Perspectives on New Materials, Part II

New developments in material technology are critical to innovations across all industries, including medical device technology. Therefore, it is crucial for designers to stay abreast of the most recent advances that could benefit their upcoming products. In this month's Perspectives, industry leaders share their opinions on which new materials are the most exciting to them.

What new material technologies are most exciting/interesting to you for use in medical device design/manufacturing?

Apur Lathiya
GM of Thermoplastics Business, Vesta

Polyurethane silicone copolymers provide an interesting evolution for lead tubing used in permanent implant applications. These materials combine the biocompatibility and biostability enjoyed by silicone, paired with the durability and ease of processing of polyurethanes. The combination of these two materials into a single copolymer allows these materials to be melt extruded using conventional techniques to produce tubing with excellent bio and mechanical properties, such as tensile, elongation, and flex. These co-polymers, though they have been around for several years, are still not prevalent in the market today, but provide the device designer an excellent improvement to the more commonly used materials. Additionally because of the expensive nature of these copolymers and because not too many extruders have experience in processing these materials, it is important for the designer to source an extrusion company that is experienced in running these materials.

Joel S. Peiffer
Advanced Engineering Specialist, 3M Electronics Solutions Division

Embedded passives are of high interest today for electronic medical device manufacturers looking to improve electrical performance and reliability, reduce EMI, reduce the size, or lower the overall system cost of their products. Ultra-thin embedded capacitor materials with increased dielectric constants may help manufacturers achieve those objectives.

More and more, designers of high-speed medical electronics are choosing a copper-clad embedded capacitance material that utilizes an ultra-thin, high-dielectric-constant material between the copper planes.

The use of thinner, high-dielectric-constant dielectrics can deliver a high capacitance density and offer many benefits when used for decoupling high-speed digital electronics, including:

• Lowering impedance of power distribution system
• Dampening board resonances
• Reducing noise on power plane
• Reducing radiated emissions
• Replacing large numbers of discrete decoupling capacitors
• Eliminating large numbers of solder joints and their associated vias and traces

This material is designed to help medical device manufacturers achieve the high performance and rugged reliability that end users demand.

Richard Brooks
VP Sales & Marketing, Pexco LLC

PVC is still the most economical, functional, compatible, and most widely used clear plastic tubing for medical and healthcare applications. Phthalate plasticizers are used in PVC to give this resin varying levels of softness and flexibility. However, due to the long time suspicion that phthalate plasticizers (such as DEHP, DIDP, and DINP) might be carcinogens, many medical OEMs are requiring DEHP-free or phthalate-free materials used to produce their medical grade plastic tubing.

Medical grade PVC compounds are now available with other plasticizers that contain no phthalates such as: polymerics, citrates, adipates, and trimellitates. Although these phthalate-free plasticized PVC compounds can cost 25% to 50% more than traditional DEHP PVC compounds, they are far less expensive than any other PVC alternatives, such as clear thermoplastic elastomers (TPE). These TPE materials range from SEBS (styrene-ethylene-butalyne-styrene) compounds to polyolefin-based compounds. Tubing produced with most of these medical grade TPEs can be sterilized by gamma, ETO, and autoclave procedures, and can be solvent bonded to traditional connectors or fittings using standard adhesives such as cyclohexanone, cynoacrylates, or THF. However, TPEs can cost 100% to 250% more than traditional DEHP PVC materials.

Michael Swartz
Growth Strategist, DD Studio

Medical device manufacturers face increasing challenges in bringing new products to market. Not only must they pass regulatory clearances to launch, but they must also consider growing environmental demands, and a healthcare system in flux. For decades, polycarbonate (PC) has been the industry standard for durable medical plastic. Spiraling costs of healthcare demand that medical grade plastics should be as durable as possible. Commonly used plastics, including PC, face difficulty on the issues of contamination and cleaning, as they cannot withstand repeated exposure to common disinfectants.

We recently discovered Tritan copolyester, an FDA-approved copolyester that delivers all the qualities of PC with the added benefits of chemical resistance, toughness, optical clarity after gamma sterilization, and hydrolytic stability. Additionally, it provides ease of processing for difficult molds, with lower levels of residual stress. It offers greater material compatibility and more options with pre-form decoration vinyls, silkscreen inks, paints, and coatings. Most importantly, it can reduce systems costs and replace PC with little or no retooling. It is truly one of the most exciting advances in materials science—ideal for medical, pharmaceutical, and healthcare applications.

Bob Ward
President and CEO, DSM PTG

Biomaterials are commonly used to repair, replace, or augment body parts damaged by disease, trauma, and ageing. The use of cardiovascular, orthopedic, opthalmic, and general surgical implants made from high-performance biomedical polymers is well established and expanding rapidly. Increased understanding of how pathogens invade the body and cause inflammation, and new methods for modifying and characterizing polymer surfaces suggest new uses for biomaterials: as selective adsorbents for bacteria, viruses, and parasites in the treatment of disease. Applications under development include extracorporeal affinity columns that "clean" the blood and reinfuse it (after depleting it of pathogens and/or cytokines), and small cartridges for "purifying" banked blood during collection or transfusion. For example, properly designed adsorbent beds with covalently bonded heparin can bind TNF-a and many pathogens onto a modified polymer surface that is well known to be safe in contact with blood.

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