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WHY INNOVATION MATTERS

Roger Hendrick, Specialty Products Division of DowDuPont, and Carolin Vogel, Specialty Plastics, Eastman Chemical Company, explain how new technology broadens medical device materials and design options

To support the growing, multi-billion dollar medical device industry, injection mouldable materials suitable for healthcare applications are continuing to improve and expand design options for device manufacturers. New liquid silicone rubber (LSR) technologies in conjunction with copolyester are making it possible to combine the benefits of each technology in overmoulding applications.

Silicone elastomers have been used in medical applications since the 1940s and have changed to meet the demands of end-use application requirements and processes which manipulate them. The properties of silicone materials can be influenced by their formulation and may provide different application benefits, but generally afford characteristics such as thermal and chemical stability, high gas permeability, hydrophobicity, biocompatibility/biodurability and high elasticity. While not an exhaustive list, many of these characteristics benefit medical applications and their suitability for various sterilization methods such as autoclave, ethylene oxide (ETO) and gamma or electron beam radiation.

FORMULATION IMPROVEMENTS

Suppliers of liquid silicone rubber have made formulation improvements since their inception in the 1970s: changing to meet application requirements of cured physical properties and their stability when exposed to post-processing conditions. In some cases, specialty LSR formulations have been developed to impart unique characteristics either in the uncured behaviours or in the cured component. This is evident in new low temperature and self-adhesive LSRSs.

Copolyesters, as silicones, have several decades’ long history within the medical device industry. Manufactured into medical devices via thermoplastic conversion processes, such as injection moulding, their value lies in their unique set of properties. These include: toughness, clarity, their advantageous regulatory profile, such as being free of BPA, and their chemical resistance.

THE EFFECT OF STERILISATION

In today’s health care environment, it is becoming more common to see medical devices that don’t work satisfactorily. They are unable to do their job—or fail prematurely—because of environmental stress cracking (ESC) or other defects resulting from exposure to disinfectants and other chemicals. Aggressive disinfectants and sterilisation in combination with more frequent disinfecting procedures take a toll on devices moulded with commonly used polymers. Brand owners are addressing this challenge by using polymers with a higher level of chemical resistance. The selection of these high-performance materials early in the design process is one of the most critical considerations for the future of patient safety.1

Testing and evaluating chemical resistance needs to be performed to answer questions around chemical compatibility of materials with various cleaners and disinfectants utilized to maintain medical devices in the healthcare industry. Desirable performance is to have little or no stress cracking or haziness from contact with cleaners and disinfectants, or from lipids, bonding solvents or drugs and their carrier solvents. Copolyesters as well as silicones have shown being high performing materials regarding chemical compatibility and therefore get chosen frequently in medical device applications. Colour-stable, transparent medical devices are of the utmost importance in the healthcare field as they embody the idea of safety, quality and peace of mind for both the patient and the healthcare professional. Though many factors must be taken into consideration when deciding which polymer to choose in the development of a medical device, understanding the effect of sterilisation is critical.

The objective of sterilisation is to reduce the bioburden to a safe level, while minimizing any changes to the physical and optical properties of the final part. The most common effect on polymers exposed to radiation is a shift in colour to yellow. In the medical device market, a significant colour shift to yellow is undesirable as it may be interpreted as a contaminated device.

Therefore, minimal shift in the polymer color after sterilisation can be an important factor when specifying a polymer for a medical device or rigid thermoformed package. Various copolyesters are suitable for nonautoclavable sterilisation methods such as gamma or electron beam (e-beam) radiation regarding color shift and retention of mechanical properties.

BRIDGING THE GAP

While heritage copolyesters as PETG, PCTG, and PCTA that were introduced into the market in the last century have heat deflection temperatures (HDTs) in a range of 67°C to 74°C (≈0.455 MPa/66 psi; ASTM D 648), newer developments of copolyesters in the recent two decades have higher HDTs of between 94°C and 100°C. This is one necessary step to bridge the gap for over moulding copolyesters with silicone. Injection molding with traditional liquid silicone rubber products is commonly done at temperatures near 150°C or greater to assure rapid cure of the silicone component which far exceeds the heat deflection temperature of traditional copolyester preventing traditional silicones from being considered in copolyester overmolding applications.

NEW PRODUCT TECHNOLOGIES

New liquid silicone rubber product technologies, however, are now available to challenge those traditional processing concepts with improved cure rates at low cure temperatures. This makes available the possibility to injection mould with mechanical interlock or with self-adhesive properties at temperatures below critical substrate heat deflection temperatures whilst maintaining necessary cycle times. During a time when an aging population requires new ways to cure diseases and manage chronic conditions, it is important that companies innovate and collaborate to deliver solutions that matter. By merging technologies to meet the needs of manufacturers and ultimately patients, one can positively impact the way healthcare is addressed globally and contribute to greater health outcomes and improved quality of life.