Medical Products Update

Medical Products Forecast: Clean, Green and Growing

In 2004 the FDA launched its Critical Path Initiative (CPI) to address what the agency called "the steep decline in the number of innovative medical products being submitted for approval—and getting to patients—despite the enormous breakthroughs being made in biomedical science."

The CPI led to a new funding partnership between FDA and NIH in February 2010. Deemed simply the FDA-NIH Collaboration, the effort "is inviting the best minds and research institutions to help develop and apply the new, 21st-century tools, standards, and approaches we need to properly assess the safety, effectiveness, and quality of medical products currently in development," according to the CPI website.

While government agencies continue to work on improving the pipeline to market, plastics manufacturers and engineers continue to push the medical products industry forward with product, material and process innovation and a strong focus on 'clean and green' – increasing the availability of sterile devices and parts with an eye on reducing the medical product industry's environmental footprint.

Acclaimed accounting and business services firm Deloitte noted in a January 2010 report, "Increased investment in research and development (R&D) can be expected in the chemicals and plastics industry with resurgent profitability and expanding global operations." Plastemart echoed Deloitte's optimism for the sector, specifically lauding antimicrobial technology in a February 2010 report. "The healthcare sector is an established market for antimicrobial plastics, with many emerging applications in this particular arena. The spawning of new applications in the industrial and consumer product sectors has enabled the market to continue on its current upward trajectory."

Why Plastic?

Plastic medical products and component parts offer numerous advantages over similar items of metal or glass, including low friction coefficients, superior chemical resistance, impact and fatigue resistance and excellent machining properties. Common examples of plastics usage in medical products include surgery patch and suture material (polypropylene), lab equipment (LDPE and polycarbonate) and orthotics and prosthetics (HDPE).

In *Minimizing the High Risk of Developing Plastic Medical Products,* John P. Beaumont of Beaumont Technologies writes that more than 100,000 varieties of plastic materials are available for production of medical product parts. Those parts, says Beaumont, "must be produced

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consistently—and profitably—over an extended timeframe (e.g., hundreds of thousands to hundreds of millions of parts). Even then, shortfalls will crop up in the tooling, the process and the plastic material because of the complexities of the interaction between:

- The part design
- The plastic material
- The mold design
- The molding process
- The ultimate application of the part

Historically, plastics weren't much different from other materials when it came to fighting infections. Microbic growth on product parts and surfaces yielded odors, discoloration… and communicable germs. Plastics, however, are significantly adaptable in the laboratory. Plastic resins can be infused with antimicrobial additives during compounding or as an additive masterbatch to produce antimicrobial products and parts.

The Plastemart report explained the benefits this way: "Materials that restrict the growth of microorganisms on equipment and surfaces in the medical environment help control the potential for infection in hospitals, clinics and doctor's offices." Those materials work by inhibiting bacteria's ability to reproduce. "The inorganic, antimicrobial technology built into this acetal series is present throughout the polymer matrix and not just on the surface as with coatings. This means its protection won't abrade or scratch off, so it can continue to limit microbial growth over the long term. This deterrent to bacteria and fungi also keeps them from attacking the plastic and causing the odors, stains, biofilms and loss in mechanical properties that can compromise product performance."

The report notes that the new antimicrobial grades are perfect for many components and surfaces touched by medical staff or patients, and the polymers' high lubricity "also makes them ideal for sliding parts, such as those in hospital beds." The materials are dimensionally stable and abrasion resistant and "can be sterilized by all common chemical, thermal and irradiative methods." And because the polymers are naturally white, they can be tinted or color coded.

In March 2010 Bayer Material Science announced two new polycarbonates for medical technology. Bayblend® M850XF is recommended for opaque medical applications such as components for surgical instruments, diagnostic equipment, systems administering drugs and intravenous systems. The product is particularly suitable for injection molding thin-walled components. Makrofol® polycarbonate film contains an antimicrobial thermoplastic coating that "offers effective protection against numerous bacteria and other microbes that adhere to frequently touched surfaces in large numbers and can multiply quickly," according to a Bayer press release. "Our film significantly reduces the number of microbes that adhere to it by preventing cell adhesion and suppressing the growth of germs," explains Dr. Heinz Pudleiner, product developer for polycarbonate films in the Functional Films segment at Bayer. Microbiological tests at Bayer HealthCare have shown that the new film reduces the number of colony-forming units of pathogens by at least 10^3. "As a result, objects whose surfaces are

covered with this film significantly reduce the risk of infection," explains Pudleiner.

The antimicrobial coating, which contains a silver-bearing substance functioning as an active agent, can be applied on one or both sides using a coextrusion process. This substance is chemically bonded into the abrasion-resistant, inorganic matrix so it does not leach out over time, even when exposed to moisture. The film can be formed cold under pressure, thermoformed and formed into decorative parts using Film Insert Molding (FIM). Common procedures such as screen, digital and laser printing can be used to print the film with decorations and lettering, and the film's antimicrobial surface also exhibits good chemical resistance.

Pittsburgh-based Biosafe, Inc. has also seen success with its BIOSAFE technology, a quaternary ammonium compound converted to a dry crystalline powder "that is thermally stable for use in extrusion and injection molding," according to a March/April 2008 article in *Plastic Additives and Compounding* magazine. "When mixed with any common resin and subjected to conventional thermoplastic processing, the BIOSAFE system blends within the base-resin polymer structure rendering the resulting finished product permanently antimicrobial."

Clean and Green

The worldwide demand for bioplastics is expected to quadruple to 900,000 metric tons in 2013 with an estimated value of $2.3 billion, according to a 2009 report from the Freedonia Group.

Leading the charge for the plastics industry are products made from polylactic acid (PLA), which Freedonia says accounted for almost 90 percent of all bioplastics demand in 2008. Made from starches such as sugar and corn, PLA is gaining acceptance as an eco-friendly choice for use in implants and drug delivery applications.

Medical Product Manufacturing News cites Placon and Cereplast as examples of pioneers staking their futures on bioplastics to change the medical products landscape. Because of cost and regulatory concerns and an initial lack of demand from end users, the medical industry had generally been slow to incorporate biodegradable, bio-based or recycled plastics in their designs, noted MPMN.

With demands for clean and green plastic medical products expected to remain strong, supporting roles are becoming more critical as molders and suppliers forge strategic partnerships and gear up to meet anticipated needs. In March 2010 thermoplastic injection molder Caroba Plastics of Colorado announced the addition of a 12,000 square foot clean room featuring 120-ton and 300-ton presses. Both pieces of equipment were purchased for Caroba by Baxa according to a *Plastics News* article. Baxa makes medical devices and systems that automate pharmacy operations and improve patient safety, and Caroba makes about 70 percent of Baxa's molds according to the article.

To meet the additive masterbatch and plastics color demands of the medical industry, PC

(Plastics Color Corporation) opened its 7,000 square foot *Plant Within a Plant* in 2008 in Asheboro, N.C. This closed-loop production facility was designed with input from medical experts who cited reducing contamination risk as a paramount concern. "It has been important for customers to see how we handled materials and how the cross-contamination risk has been almost eliminated by using such equipment as a sterilized water bath utilizing UV filtration and a closed-loop water system," explains Joe Byrne, PCC's vice president for sales and marketing.

PCC President Douglas Borgsdorf adds that the *Plant Within a Plant* anticipates the industry's general requirements for 2014: optimal production turnarounds and a closed-loop manufacturing system — a resource-planning architecture in which production planning drives the master schedule that in turn drives the material plan that dictates the capacity plan.

This May, PCC announced plans to open a new facility in California that is based on the success of its Plant Within a Plant clean compounding facility. The plant will open this fall with two segregated clean lines targeted squarely at the medical, pharmaceutical and food packaging industries.

For more information on color and masterbatch additives for the medical devices industry, contact Joe Byrne of PCC at 800-922-9936 or visit www.plasticscolor.com.

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