

ELASTOSIL® P

Silicone Elastomers for Orthotics and Prosthetics

The human body is a wonderful work of art and a highly complex piece of engineering. But sometimes it is necessary to provide support or artificial replacements for particular physical functions of the body. Orthotic or prosthetic devices can help to improve the lives of patients significantly. WACKER silicone products meet the modern industry's highest demands.

The primary characteristics of these products are outstanding functionality, permanent stability and ease of processing, along with a broad scope of possible applications.

Performance That Fits Like a Glove

Prosthetics is a highly sensitive area. WACKER RTV-2 silicone rubber grades have an extraordinary property profile that makes them ideal for producing aesthetic and functional artificial limbs as well as epitheses and external mammary prostheses. They provide excellent mechanical properties and can be easily combined with WACKER ELASTOSIL® FL color pastes to create perfectly matching prostheses that are comfortable to wear and nearly invisible.

As Versatile as the Requirements

Orthopedic products must be able to absorb considerable amounts of shock

or vibrations. They also have to be durable and easy to fit. This is where ELASTOSIL® P silicone elastomers come into play, as they provide a comprehensive portfolio of products and services. WACKER's silicone elastomer portfolio offers products with various durometers combined with good mechanical strength, making them the products of choice for pelottes, orthotic devices and pediatric products. The ability to combine different durometers and the compatibility with a large range of color pastes gives manufacturers freedom of design to find the perfect fit for their patients' needs.

Table 1: ELASTOSIL® P, ELASTOSIL® FX and SILPURAN® Product Range

Product	Viscosity A [mPa s]	Viscosity B [mPa s]	Hardness Shore A	Hardness Shore 00	Tear Resistance [N/mm]	Elongation at break [%]	Tensile Strength [N/mm ²]
ELASTOSIL® P 7600	4,000	2,000	< 0	28	3	650	1.2
ELASTOSIL® P 7670	1,800	1,800	7	55	3	580	1.9
ELASTOSIL® P 7671	1,500	1,800	< 0	21	2	400	0.5
ELASTOSIL® P 7683/25	1,200	3,500	< 0	25	5	650	1.5
ELASTOSIL® P 7684/40	1,500	2,300	< 0	40	8	670	2.2
ELASTOSIL® P 7684/60	1,400	2,600	12	60	13	650	3.8
ELASTOSIL® P 7915		kneadable	17	70	1.2	550	5.0
ELASTOSIL® P 7950		kneadable	50	-	2.4	250	7.0
ELASTOSIL® FX 10 A/B	6,000	4,500	10	---	20	950	4.5
ELASTOSIL® FX 20 A/B	5,000	4,000	20	---	25	750	6.0
ELASTOSIL® FX 28 A/B	10,000	10,000	28	---	28	500	6.0
ELASTOSIL® FX Gel 30 A/B	4,000	4,000	---	30	5.5	900	1.5

For standard specifications and technical parameters, refer to the technical data sheet.

Improving Comfort Every Day

Silicone elastomers are ideally used for applications in which reduction of friction is needed to avoid skin abrasion or creation of blisters. One example is the use of WACKER ELASTOSIL® P grades in prosthetic liners, where the soft and flexible material can be fitted to an amputee's residual limb to protect the patient from pressure soreness and stress from the outer prosthetic device. Swelling of the limb is reduced due to the gentle compression, and the pain that amputees often experience is significantly alleviated. Thus the excellent properties of WACKER silicone elastomers help to improve patients daily lives in many ways.

Easy Processing

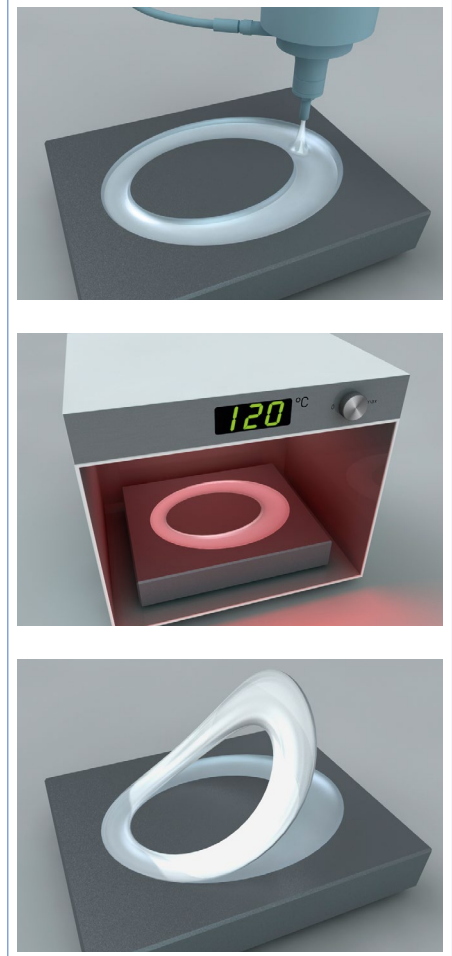
WACKER ELASTOSIL® P brand silicone elastomers are designed to meet specific prosthetic and orthopedic demands. The addition-cure two-component silicone rubbers (RTV-2) cure at room temperature. The platinum catalyst is separated from the curing agent. After components A and B have been mixed, the mixture cures to form a comfortable silicone elastomer. The process can be greatly accelerated by raising the temperature to between 70 and 130°C. Notable char-

Much More Than Just a Product

The product range comprises materials that have undergone biocompatibility testing according to selected ISO 10993 and USP Class VI tests.

acteristics of WACKER's RTV-2 silicone rubbers are their relatively low viscosity and hence excellent pourability. A broad range of different hardness levels of the cured silicone rubber (Shore 00 to Shore A) is available. Its consistency can additionally range from low viscosity to spreadable or even kneadable. The pot lives and curing times of our ELASTOSIL® P grades can be adapted, making these rubbers suitable for standard manufacturing processes. They can be applied in a number of ways, such as pouring, brushing and dip-coating. ELASTOSIL® silicone elastomers fulfill even the highest medical standards and can be used in most sensitive applications on highly compromised skin.




Figure 1: Example of Pelotte Molding Using an ELASTOSIL® P Silicone



Benefits of WACKER SILPURAN® and ELASTOSIL® P Silicone Elastomers

- High transparency
- Biocompatibility
- Breathability
- No byproduct formation on curing
- Do not support microbial growth
- No organic plasticizers involved
- Anti-allergenic
- Easily adaptable to skin temperature
- Good resistance to a large number of solvents and chemicals
- Sterilizable by steam, ethylene oxide, e-beam and γ-radiation
- Highly resistant to aging, weathering, heat and radiation
- Biodurability: low surface tension, thermal and chemical stability
- Broad range of Shore hardnesses

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