

Silicone Tubing Solutions for BioPharma Applications — A Manufacturer's Q & A

The world's leading pharmaceutical and medical device companies rely on Freudenberg Medical to deliver an extensive selection of high-quality silicone tubing and fluid processing solutions. Cleanroom manufactured in the U.S. and Germany, Freudenberg Medical offers two different platinum-cured silicone product lines, PharmaFocus® Premium and HelixMark®.

Q: Why is it important to use tubing made with platinum-cured silicone?

A: Peroxide and platinum are used as catalysts in the manufacturing process to cure silicone. In the extrusion process, they help to convert the elastomer into its final tubing form. Using peroxide as a catalyst results in byproducts that require additional processing (heat) to drive off volatiles that may be left in the tubing, and could potentially increase leachables. Using platinum to cure the silicone leaves none of the derivatives in the tubing that are associated with peroxide-cure systems. This is why platinum-cured silicone is the superior choice when considering silicone for more critical applications in medical and pharmaceutical fluid transfer. At Freudenberg Medical, we only extrude platinum-cured silicones that are classified as USP Class VI medical grade and nothing less (no food or industrial-grade silicones).

We also do not extrude peroxide-cured silicones. There are companies that extrude both platinum and peroxide cured silicones in the same facility and on the same equipment — which can lead to cross-contamination. We have pharmaceutical and medical device customers that audit our facility specifically to ensure that we only extrude platinum-cured materials, because they have had issues with contamination in the past when tubing suppliers process both peroxide and platinum materials in their facility and on their equipment. If product purity is a concern, it makes sense to purchase your tubing from suppliers that only process platinum-cured silicones.

Q: What quality standards should I look for in a tubing supplier?

A: At a minimum, one should ensure that the tubing supplier has a controlled

manufacturing environment and a stringent quality system. Freudenberg Medical's U.S. silicone extrusion facility manufactures finished medical devices that require a medical device quality management system (ISO 13485) as well as FDA registration. FDA registration confirms that the facility is regularly audited by the FDA. An FDA-registered supplier complies with extremely strict quality procedures and processes. This warrants that the products manufactured are of the highest quality and consistency. The tubing we make for medical device implant applications is manufactured in the same manner and on the same equipment as the tubing our pharma customers would purchase for their fluid transfer applications.

Q: What if my application contains sensitive fluids?

A: For highly sensitive fluid processing, we recommend using the most premium silicone material as well as verifying the purity of the extrusion process and manufacturing environment to safeguard against foreign matter or contaminants within the tubing or on the surface of the tubing. The silicone should be medical grade and tested to meet USP Class VI biocompatibility requirements. Additional testing and material characterization depends on the individual risk assessment and the contacting media and processing conditions.

Q: What tubing do you recommend for high-pressure applications?

A: Our HelixMark product line has recently introduced Double Braided Silicone Tubing, ideal for high-pressure transfer-type applications. Double Braided Tubing is manufactured using a complex, multistep process that incorporates two separate strong layers of polyester fiber braiding between the



PHARMAFOCUS®
PREMIUM



extruded layers of USP Class VI platinum-cured silicone (inner core, middle layer and outer overcoat). Double Braided Tubing is difficult to manufacture and requires specialized equipment, complex systems and procedures, as well as advanced silicone extrusion expertise. Visit our website to learn more.

Q: I purchase tubing in bulk, what options are available?

A: If your application requires large quantities of tubing or longer lengths of tubing, we can customize any of our tubing options (ID/OD or silicone material used) to accommodate your needs. We can offer longer length coils, tubing on spools and special bulk-packed style containers.

More questions for Freudenberg Medical?

Jeff Hana is the National Sales Manager Extrusion at Freudenberg Medical. The company has been providing silicone tubing for pharmaceutical applications for 32 years and Jeff has been digging deep in silicone for the past five; any questions you have, he can try his best to answer.

Email Jeff at:
jeff.hana@freudenbergmedical.com

Or visit our website:
www.freudenbergmedical.com/tubing