

# Implantable Solutions

## In Silicone and PEEK

Freudenberg Medical offers implantable product solutions in long-term implantable silicone material as well as implantable-grade PEEK polymers. Both long-term implantable silicone and implant-grade PEEK are suitable for long-term implantation in the human body, longer than 30 days.

At Freudenberg Medical implantable product solutions are manufactured in ISO 13485 certified facilities within ISO certified cleanrooms. If your products require compliance with stringent regulatory requirements, specific facilities are in compliance with FDA, European MDD, and Health Canada requirements as well as equipped with ISO Class 7 & 8 cleanrooms.



## A Long History with Implantables

Freudenberg Medical has been molding and extruding silicone for long-term implantable devices since our earliest days in 1984 as Helix Medical. Today we are one of the few companies in the U.S. market processing long-term implantable silicone.

We began with implantable neurosurgical hydrocephalus valves and catheters for pediatric patients with Hydrocephalus (water on the brain), and built our implantable business manufacturing devices like peritoneal dialyses shunts, gastric feeding tubes, and implantable silicone insulation extruded for pacemaker and defibrillator leads.

## Implantable Silicone Solutions

Some components and devices we manufacture in long-term implantable silicone include gastric bands, shoulder and knee joints, lip implants, heart pump components, cementon components, tear duct plug, and bone cement. We extrude long-term implantable silicone for pacemaker leads and drainage devices. Our micro-scale services include silicone molded components, weighing as little as .004 g, and extruded implantable silicone tubing, scaling as small as .006" ID.

## Implantable PEEK Solutions

In addition to benefiting from the mechanical, chemical, and biological characteristics of implantable-grade PEEK, many device manufacturers use PEEK because of the wide variety of design solutions it provides. PEEK is often used in injection molding operations to economically produce high-performance components without the need for post processes such as annealing or machining.

Because of implantable-grade PEEK's versatility, it is being used in the development of many applications requiring mechanical strength and dimensional stability such as joint-replacement systems; spine surgery; cardiovascular applications such as heart valves and intracardiac pumps; suture anchors for arthroscopy; and for dental applications.

## Contact our Business Development team for more information

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