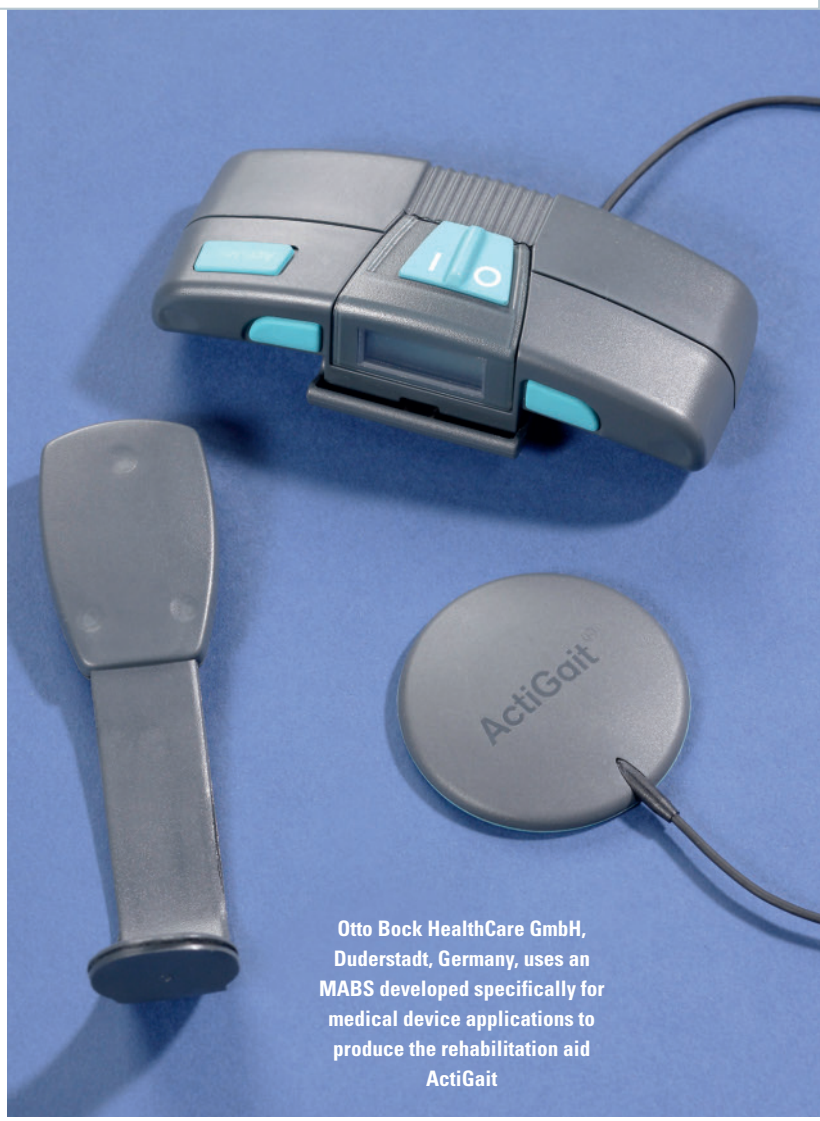
Challenges in Medical Technology.

Hardly any other branch of the plastics processing industry places such stringent requirements on materials, reliability and the service provided by its suppliers as the medical device sector. Contractually agreed upon product characteristics, tight specifications and verifiable compliance with international standards guarantee long-term planning capabilities and ensure a reliable supply as well as a secure investment. With an expanded service package for special MABS, ABS and now even copolymer POM grades, BASF is ready to address the great challenges encountered in the fields of healthcare and diagnostics.



Otto Bock HealthCare GmbH, Duderstadt, Germany, uses an MABS developed specifically for medical device applications to produce the rehabilitation aid ActiGait

PE104217

Safety Has Priority

CHRISTIAN BONTEN
JÜRGEN DEMETER
SABINE VOGT

Products for the medical device sector are subject to stringent national as well as international standards and test procedures. In turn, the producers of such products place similarly high requirements on the safety and absence of physiological concerns when it comes to the resins being used. Even the slightest variations in product composition can translate into a major business risk: expensive and image-damaging recall campaigns would be possible consequences. At the same time, approval procedures in the medical device sector are especially time-consuming and costly, so that the time and expense associated with a new approval require careful consideration. It is also for this reason that product life cycles for medical devices last about ten to twelve years and are thus considerably longer than in most other sectors. To be successful in the medical device market, activities relating to medical and pharmaceutical applications focus not only on innovation but also on minimizing risk. Requirements include safety in terms of consistent product characteristics, minimal interaction of the material with the contents and active ingredients and a continuous, reliable supply of the selected resin. Moreover, in an optimal situation, OEMs (original equipment manufacturers) and their suppliers receive valuable support from the producer of the resin with regard to approval of the final products. Such cooperation is long-term in nature and characterized by reliability as well as a spirit of partnership.

In addition to a new styrenic specialty resin, BASF SE, Ludwigshafen, Germany, has recently started offering the engineering polymer POM (trade name: Ultraform) for medical device applications. Furthermore, the company has also expanded its extensive service package for healthcare and diagnostics applications, which is tailored specifically to the requirements of the medical device market.

Simplified Approval Process

BASF offers proof that its resins raise no concerns regarding compliance with legal regulations related to their safety in food contact and medical device applications and conducts basic research con-

Translated from Kunststoffe 4/2008, pp. 122–124

Fig. 1. Products for medical devices based on engineering plastics: BASF is committed to not change its product formulations; however, should this nevertheless become necessary, the customer will be informed at least 36 months in advance

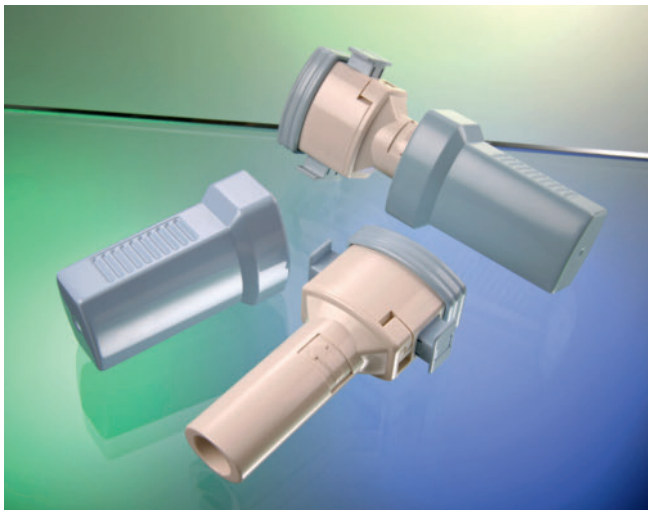


Fig. 2. Inhalers from Novartis made of a special ABS

cerning their compatibility with the chemicals commonly encountered in this sector. Testing of formulations and/or tests performed on the pellets ensure conformance to, for instance, the EU Pharmacopeia (EP 5.2, Chapter 3.2.2 "Plastic Containers and Closures for Pharmaceuticals" and the US Pharmacopeia ("USP Biological Test Classification VI"). Additional biocompatibility tests of the resins in accordance with international standards (such as cytotoxicity as specified in ISO 10993) along with creation of a drug master file (DMF) simplify the application and approval processes for the OEMs regarding their products. This is also important from the aspect of the even more stringent requirements of the American Food and Drug Administration (FDA) that are expected.

Reduced Outlay for New Approvals

BASF has documented its intent to not make any significant modifications to the resin formulations defined in the drug master file (Fig. 1). To make this possible, the company requires from its own suppliers the same commitment with regard to maintaining their formulations – the purity of material supplied to BASF must be assured. For medical device manufacturers, this means considerably reduced outlay for repeat tests and new approvals. Exceptions arise only in extreme situations, for instance, changes to the applicable laws. If such a situation should occur, BASF is committed to notify its customers of a product modification not only 24 months in advance, as was previously the case, but at least 36 months in advance now. These three years give the OEM time to complete a repeat application process for the final product with the modified resin. Long-term availability of the product ensures not only greater security with regard to planning, but also minimized risk for the customer from a business standpoint. The expanded service package also includes support in terms of application technology as it relates to component design, resin processing and subsequent processing of the plastic products.

Manufacturer

BASF SE
Fachpressestelle Kunststoffe
D-67056 Ludwigshafen
Germany
Tel. +49/6 21/60-43348
Fax +49/6 21/60-49497
styrenics.infopoint@basf.com
www.basf.com

Established Products in the Medical-grade Line-up

The already introduced medical-grade resins from BASF include a transparent MABS (methylmethacrylate-acrylonitrile-butadiene-styrene copolymer) with the trade name Terlux 2802 HD (Title photo) and the broadband ABS grade Terluran HD-15 that has been commercially available since 2006 and can be used for a variety of housings and enclosures. The inhalers produced by Plastiape S.p.A., Osnago, Italy, for Novartis Pharma GmbH, Nuremberg, Germany, represent one of the first high-volume applications for this ABS (Fig. 2). With a melt index (MVR) of 15 cm^3/10 min, it is easily injection molded. Compared to conventional ABS, it exhibits improved chemical resistance and a good relationship between toughness and stiffness. As with all HD products, it belongs to the specialty styrenic resin line-up that BASF has bundled together under the designation PlasticsPlus along with numerous other resin specialties and the associated services.

MABS with Improved Flow Characteristics as an Alternative to Polycarbonate

The new Terlux 2812 HD member of the HD family is a material that represents a useful addition to the existing offering in the medical-grade area. Compared to the already introduced Terlux 2802 HD, the transparent MABS Terlux 2812 HD offers a higher melt index (MVR = 8 cm^3/10 min): for instance, the considerably easier-flowing material can be injection molded in multi-cavity molds more readily and now permits economical production of especially complex transparent components (Fig. 3). This makes the material an interesting alternative to polycarbonate (PC), since better processability translates into improved functional integration such as that needed for lab-on-a-chip applications. The ability to replicate fine surface structures and the decisive benefit of colorability are advantages for this new member of the styrene copoly- ▶

Fig. 3. Complex transparent components can be injection molded from a new MABS with improved flow characteristics

mer family. Compared to PC, Terlux offers improved resistance to chemicals and stress cracking as well as a definite density benefit with its value of 1.05 versus 1.30 g/cm^3. The material exhibits over 90 % transparency, even at higher wavelengths. It is only for hot steam sterilization that this versatile resin is not suitable. On the other hand, is withstands alpha and gamma radiation as well as ethylene oxide. In the near future, BASF will expand its healthcare and diagnostics product line even further: Luran HD, an SAN from BASF, is expected to become a crystal clear and chemical-resistant alternative to many of the PMMA grades currently used for medical devices.

First Engineering Plastic with an HD Profile

In contrast to the amorphous resins Terluran HD and Terlux HD, which are employed primarily as housing materials, the two new copolymer POM grades from BASF (POM: polyoxymethylene; polyacetal) Ultraform S2320 003 PRO and W2320 003 PRO are semi-crystalline resins. The can withstand high mechanical loads and are thus suitable for functional elements such as springs, gearing and fasteners. The combination of good hydrolysis resistance and heat deflection temperature means that Ultraform components can be sterilized in hot steam. The hard, smooth surface opens up opportunities for use in functional parts where friction is a concern. Since these POM grades are also very chemical-resistant, they can be used to produce valves and metering systems. The Ultraform PRO material is the first engineering resin from BASF that has been optimized for medical device applications and represents an ideal complement to Terluran HD and Terlux HD. The suffix PRO in the name (Profile-covered Raw materials Only) results from the claim that only very specific, strictly controlled precursor materials – as a rule, only from one supplier – are employed. These copolymer polyacetals are sold with the same service package as the resins in the HD family. The grades S and W differ in terms of their MVR values (11 versus 25 cm^3/10 min).

Conclusions

Today, it is not possible to think of medical technology without plastics, regardless of whether housings or cannulae, inhalation systems or multiflow directional valvesa are concerned. When compared to the overall market for plastics, the segment involved with medical devices may be small, but it is characterized by high growth rates. For instance, analyses cited the medical market volume for ABS in Europe at about 20,000 t per year. The resins employed here are – because of the stringent requirements – in most cases true specialties. In this environment, binding and comprehensive service packages represent opportunities that make sense for resin suppliers and processors alike. ■

THE AUTHORS

DR.-ING. CHRISTIAN BONTEN, born in 1969, is director of thermoplastic resins for the "Healthcare and Diagnostics" industry management unit within BASF SE, Ludwigshafen, Germany.

DR. RER. NAT. JÜRGEN DEMETER, born in 1970, works in the same company and is responsible for technical marketing of Ultraform.

DR. RER. NAT. SABINE VOGT, born in 1964, is an expert for product safety and approval questions regarding BASF's resins.