

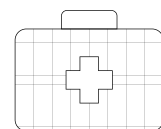
Medical Grade High Consistency Rubber (HCR) for Healthcare applications

Elkem Silicones understands the importance of durability and processability when producing parts for the healthcare market. Silbione™ High Consistency Rubbers (HCR) are designed for high strength molding and extrusion processes.

Our expanding Silbione™ product line offers advantages for producing high quality parts for the healthcare market including easy milling and extrusion, good clarity, high mechanical strength, temperature resistance and high-performance physical properties.

Elkem's product line includes :

- Silbione™ HCR used in general Healthcare applications
- Silbione™ Biomedical HCR M series used in Long Term Implantation
- Silbione™ Biomedical HCR D series used in Drug Deluting Systems



Medical Grade High Consistency Rubbers applications include:

- Catheters
- Balloons
- Pharmaceutical tubing
- Peristaltic pump tubing

Silbione™ HCR used in general Healthcare applications

Thanks to their excellent mechanical characteristics, Silbione™ HCR are used in a variety of medical device applications, including catheters, extruded tubing, balloons or needle entry ports.

	Silbione™ products	Shore A Hardness	Tensile Strength MPa / psi	Elongation %	Tear Strength kNm ⁻¹ / ppi	Density	Appearance	Biocompatibility support *
Platinum curing 2K, Extrusion, High performance	HCRA 4520	20	8,6 / 1250	1000	39 / 225	1,11	Clear	■
	HCRA 4530	30	11,7 / 1700	1000	44 / 250	1,12	Clear	■
	HCRA 4540	40	11,4 / 1650	975	44 / 250	1,13	Clear	■
	HCRA 4550	50	11,4 / 1650	950	52 / 300	1,14	Clear	■
	HCRA 4560	60	10,7 / 1550	775	46 / 265	1,15	Clear	■
	HCRA 4565	65	10,3 / 1500	725	44 / 250	1,17	Clear	■
	HCRA 4570	70	10,0 / 1450	700	41 / 235	1,18	Clear	■
	HCRA 4580	80	8,6 / 1250	650	39 / 225	1,20	Clear	■
Platinum curing 2K, Extrusion, general purpose	HCRA 4250	50	8,2 / 1200	400	21 / 120	1,14	Hazy	■
	HCRA 4265	65	8,8 / 1275	600	30 / 170	1,16	Hazy	■
Peroxide curing**	HCRU 4440	48	> 8,5 / >1160	> 450	>25 / > 142	1,10	Clear	■
	HCRU 4460	62	> 8,5 / >1160	> 360	> 28 / > 160	1,15	Clear	■
	HCRU 4470	70	> 8,5 / >1160	> 330	> 30 / > 170	1,18	Clear	■

*Silbione™ grade materials have been tested for biocompatibility according to applicable ISO 10993 and/or USP Class VI standards

**HCRU is an uncatalyzed base: typical properties were achieved with the addition of a peroxide catalyst.

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 HCR M series used in Long Term Implantation

Silbione™ Biomedical High Consistency Rubbers (HCR) are 2-component platinum-catalyzed heat cure rubber designed for compression moulding and extrusion processes.

These products are designed to be used in 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 HCRA Series	Shore A Hardness	Tensile Strength MPa / psi	Elongation %	Tear Strength kNm ⁻¹ / psi
HCRA M520	20	8,6 / 1250	1000	39.4 / 225
HCRA M530	30	11,7 / 1700	1000	43.8 / 250
HCRA M540	40	11,4 / 1650	975	43.8 / 250
HCRA M550	50	11,4 / 1650	950	52.5 / 300
HCRA M560	60	10,7 / 1550	775	46.4 / 265
HCRA M565	65	10,3 / 1500	725	43.8 / 250
HCRA M570	70	10,3 / 1500	700	41.2 / 235
HCRA M580	80	8,6 / 1250	650	39.4 / 225

Density	Room temperature pot life	Appearance	Biocompatibility support *
1,11	≥ 2hr	Clear	■
1,12	≥ 3hr	Clear	■
1,13	≥ 4hr	Clear	■
1,14	≥ 4hr	Clear	■
1,15	≥ 4hr	Clear	■
1,17	≥ 4hr	Clear	■
1,18	≥ 4hr	Clear	■
1,20	≥ 4hr	Clear	■

*Silbione™ grade materials have been tested for biocompatibility according to applicable ISO 10993 and/or USP Class VI standards

All reported typical properties are press cured 15 min at 177°C using a cold mold. Tests conducted on final product A+B. The typical properties listed above are not intended for use in preparing specifications for any particular application. User has sole responsibility to determine product suitability for intended uses and applications. Customized grades, including those with Barium Sulfate (BaSO4), may be available upon request. Silbione™ is a registered trademark of Elkem Silicones.

Silbione™ Biomedical grade silicones meet the highest quality and manufacturing standards, complying with the Elkem Silicones 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 HCR D series used in Drug Eluting Systems

Available upon request
Please contact an Elkem representative

For detailed commercial contacts please visit our website: elkem.com

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