MOMENTIVE®
SOLUTIONS FOR A SUSTAINABLE WORLD™

SILICONES
FOR HEALTHCARE

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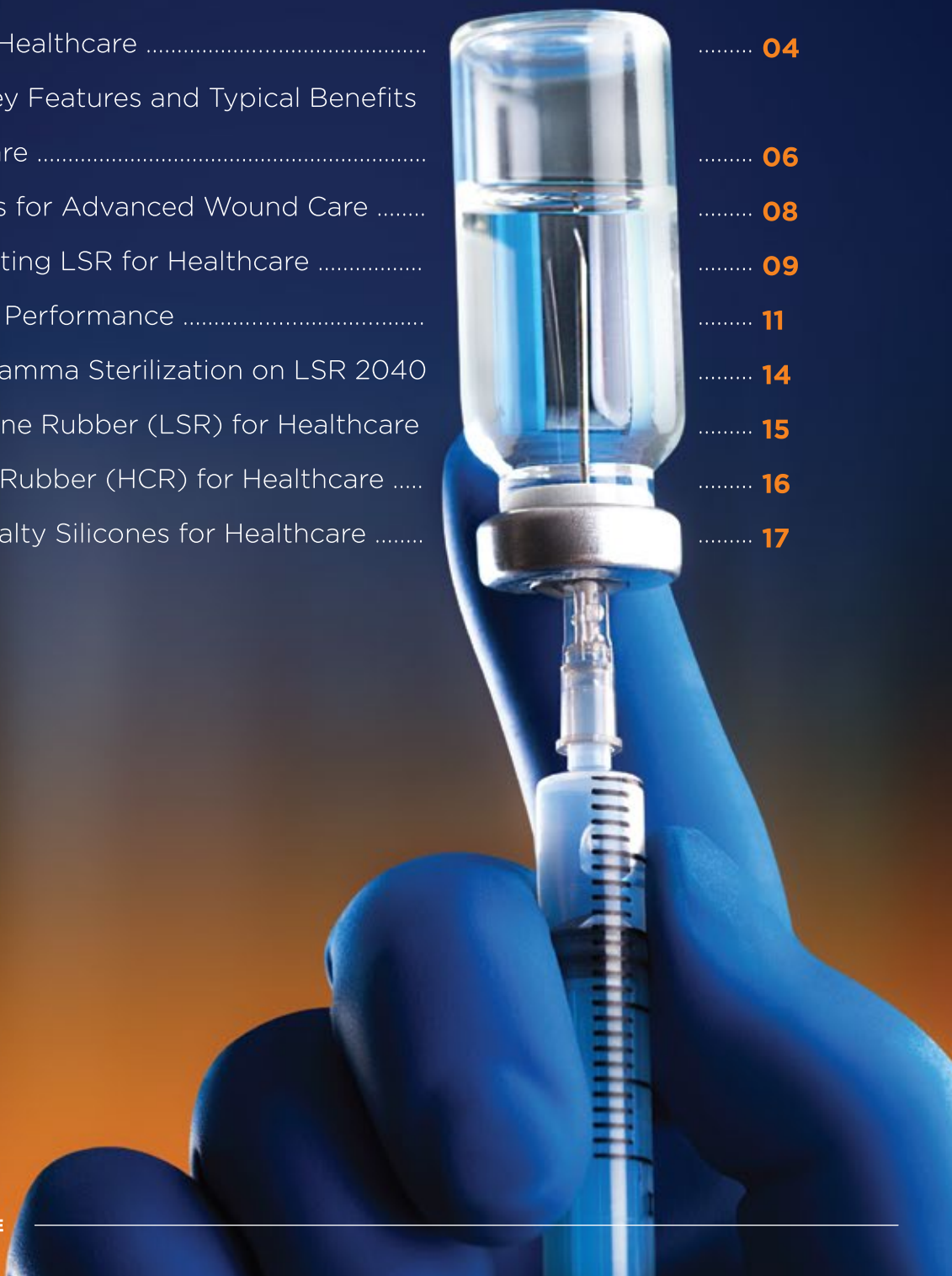


At Momentive we pride ourselves on creating solutions for a sustainable world

As a premier global high-performance silicones and specialties company, Momentive aims to create solutions that improve quality of life for people and enable a more sustainable future. Our products are the result of a tireless pursuit of progress where the sun never sets on our global marketing and R&D efforts, resulting in innovations that help propel our customers' businesses forward and positively impact all aspects of life – today, tomorrow, and into the future.

Silicones in Healthcare

01

Strong Solutions for Healthcare

Finely tuned formulations are nowhere more important than in healthcare applications. Momentive silicones elastomers can meet healthcare's rigorous challenges. We help medical manufacturers produce strong yet comfortable orthopedic devices, optically transparent yet flexible medical tubing, sterilization-tolerant yet durable dental and surgical devices.

From ease of processability in manufacturing to easy tolerance when in contact with the human body, Momentive silicones can meet the exacting demands of the healthcare industry. Our decades of biomedical collaboration have led to a range of products that have made new equipment possible and standard equipment work better.

Our breadth of experience ensures that wherever there is a need, we'll have the industry knowledge and expertise to help our customers meet it.

Exceptional Range

The exceptional performance properties of silicone elastomers – purity, clarity, strength, thermal stability – coupled with ease of processability, have allowed their use in a broad range of medical device applications.

Typical applications include, but are not limited to:

- Dental / surgical devices
- Diagnostics / imaging
- Fluid and drug delivery devices
- Orthopedics / prosthetics
- Advanced Wound Care & Scar Management
- Septa / stoppers / laboratory accessories
- Medical tubing
- Wound drains and bulbs
- Sterilization mats
- Pharmaceutical closures
- Instrument grips
- Positioning devices
- Catheters
- Seals / dialysis o-rings / valves
- Respiratory / anesthesia
- Medical equipment keypads

Whether it is self-bonding for two component molding, low hysteresis for improved pump life performance, the ability to withstand repeated sterilization, or radio-opaque materials to enable x-ray detection, Momentive has a product with the characteristics that can meet even the most challenging medical design requirements

Silicone's Key Features and Typical Benefits for Healthcare

02

Silicones:

Endure repeated sterilization. Medical devices that incorporate silicone maintain their performance characteristics after many rounds of sterilization with steam, ethylene oxide, gamma or e-beam radiation. Silicone's high thermal and chemical stability helps make this possible.

Offer biocompatibility. Silicones are generally compatible with both body fluids and medications and are skin friendly and atraumatic.

Innately create comfort and good ergonomics. Without plasticizers or other organic additives, silicones can provide elasticity, high friction, soft grip, minimal insertion force and smooth operation. They also possess neutral odor and taste.

Generate long service life. Silicones exhibit resiliency and recovery after puncture. They can reduce material fatigue and endure dynamic stress.

Comfort

Contributing to the comfort and care of patients, which has become an essential factor in device design, our low-durometer elastomers and visco-elastic gels can deliver enhanced cushioning and pressure care relief.

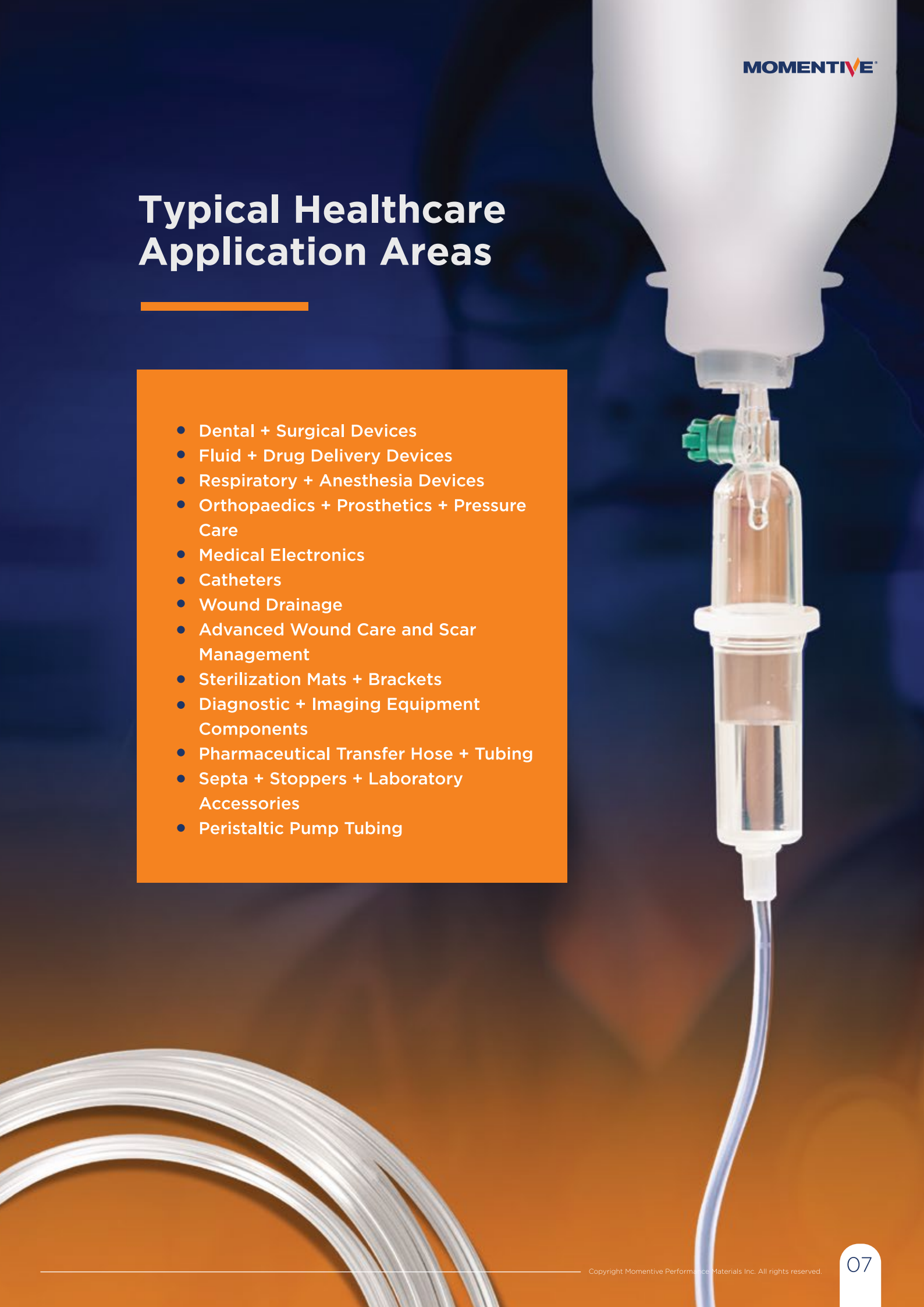
Biocompatibility

At Momentive, we offer a comprehensive portfolio of silicone products that are ISO 10993 and/or USP Class VI compliant.

Please refer pages 11-14 for more information

Typical Healthcare Application Areas

- Dental + Surgical Devices
- Fluid + Drug Delivery Devices
- Respiratory + Anesthesia Devices
- Orthopaedics + Prosthetics + Pressure Care
- Medical Electronics
- Catheters
- Wound Drainage
- Advanced Wound Care and Scar Management
- Sterilization Mats + Brackets
- Diagnostic + Imaging Equipment Components
- Pharmaceutical Transfer Hose + Tubing
- Septa + Stoppers + Laboratory Accessories
- Peristaltic Pump Tubing



Silicone Gels for Advanced Wound Care

03

Innovative Materials with the Patient in Mind

The health care industry is faced with a growing challenge of developing products that can improve patient care and adhere to the highest safety standards, while also contributing to cost- effective production. With our long history as a leading provider of silicones to the medical field, Momentive prides itself on the innovative material solutions we have created to help solve tough manufacturing challenges.

Equipped for both open and closed wound applications, Momentive's silicones for wound care combine atraumatic properties and high adhesion with biocompatibility to help improve production efficiencies.

Silicones Enable Advanced Wound Care

Momentive's Silopren™ silicone gel product family, with its inherent water vapor and gas permeability properties, promotes wound healing through improved moisture transport. Even when applied to the fragile skin of elderly and medically compromised patients, the Silopren silicone gel family enables both secure skin adhesion and atraumatic removal.

These properties make Silopren silicone gels an exceptional choice for patients requiring repeated wound care application and removal over the same area. Silopren silicone gel also enables easy repositioning of wound dressings.

The high tack of Silopren silicone gels facilitates the manufacture of wound care dressings at lower silicone coat weights, which can enable production efficiencies. The Silopren silicone gel product family for advanced wound care includes kit matched, addition-cure, solvent-free, and transparent two-component (1:1 mix ratio) silicone rubber gels that are compatible with most coating processes.

Self-Lubricating LSR for Healthcare

04

Productivity & Performance for Molded Parts

Momentive's family of liquid silicone rubber (LSR) materials enable health care device designers and equipment manufacturers to improve material functionality for critical applications such as needle-free access valves, o-rings, stoppers, seals and assembled parts. One especially significant advancement is our line of self-lubricating LSRs, which includes Silopren LSR 4655 SL.

Lubrication produces a high-slip surface (low coefficient of friction), which can improve mounting efficiency of molded parts during the assembly of medical devices. Traditional silicone molded parts cannot achieve high slip, leaving manufacturers to employ secondary lubrication processes.

Silopren LSR 4655 SL is a two-component, self- lubricating LSR for injection molding processes. Without the need for a secondary lubrication process, Silopren LSR 4655 SL can provide a lubricious surface on the molded part after vulcanization. The product's delayed lubricant surface bloom after vulcanization helps prevent mold fouling. It also helps improve part longevity, and reduce the occurrence of self-healing of slit valves.

Silopren LSR 4655 SL can be customized in a range of durometers and lubricant load levels to meet specific performance requirements.

Antimicrobial

The Benefits of Silver

Addressing the heightened concern over microbial contamination on critical medical device surfaces, our StatSil™ antimicrobial silicone elastomers can offer medical device designers an added layer of built-in protection, to help minimize microbial growth in or on the human body.

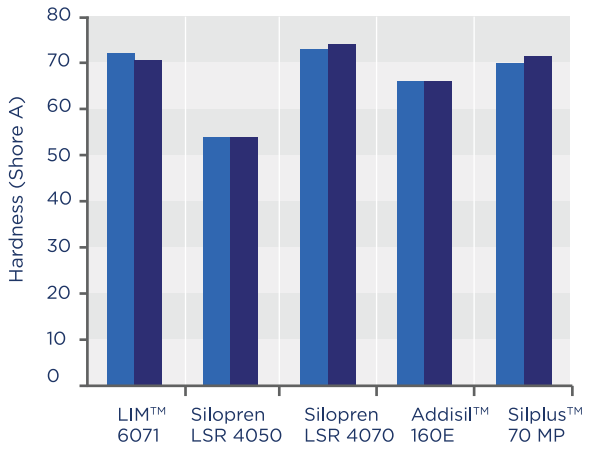
Sterilization Performance

05

The strength of the silicone-oxygen backbone leads to high thermal stability of silicone elastomers. Due to this property, silicone elastomers are excellent candidates for products and applications requiring sterilization, whether by steam autoclave, ETO, or gamma radiation. These charts depict the performance of a sampling of our products after exposure to sterilization.

Effects of ETO Sterilization

ETO Sterilization Resistance [1] Hardness



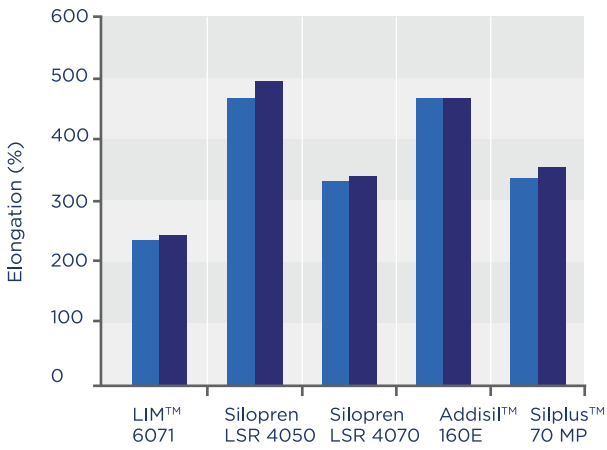
1 Exposure to ethylene oxide 30 minutes at 54,4 °C, 600 mg/l

Untreated ETO Treated

After ETO exposure, minor changes were measured vs. baseline values.

Note: Test data. Actual results may vary.

ETO Sterilization Resistance [1] Elongation

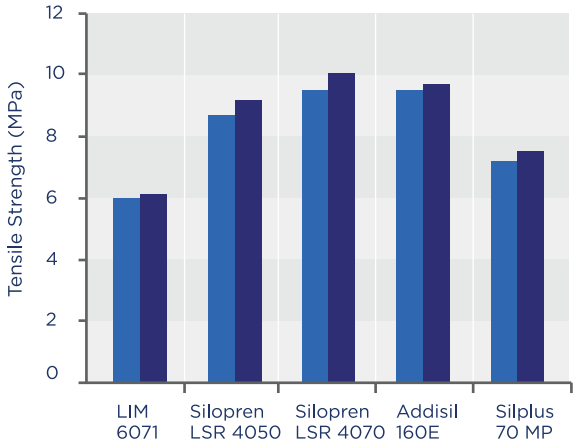


1 Exposure to ethylene oxide 30 minutes at 54,4 °C, 600 mg/l

Untreated ETO Treated

After ETO exposure, minor changes were measured vs. baseline values.

ETO Sterilization resistance [1] Tensile Strength



1 Exposure to ethylene oxide 30 minutes at 54,4 °C, 600 mg/l

Untreated ETO Treated

After ETO exposure, minor changes were measured vs. baseline values.

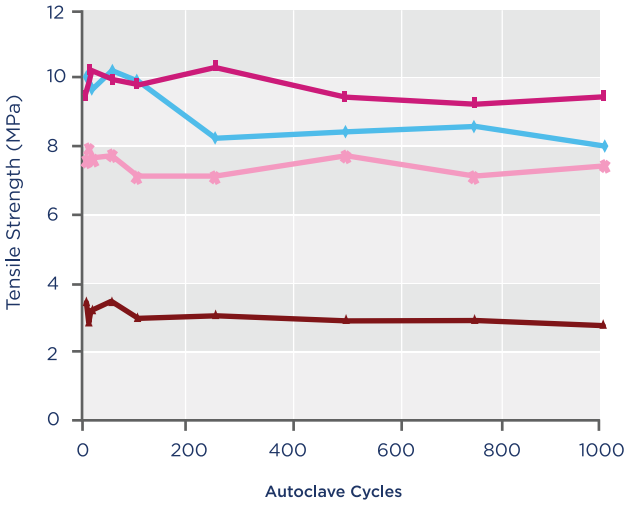
Note: Test data. Actual results may vary.

Conditions

ETO concentration	600 mg/L
ETO pressure	26.6 psia
Pre-humidification time at 60% RH	30 min
Pre-vacuum	1.5 psia
Chamber Temperature	54.4 ºC
Exposure Time	2 h
Post vacuum	1.45 psia
Air washes	3

Effects of Autoclave

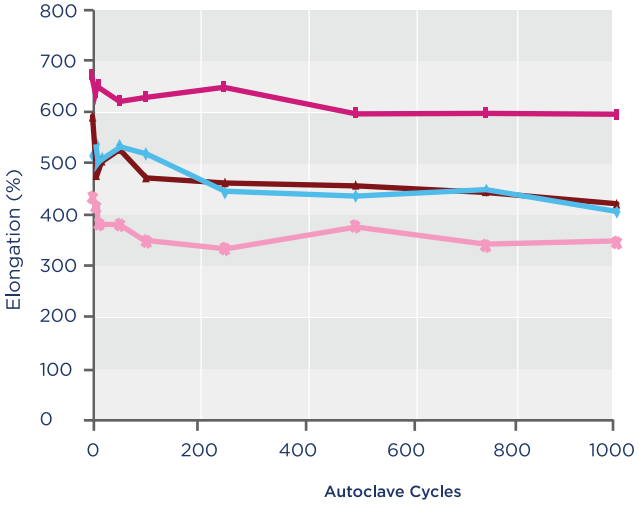
Sterilization resistance at 134 °C Tensile Strength - LSR



All grades show a stable performance in terms of tensile strength (initial fluctuations due to post curing effect).

- Silopren LSR 4070
- Silopren LSR 4050
- Silopren LSR 4040
- LIM 6010

Sterilization resistance at 134 °C Elongation - LSR



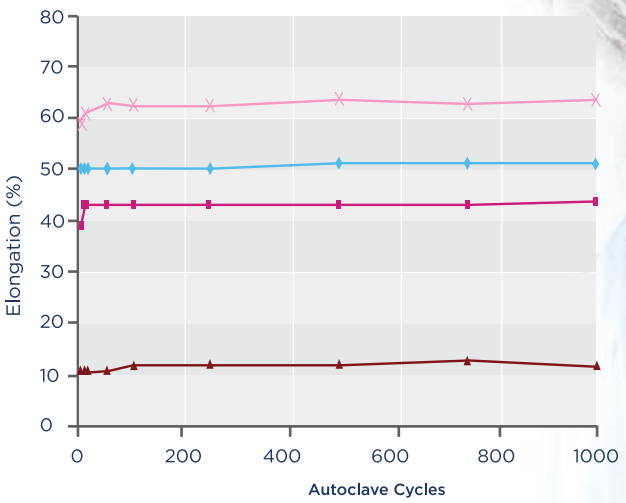
At 134 °C, a slight reduction of Elongation over time can be observed (initial fluctuations due to post curing effect).

- Silopren LSR 4070
- Silopren LSR 4050
- Silopren LSR 4040
- LIM 6010

Note: Test data. Actual results may vary.

*Trademark of Momentive Performance Materials Inc. or its affiliates.

Sterilization resistance at 134 °C Shore A Hardness - LSR

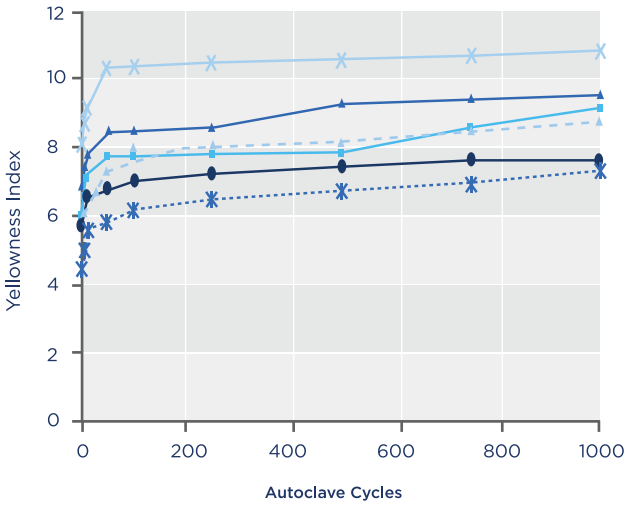


No significant impact on hardness, independent of hardness level.

Lab results. Actual results may vary.

- Silopren LSR 4070
- Silopren LSR 4050
- Silopren LSR 4040
- LIM 6010

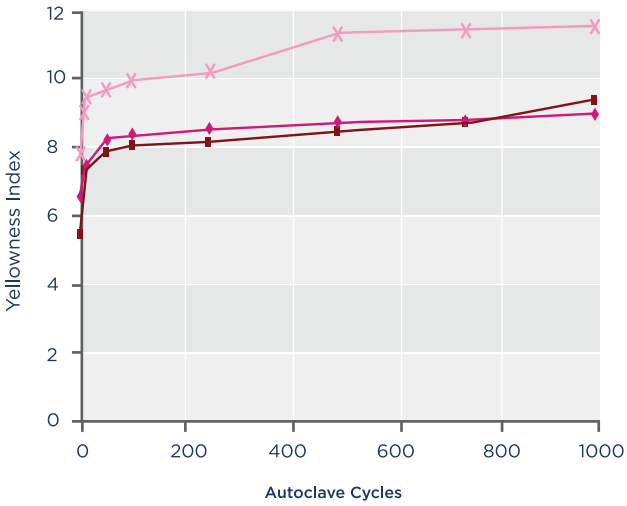
Sterilization resistance at 121 °C Yellowness Index - LSR



All grades show a stable performance in terms of tensile strength (initial fluctuations due to post curing effect).

- Silopren LSR 4070
- Silppren LSR 2070 Top Coat
- Silopren LSR 4050
- Silopren LSR 4040
- LSR 4040 Blue
- LIM 6010

Sterilization resistance at 134 °C Yellowness Index - LSR



In most cases yellowing will occur during the first 100 cycles, independent of grades used. Yellowing at 134 °C is slightly higher compared to sterilization at 121 °C.

- Silopren LSR 4070
- Silopren LSR 4040
- LIM 6010

Note: Test data. Actual results may vary.

*Trademark of Momentive Performance Materials Inc. or its affiliates.

Effects of Gamma Sterilization on LSR 2040

06

General Information

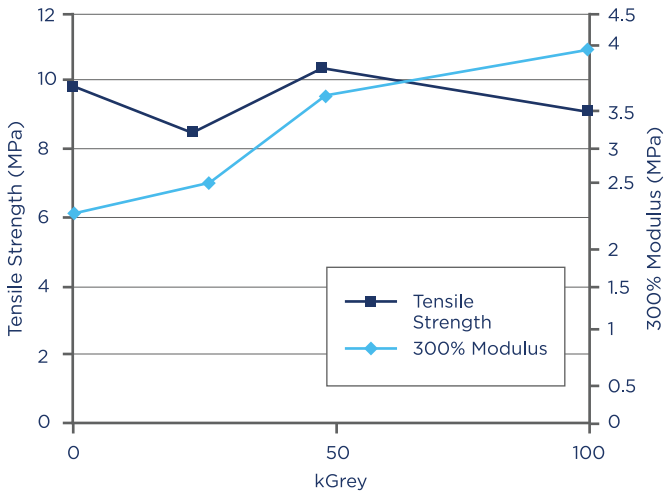
- Generally recommended for one time pre-use sterilization of disposables
- Gamma radiation has become a viable alternative to ethylene oxide sterilization. Cleaner, leaves no residue
- Packaged products can be sterilized using gamma radiation
- Gamma radiation also offers significant improvements in cycle time & inventory cost
- Radiation level and number of exposures depends on the customer requirements, the product and the end user operating practices

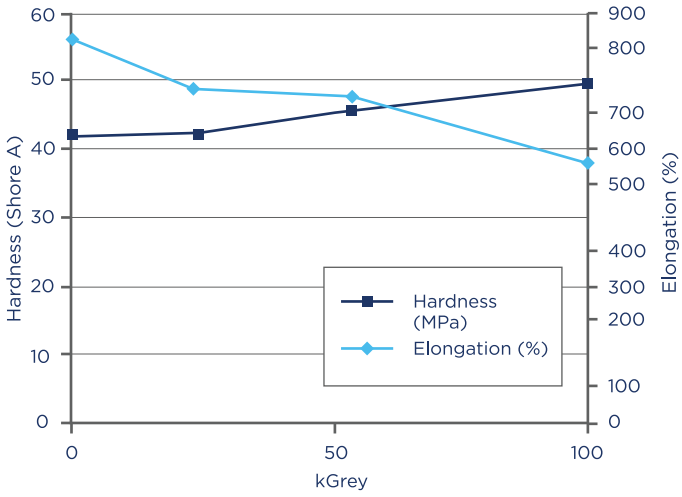
Test conditions:

- Radiation dosage 2,5 Mrad or 25 kGray
- Test results of 1- 4 times of typical dosage

Sterilization resistance Silopren LSR 2040

Gamma Radiation





Minor impact after commonly used dosage of Gamma radiation (25 kGray).
Properties after four gamma sterilization cycles still sufficient.

Lab results. Actual results may vary

Liquid Silicone Rubber (LSR) for Healthcare

07

Product Name	USP Class VI [a]	ISO10993 [b]	European Pharmacopoeia [c]	Appearance	Density g/cm³	Hardness/Durometer Shore A	Tensile Strength MPa	Elongation %	Tear Strength, Die B N/mm	Compression Set % (post cured)
Healthcare										
Silopren LSR 4020	●	●	-	Translucent	1.08	22	7.0	1000	15	20
Silopren LSR 4030	●	●	●	Translucent	1.10	31	8.0	800	18	15
Silopren LSR 4040	●	●	●	Translucent	1.12	40	9.0	750	25	25
Silopren LSR 4050	●	●	●	Translucent	1.12	51	10.0	600	35	25
Silopren LSR 4060	●	●	●	Translucent	1.13	60	10.0	450	30	25
Silopren LSR 4070	●	●	●	Translucent	1.14	70	9.0	400	20	25
Silopren LSR 4080	●	●	●	Translucent	1.13	79	7.0	150	5	25
Fast Cure/High Tear										
Silopren LSR 4640	●	●	-	Translucent	1.12	42	8.0	600	45	25
Silopren LSR 4650	●	●	-	Translucent	1.12	52	10.0	550	50	25
Silopren LSR 4660	●	●	-	Translucent	1.13	62	9.0	400	45	20
Silopren LSR 4670	●	●	-	Translucent	1.13	69	10.0	350	30	20
LIM 6010	●	●	-	Translucent	1.05	15	3.0	440	10	-
LIM 6030	●	●	-	Translucent	1.12	35	9.0	675	31	-
LIM 6040	●	●	-	Translucent	1.12	42	9.0	600	39	-
LIM 6045	●	●	-	Translucent	1.12	44	9.0	650	39	-
LIM 6050	●	●	-	Translucent	1.12	53	9.0	530	43	-
UV LSR										
Silopren UV LSR 4030	●	●	-	Translucent	1.10	28	8.0	750	20	-
Silopren UV LSR 4060	●	●	-	Translucent	1.15	59	13.0	500	25	-
Self-Lubricating										
Silopren LSR 4625 SL	▲	▲	-	Translucent	1.09	25	6.6	758	24	-
Silopren LSR 4635 SL	▲	▲	-	Translucent	1.10	35	7.3	627	40	-
Silopren LSR 4645 SL	▲	▲	-	Translucent	1.12	45	8.0	517	50	-
Silopren LSR 4655 SL	●	●	-	Translucent	1.13	55	8.0	450	45	-
Silopren LSR 4665 SL	▲	▲	-	Translucent	1.13	65	9.1	412	30	-
Self-Bonding to PC, PBT and copolyesters										
Silopren LSR 4739	●	●	-	Translucent	1.1	30	8.0	700	40	-
Silopren LSR 4749	●	●	-	Translucent	1.1	41	7.0	570	40	-
Silopren LSR 4759	▲	▲	-	Translucent	1.11	51	7.0	400	40	-
Silopren LSR 4769	▲	▲	-	Translucent	1.14	61	9.0	500	43	-
Self-Bonding to other substrates										
LIM 8040	●	-	-	Translucent	1.08	43	5.0	390	37	-
CLS 8150	●	●	-	Translucent	1.10	52	8.0	515	34	-
CLS 5000	●	●	-	Translucent	1.12	67	11.0	460	44	-
CLS 3060	●	●	-	Translucent	1.12	59	11.0	500	35	-
Radio Opaque (X-Ray Detectability)										
LIM 6041	●	-	-	White	1.19	45	7.0	700	32	-
Antimicrobial										
StatSil LSR	Momentive's StatSil technology can be added to our LSR as a custom compound									

Typical properties are average data and are not to be used as or to develop specifications.

Heat Cured Rubber (HCR) for Healthcare

08

Product Name	USP Class VI [a]	ISO10993 [b]	European Pharmacopoeia [c]	Appearance	Density g/cm³	Hardness/Durometer Shore A	Tensile Strength MPa	Elongation %	Tear Strength, Die B N/mm
Addisil Extrusion									
140 E	●	●	●	Translucent	1.15	45	10.0	700	35
150 E	●*	●*	●	Translucent	1.15	52	10.0	650	36
160 E	●	●	●	Translucent	1.16	61	10.5	530	32
170 E	●	●	●	Translucent	1.20	71	9.5	470	32
440 E/442 E	●	●	-	Translucent	1.13	40	11.5	800	35
450 E/452 E	▲	●	-	Translucent	1.14	50	11.5	800	43
460 E/462 E	▲	●	●/▲	Translucent	1.14	60	11.0	600	37
470 E/472 E	▲	●	●/▲	Translucent	1.17	72	10.5	500	41
480 E/482 E	▲	●	-	Translucent	1.19	81	9.0	400	30
NC452E	●	●	-	Translucent	1.13	50	10	750	35
NC462E	●	●	-	Translucent	1.15	60	10	550	35
NC472E	●	●	-	Translucent	1.18	70	10	450	35
NC482E	●	●	-	Translucent	1.20	80	8.5	450	15
Tufel II Low Volatile Extrusion or Molding									
9420X	●	-	-	Translucent	1.07	22	8.2	1000	22
9430X	●	-	-	Translucent	1.10	28	9.3	1050	30
9440X	●	-	-	Translucent	1.11	43	9.6	780	40
9450X	●	-	-	Translucent	1.15	52	9.7	880	47
9460X	●	-	-	Translucent	1.19	62	8.6	690	46
9470X	●	-	-	Translucent	1.22	72	9.2	580	57
Tufel III Low Hysteresis/ High Resilience									
92506	●	●	-	Translucent	1.12	50	7.6	500	18
92656	●	●	-	Translucent	1.14	65	8.9	350	21
UV Extrusion									
Addisil UV 460 EX	●	●	-	Translucent	1.17	60	10.5	580	47
Radio Opaque (X-Ray Detectability)									
Addisil 60 X-Ray Detectability	▲	▲	-	White	1.27	60	9	600	35
Antimicrobial									
StatSil HCR	Momentive's Statsil can be added to our HCRs as a custom compound								

NC4X2E Series - APAC ONLY

The aforementioned test results are average data derived from a sampling of a finite number of lots of material. While lot-to-lot variance would not be expected to show significantly different results, these average data are not to be used as or to develop product specifications. It is the user's sole responsibility to determine the suitability and safety of any Momentive material in its end use application.

All LSR grades are platinum cured materials. The mixing ratio is 1:1 by weight, except for the UV-curing LSR the mixing ratio is 100:2.
Laboratory Vulcanization Conditions: exposure to a Hg-(Fe-doped) middle pressure lamp for 2 min at 80 mW/cm2 intensity, without further heat curing

a Based upon USP Class VI testing, on a representative sample of the product, for intramuscular implantation, intracutaneous injection and systemic injection. For some products, additional testing has been conducted. Please contact the Product Regulatory Group for details.
b Based upon ISO 10993 part 6, 10, and 11 testing conducted on a representative sample of the product. For some products additional testing has been conducted. Please contact the Product Regulatory Group for details.
c Based on testing conducted on a representative sample of a single lot of the product as per the test requirements of EP. 3.1.9.• = Meets the requirements for passing the test standard, + = Product is compositionally compliant, - = Not tested. ▲= a representative sample analogous to this grade has been tested.

*Testing in progress, final results pending.

Additional information may be contained on the technical datasheet. For custom opportunities, please contact your local Momentive sales representative.
*Trademark of Momentive Performance Materials Inc. or its affiliates.

09

Other Specialty Silicones for Healthcare

Product Name	USP Class VI [a]	ISO10993 [b]	European Pharmacopoeia [c]	Appearance	Density g/cm³	Hardness/Durometer Shore A	Tensile Strength MPa	Elongation %	Tear Strength, Die B N/mm	Compression Set % (post cured)
Soft Touch LSRs										
LSR 2003	•	•	-	Translucent	1.05	<8	3.0	500	4	20
LSR 2010	•	•	-	Translucent	1.07	8	3.0	970	6	15

Product Name	USP Class VI [a]	ISO10993 [b]	Description	Density g/cm³	Hardness/ Durometer Shore A	Tensile Strength MPa	Elongation %
Silicone Adhesives and Encapsulants							
RTV108	•	•	1-part acetoxy, translucent, paste adhesive	1.05	30	2.7	450
RTV118	•	-	1-part acetoxy, translucent, flowable adhesive	1.05	25	2.3	325
RTV615	•	-	2-part, heat cured, flowable encapsulant	1.02	44	6.3	120

Product Name	USP Class VI [a]	ISO10993 [b]	Viscosity	Working time at23 °C[1]	Penetration[2]	Peel Force on Bristol Paper[3]
Silicones for Advanced Wound Care and Scar Therapy						
Silopren Gel 4900 – Scar Gel	•	•	A-Component 950 mPas at 20°C B-Component 650 mPas at 20°C	180 min	95 mm/10	0.9 N/25 mm
Silopren Gel 4950 – Wound Gel	•	•	A-Component 10,000 mPas at 20°C B-Component 9,000 mPas at 20°C	180 min	135 mm/10	1.7 N/25 mm
Silopren Gel 4970 - Wound Gel	•*	•*	A-Component 35,000 mPas at 20°C B-Component 27,000 mPas at 20°C	100 min	195 mm/10	3.4 N/25 mm

All Gels tested for the below:
Cytotoxicity: Agar Diffusion (ISO 10993-5), MEM Elution (ISO 10993-5)
USP Class VI & ISO 10993 (6, 10, & 11): Systemic toxicity, Intracutaneous toxicity, implantation (14 days)
Clinical Testing: HRIPT (Human Repeat Insult Patch Test), CIT (Cumulative Irritation Test) (14 days)

1. Each 10 degree increase in ambient temperature reduces the working time approximately by half.
2. Cured for 60 minutes at 110°C; hollow cone; 62.5 gr, 60 sec
3. Internal test method: 180° Peel-off test; Bristol paper as substrate;thickness ca. 150Qm.

Typical properties are average data and are not to be used as or to develop specifications.

*Testing in progress, final results pending.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Notes:

MOMENTIVE®
SOLUTIONS FOR A SUSTAINABLE WORLD™

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Disclaimer

Learn more about Momentive's silicone solutions for healthcare.