Using Dry Lubricants to Address Stacked Tolerances

Addressing tolerances is something with which most design engineers developing medical devices are familiar. The challenge can be even greater when dealing with stacked tolerances. This article offers insight into addressing these stacked tolerances using dry lubricants to reduce the force needed to actuate or execute a device.

One of the most familiar challenges that medical device design engineers and manufacturers grapple with is tolerances. In engineering, the tolerance refers to the permissible limit or limits of variation in a physical dimension. These dimensions can vary within certain limits without significantly affecting function of a finished assembly or process. Thus, tolerances are specified by the design engineer to allow reasonable leeway for imperfections and variability without compromising performance. This is a particularly common challenge with complex, single-use mechanical assemblies, such as staplers and arthroscopic devices.

Tolerances become a challenge for design engineers and manufacturers when they begin to "stack up" against each other. For example, when a mechanical assembly, such as a medical stapler, is assembled, the tolerances of each metal stamping, spring, or plastic part may begin to combine in such a way that the assembled device requires more force to actuate, or execute. This is most common in high-volume production, when tooling used to manufacture metal stampings, springs, and plastic parts begins to wear. In this case, manufacturers want to maintain the quality and consistency of the finished device while controlling costs. Obviously, how these tolerances are addressed has implications all the way into the operating room, where the doctor needs the device to function precisely and smoothly in order to complete a procedure.

There are several ways that design engineers and manufacturers can deal with stacking tolerances. Engineers can choose to design everything with tighter tolerances to gain higher precision. However, "precision" commonly means more frequent inspection and maintenance of tooling and fixtures during manufacturing, driving up the unit price of a finished device. A more common way of dealing with stacking tolerances is to apply a lubricant coating, such as PTFE or silicone, on the finished assembly to reduce friction.

The Dry Lubricants Solution

Dry lubricants using PTFE particles are a superior way for the design engineer and manufacturer to reduce the impact of tolerance stacking. In fact, many single-use medical devices used today would not be commercially viable without this coating.

Dry lubricants are used on many devices or mechanical assemblies found in the operating room, including catheters, cutting tools, staplers, hypotubes, and other surface-to-surface complex assemblies.

Dry lubricants typically reduce the force needed to actuate or execute a device by 25% to 30%, and provide a silky, almost effortless actuation for the medical professional performing the procedure. In comparison to silicone coatings, which are oil-based, dry lubricants impart a lower coefficient of friction and are non-migrating so they will not transfer to packaging.

There are many variables to consider in choosing a dry lubricant. Consistency and quality of the coating is essential. Many coatings with PTFE micropowders require constant agitation because of large PTFE particles that have low "hang time" in the liquid carrier; even with constant agitation, this can often produce inconsistent, streaky coatings. Another consideration is the evaporation of the carrier fluid used to apply the PTFE, which can evaporate during the process so that there is inconsistency in the PTFE coating between device production lots.

Some providers of these dry lubricant coatings, such as MicroCare Medical and its Duraglide dry film lubricants, provide a pre-mixed and calibrated formula that actually maintains the ratio of carrier fluid to PTFE particles. In addition, MicroCare Medical uses proprietary "microdispersion" PTFE technology to deposit a thin, smooth film over the treated surface. These microdispersions actually suspend the PTFE in unique carrier fluids to create a better "hang time," resulting in a more consistent coating and smoother device movements. In addition, with environmental concerns top of mind for engineers and manufacturers, Duraglide dry film lubricants provide nonflammable handling, storage and use, excellent materials compatibility, and excellent environmental properties.

Another consideration for manufacturers outside of the dry lubricant product quality should be the actual process of applying the coating. Some providers will work with manufacturers to make sure that their application process is optimized to provide consistency and quality in the coating, improving product functionality while saving money and time on the assembly floor.

Conclusion

For medical design engineers and manufacturers addressing dimensional tolerances and working to make devices viable, dry lubricants can provide a superior way to overcome friction, reducing the force needed to actuate a device. For both the design engineer and the manufacturer, a consistent, dry lubricant coating can ultimately maintain precision and ensure consistent device performance. Down the

line, the doctor reaps benefits from the dry lubricant coating in the smooth actuation of the finished device to complete a successful procedure.

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