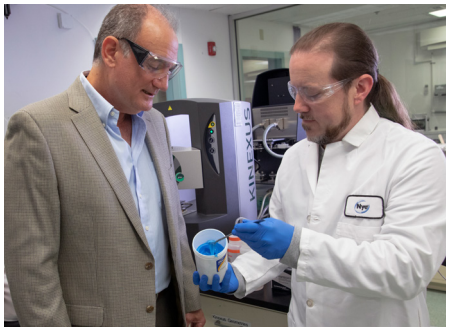
Since 1844

Nye® Medical News

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.

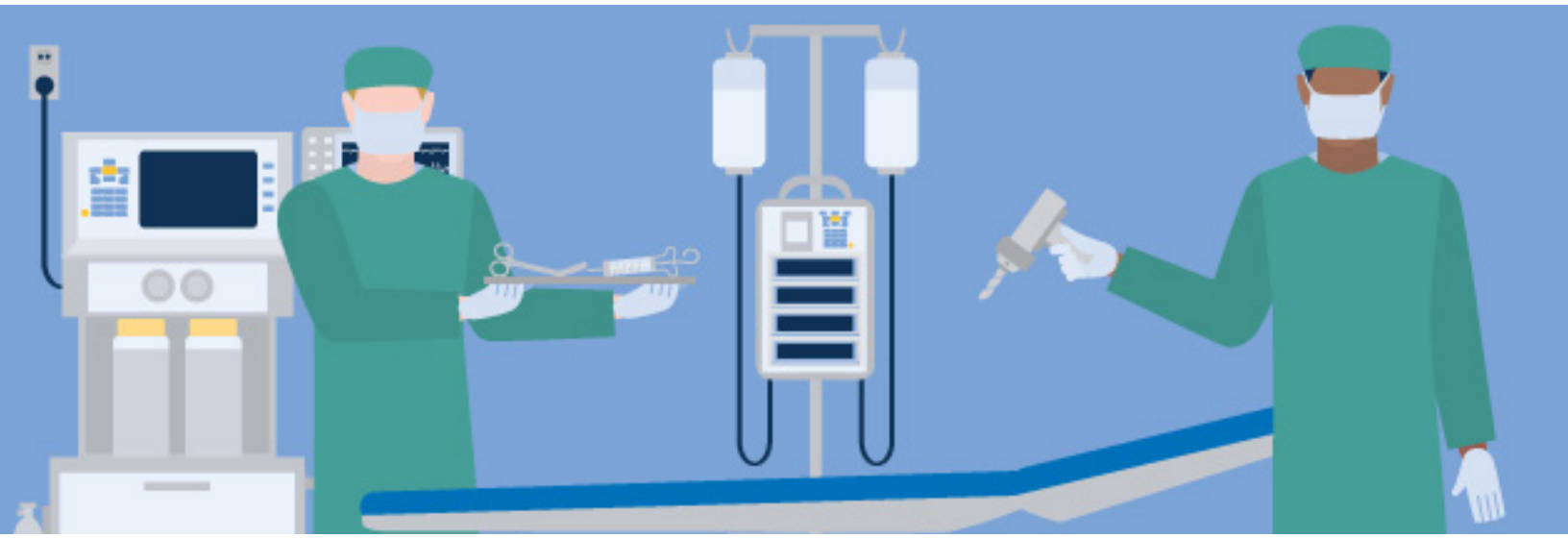
Fact: Per the FDA, food-grade lubricants are only approved for incidental food contact up to 18 ppm. They are not required to pass biocompatibility tests like ISO 10993 that ensure a lubricant can safely come into indirect contact with the skin or body cavity. Our NyeMed® product line is backed by ISO 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.

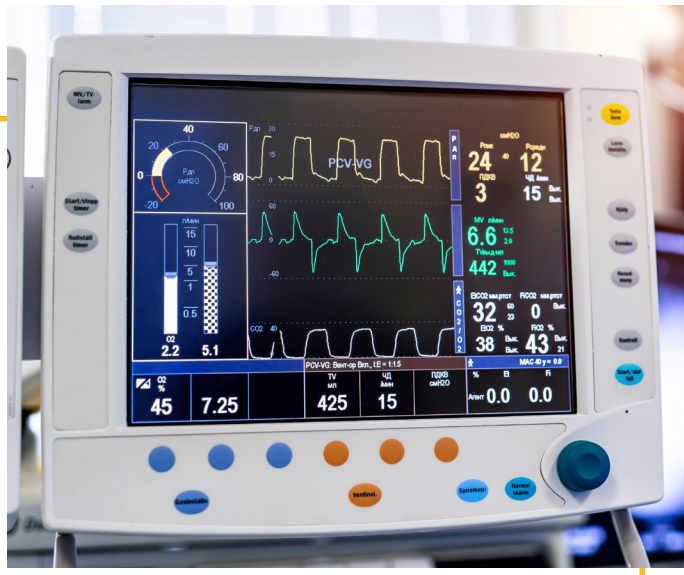
Myth: Myth: Lubricants for medical devices must be approved by a government organization before use.

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.

Case Study: Grease for ControlAir Ventilators



Background

The United States federal government tasked NASA/Jet Propulsion Laboratory (JPL) to design a mass-producible ventilator device that could be built with "off the shelf" parts in response to the COVID-19 pandemic. The design was completed by JPL Engineers in April 2020 and was released to twenty manufacturers all over the world. ControlAir, a worldwide leading manufacturer of precision pneumatic and electro pneumatic control products, was one of the first manufacturers rewarded with a contract. The dynamic lip seal within the device's two regulators needed to be lubricated and ControlAir, Inc needed the grease quickly to stay ahead of their production schedule.

Challenge

- Can Nye provide a ventilator grease in time to accommodate the manufacturer's critical production schedule?

Soultion

Uniflor™ 8612

A stiff, PTFE thickened, medium viscosity, completely fluorinated grease.

- Resists aggressive chemicals.
- Very wide temperature capability
- Excellent plastic, elastomer, and oxygen compatibility

Product	Chemistry	Temperture Range	Oil Separation (22 h @ 150 °C)	Evaporation (22 h @ 15 0°C)
Uniflor™ 8612	PFPE/PTFE	-20 to 250 °C	3%	0.3%

Results

Nye's grease, Uniflor™ 8612, was specified by ControlAir to lubricate the dynamic lip seal within the regulators of the ventilator device. ControlAir was extremely pleased with Nye's rapid response, with the project lead saying, "After a brief exchange with Nye's production team, they let us know they were shipping product the very next day, weeks ahead of schedule. I have used Nye Lubricants at my current and previous employers, and they always seem to have the answers. Many thanks to the Nye team."

Meet Nye - Joe Sahl

Meet Joe Sahl, Nye's Medical Industry Leader. Joe came to Nye in 2019 with more than 12 years of Engineering experience at prominent metal working, aviation, and medical device companies. Residing in Boston, Joe helps our customers in the Northeast United States find lubricants for demanding and sensitive mechanisms. As the new Medical Industry leader, Joe will investigate new lubrication trends and solutions for pharmaceutical manufacturing, medical devices, and surgical tools. Joe holds a bachelor's degree in Materials Engineering from Lehigh University and an MBA from the University of Pittsburgh.

How has the Nye medical team worked to address some of the logistical issues surrounding medical device production during the COVID-19 pandemic?

Nye was able to remain open and operating through the pandemic, which allowed us to continue to serve many of our customers – medical among them – who were deemed essential businesses. Thanks to modern connectivity tools, our medical team was able to continue to virtually support efforts in this market. We've also been doing our part to ensure the supply chain for life-saving applications like ventilators remains uninterrupted by fast-tracking them when necessary.

What are the lubrication requirements for ventilators?

Depending on the application, the requirements vary. For plastic/elastomer components, such as valves and seals, it's crucial that the lubricants be neutral in color, and avoid reacting with polymers like polycarbonate. PFPEs like our NyeMed® 7477 work well in these applications. For gearing applications, a lubricant must be able to handle moderate to heavy loading making PAOs like NyeMed® 7630 a good choice. The common thread through these applications is biocompatibility. It is critical that incidental contact with a lubricant or possible off-gassing not present a health threat to the patient. Our certification to provides this assurance.

What lasting impact will COVID-19 have on the medical device and diagnostic industry?

Clinical work is critical to the development of medical devices. As employees worked remotely during COVID-19, labs ran with reduced workforces or closed entirely; this resulted in a temporary slowing of the development cycle. The backlog from this slowdown will probably persist for a while, as companies ramp back up. Additionally, the tide really went out with COVID. Those companies that survive - especially the larger ones with cash on hand – will likely be looking to make acquisitions of smaller companies and startups.

What role will lubricants play in the future of surgical technology?

We're still exploring this space, however on the surface, I'd say complexity and sophistication in design is growing as surgical devices become more effective. Developers are targeting specific applications, new usage situations, and often utilizing new materials of construction. If we can help simplify the design by removing a mechanical element and allowing a lubricant to do the work, that's one less component to worry about.

What is your favorite part about working at Nye?

No day is the same. Working every day to help our customers solve their design issues is a very satisfying feeling. I also enjoy learning about interesting new technologies and identifying potential new uses for our products.

Stay tuned for more updates next month!

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