

Medical tubing of low-friction silicone elastomers is easier to push through other components

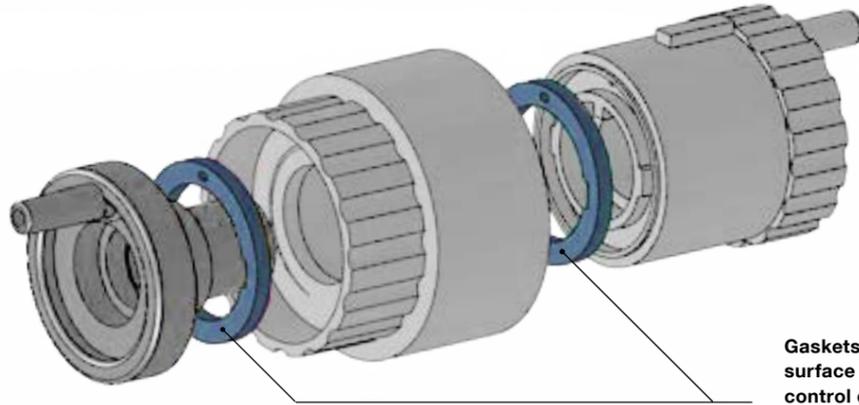
# SAFELY ON THE DRIP

Silicone elastomers have inherent properties that make them ideal for medical applications. By developing a line of new, low-friction silicones, WACKER has opened up novel applications, such as gaskets in syringes or intravenous drips .

Intravenous (IV) drips are used to give infusions of nutrients, minerals and medication to patients to speed their recovery. The physician can adjust the flow rate of the IV regulator to deliver exactly the right dosage – neither too little nor too much. Manufacturers of these medical devices must follow the highest standards of safety, reliability and precision. Like most medical equipment, intravenous drips are subject to approval from the health authorities; strict guidelines therefore apply for all materials involved in their manufacture as well as for each step of the process.

WACKER is able to meet these high standards because of its special production environment: “Two years ago we began using a clean room to produce silicone rubber for medical purposes,” says Dr. Christoph Briehn, technical manager for Health Care in the Rubber Solutions business team at WACKER SILICONES. “Here, we produce not only conventional silicones with the usual surface friction, but also novel elastomers with good sliding properties.”

**Lower Friction** These new low-friction elastomers are opening the way to more widespread



Gaskets of SILPURAN® 6600 with low surface friction allow for easy and safe control of flow volume and drip rate.

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use of silicone elastomers in the field of medicine. Because of their distinctly smoother surface, they can be applied in areas where ease of movement is of primary importance. Their advantages are beneficial not only to the end user but also to the production process itself – anywhere, in fact, where friction could cause problems during fabrication. The assembly of various parts (pushing tubes through other components, for example) is simplified. Finally, the patient benefits from more comfort and, in the case of an intravenous drip, from reliable administration of the correct dose.

These advantages attracted the attention of Dominique Dupard, managing director at the French silicone processor, Top Clean Silicone. For a long time, he had been looking for an elastomer to improve the performance of an IV flow regulator. Up to now, the valves used to control the drip were typically covered with lubricants so that they could be opened and closed easily and smoothly. “After an infusion bag has been

sitting in storage at a hospital for two years or longer, it is no longer certain that the oil used to lubricate the valve in the flow regulator is still evenly smeared and will do its job properly,” says Dupard, explaining a practical problem. And that can make things difficult for both the nursing staff and patient: a stuck flow regulator valve can only be opened with great difficulty, and it takes more effort to ensure exact dosage of the administered drug.

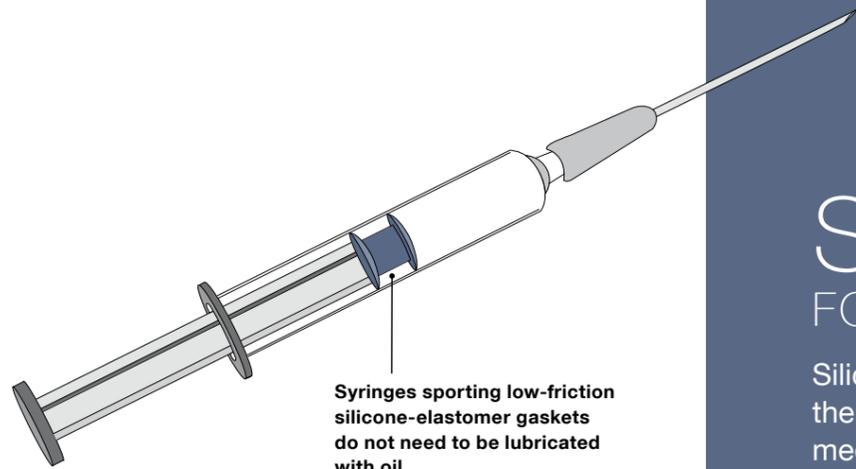
**Smooth Running** The new class of low-friction silicones is ideally suited for use in an IV flow regulator: their excellent resistance to chemical and thermal exposure makes them easy to sterilize and their coefficient of friction has been reduced by more than 50%. Thus, the valves made from the new material do not need an additional processing step to make them smooth-running. In fact, they need no lubrication at all.

**APPLICATIONS**

Silicones currently account for two to three percent of the plastics used in medical devices. Areas of application include:

- ▶ **Catheters (tubing, balloons, shaft)**
- ▶ **Medical and pharmaceutical tubing, drainage**
- ▶ **Moldings for medical devices, e.g. gaskets, valves and membranes**
- ▶ **Parts for pharmaceutical packaging, stoppers for injection vials**
- ▶ **Respiratory masks/face masks**
- ▶ **Wound dressings and scar treatment**
- ▶ **Orthopedic technology truss pads, orthoses, dressings (bandages) etc.**
- ▶ **Liners for prostheses**

The patient receives infusions of nutrients, minerals or medication via an intravenous drip.



Syringes sporting low-friction silicone-elastomer gaskets do not need to be lubricated with oil.

## SILICONES FOR MEDICAL DEVICES

Silicones have properties that make them especially suitable for use in medical devices:

- ▶ They are chemically and physiologically inert: that is, they are compatible with the detergents and disinfectants used in health care, and with medication.
- ▶ Their good thermal resistance enables them to be easily sterilized by heating. Furthermore, they are very well suited for sterilization by steam, gamma rays and ethylene oxide. Silicones hardly age, even under the influence of oxygen, ozone or radiation.
- ▶ They do not take up water, yet are permeable to water vapor, air and other gases.
- ▶ They are transparent, i.e. can be used to make see-through articles, yet they can be easily pigmented. Thus, they can take on a practically unlimited spectrum of colors.
- ▶ They contain no additives such as organic plasticizers. Silicone elastomers consist entirely of synthetic polymers and therefore do not contain any plant proteins, which could trigger allergic reactions.
- ▶ Silicones intended for medical applications are marketed by WACKER under the brand name SILPURAN®. They are available as high temperature vulcanizing solid and liquid silicone rubbers, or as room temperature-vulcanizing silicone rubbers. All these products have been evaluated for their biocompatibility according to ISO 10993 and USP Class VI Testing. Great care is taken to meet the strictest purity standards during production and packaging.

**All the Necessary Certificates** “Before we can offer our new flow regulator to an IV drip manufacturer, however, we need to have more than just an elastomer with the right properties,” explained Dupard, adding “We must also be able to show certification stating that our materials meet the regulations for use in medical devices.”

Of course WACKER takes care of the appropriate testing and certification itself. The company manufactures the SILPURAN® line of products for medical applications at its production site in Burghausen. These products satisfy the biocompatibility and exceptionally stringent purity requirements demanded by the medical and pharmaceutical industries. This is secured in part by special packaging measures and very fine filtration of the materials used.

“We are convinced that the effort is well worthwhile,” states Andrea Biedermann, marketing manager for Health Care at WACKER SILICONES, “because regulations in the medical field are rigorous, and the trend is toward ever more specifications throughout the entire process chain, starting with the raw materials manufacturer.”



Clean room at Wacker Chemie AG in Burghausen, where silicones are produced for medical purposes.

**Promising Market** A very promising market awaits those who can fulfill these requirements and offer additional advantages on top – and with its new, low-friction silicone elastomers WACKER can do just that. Worldwide, several hundred million flow regulators for infusion bags alone are produced each year. The demand for ready-made materials continues to decline as more and more customers seek solutions that have been customized to their needs.

“WACKER really gave us good advice when we were developing the gaskets for our new flow regulator,” said Dupard, praising the cooperation with the silicone manufacturer. “With SILPURAN® 6600, we found a way of doing away with lubrication of the flow regulator valve.” Moreover, Dupard highlighted an advantage that SILPURAN® 6600 has over the conventional product during processing: “Demolding after injection molding is considerably easier.”

Incidentally, Top Clean Silicone did not need to change its manufacturing method to process this low-friction silicone – it can be injection molded just

like any other liquid silicone rubber. WACKER offers a complete, low-friction product portfolio for alternative production practices and purposes: in addition to liquid silicone rubber, it offers solid silicone rubber products that can be used in extrusion or press curing techniques.

**Established Material** Thanks to their useful properties, such as good compatibility and ease of sterilization, silicone rubber grades have already become firmly established for many medical engineering uses (see box). The new, low-friction silicones are opening the way to still further areas of application that require minimal friction. Another interesting use of the new materials is in the disposable syringes used to inject medication. To date, these devices have usually been lubricated with oil. The plunger of future syringes may sport a gasket made of low-friction silicone that provides the required air-tightness without the need for a lubricant. And, this saves a step during manufacture. ◀