

FUCHS Special Applications

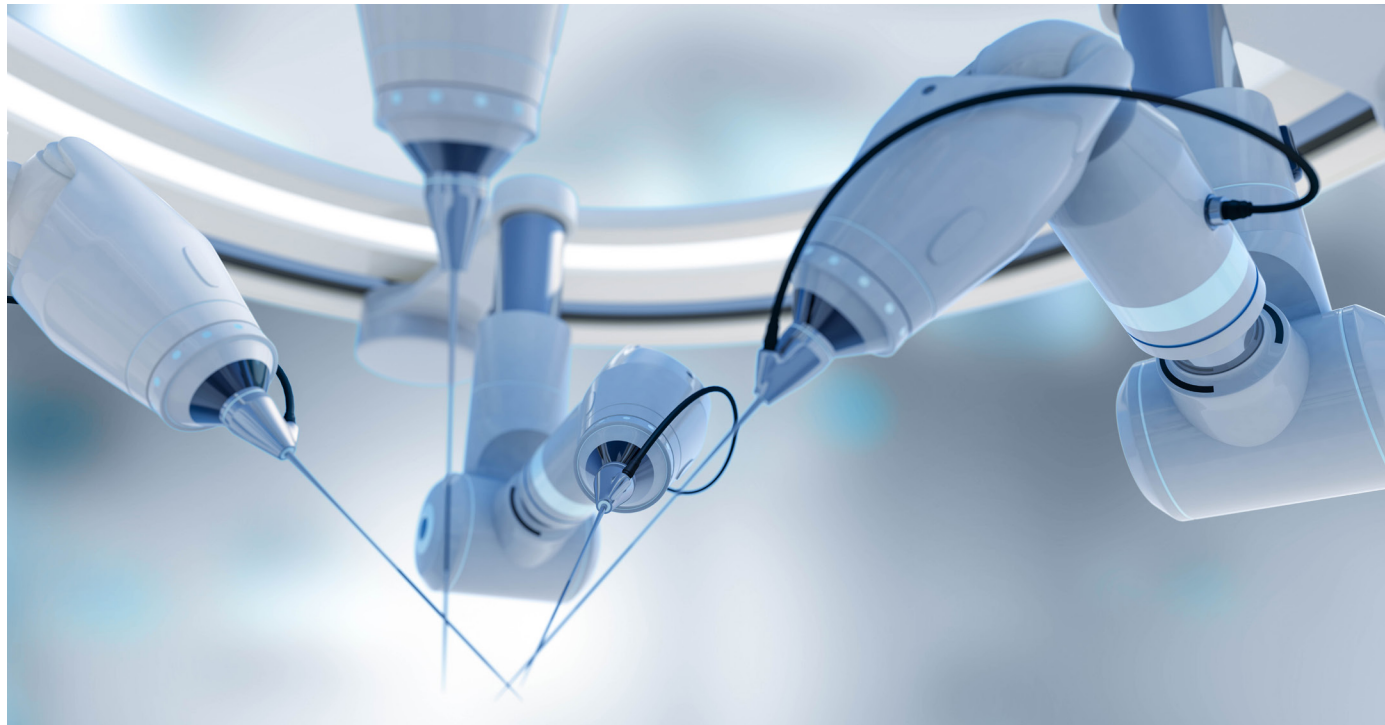
Specialty Lubrication Solutions for Medical Components



MOVING YOUR WORLD

Optimizing Medical Device Performance

Medical device engineers often contact lubrication companies after encountering excessive or unexpected friction or wear in mechanical or electromechanical device mechanisms, or between components. This can be uncovered during the proof-of-concept, design, verification, manufacture or even field trials of medical devices. Friction and wear can compromise device performance and perhaps even the success rate of a medical procedure. However, protecting against friction and wear is not the only way that a gel or fluid can improve device performance. As new device solutions in MedTech demand innovative and exacting design, our precision products are often called on to perform functions outside those of "traditional" lubrication.



Advantages

- Extend operating life
- Control free motion
- Reduce assembly force
- Optimize haptic feedback
- Eliminate undesirable noise
- Control or dampen energy release
- Broaden operating temperature range
- Mitigate the effect of tolerance stacking
- Seal against environmental contamination or ingress



Biocompatible Lubricants You Can Trust

High-quality standards with fully qualified and consistent processes are critical to reduce risk when selecting supply partners for medical applications. As an ISO 13485:2016 certified manufacturer, our quality management system meets regulatory requirements for medical devices and related services. Our manufacturing processes are strictly followed and documented to support our customers' need for product traceability as well as audit and regulatory support. While a commonly used term, an official 'medical-grade' certification does not exist for lubricants. In critical applications where patient exposure is a possibility, lubricants backed by biocompatibility testing should be considered. Our NYEMED® product line is tested to:

- ISO 10993-10: Skin Irritation (Direct Contact)
- ISO 10993-5: Cytotoxicity (Direct Contact)
- ISO 10993-11: Acute Systemic Toxicity (Direct Injection)

Sterilization Testing & Data

Products from our NYEMED® product line have been tested and proven to withstand common sterilization methods including gamma radiation, ethylene oxide (EtO), and steam autoclave.

Why Choose FUCHS?



About FUCHS

Since 1931, we have been pursuing the same goal: to keep the world moving. With innovative and technological lubricant solutions that have a sustainable impact on the future. Unconditional reliability is our top priority, it is the foundation of our company and the basis for everything that defines us.

Long-term experience, high development strength and the fulfillment of far-reaching standards are the basis for the special quality of our world-leading product brands. We deliver solutions that are simply more efficient and therefore more sustainable. We always think in holistic solutions. For the development of individual solutions, we enter into an intensive customer dialog with you. This is the way we live up to our claim of moving your world.



Your Partner from Development to Post-Production

Leading medical device, biopharmaceutical, engineering, contract design and manufacturing organizations have partnered with FUCHS for over 30 years. As a trusted partner, we are proud to support our customers along every step in their product development cycle.



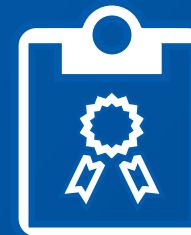
Global Support

The FUCHS Group comprises 58 operating companies in more than 45 countries, strategically placed around the globe to offer the most effective support to our customers.



Products

FUCHS has developed a broad range of specialty products and formulation technologies with raw materials selected for safety, materials compatibility, and long-term product availability for our customers. These products can also serve as a starting point for custom formulations where our team will work closely with yours to develop a product that meets your specifications.



Manufactured to the Highest Quality Standards

Lubricants for the medical industry are manufactured to the ISO 13485:2016 certification. We also have an ISO 14644-1 Class 7 Cleanroom that can be adapted to suit your needs.



Testing

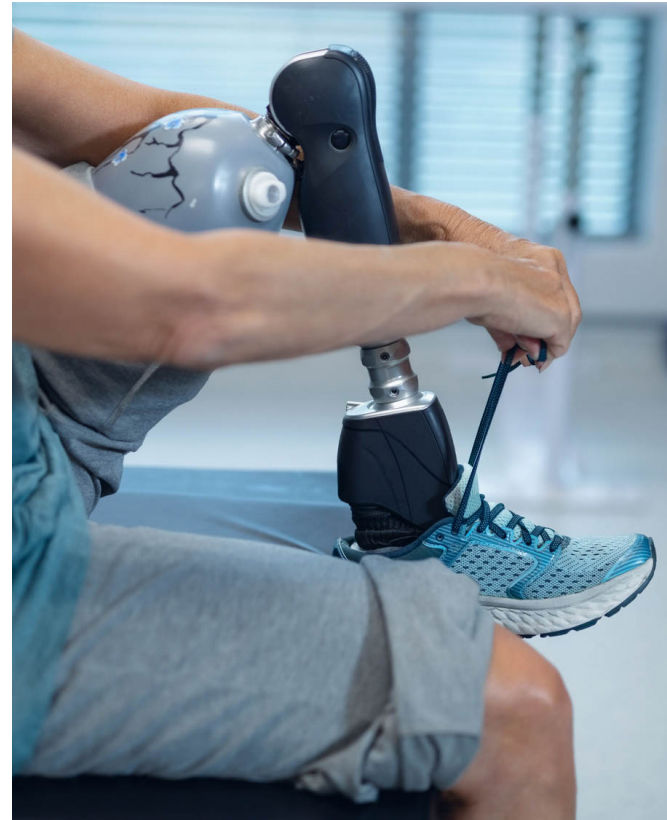
Our innovative lubricants are conceptualized, developed, and extensively tested in our state-of-the-art research and development laboratories. At FUCHS we have the capability to replicate your conditions to ensure optimal performance in your application.



Packaging

Our lubricants are available in a variety of packaging sizes for both high and low-volume production dispensing. We can work with you to determine the most appropriate packaging option for your operations.

Lubrication Solutions for Medical Components



Motion Control & Sealing

Viscous damping greases/gels can smooth operation, eliminate noise, and reduce the impact of environmental factors, e.g. by sealing gaps and orifices. These products provide viscous drag on moving parts which controls motion, enhances haptics, and minimizes free-motion problems, such as backlash, stick-slip, or coasting. Our damping products possess controlled flow properties, low oil separation, and good compatibility with plastics. Our products can also be used as an assembly aid.

O-Rings and Seals

The correct lubricant can help extend the life of your O-ring and seals while also improving their reliability. FUCHS offers lubricants compatible with a wide range of plastics and elastomers.

Electrical Connectors, Contacts & Switches

Microelectronics are proliferating in medical devices, requiring increasing numbers of connectors and contacts. The benefits of lubricating electrical connectors and switches in medical devices include; protection against sterilizing conditions, dust, reagents, moisture, and corrosive substances as well as reducing friction and wear and lowering insertion force.

Bearings

We offer a wide range of lubricants, from impregnating oils for sintered bearings to ultrafiltered greases for precision rolling element bearings. Greases can provide the elastohydrodynamic lubricating film needed to reduce friction and wear, while also serving as an effective seal to protect from contaminants and moisture.

Gear Motors & Gear Boxes

Gear lubricants meet broad temperature requirements without oxidizing or evaporating. Lubricants minimize friction, inhibit wear and corrosion, dampen noise and control free motion.

Linear Positioning Devices & Sliding Parts

Mechanisms require lubricants that exhibit stay-in-place properties, while minimizing friction, inhibiting wear, rust, and corrosion, dampening noise, and controlling free motion.

Lead Screws & Ball Screw

Lubricants reduce torque, increase efficiency, and extend performance life.

FUCHS is your partner in selecting and designing the right formulations that serve not only to lubricate, but also to seal, protect, and control motion. Our products perform in a vast array of critical applications including:

Powered Surgical Tools & Equipment

**Medical
Devices**

Drug Delivery Devices

**Diagnostic Equipment
& Instrumentation**

**Assembly
Processes**

**Robotic
Automation**



Drug Delivery Performance

As new parenteral drug products are developed, they often require easy-to-use, precise, consistent, portable, safe, and environmentally stable devices to deliver the active drug formulation to the patient. These devices include auto-injectors, on-body injectors, injection pens, pumps, infusion systems, and inhalers, among others.

Gels can be applied to a shaft or in a damping mechanism. The gel acts as a source of viscous friction, the resistive force between surfaces in relative motion through a fluid. This viscous friction controls the speed at which the plunger is deployed, absorbing the initial release of spring energy. The spring retains enough force to advance the plunger but is slowed by the fluid to create a smoother, less abrupt injection, thus improving the patient experience.

Our gels and fluids, which can be customized for the application, either lubricate contacting surfaces or provide controlled and consistent viscous drag on moving parts. Precision motion control gels and fluids enable:

- Optimum Device Functionality, Useability & Patient Safety
- Stable Device Performance Over the Required Shelf Life
- Proven Performance Over the Operational Temperature Range



Carefully designed and formulated to precise specifications, lubricants and motion control gels from FUCHS assist device designers and manufacturers confronted with design and modification challenges.

Control Mechanism Timing

It may not be easy to match a spring's force profile to the complex mechanical actions of a device tuned to the delivery requirement of a particular drug formulation. The release of force may be too rapid or too slow during various stages of the delivery cycle. Injection timing can also be critical to ensure complete injection at the right depth. These forces can be moderated or controlled by means of viscous damping. FUCHS can simulate and model the forces applied in our laboratories and match the desired energy release to the performance of customized motion control gels.

Optimize Haptic Feedback

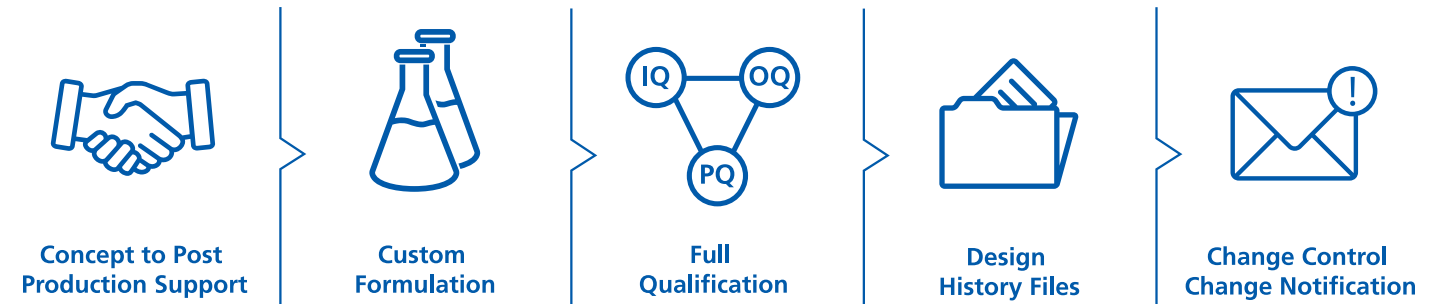
A viscoelastic gel or fluid can be used to ensure the mechanical design imparts desirable haptic feedback while eliminating mechanical shock, noise or vibration that may worry the patient or caregiver. The fluid deformation properties of a motion control gel can be changed to impart the desired "feel" when actuating a device. Gels and fluids can also minimize any vibrations that may be felt by the patient.

Control Activation Force

While there are many mechanical approaches to drug delivery activation, a gel or fluid can help to resolve any surface friction variation that may lead to improper operation. Whether it is plastic-on-plastic or metal-on-metal friction, the lubrication properties of a gel or fluid can be optimized or customized to control the amount of force required to activate a device.

Biocompatible Gels & Fluids for Medical Components

All products in the NYEMED® product line are tested to ISO 10993-5 Cytotoxicity (Direct Contact), ISO 10993-10 Skin Irritation (Direct Contact), and ISO 10993-11 Systemic Toxicity (Direct Injection). NYEMED® products included below show no cytotoxic potential; are negligible irritants, and pass systemic toxicity testing



Product	Chemistry	Flash Point ASTM D92	Base Fluid Apparent Viscosity (cP) CTM 25 °C 45 °C		Color / Appearance	Apparent Viscosity CTM 25 °C, 50/s shear rate	Density (g/cm³) CTM 25 °C	NLGI Grade ASTM D217	Oil Separation ASTM D6184 24 h, 100 °C	Evaporation ASTM D972 24 h, 100 °C	Product Description
NYEMED® 7325	Silicone	> 300°C	60,000	42,000	White, Opaque	116,000	1.23	2.5	0%	0%	A UV-dyed, silicone-based grease with a narrow viscosity specification, appropriate for both motion control and lubrication in medical applications.
NYEMED® 7328	Silicone	> 300°C	165,000	116,000	White, Opaque	125,000	1.18	2	0%	0%	A silicone-based damping gel with a narrow viscosity specification. Developed for precision motion control in medical devices.
NYEMED® 7364	Synthetic Hydrocarbon	> 250°C	520,000	105,000	Light Amber, Translucent	710,000	0.93	5	0%	0.15%	A high-viscosity, tacky synthetic hydrocarbon-based damping grease that can also be used as a sealant or temporary adhesive for medical applications.
NYEMED® 7560	Synthetic Hydrocarbon	> 310°C	767	260	Light Yellow, Clear	27,500	0.88	2	1.50%	0.30%	A multi-purpose UV-dyed, synthetic hydrocarbon grease that is proven to protect electrical contacts and reduce mating force in connectors.
NYEMED® 7630	Synthetic Hydrocarbon	> 280°C	112	44	Tan, Translucent	11,530	0.87	2	0.50%	0.10%	A paste-like, synthetic hydrocarbon grease . Benefits include corrosion protection and wear reduction for sliding and rolling metal components, even at high temperatures and speeds.
NYEMED® 7492	Polyol-ester	> 245°C	29	27	Yellow-orange, Translucent	8,390	0.91	2	4.50%	0.30%	A paste-like, UV-dyed, synthetic polyol-ester grease with excellent high-speed metal-on-metal performance for applications like precision bearings.
NYEMED® 7471	Perfluoropolyether	Nonflammable	840	476	Clear, Colorless	N/A	1.83	N/A	N/A	0.01%	A completely fluorinated, inert fluid , exhibiting low solubility in most materials and liquids encountered throughout the medical industry.
NYEMED® 7477	Perfluoropolyether	Nonflammable	202	106	White, Opaque	17,540	1.95	2	4.6%	0.04%	A completely fluorinated, inert lubricating grease with broad utility, exhibiting low solubility in most materials and liquids encountered in the medical industry.
NYEMED® 7571	Perfluoropolyether	> 395°C	241	137	White, Opaque	13,420	1.78	2	4.70%	0.05%	A smooth, paste-like grease based upon a completely fluorinated, inert fluid. Provides lubricity and environmental protection for plastic and metal substrates, including electrical contacts and connectors.

The typical properties shown on this document should not be used as a basis for preparing specifications. The NYEMED® product line is manufactured in Fairhaven, MA by FUCHS Lubricants CO, formerly Nye Lubricants, Inc.

CTM = Company Test Method

FUCHS Lubricants

Innovative lubricants need experienced application engineers

Every lubricant change should be preceded by expert consultation on the application in question. Only then the best lubricant system can be selected. Experienced FUCHS engineers will be glad to advise on products for the application in question and also on our full range of lubricants.

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