

Thermoplastic Elastomers in Medical Devices

Synthetic materials are used extensively, and are often crucial, in medical practice. They are applied for numerous purposes, such as bags for infusion solutions, components of medical devices, disposables (for instance syringes or tubing) and implants such as artificial heart valves and joints. The most important reason for the use of synthetic materials in medicine was, and still is, hygiene – synthetic disposables can be used to replace medical instruments made out of other materials. Another crucial aspect is biocompatibility: on the one hand, the synthetic material may not be harmful to the patient, on the other hand the properties of the synthetic material may not be affected by the biological environment where it is used.

Synthetics are innovative materials that have contributed to shape technological developments. Although their use in medical practice and medical technology is, however, still minor compared to their main application areas – the packaging sector, construction applications and the automobile industry – the versatility of synthetic materials, however, provides optimal adjustments to biomedical requirements, from the manufacturing of so-called 'intelligent' materials to the use as artificial organs.

TPEs – pure and safe materials for medical applications

Since their introduction, TPEs have been used in many important application areas due to their high degree of purity (low level of extractable compounds), their recycling ability and cost effectiveness. They are also used to replace latex and PVC materials. Latex, for instance, can cause allergic reactions in some individuals.

GLS Corp. is the global market leader in the development of thermoplastic elastomers (TPEs) and has gained considerable experience from their longstanding cooperation with medical products manufacturers. For more than 27 years, GLS has been specialized in the manufacture of application-specific custom formulated TPE materials for injection molding and extrusion.

TPEs for medical device applications offer many advantages, such as the low level of extractables, FDA compliance and sterilizability (gamma, e-beam, EtO and autoclave). The products are latex and PVC-free and, in comparison to silicone, cost-effective, they offer excellent sealing and adhesion performance (overmold adhesion), and several USP VI certified TPE classes are available. TPEs can be easily and uniformly colored and are recyclable.

TPE alloys with excellent barrier properties

GLS's most recent development is a new TPE alloy series with excellent barrier properties. The alloys were especially developed for applications that require intact, impermeable wrapping in medical applications, such as IV-infusion bags, and for applications that require barrier to oxygen such as stoppers and septums.

The key benefit of this technology is its impermeability to air and moisture. The oxygen permeation coefficients of the new TPE alloys range from 2,000 and 20,000 cc-mil/m² per day at atmospheric pressure and 23°C.

In comparison, the gas barrier of standard TPE qualities is typically within the range of 50,000 to 90,000 cc-mil/m² per day at atmospheric pressure and 23°C. And the MVTR¹ is within the range of 2.3 to 3.8 g/m² per day at 38°C and 100% relative humidity. The use of this technology could provide a 2 x to 5 x increase in shelf-life over conventional materials.

Special features of these TPE materials include their ease of processing in conventional injection molding, blow molding, and extrusion thermoplastic processing methods, as well as their extremely consistent quality. Due to their translucency, some new TPE grades offer extremely aesthetic packaging appeal and are easy to color. The technology ranges in hardness from Shore A 40 to 90.

Additional product lines for sophisticated applications

The DYNAFLEX G2700 and the DYNAFLEX G6700 series are FDA approved for contact with food products with select grades available as USP Class VI, and are therefore ideally suited for medical product applications. These products range in hardness from Shore A 13 to 84.

The TPE product series were designed for injection molding and extrusion applications to impart a 'soft touch', a rubbery feel to end products, a translucent tubing, or to provide sealing or gasketing characteristics. Additional features of this material quality are its excellent colorability properties as well as good ozone and UV stability and excellent overmolding adhesion properties to polypropylene substrates.

ISO standard 10993

The DYNAFLEX G2706 and G2711 TPE product lines comply with the ISO standard 10993 and can be used in medical devices. The ISO standard is comparable to the American USP Class VI. GLS has taken this step in order to serve those customers that need approved products for medical applications. The DYNAFLEX TPEs

¹ [MTVR = Moisture Vapor Transition Rate](#)

have been specifically tested for hemotoxicity, cytotoxicity, and systemic and intracutaneous toxicity.

Medical instruments and devices

The possibility to use TPEs in medical devices are endless: from high-performance TPEs for syringes, materials with high barrier resistance properties or gel-soft cushioning, to gaskets and seals, vial caps and soft touch cushions for glucose measuring devices.

The soft TPEs feature very low levels of extractables, they are FDA compliant, easy to sterilize, latex and PVC-free, they offer excellent sealing performance, are cost effective, easy to recycle and feature excellent overmold adhesion to a wide range of plastics. Ultrasoft gel TPEs are also available.

Medical tubing

The trend towards latex and PVC replacement, has led to a significant increase in the application of TPEs in medical tubing. Also here the advantages are numerous – FDA compliance, easy sterilization and recycling, low coefficient of friction, low opacity and high translucency. GLS offers cost effective TPEs for extrusion processing that have proven their performance in many medical device applications such as drainage tubing, tourniquets, peristaltic pump tubing or catheter tubing.

Elastomer sheets and films

Several selected GLS elastomer products have proven well suited especially as elastomer films and sheets in medical applications. Typically, single-layer blown films can be produced down to 0.1 mm layer thicknesses. TPEs are used as surgical elastomer wipes, as tapes for gauze bandages, for disposable surgical gowns or tourniquet bands.

In addition to FDA compliance, easy sterilization properties as well as being latex and PVC-free, important TPE features are their excellent elasticity and soft, flexible surface.

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New Technologies

Avoid sources of infection and contamination

US Endoscopy in Mentor, Ohio, USA has decided to replace silicone used in their BioShield series disposable biopsy valves by a different material that offers good construction, sealing and handling properties as well as being user and patient friendly. "GLS was able to provide the most suitable grade of TPE quality to meet FDA compliance" according to Christopher J. Kay of US Endoscopy. "We achieved what we needed – ease of processing, a rubbery feel, a soft touch and excellent colorability with the added benefits of good ozone resistance and UV stability, along with the needed performance characteristics."

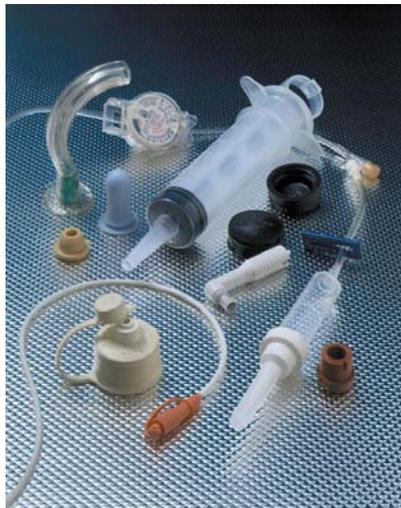
((Figures GLS_51 1-4 and captions))



Improved features and usability through replacement of silicone by TPE: US Endoscopy biopsy valve.



The new line of TPE by GLS is suitable for special applications in medical wrapping and packaging.



Numerous application examples for the use of TPE in medical devices.

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