

Since 1844  
**Nye**® **LubeLetter**  
September 2020



### Lubrication



### Collaboration



### Innovation





## Myths & Facts About Medical Lubricants

Not all lubricants are suitable for medical applications. To help you reduce risk and pick the right lubricant for your application, we've debunked the most common myths surrounding medical lubricants.



**Myth: There is an official medical-grade certification given to lubricants.**

**Fact:** An official medical-grade certification does not exist for lubricants. Nye Lubricants is ISO 13485:2016 certified. The ISO 13485:2016 certification specifies requirements for a quality management system adopted by an organization which needs to demonstrate its ability to manufacture medical devices, and provide related services, that consistently meet customer and regulatory requirements applicable to medical devices.

The primary objective of ISO 13485:2016 is to facilitate harmonized medical device regulatory requirements for quality management systems. This will define how a medical device will be manufactured including qualification and risk assessment at every stage, utilizing a failure mode effect analysis or FEMA.

Nye became ISO 13485 certified in 2015 to reassure our customers that our gels and fluids are manufactured to the same standards as medical devices. Nye is currently the only lubricant company to hold this certification.

**Myth: Lubricants only reduce friction and wear within medical devices.**

**Fact:** In addition to improving the longevity of your application, lubricants can also improve the performance and perceived quality of your application. Dirt and debris can build up on components and accelerate wear between moving parts. This can create reliability issues. For example, if debris were to form on the surface of a connector, it would eventually accelerate wear and cause connectivity issues. Grease creates an environmental seal and prevents the debris from reaching the component surface.

[Motion control greases](#) can also give greater control to the speed and consistency at which components move, making it an ideal solution for drug delivery devices. Since grease reduces friction, it also in turn reduces any noise, vibration, and harshness that may be off-putting to users.

**Myth: All food-grade lubricants are safe to use in medical devices.**

**Fact:** Per the FDA, [food-grade lubricants](#) are only approved for incidental food contact up to 18 ppm. They are not required to pass biocompatibility tests like ISO 10993 that ensure a lubricant can safely come into indirect contact with the skin or body cavity. [Our NyeMed® product line](#) is backed by ISO 10993 Cytotoxicity, Skin Irritation, and Acute Systemic Toxicity data to reduce risk for our customers.

**Myth: Medical lubricants pose a greater risk than benefit to my application.**

**Fact:** Properly selected lubricants improve device performance and biocompatibility testing helps mitigate risks to the manufacturer, device user and the patient. Nye [fully qualifies](#) all NyeMed® products and uses the ISO 13485 requirements to complete a comprehensive risk assessment that informs the development of manufacturing procedures, specifications, and tolerances. These processes are strictly followed and documented throughout manufacturing. Upon request, our lubricants can also be validated in our [Application, Development and Validation Test Laboratory](#) where our engineers can simulate the operating conditions of your application and evaluate lubricant performance.

**Myth: Myth: Lubricants for medical devices must be approved by a government organization before use.**

**Fact:** Fact: In the United States, government agencies do not regulate medical device material suppliers. However, selecting a lubricant designed for and tested to device standards can help reduce risk to device approval. Nye sources materials from our Approved Supplier List which have been selected after a diligent on-site audit.

Want to learn more? Visit our [NyeMed® page](#) or [Contact Us](#).



## Uniflor PFPE's

Nye's Uniflor™ PFPEs are the most thermo-oxidatively stable lubricants available today. Unlike any other brand of fluorinated lubricants, the Uniflor™ line utilizes every available PFPE oil to create a diverse product line and achieve optimal performance under a variety of operating conditions. Uniflor™ products can withstand temperatures from -90°C to +250°C, and even higher excursions.

### What are PFPE's?

Perfluoropolyether's (PFPEs) are fluorinated synthetic fluids that are well suited for the demanding environments or applications where chemical interaction between materials may pose an issue. While all PFPEs are composed of carbon, fluorine, and oxygen, the molecular structure of each PFPE fluid varies depending on the base materials and polymerization processes used by PFPE manufacturers. These structural differences will affect the fluid's pour point, volatility, viscosity, and viscosity index — all critical factors in lubricant formulation. Some PFPE oils, for example, have a pour point of only -20°C, while others offer pour points as low as -90°C. Similarly, some PFPE oils offer better wear resistance and vapor pressure properties than others.

### Advantages of Uniflor™ PFPEs

- Wide temperature performance
- Low volatility and vapor pressure
- Nonflammable and chemically inert
- Excellent oxidative and thermal stability
- Excellent plastic and elastomer compatibility
- Resistant to aggressive chemicals and solvents

## Automotive

To produce more powerful and efficient vehicles, automotive lubricants must be compatible with a range of materials while withstanding high temperatures. Uniflor™ lubricants are compatible with most plastics and elastomers and were designed to withstand harsh chemicals like brake fluid, and exhaust fumes. PFPE's high temperature stability helps protect against wear and arcing conditions to extend the service life.



Product	Temperature Range	Evaporation	Kinematic Viscosity ASTM D445		NLGI Grade	Product Description
			100 °C	40 °C		
Uniflor™ 8172	-45 to 225 °C	0.23%	18 cSt	167 cSt	2	General Purpose Use, OEM Specifications
Uniflor™ 8512	-50 to 225 °C	1%	15.8 cSt	65 cSt	2	Improved Low Temperature Performance
Uniflor™ 8921	-65 to 250 °C	0.1%	40 cSt	135 cSt	2	Very Wide Temperature Serviceability

- Anti-Lock Brake Bearings & Pistons
- EGR Valves
- Sensors
- Switches

## Aviation

Primary flight controls need to activate properly as desired by the pilot when the aircraft is in flight. Lubricating airframe components with a grease designed for high speed, wide temperature conditions will ensure proper long-term function and maintenance-free operation of these critical flight systems. Likewise, engine components, including the lubricant, must withstand a wide range of temperatures, be compatible with aviation fuels and resist corrosive fuel system vapors.



Product	Temperature Range	Evaporation	Kinematic Viscosity ASTM D445		NLGI Grade	Product Description
			100 °C	40 °C		
Uniflor™ 8921	-65 to 250 °C	0.1%	40 cSt	135 cSt	2	Very Wide Temperature Serviceability
Uniflor™ 8980	-65 to 250 °C	0.1%	45 cSt	140 cSt	–	Very Wide Temperature Oil
Uniflor™ 8172	-45 to 225 °C	0.23%	18 cSt	167 cSt	2	General Purpose Use

- Flight Controls
- Fuel Systems
- Electrical Systems
- Cabin Mechanisms

## Defense

Primary flight controls need to activate properly as desired by the pilot when the aircraft is in flight. Lubricating airframe components with a grease designed for high speed, wide temperature conditions will ensure proper long-term function and maintenance-free operation of these critical flight systems. Likewise, engine components, including the lubricant, must withstand a wide range of temperatures, be compatible with aviation fuels and resist corrosive fuel system vapors.



Defense	Temperature Range	Evaporation	Kinematic Viscosity ASTM D445		NLGI Grade	Product Specification
			100 °C	40 °C		
Uniflor™ 8991MT	-60 to 250 °C	5.1%	90 cSt	310 cSt	2	Honeywell ES-2155
Uniflor™ 8961MT	-80 to 200 °C	3.31%	21.7 cSt	71 cSt	1.5 – 2.5	MIL-PRF-27617 Type IV
Uniflor™ 8172MT	-45 to 225 °C	0%	18 cSt	167 cSt	2	MIL-PRF-27617 Type III

- F-15 and F-16 Engine Thrust Actuators
- Hydraulic Systems
- Oxygen Systems
- Navigational Instruments

## Medical

Medical lubricants are often selected to prevent wear and/or seal applications against fluids and debris that might adversely affect patients. Uniflor™ lubricants resist chemicals to protect your components and minimize risk. Additionally, their wide temperature capabilities make Uniflor™ the ideal choice for motorized, high temperature applications. For medical systems where proximity to patients causes concern for bio compatibility, our NyeMed® product line includes PFPE formulations that have been tested and certified.



Product	Temperature Range	Evaporation	Kinematic Viscosity ASTM D445		NLGI Grade	Product Description
			100 °C	40 °C		
Uniflor™ 8981	-65 to 250 °C	0.18%	41 cSt	136 cSt	1.5 – 2.5	Very Wide Temperature Serviceability
Uniflor™ 8512-FG	-50 to 225 °C	< 3%	15.8 cSt	65 cSt	2	NSF H-1 Food Grade Approval, Wide Temperature Use
Uniflor™ 8612	-20 to 250 °C	0.3%	33 cSt	345 cSt	3	High Viscosity, Mechanical Damping and Sealing

- Lead Screws
- O-rings
- Bearings
- Bushings

### Validated to Minimize Risk

Uniflor™ lubricants are typically selected for applications with demanding operating requirements. To assure you that our lubricants are compatible with your application, Nye offers in-house validation testing for all our lubricants. Our test equipment can be modified to meet unique design specifications and allows us to simulate conditions like temperature, load, and even in-vacuum environments.

Want to learn more? [Contact Us](#) or [Request a Quote](#).



## Case Study: Motion Control Grease for Sun Visors

### Background

Interior automotive components often require a lubricant to reduce noise and control motion in order to improve the functionality and perceived quality of the design. An Automotive OEM approached our European Channel Partner, Newgate Simms, with an aftermarket issue they were having with their sun visor design. The tight tolerances in the visor generated a great deal of friction between the sun visor bracket and the metal retaining cylinder and the spring. In order to move the visor, passengers needed to exert excessive force which was causing premature wear to the plastic components. The tight tolerances were also creating a creaking noise that was unpleasant for the driver. The OEM needed a plastic-compatible grease to make the sun visor both easier and quieter to open.



### Challenge

- Can Nye provide a grease that enables smooth, noise-free operation?
- Can Nye provide a plastic-compatible, odorless grease that will not migrate and can be dispensed by hand?

### Solution

#### NyoGel® 774L

*A silica thickened, light viscosity, synthetic hydrocarbon grease.*

- Light viscosity grease prevents wear in lightly loaded applications
- Compatible with most plastics and elastomers
- Good stay-in-place properties, low oil separation
- Odorless to accommodate proximity to driver

Product	Chemistry	Temperature Range	Kinematic Viscosity (40°C)	Oil Separation (24hrs @ 100°C)	Evaporation (24hrs @ 100°C)
NyoGel® 774L	PAO/Silica	-40 to 120 °C	2003.62 cSt	1.3%	0.2%

### Results

Newgate Simms recommended that the OEM try NyoGel® 774L, a light viscosity grease from our line of [motion control greases](#). After applying a sample of the grease to the bracket/retaining spring of the sun visor, it required much less force to move and the creaking noise was eliminated. Newgate Simms was also able to provide NyoGel® 774L in a syringe for easy repairs and hand-held dispensing. The OEM was so satisfied with its performance that they issued a service bulletin to aftermarket dealerships recommending the use of NyoGel® 774L for their sun visor design.



## Advanced Test Methods for Motion Control Applications

Grease is often used to control motion, provide a quality feel, reduce noise and vibration; friction and wear reduction come as an added benefit. Many automotive OEMs can struggle to find a non-silicone lubricant that performs consistently over a wide temperature range. Chemists at Nye Lubricants have developed a series of test methods to quantify the reliability of our [motion control lubricants](#) under various temperature and shear conditions to ensure your application has the same feel, every time, at any temperature.



### Consistency Over Wide Temperature Range

A hand-operated component, such as a shifter or sun visor, must provide the same actuation force regardless of temperature to give the user the same quality feel. Nye's custom rheological test evaluates the ability of a grease to maintain its viscosity at extreme temperatures. During this test, the grease is sheared from -40 to 120 °C. The viscosity of the grease is recorded at each temperature point and is used to create a viscosity ratio (VR).

The VR shows the viscosity consistency of a grease from -40 to 120 °C; a VR of 1 would be ideal. If a grease has a smaller VR it means that the grease is more likely to maintain the same quality feel when sheared over a wide temperature range. Nye has the capability to measure the shear response at different strains to simulate a customer's application. For example, the strain ratio can demonstrate how a grease will behave in a dial; rotating a dial should feel the same, regardless of the turning speed.

### Dynamic Wear Performance

Mechanisms operating under dynamic conditions, like seat tracks, will wear at a different rate than applications operating at a constant speed or duration. The mini-traction machine (MTM) wear test simulates how a lubricant will perform within the different [lubrication regimes](#): boundary, mixed or hydrodynamic. The wear scar is analyzed through

profilometry and a wear rate is calculated. This allows us to compare oils or greases within the same lubrication regime and rank their performance. The smaller the wear rate, the better protected your components are in dynamic conditions.

### Consistency Over Repeated Motion

A mechanism must provide a reliable feel or actuation even if the mechanism is used frequently over a short period of time. If a grease loses its structure after repeated motion, tolerance could be affected. In these applications, you want the lubricant to shear and recover its structure as quickly as possible so that the next actuation feels the same. Nye's custom rheological test method measures the percent recovery of the grease to quantify the stability of its structure after repeated use; if a grease cannot recover its structure, the performance will be inconsistent. A 100% recovery percentage is ideal.

### Low-Temperature Torque

This industry standard test is a useful measurement of how grease affects start-up and running torque at low temperatures. The test quantifies the amount of force required to rotate a bearing at the initial start-up and then after 60 minutes of running at -40 °C. This test is used to indicate the degree to which grease inhibits motion and can be particularly important for low-powered mechanisms such as those found in automotive interiors.





## Meet Nye - Martin Weinstein

Martin Weinstein joined Nye Lubricants in 2011 as its Director of Quality and Process Engineering. Martin came to Nye with extensive knowledge of quality and process engineering which he has used to solidify the QA / QC and process development aspects within Nye. With his Six Sigma Black Belt training, he has elevated the quality and engineering standards for Nye Lubricants.

Before joining the Nye team, Martin was the Director for Product Development at the Pall Corporation, a leader in the biotech filtration industry (Pall Corporation). His vast experiences in medical devices and cleanroom manufacturing combine to serve Nye well. Weinstein received his degrees in Mechanical Engineering from Rensselaer Polytechnic Institute in 1987 and holds 18 US Patents in polymer processing and medical / filtration devices.



### Martin Weinstein

Director of Quality and  
Process Engineering

#### ◆ How would you describe Nye's approach to Quality Management?

Nye's approach to quality is one of Continual Improvement. We have to keep evolving and getting better to ensure we deliver our customers the value they expect.

#### ◆ What about our Quality Management System sets us apart from other lubricant companies?

Nye's Quality Management System is a function of our daily work life. It captures the way we work and manage our daily business. It is not just a "check in the box" at audit time, it is engrained in our culture.

Other lubricant companies tend to focus exclusively on ISO 9001:2015 and IATF 16949:2016 because their target markets tend to be automotive or transportation related. While we also hold these certifications, Nye has a customer-centric approach to quality management that prioritizes the unique needs of each industry we serve. We have the right lubricants for a variety of industries each with their own high standards for product quality. Our AS9100D for Aerospace and ISO 13485:2016 for Medical are some of the most stringent quality standards of any industry. Nye's quality-engrained culture makes it possible for us to serve these high-end markets.

◆ **Nye has recently focused on incorporating Industrial Internet of Things (IIOT) technology into our manufacturing practices. How will this help us improve process efficiency?**

Nye's IOT is being used to gather in-process data for quality and maintenance. The way we are implementing it, we can set high and low alert limits for a variety of different operating conditions like mixing speed or temperature. When an IOT device senses data approaching the alert limits, we will get notified by computer or tablet. This enables our engineers and maintenance personnel to intervene and prevent a failure before it occurs.

◆ **What is your favorite part about working for Nye?**

I enjoy each day and the challenges that come about. Every day is different. Whether we are scaling up or down a process, introducing new equipment, installing IOT, or having a quality audit, my mind is always challenged. That is what I enjoy most.



**Stay tuned for  
more updates  
next month!**

**Follow Us**

Like what you see? Spread the word and share our articles on social media! Be sure to follow us on Twitter, Facebook, and LinkedIn and turn on your notifications so that you will be notified every time we post!

