

WACKER

CREATING TOMORROW'S SOLUTIONS

HEALTHCARE | PROSTHETICS | ORTHOPEDICS

SILICONES FOR PROSTHETIC AND ORTHOPEDIC APPLICATIONS

QUALITY AND SAFETY FOR EXACTING MEDICAL DEMANDS

Whatever challenges arise in the future, silicone rubbers from WACKER provide futureproof solutions that satisfy even the most exacting of demands.

The average age of the population is increasing steadily. As more and more people gain access to modern health-care, statutory requirements for medical products and services are becoming stricter.

As Fascinatingly Versatile as the Human Body

The human body is a wonderful work of art and highly complex piece of engineering. When it is necessary to provide support or artificial replacements for particular physical functions, or to promote healing, WACKER provides an impressive, customized range of silicone products and related services.

All products in the medical silicone sector have one thing in common – they come into intimate contact with the human body, where they enhance quality of life by providing support in terms of functionality and aesthetics. That is why the silicone materials used must satisfy such rigorous demands.

As a result, the healthcare industry faces ever-increasing demands with regard to the safety and efficiency of its products and solutions. WACKER's role in this trend is to provide futureproof, pure silicone grades tailored to the most rigorous of medical demands – demands that meet the ever-higher safety standards encountered in state-of-the-art medical technology.

WACKER is a European pioneer in the field of silicone chemistry. As such, its strength lies not only in its unique expertise and future-oriented research, but also in its integrated raw-material system. Combined with its innovative WACKER CLEAN OPERATIONS production standard, WACKER guarantees verified quality and purity that can be traced from the end product back to the raw-material source.

WACKER silicone rubbers face up to this challenge.

They are highly compatible and extremely reliable. Our product range is impressive thanks to its remarkable array of

applications. Individual service and personalized consultancy also play an important role at WACKER.



INNOVATIVE SOLUTIONS FOR ORTHOPEDICS & PROSTHETICS

When it comes to matters of human health and when certain physical functions need to be relieved or replaced, it is essential that the materials employed meet the highest quality requirements. High-purity silicones absolutely make the grade and therefore play a key part in medicine and medical technology.

WACKER RTV-2 Systems Make All the Difference

WACKER supplies room-temperature-curing (RTV) ELASTOSIL® P and SILPURAN® brand silicone rubber grades designed to meet specific prosthetic and orthopedic demands.



The addition-curing products are formulated as two-component systems: A and B. The platinum catalyst is separate from the curing agent. Once components A and B have been mixed, the mixture cures to an elastomer even at room temperature.

Curing can be accelerated considerably by increasing the temperature to a range of 70 °C to 130 °C.

Notable characteristics of WACKER's RTV-2 silicone rubbers are their low viscosity and hence excellent pourability. Not only does the hardness of the cured rubber range greatly (Shore 00 to Shore A), but its consistency can be varied from low viscosity to spreadable. The pot lives and curing times of our ELASTOSIL® P and SILPURAN® grades are adjustable, making these rubbers suitable for most standard manufacturing processes.

They can be applied in a number of ways, such as potting, brushing and dip-coating.

WACKER has a specialty RTV-1 bonding product – SILPURAN® 4200 – for medical applications.



Safe Application Characteristics

- Biocompatibility
- Biodurability: low surface tension, along with thermal and chemical stability
- Good resistance to a large number of solvents and chemicals
- No organic plasticizers involved
- Sterilizable for single and repeated use (sterilizable with steam, ethylene oxide, electron beams and γ-rays)
- The excellent mechanical properties are highly resistant to aging, weathering, extreme temperatures and radiation
- High transparency
- Silicones do not support microbial growth (due to their hydrophobicity)
- Easy processing due to low viscosity and good mixing characteristics
- Addition-curing RTV-2 systems do not release any by-products on curing
- Broad hardness range
- High degree of comfort for wearer; breathability

Silicones for Prosthetics: Performance That Fits Like a Glove

Prosthetics is a highly sensitive area. WACKER's RTV-2 silicone rubbers have an extraordinary property profile that makes them the perfect choice for producing aesthetic and functional prostheses for fingers, hands and partial-foot designs, as well as for orthoses, epitheses and external mammary prostheses.

Silicones are used in a range of prosthetic applications, including: functional prostheses for fingers, hands and partial-foot designs; orthoses; epitheses; external mammary prostheses; liners; and face masks tailored to fit the wearer perfectly.



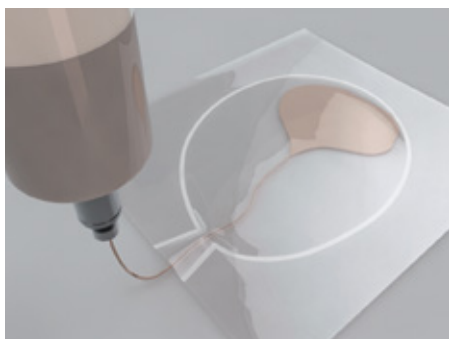
Purity Meets Peak Performance Silicone Rubber for Orthopedics

Orthopedic products must be able to damp a considerable amount of shock or vibration, and to apply gentle, comfortable compression. This is where ELASTOSIL® P and SILPURAN® silicone elastomers come into play, as they give manufacturers of

orthopedic devices a comprehensive portfolio of products and services. WACKER silicone rubbers are the product of choice for truss pads, orthotic devices, liners and other orthopedic products.



ELASTOSIL® – Production Process Used by Prosthetic Sector



Step 1

- A mammary prosthesis mold consists of a thin shell (e.g. PUR) filled with ELASTOSIL® silicone gel
- The use of thermoplastic shell material makes it possible to shape prostheses individually



Step 2

- The shell is filled with ELASTOSIL® gel
- The shape of the prosthesis is set using a negative mold



Step 3

- ELASTOSIL® gel begins curing at room temperature
- The process can be accelerated by heat input (approx. 70 °C to 130 °C)
- The prosthesis is then demolded and assembled

ELASTOSIL® RTV-2 Silicone Rubber Grades for the Prosthetic Industry

	Mixing ratio	Viscosity A	Viscosity B	Final hardness Shore A ISO 868	Final hardness Shore 00 ASTM 2240	Tensile strength ISO 37	Elongation at break ISO 37	Tear resistance ASTM D 624 B
Description	A : B	[mPa·s]	[mPa·s]			[N/mm ²]	[%]	[N/mm]
ELASTOSIL® P 7600	1:1	4,000	2,000	< 0	28	1.2	650	3
ELASTOSIL® P 7670	1:1	1,800	1,800	7	55	1.9	580	3
ELASTOSIL® P 7671	1:1	1,500	1,800	< 0	21	0.5	400	2
ELASTOSIL® P 7676	1:1	1,300	900	< 0	15	0.8	700	2
ELASTOSIL® P 7683/25	1:1	1,200	3,500	< 0	25	1.5	650	5
ELASTOSIL® P 7683/47	1:1	1,700	1,500	7	47	2.6	450	8
ELASTOSIL® P 7684/40	1:1	1,500	2,300	< 0	40	2.2	670	8
ELASTOSIL® P 7684/60	1:1	1,400	2,600	12	60	3.8	650	13
ELASTOSIL® PK 16	1:1	1,700	2,700	< 0	20	1.2	850	4

These figures are intended as a guide and should not be used in preparing specifications.

ELASTOSIL® RTV-2 Silicone Gels for External Mammary Prosthetics

	Mixing ratio	Viscosity A	Viscosity B	Pot life at 23 °C	Gel time at 70 °C	Penetration, hollow cone 62.5 g for 5 s
Description	A : B	[mPa·s]	[mPa·s]	[h]	[min]	[1 / 10 mm]
ELASTOSIL® P 7616-160	1:1	350	1,400	> 6	22	160
ELASTOSIL® P 7616-195	1:1	350	1,200	> 4	12	195
ELASTOSIL® P 7618	1:1	50	300	> 6	15	220
ELASTOSIL® P 7619	2:1	100	1,250	> 6	22	200
ELASTOSIL® P 7630	1:1	8,000	8,000	0.5	3	220 (density 0.62 g/cm ³)
ELASTOSIL® P 7636	1:1	8,000	8,000	4	10	258 (density 0.76 g/cm ³)

These figures are intended as a guide and should not be used in preparing specifications.

ELASTOSIL® RTV-2 Silicone Gel for Anti-Decubitus Applications

	Mixing ratio	Viscosity A	Viscosity B	Pot life at 23 °C	Penetration, hollow cone 62.5 g for 5 s
Description	A : B	[mPa·s]	[mPa·s]	[min]	[1 / 10 mm]
ELASTOSIL® P 26028 VP	1:1	100	2,000	9	150

These figures are intended as a guide and should not be used in preparing specifications.

SILPURAN® RTV-1 Silicone Medical Adhesive

	Viscosity D = 10 s ⁻¹	Final hardness Shore A ISO 868	Tensile strength ISO 37	Elongation at break ISO 37	Tear resistance ASTM D 624 B
Description	[mPa·s]		[N/mm ²]	[%]	[N/mm]
SILPURAN® 4200	200,000	35	5.5	300	10

These figures are intended as a guide and should not be used in preparing specifications.

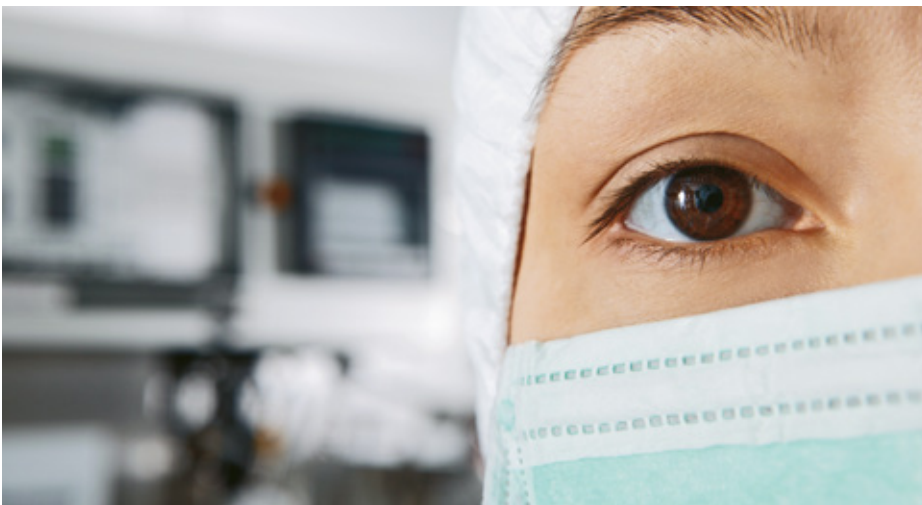
SILPURAN® RTV-2 Silicone Rubber Grades for the Orthopedic Industry

	Mixing ratio	Viscosity A D = 10 s ⁻¹	Viscosity B D = 10 s ⁻¹	Final hardness Shore A ISO 868	Final hardness Shore 00 ASTM 2240	Tensile strength ISO 37	Elongation at break ISO 37	Tear resistance ASTM D 624 B
Description	A : B	[mPa·s]	[mPa·s]			[N/mm ²]	[%]	[N/mm]
SILPURAN® 2400	1:1	1,800	1,800	7	55	2.0	600	3
SILPURAN® 2400/25	1:1	3,300	2,000	< 0	25	1.3	700	3
SILPURAN® 2420	1:1	2,500	3,500	12	60	4.0	650	14
SILPURAN® 2430	1:1	8,000	10,000	20	–	6.0	540	23
SILPURAN® 2440	1:1	15,000	10,000	35	–	7.0	400	25
SILPURAN® 2445	1:1	10,000	10,000	40	–	7.0	400	18
SILPURAN® 2450	1:1	35,000	20,000	54	–	7.0	230	14

These figures are intended as a guide and should not be used in preparing specifications.



SILPURAN® – INNOVATION FOR MEDICINE AND HEALTH



WACKER silicones meet the modern orthopedic industry's most exacting demands. The primary characteristics of these products are outstanding functionality, permanent stability and ease of processing, along with a broad scope of applications.

The SILPURAN® product line, moreover, is certified to specific test standards and complies with the WACKER CLEAN OPERATIONS production standard, thus guaranteeing verified purity that can be traced from the end product back to the raw-material source.

SILPURAN® – Much More Than Just a Product

- The SILPURAN® product line is certified as per selected ISO 10993 and USP Class VI tests
- Production complies with WACKER CLEAN OPERATIONS standard
- SILPURAN® silicone rubber grades are dispensed or packaged in Class 8 cleanrooms to prevent contamination by coarse particles
- Visual inspection and 50-µm filters ensure that SILPURAN® products reach our customers in an absolutely pure and clean state

Individual Solutions and Technical Support

ELASTOSIL®P and SILPURAN® give you the best service available, ensuring your success. Always at the ready, our teams of experts help you to optimally adapt the virtually unlimited scope and innovative strength of WACKER's silicone rubber

grades to your needs, thus creating customized product solutions which contribute to your long-term business success.



WACKER

Wacker Chemie AG
Hanns-Seidel-Platz 4
81737 München, Germany
Tel. + 49 89 6279-0
info.silicones@wacker.com

www.wacker.com/healthcare

ELASTOSIL® is a registered trademark of Wacker Chemie AG.
SILPURAN® is a registered trademark of Wacker Chemie AG.

The data presented in this brochure are in accordance with the present state of our knowledge, but do not absolve the user from carefully checking all supplies immediately on receipt. We reserve the right to alter product constants within the scope of technical progress or new developments. The recommendations made in this brochure should be checked by preliminary trials because of conditions during processing over which we have no control, especially where other companies' raw materials are also being used. The information provided by us does not absolve the user from the obligation of investigating the possibility of infringement of third parties' rights and, if necessary, clarifying the position. Recommendations for use do not constitute a warranty, either express or implied, of the fitness or suitability of the product for a particular purpose.