Next-Generation TPE Technologies for Medical Devices

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Overview

Designers and manufacturers of medical devices face challenges that are driving the use of next-generation thermoplastic elastomers (TPEs). Achieving greater design flexibility, including part consolidation, is much easier with a user-friendly TPE than a cumbersome, sometimes coarse thermoset rubber. TPEs enable new techniques such as overmolding on a variety of substrates for improved ergonomics and function. Because they can be injection-molded, TPEs can be integrated into the manufacturing process vs. a separate operation for creating and assembling thermoset parts.

TPEs also offer new approaches to barrier technology: they ease concerns about leachable and extractible heavy metals used in the thermoset curing process; and can match thermosets' low oxygen and water vapor (MVTR) permeation for longer shelf life. New TPEs can even offer silicone and polyisoprene rubber alternatives in stoppers and gaskets while eliminating concerns about extractibles such as Nitrosamine, Mercapto Benzo Thiazole (MBT) and other curing agents. They can be clear to provide see-through properties, and can deliver enhanced resistance to compression set. With these new materials, medical device makers gain greater freedom to innovate while lowering system costs and enhancing safety and performance.

What are Thermoplastic Elastomers?

TPEs have been called the fastest-growing segment in the plastics world. These lower-modulus, flexible materials combine the easy processability of thermoplastics with the excellent elastic characteristics of rubber. TPEs typically can be stretched repeatedly to at least twice their original length at room temperature, and consistently return to that length when stress is released. The softness and suppleness of TPEs appeal to consumers, making them popular for use in a wide range of products. Further, they are used to control vibration or noise in appliances and machinery. And industrial and safety equipment benefits from the sealing ability, cushioning and non-slip characteristics of TPEs.

Medical Device Challenges Requiring Next-Generation Materials

One highly promising area for TPE usage is medical devices. These materials help to address current and evolving regulatory, design, cost and performance requirements. For example, regulatory and safety concerns are driving reduction of heavy metals and other toxic materials used in thermosets, which can leach into medications and cause disposal problems. Manufacturers are also looking for improved barriers to extend shelf life and reduce extractibles from thermosets. From a design standpoint, TPEs can enable part consolidation to eliminate potential points of failure – this approach can even speed up regulatory approvals. The design flexibility of TPEs also helps manufacturers achieve

device miniaturization and improved usability. And because cost control is a constant goal, the ability to process TPEs using conventional molding equipment and to eliminate secondary operations such as assembly, which is typically required with conventional rubber parts, makes these materials an attractive choice.

Following are several key medical application areas for the newest generation of TPEs.

Next-Generation TPEs for Barrier Technologies

Currently, device manufacturers are using traditional materials such as butyl rubber and polyolefin film to provide various types of barriers for packaging, prefilled syringes, IV solution, blood collection and more. Barriers extend product shelf life, protect active ingredients from oxidation and moisture loss/gain, and retain pressure or a vacuum, among other uses. However, traditional barrier materials have important drawbacks. Heavy metals such as tin, and halogens such as chlorine and bromine, used in thermoset rubber are undesirable constituents on the package. Some of them can potentially leach into the contents or contaminate clean systems, which are increasingly used for disposable devices. Overwraps used as moisture barriers during shipments of IV bags and other containers create large amounts of waste that hospitals must dispose of.

A new generation of TPE products offers improved barrier solutions. First, unlike thermosets, they do not require the use of heavy metals or toxic materials. Second, these TPEs provide very low oxygen absorption – up to 10 times better than standard TPEs – and an excellent defense against water loss or absorption. In drug-contact applications, these new TPEs are very inert and demonstrate an extremely low level of extractibles and leachables. And they can be sterilized using standard methods such as steam, EtO, e-beam and gamma.

The design flexibility provided by TPEs can improve packaging, while their barrier performance can eliminate the need for overwraps. For example, Hospira Inc. recently announced a new IV solution bag utilizing TPE that eliminates plastic overwrap. Also, Aseptic Technologies developed a sterile packaging solution for parenteral drugs using TPE as a laser-weldable stopper to replace a conventional thermoset rubber stopper.

Soft and Clear Temperature-Resistant TPEs

Another key application area for TPEs is replacing polyvinyl chloride (PVC) and silicone rubber in tubing, bags and films. Industry is moving away from PVC due to its use of chlorine, a halogen that is being restricted in Europe and other countries. Silicone rubber is very expensive and is reported to have some absorption of proteins and antioxidants, which could reduce the efficacy of drugs. Further, thermosets in general limit design freedom.

New soft and clear, temperature-resistant TPEs can replace PVC and silicone rubber while adding performance and design advantages. These new grades are softer than PVC and of course, do not use chlorine or other halogens. They are water-clear for see-through

applications. Compared to silicone, they are more affordable while delivering comparable performance at end-use temperature. The TPEs can be sterilized using all common methods.

Saint-Gobain Performance Plastics announced SaniPure™ 60 biopharmaceutical tubing made with soft and clear TPE instead of silicone rubber. This tubing offers the benefits of silicone rubber plus added performance: extremely low absorption and adsorption; and low permeability.

Overmolding TPEs: A New Design Technology

Overmolding a plastic part with a TPE is a new design technology that offers benefits including ergonomics and soft feel, improved aesthetics, better grip, cushioning against impact and vibration, and insulation against electricity and heat. Overmolding cannot be done using conventional elastomers.

Overmolding is an injection-molding process where one material (usually a TPE) is molded onto a second material (typically a rigid plastic). If properly selected, the overmolded TPE will form a strong bond with the plastic that is maintained in the end-use environment. With overmolding, the use of primers or adhesives is no longer required to achieve an optimum bond between the two materials.

To ensure the best bond, it is important to choose the right TPE for each base resin. GLS Corporation offers a new family of TPEs that enable overmolding with olefins and engineering plastics. These materials are water-clear – enabling the substrate to be seen – and can be customized with different colors and effects.

Overmolding is finding value in disposable systems used in bio processing. For example, J&J Scientific uses overmolding with TPEs in its Bio-Simplex™ Sterile Assemblies for sampling. The TPE tube is bonded to the cap using overmolding technology. This one-piece construction enables direct, aseptic transfer of fluid and avoids contamination and product loss from loose connections.

Conclusion

New TPEs offer a combination of design freedom, system cost benefits, regulatory compliance and improved performance. These new materials are increasingly replacing conventional rubber in a wide range of medical applications. More importantly, TPEs add a new dimension in material options by offering new and unique set of performance properties that could not have been achieved before using conventional materials. GLS Corporation has helped a wide range of medical device manufacturers design innovative products that deliver high performance, attractive aesthetics and cost advantages.