Tech Article

New Processes & Controls Improve Medical Device Performance

Author:
Jay Tourigny, MicroCare Senior Vice President
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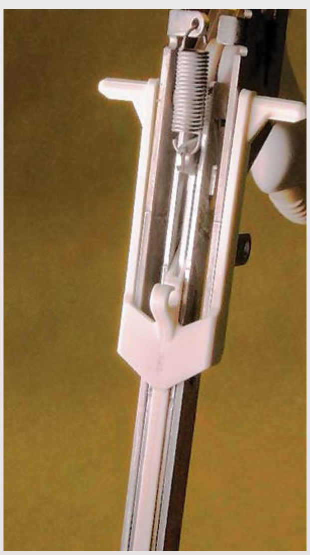

Friction from overly-tight components restrict the movement of the device.

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Engineers design minimum and maximum tolerances into almost every component, defining the allowable dimensional variation any component can carry. Stacked tolerances — when the accumulated tolerances restrict free movement — are a risk with multi-part mechanical assemblies caused when all of the components are at the high end of their dimensional limits. Modern cleaning and lubricating fluids can resolve this issue and offer an improvement in function and speed assembly not available any other way.

In a perfect world, every component of a medical device would be manufactured to exact dimensional specifications without variation. Sadly, the world is far from perfect so engineers design tolerances into almost every component. These tolerances define the maximum degree of dimensional variation any component can carry. Fundamentally, it's all about costs. Since improved perfection generally will drive manufacturing costs higher, it makes economic sense to accommodate minor dimensional variations during manufacturing as long as those variations do not compromise the performance of the finished assembly.

But there is a catch, and it is a familiar challenge faced by manufacturing engineers: the difficulty of "stacked tolerances" and how they impact the functionality of many complex devices. Fortunately there are new process options engineered to manage the cumulative effects of dimensional variability in medical devices.

The Cost of Tight Tolerances

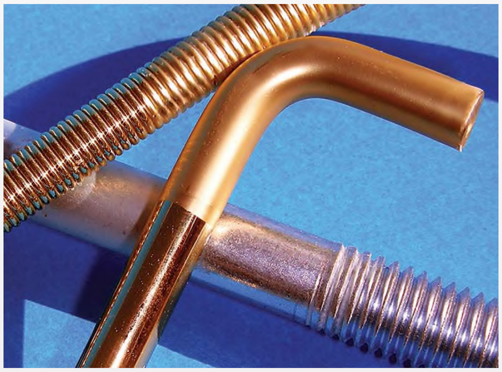
Stacked tolerances are an inevitable element of multi-part mechanical assemblies with moving parts. Hypothetically, if a device features four or five nested components, it is quite possible that sheer random variation of all the components may fall within the worst case limits of their design tolerances. This is especially true with plastic parts.

This presents two challenges to a manufacturer. First, during the assembly process mated parts may fit too tightly, which makes assembly difficult and slow. Alternatively, friction from overly-tight components may degrade the operation of the finished device. The device may function poorly because the accumulated tolerances restrict free movement.

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 everything with tighter dimensional tolerances. This clearly would ensure higher levels of performance. But in the interest of keeping costs low, ever-tighter tolerances usually are not the most cost-effective choice.

The obvious answer is to lubricate the components. This can be done several ways. Design engineers often specify plastic or nonferrous materials because they have inherent lubrication properties. Engineers also may specify a silicone- or hydrocarbon based lubricant that could reduce friction.

But these strategies have drawbacks. End-use loading requirements may preclude the use of less durable plastics and metals. Silicone and hydrocarbon lubricants also present cleanliness problems because their tendency to readily transfer to



Dry lubricants conform to virtually any surface geometry.

untreated surfaces and to attract and hold surface contamination that may be problematic in the end use.

The Dry Lubricant Answer

An often-overlooked but cost-effective way to address the challenges of stacked tolerances is to use a dry lubricant. On the consumer level, almost everyone is familiar with powdered graphite that often is used to lubricate hinges and drawers. For industrial applications, modern dry lubricant coatings usually are based on a form of dry polytetrafluoroethylene (PTFE).

To apply the lubricant, a microdispersion of PTFE in a carrier fluid is used. The ratio of PTFE in the carrier is normally specified as a percentage, by weight. The microdispersion is applied to parts using a spray or simply by dipping the parts into a liquid bath. The carrier fluid then evaporates away leaving a smooth, dry PTFE coating on the part.

Dry lubricants are a powerful addition to an engineer's bag of tricks. Dry lubricants are versatile: they can be engineered from a very thin to a reasonably thick coating. They are compatible with most plastics and metals. The dry lubricants readily conform to virtually any surface geometry including braided wire cables and complex meshing; they readily penetrate into complex shapes and blind vias. They are easy to apply in-house and may easily be incorporated into the assembly process.

Other Advantages

Dry lubricants have other advantages as well. Because components coated with dry lubricants will snap together easily, they speed the assembly of complex devices. Dry lubricants also are clean, non-migrating and can be easily applied in a variety of processes. Medical grade formulas are available with ISO 10993 certification, nonpyrogenic properties, and full compatibility with sterilizing processes. There are few, if any, toxicity or handling issues with PTFE materials, and nonflammable carriers can be specified for maximum safety. Lastly, the coating can be used as-is, or a brief heat-treating process can convert the coating into a hard, durable and highly attractive finish.

But the biggest benefit of dry lubricants is how they overcome stacked tolerance issues and improve the quality and performance of a finished device. Dry PTFE lubricants instantly will reduce the coefficient of friction on a treated part's surface to 0.06. This translates into a 25-30% reduction in actuation forces and smoother operation, greatly improving product performance. In fact, many complex medical devices manufactured today would not be commercially viable without a dry lubricant.

Too Many Choices

Choosing the correct dry lubricant and coating process can mean significant time and cost savings in the assembly room, so it is important to consider all the variables in play.

Some vendors simply sell the PTFE as a dry powder, which resembles a large bag of flour or sugar. Customers then select their own carrier fluid, which is problematic because the subtleties of the chemistries may not be well-understood. Home-grown

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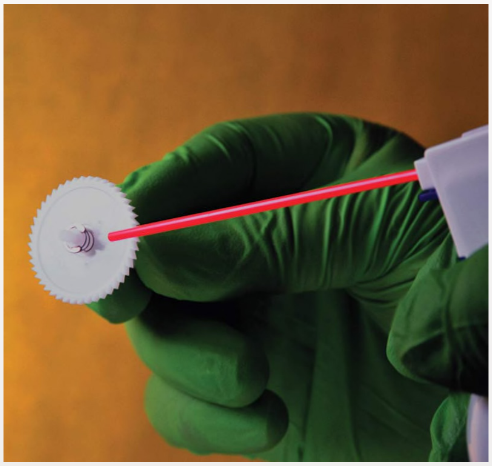

Dry lubricant is often applied to parts using a spray.

The fluid on the left has a short PTFE "hang time" compared to the MicroCare™ Duraglide™ lubricant on the right.

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dry lubricants such as these often suffer variation in both particle size and the ratio of PTFE solids to the carrier fluid, compromising the lubrication properties.

Other vendors, such as MicroCare Medical, offer engineered and calibrated medical grade products that are ready-to-use. Using high-purity carrier fluids that meet global regulations the dry lubricant is tailored to user specifications making process validation fast and simple.

Equipment for coating application is also worthy of close evaluation. In order to control evaporation and maintain lubricant-to-carrier ratios for maximum consistency and quality, engineers can now specify process-specific equipment for the coating step. For high volume production, features in this new equipment may include engineered dip tanks with carrier fluid recovery systems, temperature controls, automated feeding systems such as hoists or conveyers. As an alternative, moderate to low volume production may use programmable spray systems or brush applicators.

PTFE Content Is Key

A major challenge to maintaining a quality coating process is to manage the "hang-time" of the PTFE particles in the carrier fluid. Large PTFE particles found in many formulas are physically heavy and have a brief "hang time" within the carrier fluid . Large PTFE particles, especially when used with the wrong carrier fluid, quickly sink to the bottom of the dip tank or storage vessel, separating from the carrier fluid and degrading the consistency of the coating application.

An optimal solution to the short "hang time" of PTFE particles is to specify a precalibrated fluid using micro-particles. For example, MicroCare Medical uses proprietary "microdispersion" PTFE technology with the smallest possible PTFE particles. These microscopically small particles will stay in suspension far longer than heavier particles resulting in a thin, even, smooth film over the entire treated surface.

Naturally, there is no free lunch. Dry lubricants are most effective when the ratio of PTFE solids to the carrier fluid remains constant and correct. This is vitally important to ensure a smooth, streak-free coating over long production runs. The first challenge is controlling the evaporation of the carrier fluid. As noted above, PTFE dry lubricants are mixed with a carrier fluid that by design evaporates very quickly. This is necessary because speedy drying maintains high production throughput and improves the consistency of the coating on the device. So, it is important to frequently test the PTFE to carrier fluid ratio. It may also require "topping off" the carrier fluid to maintain the correct parameters.

The Bottom Line

For medical device design engineers and manufacturers, dry lubricant coatings can play a huge role in enhancing the performance and consistency of a finished device. Although there are numerous challenges that can impact the results, the most essential issues are understanding the coating application process and keeping the PTFE dispersion ratios consistent.

Developing a partnership with a vendor that understands the coating process will go a long way to improving the quality and consistency of finished product. This partner should be able to offer insights on regulatory compliance, the chemical parameters that affect the coating, and suggestions to make the coating as consistent, efficient and sustainable as possible. The coatings partner also should be able to evaluate and optimize the client's process — i.e., the physical footprint of a system, electrical requirements, maintenance requirements, waste disposal and waste minimization. Ultimately this emphasis on process control will help a company maximize its profitability.

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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