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he most popular dispensing technique used in the manufacturing process is time and pressure dispensing (TPD) from a syringe barrel. This method became popular because of the low-cost, simple setup and lack of required maintenance. In addition, the dispensing repeatability rate produced by the TDP method is acceptable for a range of applications.

A typical TPD system includes a dispenser, a disposable syringe assembly (barrel and piston), a syringe air adapter, and a disposable dispensing tip. The syringe barrel can be either mounted on an XYX table for automatic dispensing or handheld for manual processes.

Every component in the TPD system plays an important role in controlling the accuracy and repeatability of the dispensing process. The dispenser provides a timed air signal to the syringe barrel/piston assembly. The repeatability rate of the dispenser timing system can be as accurate as \pm 0.001% for a digital unit, so a dispenser with a reliable timer can ensure that a consistent air signal is delivered to the syringe barrel/piston assembly during the entire dispensing process.

The next important component in the TPD system is the syringe barrel/piston assembly. A high-quality syringe barrel and piston provide consistent material output from start to finish while preventing material leakage around the piston wall. Finally, the dispense tip is the deciding factor in maintaining a steady material flow rate without clogging. Once the dispensing process has been dialed in to achieve the desirable results, the operator does not have to make any changes unless one or more of the components in the TPD system have been changed.

To meet a high accuracy and repeatability rate along with cleanliness requirements, the syringe barrel, piston, and dispense tip are designed for one-time use. During the global recession, many companies have tried to reduce manufacturing costs by reusing syringe barrels, pistons and dispense tips. However, this decision can create a negative outcome, eventually adding more costs and reducing quality. A close examination of the critical features of these components provides a better understanding of the issues.

SYRINGE BARREL

The syringe barrel includes three critical features: the inside diameter (ID), the luer lock outlet and the syringe barrel ear (where the air adapter is attached). A high-quality syringe barrel is designed with zero draft on the ID, meaning that the syringe barrel ID is consistently straight from the top to the bottom. This feature allows the mating piston to travel smoothly down the syringe barrel and consistently push out the material.

The syringe barrel ID is also designed with a tight tolerance to ensure repeatable dispensing results from part to part. During the dispensing process, the syringe barrel is under pressure. If it is re-used, the ID can therefore be stretched out of round and expand by a few microns. This effect creates issues such as material blow-by if the material is not too viscous. Eventually, the leaked material will migrate back to the dispenser if no filter is connected to the air adapter. Secondly, air can drift around the piston and entrap the dispense material, causing moisturesensitive material to cure prematurely. Finally, if the syringe barrel is out of round, the dispensing output will be inaccurate and inconsistent.

The luer lock outlet function secures the dispensing tip during the dispensing process. It is comprised of a luer taper post and luer lock threads. The luer taper post is designed with a close tolerance to provide a tight seal connection with the dispensing tip. The luer lock threads keep the needle in place when under pressure.

After the syringe barrel is used more than once, both areas of the luer lock post and threads will have residual material buildup. It is difficult to completely clean out this area because of the many small gaps. There also is the possibility of the luer lock thread becoming damaged or worn out as a result of installing a dispensing tip. The combination of these problems can cause the material to leak at the joint or, even worse, cause the dispense tip to separate from the syringe barrel.

The syringe barrel ear provides a secure connection for the receiver head (syringe barrel air adapter). To work properly, the ear should not be bent or damaged. During the dispensing process, the syringe barrel ear is constantly under pressure. For applications that require more than 90 psi of pressure, the ear can be deformed permanently after use. In a mild case, the bent ear can cause an air leak; in the worst-case scenario, the ear will break.

Another issue caused by reused syringe barrels is cracking or shattering. Typically during the cleaning process, the syringe barrel is cleaned with a solvent. Some solvents could have a negative reaction with the syringe barrel, causing the plastic to become brittle. When the brittle syringe barrel is used again under pressure, it can crack or shatter.

PISTON

The piston has three functions: push material out of the syringe barrel, prevent material blow-by, and keep air from coming in contact with the dispense material. Two critical parts of the piston are the



front and back wiper seals. Wiper seals are designed with very tight tolerances. When inserted into the syringe barrel, the wiper seals are in contact with the syringe barrel's inner wall. After the piston has completed one full travel from the top to the bottom of the syringe barrel, both wiper seals are worn out.

If the piston is reused, worn-out wiper seals cannot do their job effectively. The first noticeable negative effect is leaking material. For applications that require a vacuum suck-back, leaking material can migrate back into the dispenser and eventually damage the unit. Another negative consequence of reusing a piston is excessive material waste. Worn wiper seals cannot completely wipe all of the material as the piston travels downward and, as a result, can leave material on the syringe barrel wall.

DISPENSE TIP

The dispense tip consists of two parts: the plastic hub and the stainless steel cannula (tubing). Similar to the syringe barrel luer lock post, the ID of the plastic hub is designed with a close tolerance to provide a tight seal fit. Once the material flows through the needle, it leaves residue in the hub. The accumulation of this residue prevents the hub from fitting properly with the syringe barrel, resulting in material leakage.

If the double-helix thread on the hub is worn out, the combined effect is needle separation. The inside surface of the stainless steel cannula must be clean and smooth to ensure consistent flow and repeatable shot size. During use, material residue builds up on the inside surface and is difficult (if not impossible) to remove. In a mild case, residue creates a turbulent flow that can generate minuscule air bubbles. Eventually, the residue will completely obstruct the material path, impacting quality.

ADDITIONAL ISSUES

While these issues are easily recognizable, one hidden issue may not be obvious to the operators—material contamination. High-quality syringe barrels, pistons and dispensing tips are manufactured in a clean room environment to ensure that parts meet cleanliness requirements. During the reuse process, foreign particles or residues from cleaning chemicals are introduced onto the surface of the consumable parts. Once the contaminants blend in with the dispensing material, they can interfere with the adhesive curing process and weaken the bonding structure.

The issue of contamination is especially critical in the medical device manufacturing industry. Medical device manufacturers must comply with stringent and comprehensive regulations. For most device classes, contamination control is achieved through the use of a clean room environment. Recycled syringes and dispense tips may have contaminants that are not suitable for use in a clean room facility. Another consequence of reusing barrels, pistons and dispense tips that may take some time for the operator to recognize is a deteriorated dispensing repeatability rate. As previously mentioned, the piston will be worn out and, when coupled with the expansion of the syringe barrel, the resulting negative effect will be a fluctuation in material output. For assembly processes that do not rely on a vision system or closed-loop weight check process, small dispense variations may not be detected until the problem becomes severe, causing product defects and expensive product rework or rejection.

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As mentioned previously, the main reason that companies decide to use recycled consumable parts is to reduce manufacturing costs. But is that logic really sound? Following is a sample calculation to see how much it actually costs to recycle one set of 10 cc syringe barrels, pistons and dispense tips:

- Total time to clean = 5 minutes
- Labor rate = \$7.25 per hour (\$0.12 per minute)
- Labor cost to recycle one set of these parts (\$0.12 x 5 minutes) = \$0.60
- Cost of cleaning solvent = \$0.05
- Total cost = 0.60 + 0.05 = 0.65

The average cost to buy one set of 10 cc syringe barrels, pistons and dispense tips is approximately \$0.63. This calculation shows that recycled consumable parts actually do not provide a cost savings. Instead of using recycled syringes and dispense tips to reduce manufacturing costs, companies should look to other alternatives. Optimizing the manufacturing process to improve production efficiency and reduce rejection rates are two factors that will drive down cost while using high-quality dispensing components.

THE BIG PICTURE

Before recycling consumable parts, manufacturing managers should thoroughly research if the practice is worth the risk. While some manufacturing processes do not require good process control or dispensing repeatability and contamination control, most manufacturing processes are designed to address these issues. Many managers agree that replacing barrels, pistons, and dispense tips after one use reduces rework and quality issues, which, in turn, reduces material waste and overall process cost.

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