WACKER

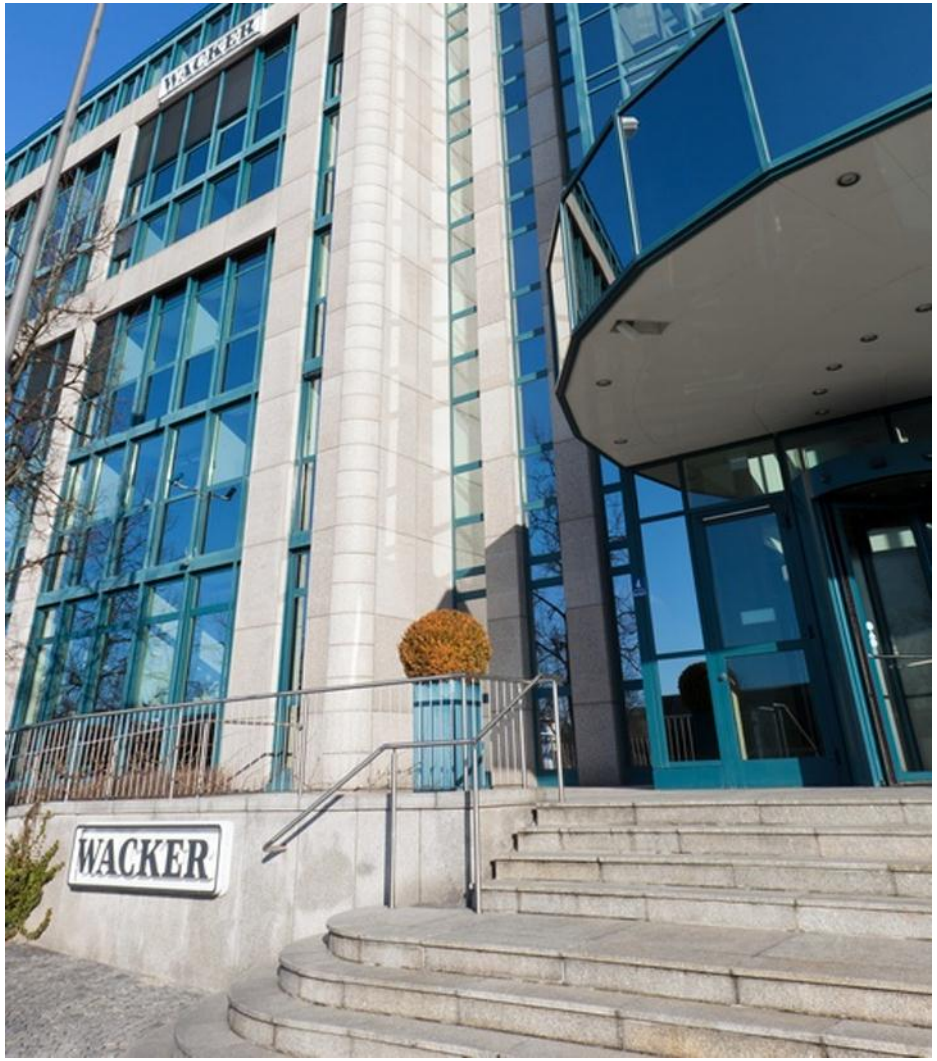
CREATING TOMORROW`S SOLUTIONS

Wacker Silicone Elastomers: Purity and Future Proof
瓦克有机硅弹性体：为医疗行业提供安全，创新的解决方案

March，2014

Content

Almost a Century of Success （瓦克跨越第一个一百年）



Wacker Chemie AG

- Founded in 1914 by Dr. Alexander Wacker （1914年亚历山大.瓦克博士创立公司）
- Headquartered in Munich总部位于慕尼黑

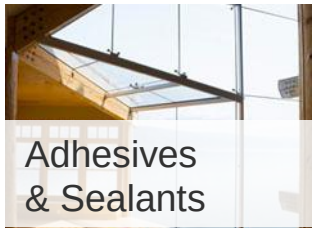
WACKER Group (2012)

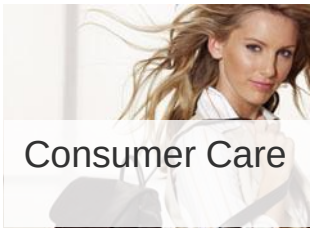
Sales:	€ 4.63 billion
EBITDA:	€ 787 million
R&D:	€ 175 million
Investments:	€ 1.1 billion
Employees:	16,292

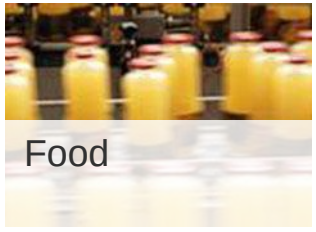
Products and Solutions for Key Global Sectors
瓦克为各个行业提供产品和解决方案

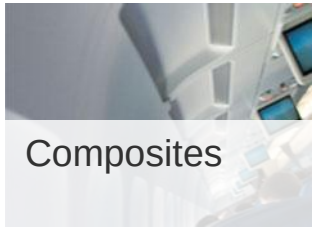
- WACKER is a technology leader in the chemical and semiconductor industries
- We forge ahead with technical innovations and the development of new products for the world's key industries.

瓦克是化学和半导体工业的技术领先者.我们通过新产品开发和技术创新来不断进步

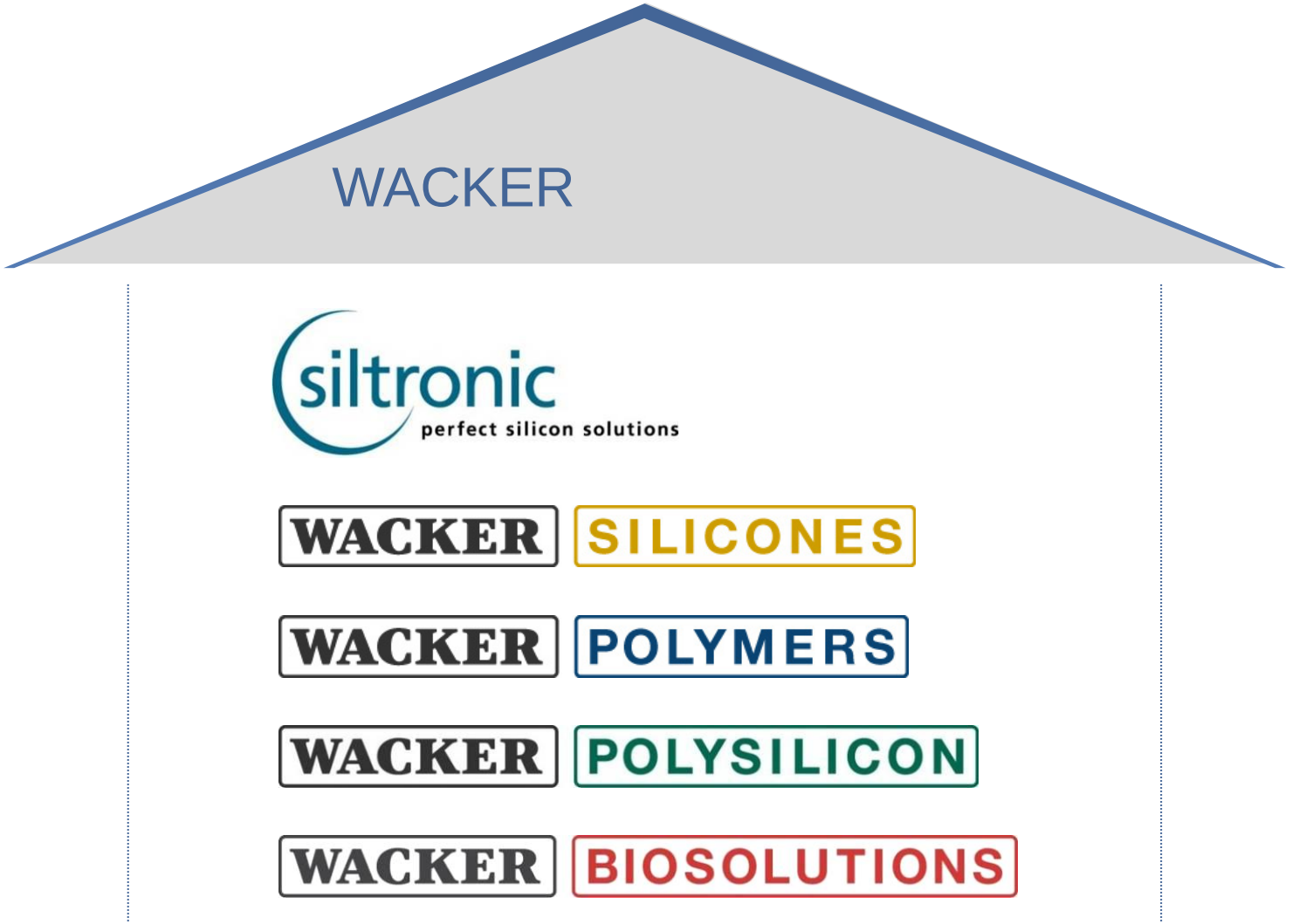








Specialists under One Roof



Wacker Silicones: A Creative Partner For Customer Solutions
瓦克有机硅部门：为客户开发创新型解决方案的合作伙伴

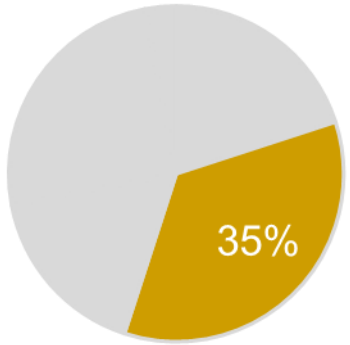
One of the global leaders in silicone-based, overarching solutions comprising products, services and strategies 提供与有机硅有关的产品、服务和策略等一体化解决方案的全球领先生产商之一:

- Over 3,000 silicone products 拥有3000多种有机硅产品
- Development of new products and production processes together with customers 与客户共同开发新产品、新工艺
- Lab support during the formulating phase, approval of customer products, and production scale-up 为配方研制、客户方产品审批和规模生产提供实验室支持
- Unique supply-chain and packaging solutions 独一无二的供应链和包装解决方案

Main Areas of Application 主要应用领域:

- Construction 建筑
- Automotive, transport 汽车、运输
- Energy, electrical and electronica 能源、电气与电子产品
- Paper and foil coatings 纸张与薄膜涂层
- Textile and leather 纺织与皮革
- Paints and surface coatings 涂料与油漆
- Healthcare 医疗保健
- Personal and household care 家用与个人护理
- Plastics and rubber industry, etc.橡胶与塑料工业等

Share of Group Sales占集团销售总额的比例



Global Manufacturing Footprint: Integrated Base Production And Local Compounding

瓦克全球生产基地分布：上下游原料整合的生胶生产基地和就近的混炼胶工厂

The Advantages of Silicone in the Health Care industry are significant for consumers有机硅对于消费者的益处

Silicones have many favourable properties.
The most important are presented below. Silicones are:

- Biocompatible, skin friendly and comfortable to wear

  高度生物相容性，对皮肤友好，舒适
- Durable and long living 耐用，使用寿命长
- Highly resistant to weathering and radiation 耐候，耐辐照
- Media resistant to sweat and water from human body耐受人体挥发的汗水
- Highly elastic 高弹性
- Highly permeable for gas, breathable in the end product高透气
- Easy to clean and little moisture absorbent 易清洁，不吸潮

The Advantages of Silicone offer best properties for the manufacturer and fabricator有机硅对于生产商的益处

Silicones are not only a beneficial material for consumers but also for the manufacturer. They offer:

- Easy processing properties 易加工
- A curing at room temperature (RTV-1, RTV-2)一些产品可以在室温固化
- A fast curing – curing time can be accelerated by temperature 高温可加速固化
- Hardness ranges from gel-like to high Shore A 硬度范围宽，从凝胶到ShA 80
- Excellent mechanical properties and gas permeability 优异的物性和透气性
- Excellent stability at temperatures from -50 °C to 200 °C 宽广的耐温性

Chemical-physical Properties Qualify Silicone Rubber For Health Care And Pharma Applications硅橡胶的物理化学特性适用于医疗保健和制药工业

Chemical Properties 化学特性

- Thermal stability up to 180 ° C, with heat stabilisers up to 300 ° C 180摄氏度以下受热稳定，添加热稳定剂可达到300摄氏度
- Good media resistance 良好的耐介质特性
- Sterilisability 可反复消毒
- Good weathering and ageing resistance 良好的耐侯和耐老化特性
- Colorability in almost every color 易着色

Physical properties 物理特性

- hydrophobic, low surface tension 疏水、低表面张力
- Low temperature flexibility up to -50 ° C 耐低温至-50 ° C
- High transparency 高透明性
- High gas permeability 高透气性

Bonding energy 健能

	E_{Diss} [kJ/mol]		E_{Diss} [kJ/mol]
Si-O	422-494	Si-C	306-326
C-O	360	C-C	348

In the production of silicones, no phtalates, organic stabilizers, nitrosamines, latex, plant proteins or animal-based materials are added

在有机硅的生产过程中，不添加邻苯二甲酸盐增塑剂、有机稳定剂、亚硝胺、乳胶、植物蛋白或动物源的物质

WACKER SILICONES

Silicone elastomers: pure and futu
Julia Henn, September, 2013, pag

why to use

Proportional Growth For Silicone Rubbers
高效率的工艺加工促进了硅橡胶的同比增长

Processing 工艺

Cost efficient bonding technologies
高效率以节省成本的结合技术
→ 2k injection molding 双色注射工艺
→ Coextrusion 共挤出工艺

Alternative vulcanisation technology
新型的固化技术
→ UV curing 紫外线固化

Vacuum post-curing 真空二段硫化
→ Energy saving 节能
→ Less emissions 低排放

Material properties 材料特性

Sterilisability 可反复消毒
→ Suitability for disposable as well as reusable devices 同时可用于一次性或可反复使用的医疗器械

Suitability for combination products
适用于组合产品
→ Drug release properties 释放药物的特性

Uncritical disposal 对于环境影响小
→ No release of chlorous substances during incineration
垃圾燃烧不排放含氯的物质

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WACKER CLEAN OPERATIONS – our standard for high quality

WACKER CLEAN OPERATIONS standards are driven by Purity, Care and Safe Quality Principles

WACKER CLEAN OPERATIONS

Purity

Care

Safe Quality

Content

Medical Silicones for Medical Devices

SILPURAN® covers well-established and innovative application fields with LSR and HCR

Hoses and Tubes

- Catheter hoses
- Breathing tubes
- Tracheal tubes
- Shunts / drainage systems
- Pressure hoses (Pharma & Biotechnolgy)

Seals / Valves / etc.

- Seals (skin, blood, plasma and dialysis fluid contact)
- Gaskets for dialysis
- Stoppers and plugs
- Membranes
- Needle free valves

Bulk Parts

- Face masks
- Bellows
- Handles for surgical instruments

Dual Brand Strategy – SILPURAN® and ELASTOSIL® for Medical Device applications

SILPURAN®

SILPURAN® is the pure silicone produced and packaged in our clean-room facilities.

Ideal for your most sensitive applications.

ELASTOSIL®

ELASTOSIL® LR and R is our long-established and industry-wide trusted silicone.

Perfect for your medical device applications.

General purpose and specialty SILPURAN® LSR grades are available

Standard grade		
LR, Pt-cure	injection molding	SILPURAN® 6000/05-70
High-tear grade		
LR, Pt-cure	injection molding	SILPURAN® 6400/40-60
Low surface friction grade		
LR, Pt-cure	injection molding	SILPURAN® 6600/40-60
Healing-free grade		
LR, Pt-cure	injection molding	SILPURAN® 6610/40-80
Self-adhesive grades		
LR, Pt-cure	injection molding	SILPURAN® 6700/40-60

Standard, high tear and low friction SILPURAN® HCR grades are available

Standard grades			
Pt-cure Pt-cure Peroxide-cure	2K 2K	Molding extrusion molding/ extrusion	SILPURAN® 8020/40-70 SILPURAN® 8030/40-70 SILPURAN® 8060/40-70
High-tear grade			
Peroxide-cure		extrusion	SILPURAN® 8461/60
Low surface friction grade			
Pt-cure	2K	extrusion	SILPURAN® 8630/60
Pt-Catalyst batches			

SILPURAN® Curing Agent M (for 2K molding grades)
SILPURAN® Curing Agent X (for 2K extrusion grades)

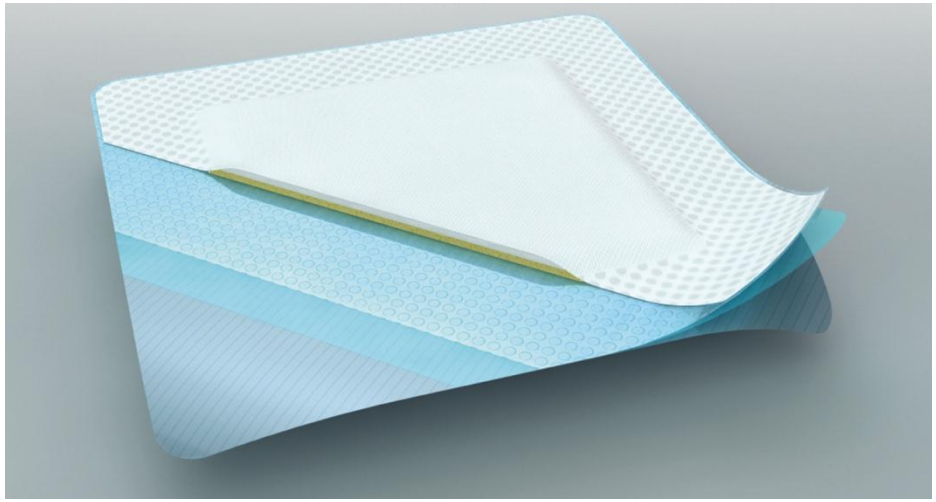
Medical Silicones for Wound Care

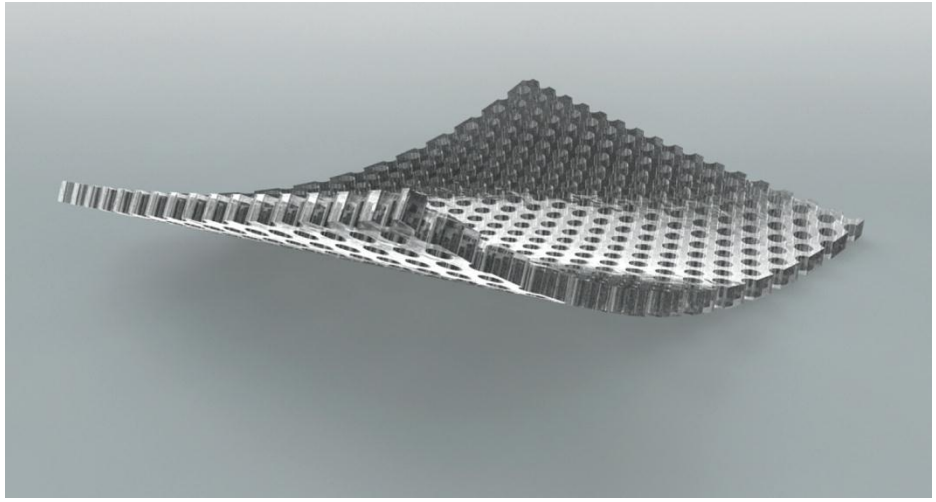
WACKER Silicone in Wound Care application and for Scar treatment

WACKER Silicones:

- ... are perfect for both wound care applications and scar treatment.
- ... offer properties which promote wound healing, e.g water-vapor and gas permeability, for an optimal healing environment and protection from external influences
- ... help scars to heal and look less conspicuous
- ... make ideal skin adhesives, as they can be rendered soft and flexible and their gentle adhesive properties enable atraumatic dressing changes.

Wound Care – Silicone coated Wound Dressings





Wound dressings:

- The dressing is coated with a soft silicone gel. These dressings are breathable due to the high vapour permeability of the silicone, protect the wound from bacteria and are water proof.
- The gentle properties of the soft silicone adhesive enables atraumatic removal of dressings, without causing damage or pain to the wound or surrounding skin.

WACKER Silicones in Wound Care applications can enhance a patient‘s quality of life

Atraumatic dressing changes

... reducing pain at dressing removal

... reducing stress from pain anticipation*

Water-vapor and gas permeability

... provide optimal healing environment

... reduce maceration, blistering, et al.

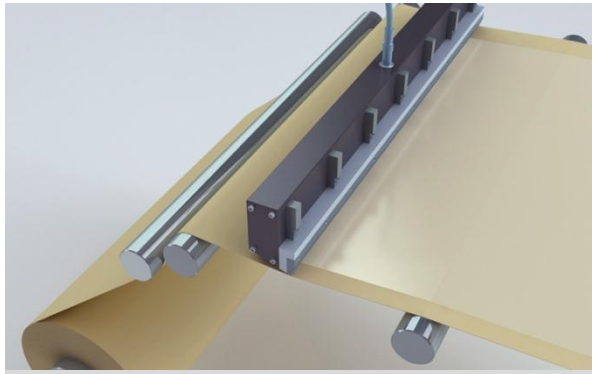
Each in turn, can lead to a wound healing quicker

Less trauma, less pain. More quality of life.

* 40% of patients stated pain at dressing removal to be worst problem of living with a wound. **Meaume S et al., Ostomy Wound Management, 2003.**

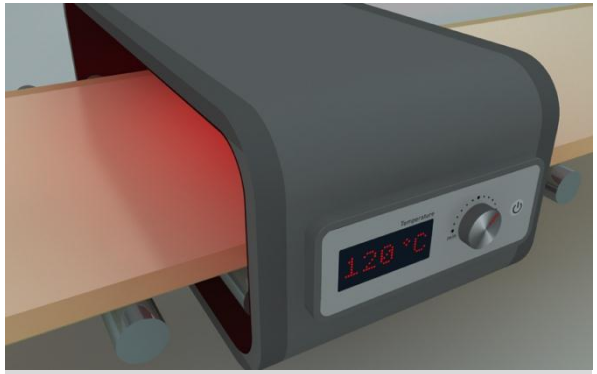
SILPURAN® – used in the manufacturing process for wound dressings

Step 1



- Apply silicone to carrier substrate with a doctor blade, slot die or similar instrument

Step 2



- Vulcanization by heat radiation

Step 3

- The silicone adhesive coated film is covered with a release paper and the material composite can be converted

Wound Care brochure 6365D/10.13

SILPURAN® – Medical Silicone for Wound Care application

Designation	Viscosity A [mPa s]	Viscosity B [mPa s]	Penetration [1/10 mm] Hollow cone 62.5 g; 60 sec	Color	Pot life at 23° C [min]	System
SILPURAN® 2100	34,000	35,500	205	transparent	73	addition-curing
SILPURAN® 2110	18,000	54,000	200	transparent	70	addition-curing
SILPURAN® 2112	11,600	11,500	225	transparent	76	addition-curing
SILPURAN® 2120	31,000	30,500	120	transparent	22	addition-curing
SILPURAN® 2130	1,100	1,000	220	transparent	74	addition-curing

Content

Content

- WACKER Services
  - Certificates
  - Biocompatible colors
  - Additional Silicone adhesives for all Health Care applications

Certificates – always complying with the necessary regulations

SILPURAN® comes with the certificates you need

- All SILPURAN® grades meet the requirements of USP Class VI and selected tests of ISO 10993:

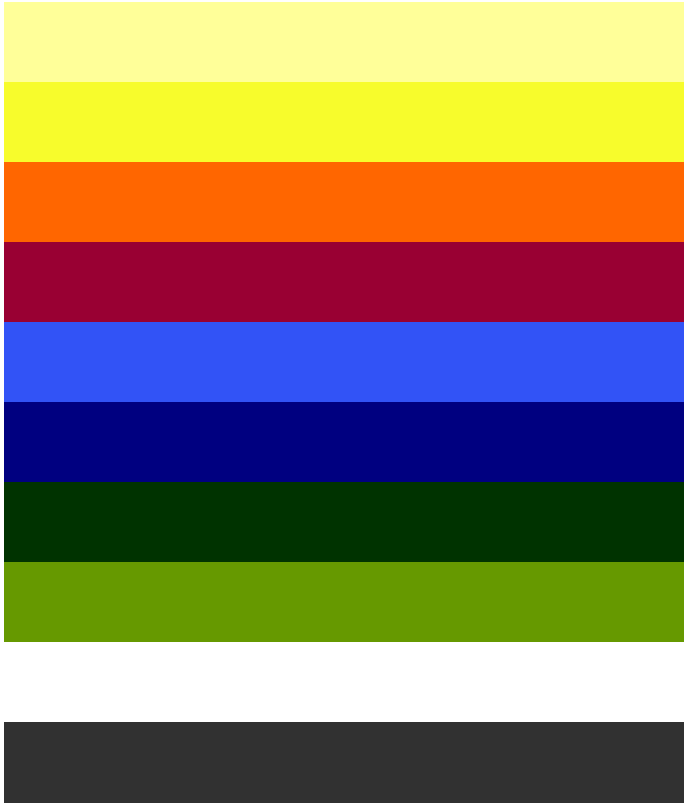
Cytotoxicity	Systemic toxicity
Sensitisation	Intracueaneous toxicity
Pyrogenicity	Implantation

- Further certificates, e.g. haemolysis, thrombogenicity, acute dermal irritation are available for selected grades
- SILPURAN® LR / HCR grades comply with selected tests of E.P. 3.1.9 (e.g. test for volatile matter and hexane extract)*
- SILPURAN® LR / HCR grades comply with food contact requirements of BfR and FDA CFR 21 § 177.2600 “Rubber articles intended f. repeated use”

* exception: SILPURAN® 6000/05+10

Available Colors for your Health Care applications

Pigment Pastes



Yellow, RAL 1016	ELASTOSIL® FL 1016
Yellow, RAL 1026	ELASTOSIL® FL 1026 F
Orange, RAL 2004 F	ELASTOSIL® FL 2004 F
Red, RAL 4002	ELASTOSIL® FL 4002
Dark blue, RAL 5010	ELASTOSIL® FL 5010
Blue, RAL 5022	ELASTOSIL® FL 5022
Green, RAL 6004	ELASTOSIL® FL 6004
Green, RAL 6010	ELASTOSIL® FL 6010
White, RAL 9010	ELASTOSIL® FL 9010
Black, RAL 9011	ELASTOSIL® FL 9011

Confirmations of conformity are available for the corresponding PT color pastes (except PT 9011), further colours on demand

more Details Medical Device brochure 6365C/10.13

Additional Silicone adhesives for all Health Care applications

SILPURAN® 4200

RTV-1 Moisture - cure
Adhesive for textile, medical devices

available in 310ml cartridge (DRAWIN) and 20kg HOB

SILPURAN® 2438 ADH

RTV-2 Addition-curing
Adhesive for textiles to silicone or silicone to silicone

available in 20kg HOB, 200kg drum

Silpuran® 4200 Allows For A Flexible, Elastic And Tin-free Adhesion
适合于灵活的，有弹性的和不含有机锡的粘接

A safe bonding between balloon and catheter is reached via glueing with a one-component RTV-1 silicone rubber

单组分的RTV-1硅橡胶是用于球囊和导尿管理想和安全的粘接材料

Advantages of SILPURAN® 4200
SILPURAN® 4200 优点

- 1-component, self-levelling单组分，自流平
- Curing by atmospheric moisture (release of acetic-acid) 室温湿气固化（释放醋酸）
- Ideal for continuous and discontinuous production 为连续和非连续生产提供理想的解决方案
- **Free of organotin catalysts** 不含有机锡催化剂
- Biocompatible (ISO 10993, USP Class VI)
  符合生物相容性（ ISO 10993, USP Class VI）
- Adhesion to silicone rubber, aluminium, glass, Polyester, Polyamide 可以和硅橡胶粘接的材料：铝，玻璃，聚酯，尼龙等材料
- 35 Shore A[(a)]; Elongation at break[(b)]: 700%
  35 邵氏硬度 A[(a)]; 断裂伸长率[(b)]: 700%

(a) DIN 53505; (b) DIN 53504

For further information, please ask your WACKER HEALTH CARE TEAM

Our SILPURAN® team is there to take care of your needs

- Laboratories & technical service help you to provide the material optimally suiting your purpose
- Laboratory teams support your product development from materials research to pilot series and registration
- WACKER in-house product safety and toxicology department provides expertise in silicones biocompatibility and in working with regulatory authorities
- WACKER's Technical Center is equipped with state-of-the-art extrusion and injection molding technology to support your material selection, prototyping, process design. Customer training, troubleshooting and consultancy available

Thank you for your attention!

Please ask your sales representative for samples, brochures and further information and visit WACKER at www.wacker.com/healthcare

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