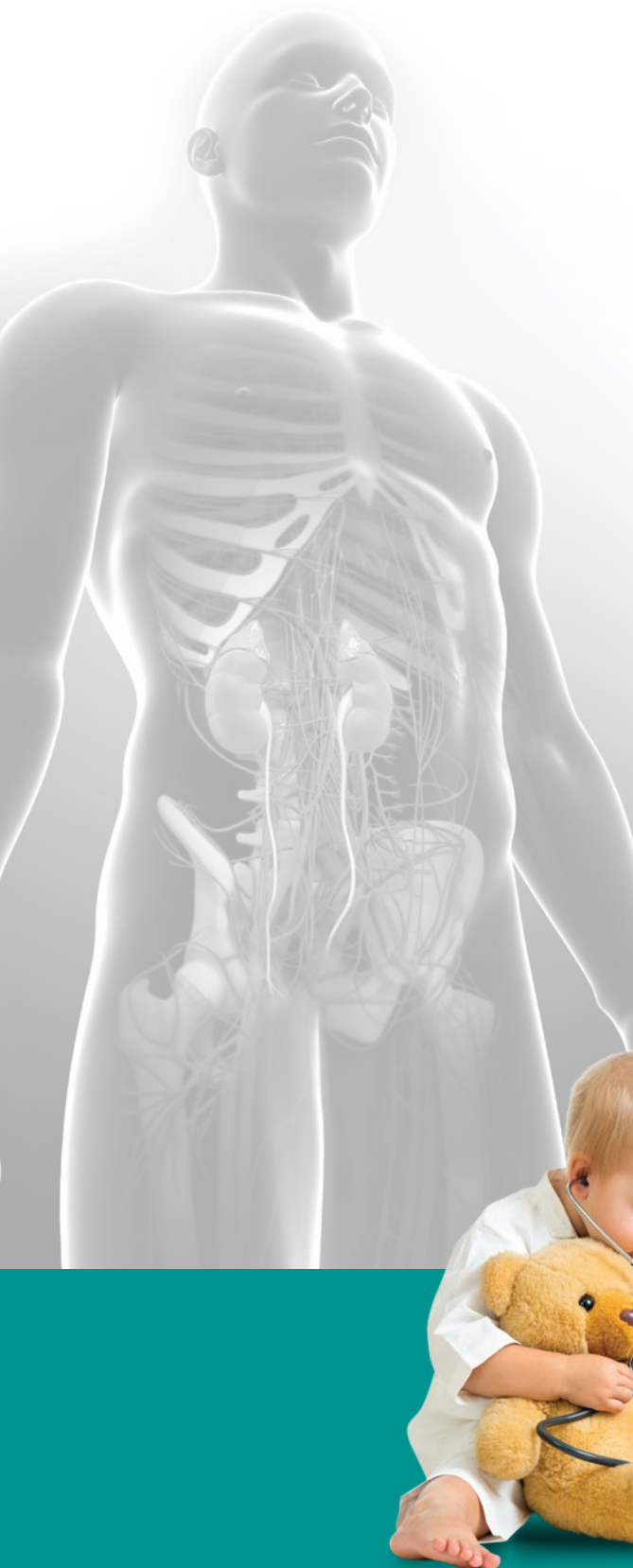
Contents of concerned cyclo-siloxanes in the Liveo™ LSR products range are below 0.1%, the Substance of very high concern (SVHC) threshold proposed by " REACH Regulation (EC) No 1907/2006."



**High consistency rubber (HCR)** products are millable thermoset silicone elastomers that can be extruded continuously to form a desired size and shape before curing, e.g. silicone tubing.

	Liquid Silicone Rubber	Liveo™ Class VI LSR	Liveo™ BioMedical Grade LSR	High Consistency Rubber	Liveo™ Class VI Elastomer	Liveo™ BioMedical Grade Elastomer
<b>Uncatalyzed</b>					●	●
<b>Platinum Catalyzed</b>		●	●		●	●
<b>Peroxide Initiated</b>					●	●
<b>Applications</b>						
<b>Long-term implant*</b>			●			●
<b>Short-term implant</b>		●	●		●	●
<b>Medical insert</b>		●	●		●	●
<b>Non-implant</b>		●	●		●	●
<b>FDA 21 CFR 177.2600 (Food Grade)</b>		●	●		●	●
<b>Select European Pharmacopeia 3.1.9</b>						
<b>Substances soluble in hexane</b>		●	●		●	●
<b>Volatile matter</b>		●	●		●	●
<b>Biocompatibility</b>						
<b>Cytotoxicity (ISO 10993-5)</b>		●	●		●	●
<b>Mutagenicity/Genotoxicity (in vitro, ISO 10993-3)</b>			●			●
<b>Hemolysis (ISO 10993-4)</b>			●			●
<b>Skin Sensitization (ISO 10993-10)</b>		●	●		●	●
<b>Pyrogenicity (USP) (ISO 10993-11)</b>			●			●
<b>90-day implant (ISO 10993-6)</b>			●			●
<b>30-day implant (ISO 10993-6)</b>		●	●		●	●
<b>7-day implant (ISO 10993-6)</b>		●	●		●	●
<b>USP Class V and VI</b>		●	●		●	●
<b>Production</b>						
<b>ISO 9001:2008</b>		●	●		●	●
<b>ISO 14001:2004</b>		●	●		●	●
<b>Produced in GMP facility</b>		●	●		●	●
<b>Change Notification (per ISO 9001)</b>						
<b>Change Control (per GMP)</b>		●	●		●	●
<b>Documentation</b>						
<b>US Drug Master File*</b>			●			●
<b>EU Technical File*</b>			●			●

\* Indemnification is required for long-term implant applications. Select Liveo™ BioMedical Grade materials have US Drug Master Files and EU Technical Files.



# How can we help you today?

DuPont™ Liveo™ silicone elastomers for medical device applications are dedicated to meeting your needs for specialty materials and are provided with innovative support.

Our rubber formulating experience and fabrication expertise, plus local market knowledge and collaborative problem solving help you make an informed choice.

## Meeting your quality and regulatory needs

Our long-term experience in healthcare gives us broad expertise with global regulatory requirements. Depending on your need or application, you can call on our worldwide network of technology centers, our Product Stewardship organization, as well as our team of Product Safety and Regulatory Compliance specialists. We can provide material from an ISO-certified site or an FDA-registered facility to the appropriate level of GMPs. You can also benefit from our regulatory support that includes Pharmacopeial Certification, Drug Master Files, Material Application Files or Technical Files for select materials.

## Meeting your safety needs

We are committed to ensuring that our products and services are safe and effective to use.

Silicones are one of the most extensively biotested materials used in the healthcare industry. The Liveo™ Elastomers have been tested according to specific USP and ISO guidelines.

All Liveo™ silicone elastomers for medical device applications are manufactured to ISO 9001 quality standards in accordance with the practices of Responsible Care® (ISO 14001).

DuPont has adopted the American Chemistry Council's Responsible Care program, which helps manage environmental, health and safety issues that could affect you.



To learn more about DuPont's healthcare solutions visit:

[www.dupont.com/healthcare.html](http://www.dupont.com/healthcare.html)

For country-level information, visit:

[www.dupont.com/corporate-functions/our-company/global-locations.html](http://www.dupont.com/corporate-functions/our-company/global-locations.html)

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