Tech Article

How Dry Lubricants Speed Medical Device Assembly

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MicroCare Medical™ Duraglide™ Dry Lubricant.

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Recent medical device design incorporates single-use devices that make procedures less complicated. This often involves device design that is minimally invasive, meaning a device that is smaller and more complex with many tiny moving parts. The higher the part count, the more likely stacked tolerances will be an issue for medical device design engineers and manufacturers.

In engineering, tolerances refer to the permissible limits of variation in the physical dimensions specified by the engineer to allow reasonable flexibility for imperfections and inherent variability, without compromising the performance of the finished assembly.

These dimensions leave some room for variation within certain limits, but as tolerances begin to stack up against each other, tight-fitting parts can make medical device assembly difficult and slow. In addition, excessive sticking and friction from overly-tight components may degrade or restrict the free movement and efficient operation of a finished device. Addressing tolerance issues has implications all the way to the end-user, especially for a medical device that must perform its mechanical function precisely and smoothly.

One option for dealing with stacked tolerances would be to design devices with tighter dimensional tolerances. This clearly would ensure higher levels of performance. However, higher precision typically means higher cost due to more frequent inspections and maintenance of the machines and tooling during the manufacturing process. In the interest of keeping costs low, ever-tighter tolerances usually are not the most cost-effective choice.

Another alternative is for design engineers to specify plastic or nonferrous materials because they have inherent lubrication properties, but that strategy has a drawback. End-use loading requirements may preclude the use of less durable plastics and metals.

The Solution

One simple solution to address the challenges of stacked tolerances is to use a dry lubricant dispersion based on polytetrafluoroethylene (PTFE). This dispersion contains a fluoropolymer powder suspended in a high-purity, nonflammable carrier fluid.

Parts are coated with the fluid mixture in a thin coat. It quickly evaporates leaving a smooth, dry fluoropolymer coating on the part. It is most commonly used on disposable medical devices. Especially those like catheters, cutting tools, staplers, hypo tubes. Also, other “surface to surface” assemblies that slide, shear, pivot, rock or twist. Dry lubricant works extremely well on high-speed, high-volume mechanical assembly operations. It is also frequently used on production fixtures to speed the assembly of plastic and metal components.

The dry lubricant minimizes friction between moving parts and reduces actuation forces by 25% – 30%. Some dry lubricant dispersions are also ISO 10993 certified medical-grade lubricants, making them easier to add to your validation processes.

Dry lubricant dispersions minimize friction on tools that slide, shear, pivot or twist.

Dry lubricants have excellent materials compatibility and have the ability to conform to nearly any surface geometry. Perhaps one of the greatest benefits of these surface treatments is that they are easy to apply in-house and incorporate into the assembly process, which further adds to their cost effectiveness.

Especially important in the case of medical devices and manufactured parts, PTFE-based coatings do not migrate, meaning they will not transfer to the packaging or other untreated surfaces. This is in contrast to silicone coatings that readily transfer to other surfaces and attract and hold surface contamination.

Optimizing Your Coating Process

There are considerations to be taken into account when determining a dry lubricant coating process that is right for a specific device, assembly or other manufactured part. When determining which lubricant and process is right for the project at hand, it is helpful to know the answers to the questions below. This will help you determine the most suitable type of lubricant for your devices or manufacturing processes.

- **What is the application or end-use of the device or part?**
  For example, will it need to pierce skin such as a surgical needle or hypodermic cannula? If the device will be invasive, typically a silicone-based coating is used, as medical-grade silicone has excellent lubricious properties and is widely accepted as safe for contact with human tissue.

- **How many cycles will the device/assembly need to perform?**
  Will it be one, a dozen, or hundreds? Knowing the number of cycles indicates if a temporary or more permanent coating is needed.

- **Will the lubricant be applied in-house or will it be done off-premises?**
  Most dry lubricants are typically easy to apply in-house and in high-production environments. However, more durable lubricants or those with specialized hydrophilic properties may require special chemistries and more advanced application methods and may need to be applied by an experienced outside vendor using highly specialized methods. Also, some types of PTFE-based lubricants need to be applied under precisely controlled thermal and atmospheric conditions to impart a more durable coating and longer surface life.

- **What is the material and geometry of the part?**
  Versatile dry lubricants are compatible with most plastics and metals. They conform to virtually any surface and they readily penetrate into complex shapes and internal surfaces.

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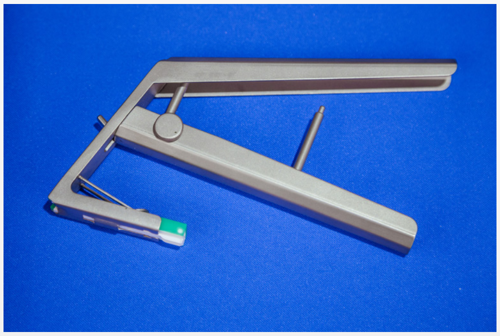

Dry lubricants can reduce actuation forces by 25-30%.

Dry lubricants smooth the operating of tight-fitting parts.

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Application & Drying Methods for PTFE-based Lubricants

There are a number of ways to coat medical devices with dry lubricant.

1. Dipping

Dipping is most commonly used for high volume production and is suitable for coating small parts, coils of wire, and irregular shapes. It provides a consistent and uniform coating to virtually any surface geometry as well as internal surfaces. Fully finished devices also may be dipped into a PTFE carrier fluid dispersion. The coating level is determined by the concentration of solids, rate of withdrawal, and number of applications. A single dip is typically adequate for most uses.

2. Wiping or Brushing

Wiping or brushing is used most often for moderate to low production runs. It is useful for coating continuous surfaces such as rods, tubing, or sheets. In addition, wiping and brushing are appropriate for coating small, selected areas of a larger part. One variation of this method is flood coating, followed by wiping.

3. Spraying

Spraying can be done using a hand-held spray gun or with automatic spray heads. Operation can be either intermittent or continuous. Typically, the technique is to apply a succession of thin coats, allowing the surface to dry between applications. Results from this technique are typically better than the application of a single thick coating, which can take longer to dry and can cause uneven coverage and poor adhesion. A nonflammable carrier fluid engineered with slower evaporation may be specified to ensure a consistent coating.

4. Aerosol Applying

Aerosol allows convenient surface application and quick coverage. Ideal for use on injection mold tooling. Some aerosol sprays have very tight spray patterns enabling pin-point lubrication, which is helpful for hinges and pivot points. However, some aerosol sprays may contain other additives to impart special properties making them unacceptable for medical device applications.

5. Air Drying

Air drying is best done in areas that are free of dust. Drying times of coatings are dependent on the carrier fluid and the thickness of the lubricant application. Increasing the temperature of the treated part may reduce drying times especially on the internal surfaces of complex assemblies.

6. Heat Curing

Heat curing is used in some applications when a more durable coating is desirable. A brief heat-treating process can turn the coating into a hard, attractive finish. Heating turns many dry lubricants completely clear, so it appears nothing is on the surface of the device. This is particularly helpful if the coating needs to be semi-permanent, or if it needs to be invisible on the device.

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The Bottom Line

Due to stacked tolerances, many medical devices would not be commercially viable without a dry lubricant. Fortunately, there are a number of dry lubricants available to address the manufacturing challenges of tight-fitting parts and friction. Other considerations when choosing a dry lubricant include cost, safety, materials compatibility, floor space availability, waste minimization and environmental concerns. The best approach when choosing a dry lubricant is to partner with a coating provider that can guide you through the selection process. They will help ensure you get the right type of lubricant to optimize your manufacturing processes and improve the quality and consistency of the finished product.

About the Author:
Jay Tourigny is Senior Vice President at MicroCare which offers precision cleaning, lubricating and debinding solutions. He has been in the industry more than 30 years and holds a BS from The Massachusetts College of Liberal Arts. Tourigny holds numerous U.S. patents for cleaning-related products that are used on a daily basis in medical, fiber optic and precision cleaning applications. For more information, visit microcare.com.

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