High-performance polymers deliver quality and stability

PLASTICS IN MEDICAL

by Anthony Verrocchi

High-performance engineering thermoplastics are increasingly replacing metals, ceramics and other traditional materials in high-cost medical technology applications — diagnostics, orthopedic implants, medical supplies, drug packaging, drug delivery and multi-use surgical equipment. The flexibility of these engineered resins allows manufacturers to bring new products to market quickly, especially in the United States, Europe and Japan, where an upward growth trajectory in demand for medical-grade polymers is expected to continue into the foreseeable future.

While medical technology manufacturers are not immune to economic downturns, they operate in a dynamic sector that benefits from several underlying factors: growing government spending, an aging population and a lengthy design to market process.

Demanding requirements of the medical marketplace

The medical market is governed by various global requirements. Many of these long-term projects involve products in a growing segment called intravenous and infusion devices, specifically insulin pens and inhalers for major healthcare and pharmaceutical companies that are leaders in their fields of medicine. But before they can reach the consumer market, these must first meet government regulations and requirements. Materials used in these devices, for example medical grade plastics, must meet the requirements of health authorities, such as the U.S. Food and Drug Administration (FDA) and European Union food-conformity and they may need to be listed on an FDA Drug Master File and an FDA Device Master File, which are required for medical and pharmaceutical applications. In addition, these materials should be biocompatible, according to the guidelines of the United States Pharmacopoeia (USP Class VI) and the International Organization for Standardization (ISO-10993). This is just one reason why the design to market process is so lengthy. As a result, approved devices typically enjoy a long life cycle which allows medical technology manufacturers to weather periodic economic dips.

GUR® ultra-high molecular weight polyethylene (UHMW-PE) is the "gold standard" for synthetic orthopedic joints or joint components such as this ball and socket joint.

Medical device manufacturers are also starting to look for ways to increase market share and launch new eco-friendly products, which will contribute to this continued growth pattern. For example, manufacturers of electrical medical device components recognize they may be required to comply with more stringent environmental laws in the near future. Plastic suppliers are working with several medical device manufacturers to identify ways to communicate the right marketing message and to use innovative engineering thermoplastics that can help them harness more cost-efficient manufacturing techniques. They are looking at future opportunities to incorporate polymers developed for new eco-friendly products — ones listed with Underwriter Laboratories and compliant with Restriction of Hazardous Substances (RoHS), Waste Electrical and Electronic Equipment (WEEE) and European Registration, Evaluation, Authorization and Restriction of Chemical (REACH).

As medical materials are pushed to perform at higher levels, medical technology manufacturers have started to look beyond low-cost commodity plastics, such as polyvinyl chloride (PVC), polyethylene, polypropylene and polystyrene, which are used in non-invasive medical products and standard medical packaging. They are turning to medical-grade polymers that are certified to conform to specific property and quality standards, as well as applicable regulatory requirements.

Novo Nordisk uses two Hostaform® acetal copolymer (POM) grades (LW90 BSX and S 9243 14) from Ticona for injection molded components of the FlexPen® insulin delivery device.

Using engineering plastics in medical technology can help reduce total manufacturing cost, through consolidation of multiple parts into a single unit and implementation of automated assembly processes. In addition, polymers can provide precise dimensions in intricate components, low friction and wear, as well as high creep strength, all of which help assure long-term performance. There is an increasing trend for "smart" products. These include "intelligent" drug delivery systems such as insulin injection pens, powder inhalers for asthmatics, needleless syringes and instruments for minimally invasive surgery. Engineering polymers are often used because they are robust, reliable, easy to process, contribute to ergonomic design and enable easy color matching. They also resist strong disinfectants and other chemicals, and many can be sterilized repeatedly by most common methods.

High-performance polymers for medical technology equipment

Today, innovative plastic materials are increasingly being used for components in diagnostic systems, such as those for blood sugar and blood pressure measurement, and in large clinical equipment, such as anesthesia systems and respirators. These polymers are also used in pharmaceutical packaging, such as blister packs, ampules and pre-filled syringes, where shatter resistance, high-barrier and glass-clear transparency are beneficial.

Several high-performance engineering polymers are ideal candidates for medical technologies that require materials which are robust, reliable, easy to process, support ergonomic design and enable easy color matching.

Acetal Copolymers (POM) — highly crystalline polymers characterized by extremely high purity with excellent thermal and oxidative stability. Although optimized for medical technology, they still have acetal's many advantages, including toughness, rigidity, lubricity and other mechanical properties along with resistance to alkalis and hydrolysis.

Typical applications: Functional components requiring high dimensional stability and excellent low-friction performance, such as mechanical elements in drug delivery systems, aerosol valves, spring elements, screw threads, gear wheels, worm gears, snap-fits and press-fits and tribological systems.

Knee replacements maintain high functionality thanks to Ticona engineering thermoplastic's combination of properties: biocompatibility, high abrasion resistance, impact strength, fatigue resistance and crack resistance.

Liquid Crystal Polymer (LCP) — offers significant benefits in microsystems where it replicates fine details with extreme precision and provides for dimensional stability and high rigidity in thin-walled structures. LCP has a low coefficient of friction, high-impact strength and withstands service temperatures as high as 464°F/240°C. It can be autoclaved for 500 cycles or more with little loss in mechanical properties. LCP has successfully replaced metal alloy components in many surgical instruments and medical appliances with its combination of strength, ease of processing and ability to hold tight dimensional tolerances along with excellent barrier properties to all common gases and liquids, and excellent resistance to chemicals and oxidation.

Typical applications: Metal replacement in surgical and dental instruments and components for minimally invasive surgery.

Polyetheretherketone (PEEK) — an exceptionally strong engineering thermoplastic, PEEK is tough and abrasion resistant with high-impact strength. It has excellent flexural and tensile properties and retains mechanical properties, even at very high temperatures. It has a low coefficient of friction and resists attack by a wide range of organic and inorganic chemicals. One of the most chemically resistant polymers available, it's biocompatible, suitable for exposure to the body or bodily fluids, biostable and is able to maintain its physical and chemical integrity after implantation in living tissue.

Typical applications: Implantable grade PEEK polymer is suitable for long-term (more than 30 days) spine and dental implantation and offers significant benefits over traditional materials, such as polyethylene, metallic alloys and ceramics.

Polyphenylene Sulfide (PPS) — has exceptional dimensional stability and works especially well in complex parts requiring high mechanical strength. PPS medical-grades are an excellent alternative to metals in anesthesia and other medical equipment. They also withstand repeated sterilization by all common methods (ethylene oxide, super-heated steam, gamma radiation) because of their outstanding chemical resistance at high temperature. PPS, developed for use in meltblown and nonwoven structures, provides great durability in biomedical filtration.

Typical applications: Functional parts needing exceptional dimensional stability and high mechanical strength as a replacement for metals; e.g., medical forceps and components in artificial respirators and nonwoven media for filtration.

Thermoplastic Polyester (PBT) — has a balanced property profile that includes high creep resistance, good dimensional stability and excellent processability. It is the material of choice for finely structured moldings that must have dimensional stability, such as elements in drug delivery systems. It also has high slip and low wear behavior when combined with POM molded parts. PBT has a use temperature up to 266°F/130°C and better acid resistance than POM. It also has excellent resistance to greases and polar and nonpolar solvents. Additionally, certain PBT grades can be processed by meltblowing to produce filter media.

Typical applications: Functional parts with high dimensional stability, such as mechanical components in drug delivery systems, aerosol valves, housings, filter systems and drug containers.

Ultra-High Molecular Weight Polyethylene (UHMW-PE) — produced in the form of a powder, UHMW-PE offers an excellent combination of properties: biocompatibility, high abrasion resistance, impact strength, fatigue resistance and crack resistance. This highly pure material complies with standards ASTM F648 and ISO 5834-1/-2, and is the "gold standard" for synthetic orthopedic joints or joint components that maintain high functionality over a long usage life. With the addition of a small, homogeneous amount (approximately 1,000 parts per million) of vitamin E (alpha-tocopherol) as a stabilizer, UHMW-PE can help extend the life of orthopedic implants.

Typical applications: Orthopedic implants (replacement knees, shoulders and other small joints), ortheses for the treatment of poor posture, endoprostheses components that bear high mechanical loads.

There is growing demand for medical-grade high-performance engineering thermoplastics for use in medical technology applications — implants must have biocompatibility to avoid rejection and medical instruments cannot trigger any negative reaction. And, with many manufacturers required by law to take back used medical instruments, recyclability is frequently a criterion that governs material selection for medical products.

High-performance engineering thermoplastics are increasingly becoming the material of choice that meets key requirements of a new generation of innovative medical technology applications. ■

Anthony Verrocchi is a Ticona technical marketing engineer. He may be reached at e-mail: anthony.verrocchi@ticona.com. For more information, contact Ticona, 8040 Dixie Highway, Florence, KY 41042 USA; (800) 833-4882, www.ticona.com.