Prescription for Change

Medical polymers are doing well—and doing good—by giving device makers and care providers the materials they need to meet evolving treatment challenges

By Pat Toensmeier

The adage “what can be conceived can be created” has special resonance in medical products. Advances in device design and application technologies allow developers to achieve broad levels of form and function in a range of products that significantly improve medical care. In many cases, these advancements can reduce the reliance by doctors and patients on conventional, costly, and often lifestyle-restricting treatment procedures.

Driving much of this development are new and upgraded resins and compounds that make possible the effectiveness of diverse devices. Notable among many such examples are body monitors and portable or implantable drug delivery units, ever-thinner catheters for placement of progressively smaller devices, long-term implantable parts including bone and joint replacements, ingestible sensors, and even custom-made pills 3D printed by pharmacists.

Add to these manufacturing enhancements like 3D printing and the growing use of smartphone apps for mobile health services, and it’s clear that healthcare professionals have access to a growing range of products that are in many cases revolutionary in both the benefits they provide and the cost savings they achieve when compared with conventional treatments.

Healthcare services and procedures extend to almost every person in developed nations and are gaining wider use in developing countries. Societies in which populations are aging, as in Japan, parts of

Trilayer catheter extruded by Putnam Plastics has among the smallest inner and outer diameters in the market (left). Trilayer catheter consists of an outer polyether block amide layer, inner layer of HDPE, and core of LLDPE (right). Courtesy of Putnam Plastics
Western Europe, and the U.S., are reliant on medical and related pharmaceutical treatments to maintain a quality of life for their citizens. Demand for treatments is reflected in growth projections for the industry.

According to The Economist Intelligence Unit, global spending on healthcare will increase to $8.73 trillion in 2020 from $7.07 trillion in 2015—an average annual growth rate of 4.7 percent. At this rate, global healthcare spending reached approximately $8.1 trillion in 2018, an amount which, if it represented gross domestic product, would give the sector the third-largest GDP in the world, trailing only China and the U.S.

North America alone accounts for two-thirds of this expenditure, studies report, or about $5.95 trillion last year. Of this amount, U.S. healthcare spending in 2018, based on previous projections by analysts, was estimated to be around $3.93 trillion and increasing by 4 percent per year.

With demand for healthcare and device spending growing, those with a financial stake in these transactions—medical providers, insurers, business, government, and of course consumers—seek solutions that balance quality care with affordability. These concerns make the product market especially receptive to innovative materials that achieve performance objectives including cost containment.

Trends Drive Changes

Various needs drive the formulation and use of polymers and compounds in medical devices. Notable among these are: device miniaturization and lightweighting; the ongoing development of minimally invasive surgical procedures; wearable technologies for drug delivery and patient monitoring; growing emphasis on home-care treatment and self-administration of medicine; and, of course, materials competition, especially continuing inroads in metal replacement in implantable joints, skeletal structures, and surgical instruments.

A corollary of metal replacement could be more automation in product fabrication and packaging, along with improved economics in such areas as single-use surgical and other medical instruments. The idea here is that as instrument fabrication transitions to high-performance polymers, resin suppliers and compounders will tailor formulations to achieve viscosity, melt flow, and other properties that allow processors to injection mold parts with dimensional tolerances that are similar to machined metals. Molding would reduce the handling that stock shapes require before and after machining and increase the use of automated processes that transport parts from a molding machine to packaging and sterilization stations.

Molding also enables the mass production of components, which helps to contain or lower per-piece prices when compared with machining. This is a valid consideration even though medical parts like surgical instruments may be molded in runs of only hundreds or thousands rather than the high volumes associated with electronics, automotive, or commodity medical devices such as luers, pipettes, and blood-testing devices.

The idea of molding, sterilizing, and packaging parts with reduced—or no—worker handling isn’t new, but it’s a benefit to single-use instruments. Such instruments are popular at ambulatory surgical centers (ASC), which were early adopters of them. ASCs provide select outpatient procedures. They offer advantages over hospitals when it comes to a number of surgical procedures. Proponents say they are less-stressful environments than hospitals and usually less expensive. In 2016, there were 5,532 Medicare-certified ASCs in the U.S. (Some estimates put the number of ASCs in the U.S. at 6,000 or more.) Globally, ASCs are increasing at a 5.4 percent annual rate, and forecasts call for growth through 2024. Pre-sterilization assures that instruments arrive in operating rooms ready for use. ASCs and other users save time and cost by not having to sterilize instruments in a central process room. Single-use instruments also help reduce the potential for infections in hospitals and ASCs.

Polyketones Target Implants

Among the performance polymers that are finding greater use in medical parts are polyketones, notably polyetheretherketone (PEEK) and polyaryletherketone (PAEK). One producer is Solvay Specialty Polymers. Dane Waund, healthcare marketing manager for instrumentation and implants, says the polymers are moving “aggressively” into orthopedic and bone implants and metal replacement.

The benefits of PEEK include biocompatibility, high mechanical properties, chemical resistance, and importantly, a Young’s modulus that is near that of cortical bone (the dense outer surface of bone).

As regards bone implants, Waund notes implantable metals like titanium, stainless steel, and cobalt chrome have far higher modulus than cortical bone.

In 2018 Solvay commercialized a 30 percent carbon fiber-reinforced PEEK grade called Zeniva ZA-600 CF30 for load-bearing spinal, hip, and knee replacements. The injection moldable material has an equivalent Young’s modulus to cortical bone (25 GPa) and twice the tensile strength of neat PEEK (200 MPa). Zeniva PEEK reportedly excels in fatigue performance, which is critical for structural implants in the body whose service life is dictated by repeat loading cycles.
“Specific applications are spinal interbody cages and suture anchors,” Waund says. As a non-metallic implant, “it improves the X-ray and MRI visibility of a device for doctors and surgeons over time. It can also offer potential quality-of-life improvements, such as less temperature-induced discomfort related to the high thermal conductivity of a metal implant, or a patient’s future ability to be security screened at public events using traditional scanners.”

Waund explains that in certain applications the “stiffness matching” of Zeniva PEEK to cortical bone density is particularly valuable to human health. “Many studies have shown a phenomenon called stress shielding, where bone structure adjacent to a metal implant can suffer atrophy, as the rigid implant carries too much of the load, effectively hindering healthy skeletal development.”

Solvay’s expertise with PEEK extends to collaborative work with research partners. The company aided in the creation of a porous implantable PEEK technology developed at the Georgia Institute of Technology. The porous features facilitate bone tissue in-growth. The surface material has 300-micrometer (µm) average pore sizes, layer thicknesses greater than 500 µm, more than 99 percent interconnectivity, and a wettable surface. Clinical testing shows that in an implant bone infiltrates within the pores, Waund says, essentially creating a mechanical lock, which improves how PEEK devices interact with bone.

Solvay’s polymer development extends to metal replacement for single-procedure instrumentation. The company supplies Ixef 1022 GS (gamma stabilized) polyarylamide, which is biocompatible, injection moldable, has high stiffness and strength owing to 50 percent glass-fiber reinforcement, and yields a smooth finish. In addition to withstanding gamma radiation, the polymer can be sterilized by ethylene oxide gas and vaporized hydrogen peroxide. As a result, color-coded instruments, used for identification during surgery, can be packaged and sterilized prior to shipment without affecting color integrity.

**Thin-Wall Parts Create Challenges**

Compounds that focus entirely on medical grades lead much of the materials development that drives innovative and emerging applications. One such is Foster Corp., which was recently named North American medical market distributor for Solvay’s KetaSpire PEEK and AvaSpire PAEK polymers. Foster intends to supply the polyketones for short-term implants, notably precision tubing, and for surgical instruments, among other applications, says Chief Executive Officer Lawrence Acquarulo.

Foster is involved in developments that highlight emerging medical needs. One such, says Acquarulo and Timothy Largier, manager of R&D polymer science, is developing compounds and additives for thin-wall catheters that allow the implantation of miniature devices like pacemakers, heart valves, and other sensors in the body including the brain.

Acquarulo believes devices for cardiovascular, gastrointestinal, and other procedures will become smaller as manufacturers continue to miniaturize components, including electronics, to reduce surgical trauma. The outer diameter of catheters, which position such devices, will likewise continue to shrink. “Some pacemakers can fit through catheters,” he remarks, “and heart valves can be put in place through catheters. Thin-walling lets you put more features in a device and fit it in a catheter. As a result, catheter outer diameter can only be so big.”

In fact, one factor driving much of the company’s compound development, Acquarulo notes, is achieving tighter tolerances in end products. “There is pressure to meet stringent device needs, and this in turn affects the viscosity and cleanliness of the material. Processing counts as much as performance,” he says.

This requirement extends to additive packages and masterbatches as well. One new additive the company is showing at this month’s Medical Design & Manufacturing West expo in California, for example, is ProPell T, which shows transulence and lubricity to flexible, low-durometer catheters extruded of thermoplastic polyurethane or polyether block amide. Foster’s original ProPell grade was opaque. Acquarulo says transulence allows medical personnel to monitor whatever material or device is transported through a catheter and detect problems before body entry. The additive also reduces the tack and coefficient of friction that’s common to soft, interventional vascular catheters and central venous catheters, thereby improving manufacturing, handling, and insertion.

Foster also recently developed Combat, a universal antimicrobial masterbatch. The masterbatch incorporates Agion, an ionic silver and proven antimicrobial in a zeolite carrier supplied by Sciessent LLC. When blended with polymers at letdown ratios of 2 to 10 percent, the antimicrobial counters bacterial growth in implantable medical devices, high-touch surfaces, and other body-contact devices.

The masterbatch kills infectious bacteria like methicillin-resistant staphylococcus aureus (MRSA) and carbapenem-resistant enterobacteriaceae (CRE). Tests on six resin samples—two each of thermoplastic polyurethane, ABS, and polycarbonate, each with different loadings of Agion—demonstrated a 99.9999 percent microbial reduction with the antimicrobial, according to data in a 2018 report written by Acquarulo on the development.

Use of the material could speed compound formulation once a letdown ratio is determined for a polymer. “It’s a slow-release, long-lasting material that can be in the body for eight weeks and won’t run out,” he says.
The masterbatch could ultimately help shorten hospital stays—even save lives—and reduce medical expenditures for insurers. Acquarulo, citing data from the U.S. Centers for Disease Control, wrote in the 2018 report that 4 percent of patients in U.S. acute-care hospitals develop at least one healthcare-associated infection during their treatment. Of these, device-associated infections accounted for 25 percent of the cases.

Developmental work at Foster is moving in high-tech directions. Though he declines to reveal details, Acquarulo says the company has looked at applications ranging from ingestible electronic sensors—a specially compounded pill with a transmitter that sends signals to a recording device worn on a user’s belt—to materials that can be used by pharmacists to 3D print custom drug-delivery pills.

“There is no shortage of applications coming down the road,” he says.

Size and Tolerances Matter

Many medical devices are evolving into smaller, stronger, higher-tolerance components, agrees Ryan Dandeneau, vice president of medical processor Putnam Plastics, a specialist in extrusion technology and catheters. Putnam’s product offerings include a major achievement in thin-walling—the Trilayer line of three-layer catheters.

The company, whose products include catheters for cardiovascular, neurovascular, and gastrointestinal procedures, extrudes Trilayer products with inner diameters down to 0.0165 inches and outer diameters as low as 0.0215 inches, among the smallest such devices in the market. The core of the catheter is linear low-density polyethylene, the inner layer is high-density PE, and the outer layer is a polyether block amide elastomer.

The challenge of fabricating a multilayer structure this thin is formidable, but Putnam draws from a well of materials and process knowhow. Some of its expertise was acquired after periodic changes in materials specification, often caused by supply disruptions from resin producers. Many producers see the comparatively low volume of medical polymers and concerns about potential product liability as not worth continued the production and supply of some materials. Raymond Rilling, director of advanced technology development, says around 25 percent of the products Putnam sells involve materials—resins, coatings, solvents—that have been tweaked by the processor to meet these supply challenges and, equally important, changing global regulatory standards.

Putnam is finalizing the development of a series of conformal coatings for various extrusion needs that Rilling says will allow it to add a dozen base resins to its catalog of process materials. Most coatings involve fluoropolymers. All will need to be reviewed and certified for use by regulatory authorities in Europe, the U.S., and even locally in states like California.

Certification is long and expensive. Nevertheless, Dandeneau is bullish on the business. “Even if there’s a recession in the next couple of years, we’ll still see significant growth from the aging Baby Boomers coming in for procedures that use our products,” he says.

3D Printing Pushes Applications

The market is beginning to see personalized medical devices that meet the specific needs of individual patients. The objective is to provide custom medicine, including vitamins, that are faster-acting in the body and which more directly address recovery or health maintenance needs than mass-market prescriptions and delivery systems. Personalized devices would also be part of mobile health units, since with ongoing advances in digital technologies and microelectronics, they could monitor special-care individuals remotely and transmit wellness data to care providers.

SABIC supplied a Lexan PC copolymer for eNeura device that uses transcranial electronic pulses to relieve migraines (right).

3D printing creates custom devices. Examples include an arm splint printed with SABIC polymer filaments (below). Courtesy of SABIC
An important factor driving this trend is the wide availability of 3D printing, which permits the rapid and economical design, trial, and final fabrication of personalized devices.

Among companies that supply healthcare-grade materials for 3D printing is SABIC, which recently added two filaments for fused deposition modeling: AMHU1010F, an Ultem polyetherimide, and AMHC620F, a Lexan polycarbonate (PC).

“These filaments can enable additive manufacturing [3D printing] of personalized, complex parts without the need for traditional production tooling,” says Ashir Thakore, global healthcare segment leader.

Both filaments provide outstanding mechanical performance, Thakore says. “They may be used for a wide variety of applications, from conceptual modeling to functional prototyping and end-use parts.” These include single-use devices, as well as splints and surgical instruments.

The materials are included in SABIC’s Healthcare Product Policy and offer traceability. The policy pre-assesses resin biocompatibility according to ISO 10993 or USP Class VI standards, and FDA Drug or Device Master File listings.

SABIC has many product offerings in medical resins and expertise in device development. One recent application reflects this and highlights the trend toward remote medical care. SABIC worked with medical OEM eNeura Inc. and molder PTA Plastics to develop a housing of Lexan PC copolymer for an electronic device that relieves migraines through placement behind a patient’s head. The sTMS mini is a physician-prescribed, portable delivery system for single-pulse, transcranial magnetic stimulation.

The Lexan housing has chemical resistance, impact resistance, and good colorability. The resin additionally processes well—to achieve a watertight seal, for example, it is overmolded with a thermoplastic elastomer.

Home-Care Needs

Polymer developments are upgrading options for home treatment and wearable medical devices, markets that are large and growing for the benefits they provide in minimal lifestyle disruption and lower-cost care alternatives to hospitals and doctor visits. Two suppliers that will officially merge on June 1, Dow Corning and DuPont, are among the producers that supply polymers tailored for these markets.

In conditions that involve the self-administration of medicine by patients at home, usually by needle in disposable injector pens, the dynamics of injection go beyond the transfer of a prescribed dose. "The product properties of injector pens
and wearables that treat diabetes and other conditions are also important,” says Laurent Hanen, DuPont’s application developer for healthcare in Europe.

Hanen explains that because users, especially children, can mishandle and drop devices like injector pens, they must be impact resistant. Also important is the sound and haptics of operation. The plastics used in their construction need a low coefficient of friction to assure smooth actuation (i.e., minimal pressure for injection), as well as low noise during operation so users know everything is working well.

Among the materials DuPont offers for these applications are Delrin acetal homopolymer, Crastin polybutylene terephthalate, and Zytel polyamide 66. Each provides the necessary properties for reliable home-care device performance, he notes. In addition, all three provide aesthetic finishes that allow the use of different color combinations in the styling of devices, a plus for brand identity that is also pleasing to consumers. “In the past, most of these pens were white or blue,” Hanen notes. “Their surface aesthetics allow designers to use more colors and add fancy looks to them.”

These materials, when reinforced with glass fiber, also find use as metal replacements in surgical and dental tools, Hanen notes. The reinforcements, usually at loadings of 30 percent for Crastin PBT and 33 percent for Zytel PA, provide the necessary strength and stiffness for use. When compared with the metals they replace, the polymers are lighter in weight, a plus in handling, he adds.

Meanwhile, the new DowDuPont Specialty Products Division is absorbing the lines of silicone polymers, including adhesives, that have been developed by Dow Corning. Marie Crane, Dow Corning’s global medical development market manager, says that some of these silicones are tailored to provide wearables like medicinal patches with secure skin adhesion to treat diabetes and other conditions, yet achieve easy and painless separation that does not leave marks or otherwise irritate skin.

One new material in this category is Dow Corning MG 7-1020, a high-tack silicone that’s gentle to the skin. “Acrylics have been the go-to adhesive for wearables, but they can hurt when removed,” Crane notes. The new Dow Corning material is inert, biocompatible, and does not irritate skin.

Silicone, of course, has long been used as a long-term implantable material, owing to its biocompatibility and inert chemistry. Crane says microelectronics can be hermetically sealed in some silicone implants to monitor health.

When it comes to microelectronics and ingestible devices, Hanen notes that “reading vital signs is where the market is going.” DuPont has a flexible electronics business, and he suggests that film circuitry or similar devices could eventually be developed that would stimulate parts of the body to counter stroke and other critical conditions.

Conclusion
Medical products have always been able to capitalize on advanced resins and high-tech device designs. Many trends in healthcare now stress alternatives to costly and personally disruptive medical services. Combined with the potential of new medicines and evolving digital technologies, OEMs and care providers are raising the stakes for polymer suppliers when it comes to getting safe and effective materials for new and enhanced applications. Materials suppliers are responding, and their development efforts will help advance procedures that improve the quality, availability, and cost of medical care.

ABOUT THE AUTHOR
Pat Toensmeier is a Hamden, Conn.-based freelance writer and reporter with more than 35 years of business journalism experience, much of it with Modern Plastics and Aviation Week. Over the years he has specialized in writing about manufacturing, plastics and chemicals, technology development and applications, defense, and other technical topics.