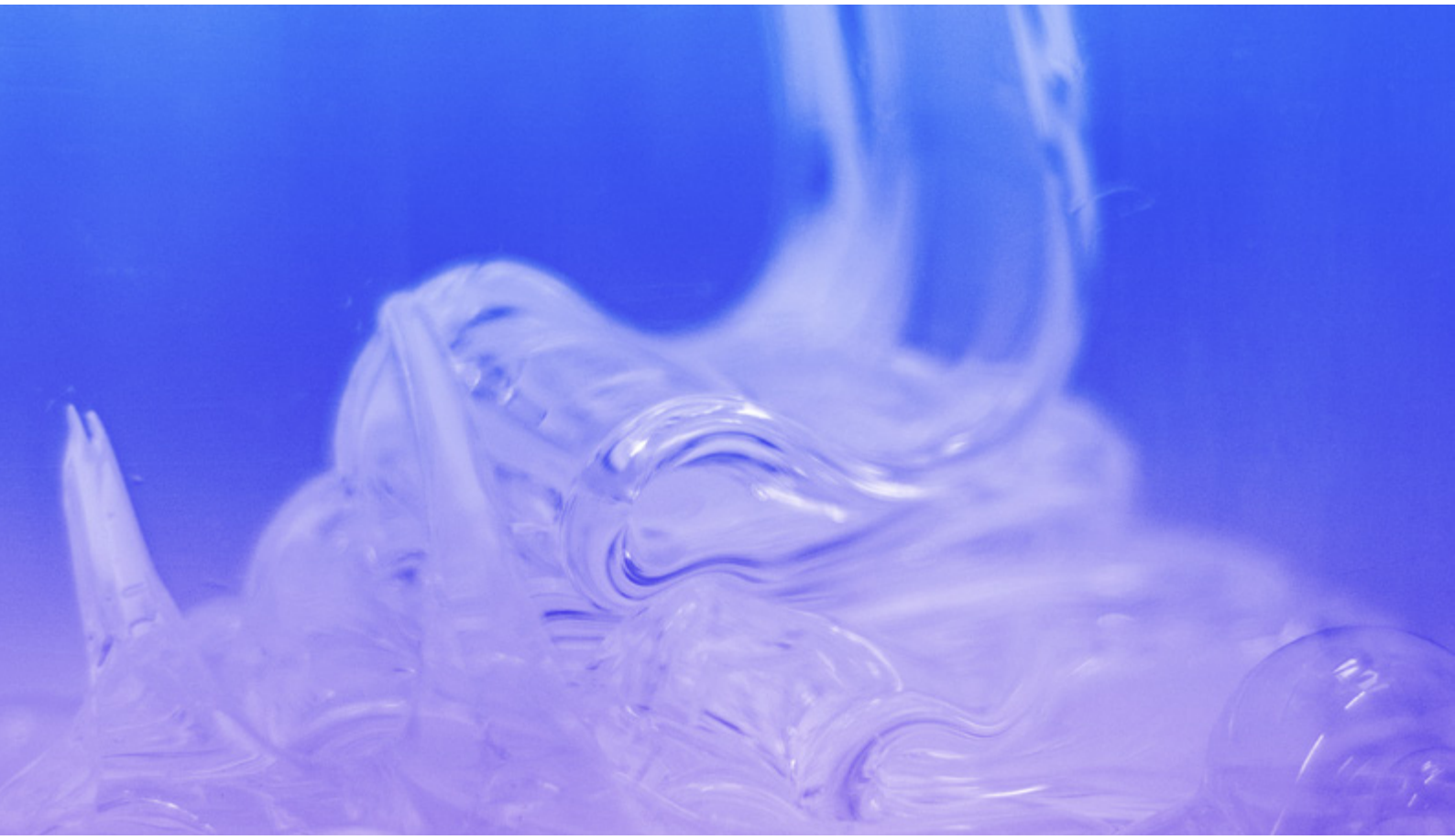

Medical Grade Liquid Silicone Rubbers (LSR) for Healthcare Applications

Elkem understands how important performance and processability is when producing high quality precision molded parts for the healthcare market. Liquid Silicone Rubbers (LSR) are typically used with injection molding processes, enabling consistent production of reproducible silicone parts with optimum quality, excellent process control and minimum cost.

Medical Grade Liquid Silicone Rubber applications include:

→ Valves
→ Seals & O-rings
→ Respiratory masks
→ Prosthetic liners

Elkem's product line includes :

→ Silbione™ LSR used in general Healthcare applications
→ Silbione™ Biomedical LSR M series used in Long Term Implantation
→ Silbione™ Biomedical LSR D series used in Drug Delivery Systems

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Silbione™ LSR used in general Healthcare applications

Our expanding Silbione™ LSR product line offers distinctive advantages for producing high quality precision molded parts for the healthcare market including easy processing, easy release and high-performance physical properties to improve part appearance, functionality, and productivity. These products can be considered for applications requiring implantation less than 30 days in the body.

	Silbione™ products	Shore A Hardness	Tensile Strength MPa / psi	Elongation %	Tear Strength kNm^{-1} / ppi	Density	Viscosity at 0.01 s^{-1}, Pa.s	Biocompatibility and regulatory support *
High performance, efficient processing LSRs	LSR 4301	1	1,9 / 270	1100	8 / 45	1,07	75	■
	LSR 4305	5	3,3 / 480	1050	11 / 65	1,07	70	■
	LSR 4310	10	5,8 / 850	1020	20 / 115	1,09	230	■
	LSR 4325	25	8,6 / 1250	970	32 / 180	1,11	600	■
	LSR 4330	30	9,2 / 1340	800	32 / 180	1,11	620	■
	LSR 4340 (HC)	40	8,5 / 1250	660	40 / 230	1,12	630	■
	LSR 4350 (HC)	50	8,4 / 1225	600	47 / 270	1,12	680	■
	LSR 4360	60	8,8 / 1275	480	42 / 240	1,12	770	■
	LSR 4370	70	8,9 / 1290	475	39 / 225	1,14	1000	■
Overmolding to silicone	LSR 60	59	9,1 / 1330	440	33 / 190	1,12	-	■

*Silbione™ grade materials have been tested for biocompatibility according to applicable ISO 10993 and/or USP Class VI standards
The typical properties listed above are not intended for use in preparing specifications. For test methods and specifications, please contact an Elkem representative.
User has sole responsibility to determine product suitability for intended uses and applications.

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Silbione™ Biomedical LSR M series used in Long Term Implantation

Silbione™ Biomedical Liquid Silicone Rubbers (LSR) are 2-component platinum-catalyzed silicone elastomers designed for liquid injection molding, compression molding, casting and sheeting manufacturing processes.
These products can be considered for applications requiring implantation for greater than 30 days in the body.

The biocompatibility of Silbione™ Biomedical grade silicones is tested according to ISO 10993/USP Class VI procedures, which include:

→ 12-week implant tests
→ Hemolysis
→ USP Intracutaneous Reactivity
→ USP Acute Systemic Toxicity
→ Cytotoxicity
→ Mutagenicity & pyrogenicity
→ Skin Sensitization
→ Tissue Irritation

Silbione™ medically implantable silicones are also given full Master-file Support through Device Master Access Files (MAF) at the FDA Center for Devices and Radiological Health (CDRH).

	Silbione™ Biomedical LSR series	Shore A Hardness	Tensile MPa / psi	Elongation %	Tear Strength kNm^{-1} / ppi	Density	Viscosity at 0.01 s^{-1}, Pa.s	Biocompatibility and regulatory support*
Very soft low durometer	LSR M301	01 (Sh00 35)	1,9 / 270	1100	8 / 45	1,07	55	■
	LSR M305	05 (Sh00 48)	3,3 / 480	1050	11 / 65	1,07	60	■
	LSR M310	10	5,8 / 850	1020	20 / 115	1,09	500	■
Mid durometer	LSR M325	23	8,6 / 1250	970	32 / 180	1,11	1000	■
	LSR M330	30	9,2 / 1340	800	32 / 185	1,11	1000	■
	LSR M340	40	8,6 / 1250	660	40 / 230	1,12	1000	■
	LSR M350	50	8,4 / 1225	600	47 / 270	1,12	1000	■
High durometer	LSR M360	60	8,8 / 1275	480	42 / 240	1,12	1000	■
	LSR M365	65	8,8 / 1270	470	43 / 250	1,14	1000	■
	LSR M370	70	8,6/ 1250	475	40 / 230	1,14	5000	■
Low consistency elastomers	LSR M125 10:1	28	5,3 / 770	480	13 / 70	1,08	85 & 2	■
	LSR M130 10:1	31	4,5 / 650	480	12 / 145	1,08	90 & 0,5	■
	LSR M140 10:1	40	6,7 / 975	350	24 / 76	1,09	100 & 0,3	■

All reported typical properties are press cured 5min at 177°C. Tests conducted on final product A+B.
* grade materials have been tested for biocompatibility according to applicable ISO 10993 and/or USP Class VI standards
The typical properties listed above are not intended for use in preparing specifications. For test methods and specifications, please contact an Elkem representative.
User has sole responsibility to determine product suitability for intended uses and applications.

Silbione™ Biomedical grade silicones meet the highest quality and manufacturing standards, complying with the Elkem Quality Management System. This includes:

→ Inhouse clean operation standards, applying the principles of Good Manufacturing Practices (GMP) for medical devices and ISO 14949 guidelines
→ Certified ISO 9001 Manufacturing Facilities
→ Certified ISO Class 8 Manufacturing Environments
→ Certified ISO Class 7 Packaging Environments
→ Application of the Responsible Care Management System®

Silbione™ Biomedical LSR D series used in Drug Eluting Systems

Available upon request
Please contact an Elkem representative

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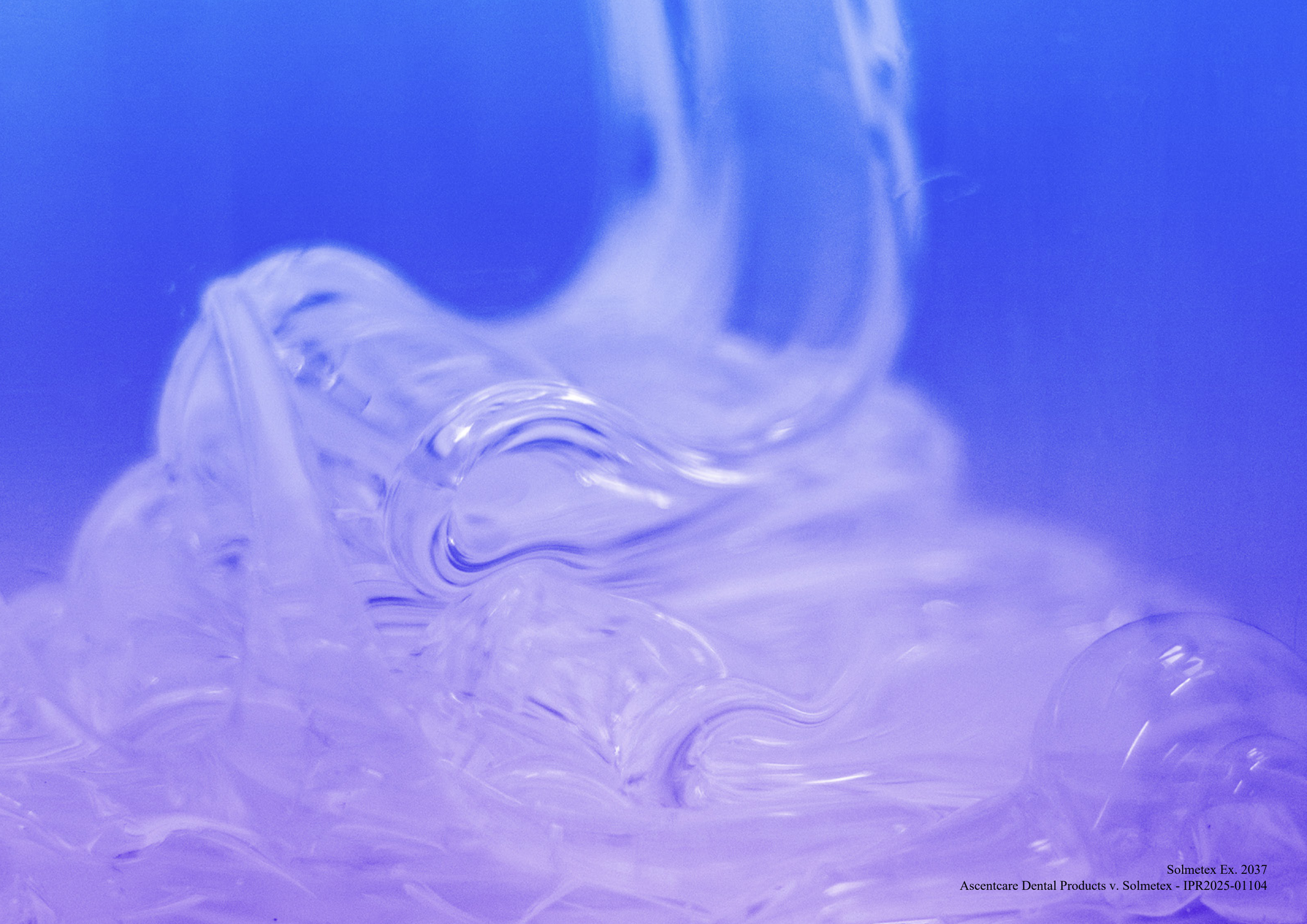

Elkem supports you

We focus on developing state-of-the-art application expertise to help our customers challenge their boundaries. At Elkem, we're more than just high quality silicone products.

We are dedicated people located around the globe committed to your success. From technical support to customized formulations and regulatory support, Elkem has the people in place when and where you need them.

Contact us

Elkem ASA

elkem.com

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