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potential

Silbione

# Silbione™ Biomedical

Heat Cure Rubber for Implantables

# Silbione™ Biomedical HCR elastomers

Silbione™ Biomedical High Consistency Rubbers (HCRs) 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.

Silbione™ Biomedical HCRA Series	Durometer ShA	Tensile Mpa - psi	Elongation %	Tear Strength kN/m - ppi	Density	Room Temperature Pot Life	Appearance
HCRA M520	20	8.6 - 1250	1000	39.4 - 225	1.11	≥ 2hr	Clear
HCRA M530	30	11.7 - 1700	1000	43.8 - 250	1.12	≥ 3hr	Clear
HCRA M540	40	11.4 - 1650	975	43.8 - 250	1.13	≥ 4hr	Clear
HCRA M550	50	11.4 - 1650	950	52.5 - 300	1.14	≥ 4hr	Clear
HCRA M560	60	10.7 - 1550	775	46.4 - 265	1.15	≥ 4hr	Clear
HCRA M565	65	10.3 - 1500	725	43.8 - 250	1.17	≥ 4hr	Clear
HCRA M570	70	10.3 - 1500	700	41.2 - 235	1.18	≥ 4hr	Clear
HCRA M580	80	8.6 - 1250	650	39.4 - 225	1.12	≥ 4hr	Clear



↑ Catheters



↑ Active Implantable Devices

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 (BaSO<sub>4</sub>), may be available upon request. Silbione™ is a registered trademark of Elkem Silicones.

## Quality and Manufacturing Standards

- Silbione Biomedical grade materials are produced following the principles of GMP and tested in accordance ISO 14949 guidelines
- Certified ISO Class 8 manufacturing environment and ISO Class 7 packaging environment
- Certified ISO 9001 manufacturing facility

## Biocompatibility and Regulatory support

- Tested in accordance with ISO 10993 and USP Class VI
- Attestations and Toxicological Summaries available
- Master Access File (MAF) with FDA CRDH

## Research and Development

The Silbione™ Biomedical HCRA M500 series was developed by our elastomer formulation experts and validated by our service technicians using industry leading extrusion equipment.



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