Ask the Expert

Tom O'Brien

An interview with Tom O'Brien of SABIC Innovative Plastics on materials for home healthcare medical devices.

What are today's most important trends regarding home healthcare medical devices?

One of the most important trends SABIC Innovative Plastics [1] is seeing in the use of home healthcare medical devices is increased usage due to the move toward self-care to reduce costs and boost efficiency of home care delivery; consumers' increasing medical knowledge and desire to play a larger role in their own care; and greater emphasis on monitoring of widespread, chronic conditions such as diabetes and high blood pressure to improve outcomes. Examples of home healthcare devices include continuous positive airway pressure (CPAP) devices, nebulizers, drug delivery devices, digital signal processing hearing aids, glucose monitoring systems, and self-test (in vitro diagnostic) devices. The global market for home healthcare devices is set to grow by more than nine percent by 2012 with the market exceeding $70 billion in 2012[1].

Why are plastics increasingly important in the design and manufacture of home healthcare medical devices?

Home healthcare is a fast growing market segment where SABIC Innovative Plastics' materials are playing a pivotal role. Consumers using devices at home have specific needs that only plastics and plastic compounds can address. First, devices need to be lightweight and portable so patients (particularly the elderly, ill and disabled) or their caregivers can lift, move, and operate them without assistance. Plastics can significantly reduce weight and mass when used as replacements for metal and other traditional materials.

Another requirement for home use is ease of maintenance — plastics are easy to keep clean and are resistant to common household cleansers. To encourage consumer use, these devices need to be aesthetically pleasing. In fact, they are, in many respects, becoming household furniture that needs to blend with home furnishings. Plastics can be colored, given different manufacturing surface textures and finishes, and, of course, are easily molded into pleasing designs. Finally, it is important to control costs so that these consumer devices are affordable. Plastics help reduce system costs through part consolidation, elimination of secondary operations such as painting, and acceleration of throughput.

What material technologies support design and development of new home healthcare devices?

The wide variety of high-performance plastics available from SABIC Innovative Plastics offer different property combinations needed to meet diverse device requirements. One of the most promising areas is the evolution of plastic compounds. Compounds can deliver exceptionally high performance, including mechanical strength, lubricity, wear resistance, and dimensional stability, to facilitate tight tolerances for device specifications. For example, SABIC Innovative Plastics' LNP Lubricomp compounds are excellent candidates for applications where lubrication and wear resistance are required, and LNP Thermocomp compounds are known for their inherent toughness.

In addition to plastic compounds, materials such as SABIC Innovative Plastics' Xylex polycarbonate (PC)/polyester resin is an excellent fit for healthcare applications primarily because of its ability to be water-clear or colorable, biocompatible, lipid resistant, gamma sterilizable, and maintain a good balance between chemical resistance and toughness. Xylex resin is also a good choice for disposables and device/pump housings.

What about consumer appeal – how do plastics help drive adoption of home devices?

With the expansion of home healthcare, designers are focusing on greater ergonomics and aesthetics to make devices comfortable and attractive for consumers. Plastics give device manufacturers greater design freedom than metal and glass. The ability to mold complex shapes and to consolidate parts are important in creating eye-catching ergonomic designs. Just as the right design makes a device easier and more comfortable to use, particularly when used repetitively, an attractive appearance makes it less intrusive in the home setting. Again, plastics can be enhanced with an almost infinite array of colors, special effects, textures, and finishes to blend in with home decor. SABIC Innovative Plastics' Visualfx resins and color-matching services provide a huge choice of colors and effects that can add to the appeal of a design.

Additionally, a combination of durability and light weight is critical for many home healthcare devices. They need to be easy to lift and transport, yet tough enough to withstand being dropped onto hard floors. Plastics can provide a lighter-weight alternative to metal, especially through thin-wall molding technologies that preserve strength while reducing mass and weight.

For example, to create its Breastlight device for home breast examinations, PWB Health Ltd. looked for a housing material that would be tough and impact resistant. The company selected SABIC Innovative Plastics' Cycoloy PC/acrylonitrile butadiene styrene (ABS) resin for the housing components due to its excellent impact properties and high flow for thin-wall molding. Excellent impact strength and overall toughness were also important for the Breastlight lens, which was made with SABIC Innovative Plastics' Lexan PC resin, also selected for its high optical clarity.

With the emphasis on reducing healthcare costs, how can plastics help make devices more affordable?

By using plastics to create high-end home healthcare devices, manufacturers can slash system costs and help drive down the overall cost of the product – via part consolidation, elimination of secondary operations, and accelerated throughput. For example, molded-in colors and effects in plastics eliminate the need for secondary painting and coating. Plastics can improve mold flow and mold release properties. SABIC Innovative Plastics' products are also able to provide the benefits of copolymer technology to improve flow characteristics while maintaining impact strength. Impact strength is a key characteristic that makes the Lexan HPX resins excellent candidates for home healthcare applications such as respiratory and drug delivery devices.

How is SABIC Innovative Plastics making it easier for device manufacturers to get their products through the regulatory approval process?

SABIC Innovative Plastics has created a comprehensive healthcare product policy – including more than 50 high-tech healthcare materials that were designed with the intent of supporting OEMs in achieving regulatory compliance. This high-value service ensures the consistency and biocompatibility of SABIC Innovative Plastics' healthcare grades. SABIC Innovative Plastics' healthcare product policy provides the following:

- Pre-assessment of resin biocompatibility according to ISO 10993 or USP Class VI standards
- U.S. Food & Drug Administration (FDA) or Device Master File listing, with letter of authorization provided if needed
- Products subject to formula lock and change management process
- Healthcare product nomenclature for easy identification

Formula lock and management of change policy can save significant time and

money. These provisions can avoid requalification delays of up to 12 months and, depending on the number of parts, the provisions can also avoid costs in excess of $1 million.

Is SABIC Innovative Plastics investing in development of new materials for the healthcare industry?

Yes, SABIC Innovative Plastics has a dedicated team of healthcare industry managers with specialized expertise and knowledge in developing materials focused on the needs of healthcare device manufacturers, clinicians, and patients. This team assesses market drivers and trends and guides the expansion of the company's portfolio to meet these market dynamics. SABIC Innovative Plastics has created a Center of Excellence in its Processing Development Center (PPDC), in Pittsfield, MA to support the healthcare industry with laboratory testing and evaluation equipment that enable the company to better assess the performance of their materials in medical applications.

SABIC Innovative Plastics has increased the company's healthcare products portfolio by approximately 20 percent in the last two years, including new capabilities for autoclaving and new materials for smaller, more intricate parts as well as long or complicated flow lines. The company's Lexan HPX copolymer resin series, for example, offers new improvements to balance flow and impact, while new grades of Lexan HP resin give customers yet another option for higher-flow healthcare materials.

Ongoing innovations in the company's LNP specialty compounds continue to address the many challenges of medical device design. An example is the increasing call for electromagnetic interference (EMI) shielding requirements as a result of massive growth in remote home diagnostics. SABIC Innovative Plastics' LNP Faradex compound materials can help local and global medical device manufacturers meet electromagnetic compatibility (EMC) regulatory requirements by providing a highly effective EMI shielding solution that can lower part weight and reduce system costs. Additionally, by using a non-brominated, non-chlorinated flame retardant system, LNP Faradex compound can help manufacturers curtail the use of hazardous substances in healthcare electronics.

References

[1]"Top 10 Medical Equipment Trends in 2009" available now through Aarkstore Enterprise [press release]. March 20, 2009. Available at http://www.prlog.org/10202269-top-10-medical-equipment-trends-in-2009-available-now-through-aarkstore-enterprise.html</ref [2]>

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