Tech Article

Medical Device Coatings: 10 Things to Consider

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Industry:
Medical Device

Published:
MedTech Innovations

A non-migrating lubricant coating is essential in a cleanroom environment.

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Medical Device Coatings Boost Manufacturing Performance

When disposable medical equipment manufacturers design precision mechanical devices, friction between moving parts can be difficult to manage. Engineers typically use medical device coatings including oils, greases or dry powders to smooth the delicate movements of parts. The coatings reduce the friction and sticking of parts that slide, shear, twist, rock or pivot. They resolve the "stiction" problems commonly found in disposable medical devices such as catheters, cutting tools, staplers, hypo tubes and other "surface to surface" assemblies. Lubricating coatings can reduce the coefficient of friction on treated parts to as low as 0.06. This typically translates into a 25-30% reduction in actuation forces, greatly improving the part performance. Many of today's complex medical devices would not be commercially viable without the aid of a lubricating coating.

In addition, lubricating coatings are also used on the manufacturing equipment and assembly fixtures themselves to help speed the production of plastic and metal components. They are used on chains and pulleys, metal extrusions, machine window guides and door tracks, chutes and slides, conveyors and almost any other surface or assembly that requires a clean, durable, slick coating for optimum performance. Lubricating coatings are also used to release plastic parts from their injection mold die cavities.

However, not all coatings are the same. Here are some key factors to consider when choosing a lubricating coating for medical device assembly.

Good Solubility And Low Viscosity:

Lubricating coatings are typically applied via dipping, spraying or wiping. The carrier fluid, or fluid used to disperse the coating, should be engineered to either dissolve or disperse the coating so that when the carrier fluid evaporates, it leaves a very thin, uniform layer on the surface of the treated part. It should also have low viscosity to wet and conform to the treated parts' surface geometry, ensuring highly-consistent surface coating.

Hostile To Bioburden:

Device makers should choose a lubricating coating with a non-aqueous carrier fluid to prevent bacterial growth and other biologic contamination. In addition to being pyrogenically-inert, it should be compatible with all commercially used EtO (Ethylene Oxide) and radiation sterilization processes.

Nonflammable:

The lubricating coating should be nonflammable to reduce the risk of fire as it is applied. This is especially important for high-volume, high-speed production facilities. Many mechanical assembly operations are prone to static discharge, so nonflammability for safety in both storage and use is essential.

Good Materials Compatibility:

Lubricating coatings should have excellent materials compatibility. They should be safe to use on materials including metal, glass, plastic and ceramic parts.

Lubricant coatings solve "stiction" problems commonly found in disposable medical devices such as catheters, cutting tools, staplers and hypo tubes.

A non-aqueous carrier fluid prevents bacterial growth and other biologic contamination.

Easy To Apply:
The lubricating coating should be easy enough to apply during the in-house assembly process. By not outsourcing the coating process, device manufacturers save both time and money by validating a process where they always maintain custody of parts being treated.

Fast Drying And Low Odor:
Device manufacturers should look for a coating with a carrier that evaporates quickly, has a low odor and leaves no residue (other than the coating being deposited on the substrate).

Durable And Attractive:
A good coating dries into a finish that will last the service life of the device. It should maintain a uniform finish without any staining or unsightly clumps, drips or runs.

Non-Migrating:
The coating should not migrate or transfer to the packaging or other untreated surfaces. The lubricating coating should stay where it is applied. This feature is an essential attribute when the coating is applied in a cleanroom environment.

Safe for Workers and the Environment:
Device makers should choose a lubricating coating with a higher worker exposure limit. Choose one with an 8-hour time weighted average of 200 ppm or more.

Medical Grade:
Ensure the coating is ISO 10993 tested and certified as medical-grade. It should also be cleanroom compatible. This helps ensure a faster and easier validation process for both the coating and the associated device.

To Sum Up:
There are many lubricating coatings available to disposable medical device makers. When specifying a coating, manufacturers should look for a supplier that can provide expert advice to help them simplify the selection process. This includes individualized consulting, in-lab testing, and the ability to provide both off-the-shelf and customized formulations to ensure the right coating for their specific needs.

About the Author:
Venesia Hurtubise is a Technical Chemist at MicroCare which offers precision cleaning solutions. She has been in the industry more than 6 years and holds a MS in Green Chemistry from Imperial College. Hurtubise researches, develops and tests cleaning-related products that are used on a daily basis in precision cleaning and medical applications. For more information, visit www.microcare.com.

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