

Cleaning the Lungs

The Processor Paritec Combines Materials and Functions in 2-Component Injection Molding

While it is not entirely common practice, just about everyone has inhaled before. In modern inhalation devices, sophisticated 2-component parts made of TPE and PP or ABS form the link between the sensitive face and a technical control unit. A look at the product development shows how materials and functionality are skillfully combined.

The face mask for children is available in trendy colors and with special designs. Pari distributes these 2-component masks made of PP and TPE in the entire European market. In the past, the masks for children were made of PVC and elaborately hand painted

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She gave it her all but did not win. When German athlete Claudia Pechstein looked at the display board at the end of her 5000 m speed skating run during the Olympic Games in Pyeongchang, disappointment was written all over her face. Eighth rank only, no medal. Red-faced, she panted for air. As soon as she reached the boards around the rink, an attendant handed her a mobile inhaler – to be precise, the Velox membrane nebulizer from Pari GmbH, Starnberg, Germany (Fig. 1). The medical technology and pharmaceuticals company is manufacturer for medical devices in the field of airway with focus on inhalers, and supplier of Germany's 2018 Olympic athletes. The sister company Paritec GmbH in Weilheim, Bavaria, fabri-

cates nebulizers, mouthpieces, masks, housings, and technical components for the medical devices using thermoplastic elastomers (TPE) and polypropylene (PP) or acrylonitrile butadiene styrene copolymer (ABS) using 2-component injection molding. For the wafer-thin seals and contours of TPE, barely thicker than the width of a pencil line, Paritec has been working together for many years with the material experts at Kraiburg TPE GmbH & Co. KG, Waldkraiburg, Germany (Fig. 2).

Airway Therapy with Aerosol

Lung and airway diseases are treated with the inhalation of approved medications. Isotone saline »



Fig. 1. The Velox mobile inhaler: To the left the junior version with an all-round soft silicone mask for infants and preemies, to the right the adult version. The nebulizer unit with the mixing chamber is behind the mouthpiece, and even further back is the control unit with the on/off button (© Hanser/F. Gründel)

Company Profile

As a company of the Pari Group, **Paritec GmbH**, is a system supplier of medical equipment. There, plastic components including construction, material selection, tooling and final assembly are manufactured. Last year around 140 employees produced some 18 million plastic components at the German Weilheim site, which were installed in compressor and diaphragm systems. In 2011/2012, a completely new injection molding production was put into operation. In 2014, the entire site including the material supply and office building was redesigned and brought up to date.

In addition to the company headquarters in Starnberg and the production in Weilheim, **Pari-Pharma, Gräfelfing**, is one of the German-based companies in the group dealing with pharmaceuticals and related equipment (eFlow technology). Further, there are international branches and a worldwide distribution network. Besides inhalation devices such as the **Pari Boy** and nebulizers, the range also includes products in the field of spirometry, inhalation aids for the easier application of sprays and salt-based inhalation solutions, inhalable antibiotics and an inhalable corticosteroid in liquid form. The products are sold in 80 countries worldwide. In the past fiscal year, the group generated sales of approximately EUR 114 million.

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solution moisturizes the lungs and helps cough up phlegm more easily in higher concentration. Preventive airway treatment by inhalation is the order of the day in countries like China, Italy, and Brazil, where residents are among other things exposed to high levels of air pollution. In fact, hospitals in China have inhalation rooms where people stand in line.

Aerosol treatment is the basis of inhalation. Various methods are used to turn liquids into fine droplets that are easy to inhale and are thereby transported into the breathing apparatus. With an average size of 5 to 8 µm, they act in the upper airway including sinuses and throat. Smaller droplets in the range of 2 to 5 µm pass the soft palate and are transported deep into the lower airways. Michael Koch, Vice President Operations and authorized representative at Paritec, knows how to turn a liquid into defined droplets. He has been involved in the production of jet and membrane nebulizers for almost ten years. Pari brought the first compact inhaler for end customers to market in 2015, which was also every year on site at the Olympic Games since then.

Stroke of Genius with TPE

Pari's devices have to master contact with sensitive areas such as the patient's face and mouth just as reliably as the pharmaceutical medications and technical control units that are used. The combination of soft TPE and hard PP is predestined for such applications (Title figure). Erich Steiner, Technical Specialist Application Technology at Paritec, has dedicated himself to the development of new products for years. "Plastic is a living material that



Fig. 2. Michael Koch of Paritec (left) and Matthias Schmidt of Kraiburg TPE (right) work together closely. "We are involved in projects very early on, so we can for example develop special formulations for complex flow paths," says Schmidt (© Hanser/F. Gründel)



Fig. 3. This mouthpiece is commonly used for Pari devices. However, its technical development was unique, both for Paritec and for Kraiburg TPE (© Hanser/F. Gründel)

keeps changing its behavior. That makes every day a new challenge," Steiner says. Two material components further increase the level of complexity. That is why a close partnership has been established with the TPE manufacturer Kraiburg TPE located only about 100 km away. Matthias Schmidt, Head of Sales in the Medical & Consumer Team at Kraiburg TPE, well recalls the shared beginnings some 16 years ago: "Kraiburg developed medical materials with special autoclaving temperature characteristics for the first time to use in the inhalers." That was his company's first step in the direction of medical technology. Today Kraiburg TPE realizes numerous projects in this sector with the Thermolast M series of products.

It all began with a 2-component mouthpiece with a small silicone plate that had to be inserted manually in order to exhale (Fig. 3). This manufacturing method was very expensive and there was a risk that the separate silicone plate could be swallowed. Molding silicone directly onto the PP base body was not possible since the two materials do not combine well because of thermal differences. This is possible with TPE, but the component had to be suitable for steam sterilization at a temperature of 134°C in the autoclave. "There was no TPE with a corresponding temperature resistance at the time," Steiner says. With extensive material know-how, the experts at Kraiburg TPE managed to achieve the desired temperature resistance and thus expanded their own portfolio.

The fine plate with an approximate thickness of just 0.3 mm has to lift slightly on exhaling, so the exhaled air can flow out. Schmidt and his colleagues ultimately tailored the TPE precisely to exhaling, therefore the plate opens with sufficient ease. Now the plate that was previously connected manually could be fabricated directly, firmly connected in 2-component injection molding. "The mouthpiece was a stroke of genius for us at the time," says Steiner, pleased to this day. All technical

challenges were overcome and the manufacturing costs considerably reduced, because all assembly steps are fully automated on the machine. It has been produced in series since 2003 and was proven millions of times.

A Full Repertoire of 2-Component Technologies

Paritec's production site in Weilheim specializes in 2-component injection molding. "We use all available 2-component processes and tools," says Koch and names the transfer technology, turning with an index plate, rotary plate, or center block. This is put into practice with multi-cavity molds, maximum 4+4. The site has 14 injection molding machines with closing forces between 220 and 2800 kN. Most of them have no tie bar because of the tool size in relation to the shot weight, and the necessary automation. In 2012, investments were made to modernize production including new machines. Now mainly electric and a few hydraulic machines from Engel Austria GmbH, Schwertberg, Austria, stand in rank and file on the factory work floor (Fig. 4). Most of them have a corresponding robot system for unloading and handling. "We wanted to obtain as much of the production equipment as possible from one source, to make our production facility highly flexible with standardized machine technology," Koch says. For example, all robots are equipped with flange couplings for which Paritec has numerous different gripping and handling elements that can be used by all the machines. Small lot sizes can also be produced as a result, since the number of versions for these medical technology assemblies continues to increase.

Without a lot of post-processing steps, the components are assembled and mounted after injection molding, packaged, and sent all over the world. Of course, as is necessary for medical devices of this class, with batch or rather serial number to ensure the traceability throughout »

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Fig. 4. A look at the factory work floor, fully modernized in 2012. "In production, I want to have information locally and remotely to make decisions quickly," Koch says. "If I have to rely on the bush and corridor telegraph, we lose."

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the entire process chain. Quality assurance is just as important in this field. In part it takes place directly at the machine. "Wherever the material or viscosity may fluctuate, inline inspections have been integrated, often optically using a camera," says Koch. Thus, good and bad parts are identified directly in the plant. Some functional tests are also performed directly at the machine to eliminate downstream processes. For example, during automatic assembly of the nebulizer insert with the nozzle at the bottom part the airflow is measured and evaluated directly at the machine. "The component comes out of the plant fully tested and selected," Steiner says.

The in-house tool shop is just a few steps further on. Originally it primarily did tool maintenance. "But if you can perform high quality maintenance on injection molds, you can also build them yourself," says Koch. In the meantime the department has developed into a very good 2-component tool maker. This is also important because TPE processing requires absolute tool precision. The material has a low viscosity and forms a ridge on the component with a gap of just 0.1 mm in the tool. Koch explains that "spotless" venting for the off-gassing of the material is also essential. Meeting these criteria for complex rotating and turning molds of 1t or more over the course of years is Paritec's actual core competency.

Formulation and Processing Parameters Crucial for Adhesion

The experience of the TPE supplier and processor was also in demand for the Velox membrane nebulizer (Fig. 1). This mobile inhaler consists of a con-

trol unit and a nebulizer unit. A stainless steel membrane is located between the mixing chamber with the inhalation solution and the nebulizer. It is perforated by about 3000 small holes with a diameter of about 1.5 µm. High-frequency vibrations of the membrane are incited by a control unit and a piezo crystal. This produces a vacuum that suctions the inhalation solution through the membrane in defined droplets.

Assembly development focused on an ergonomic design, the smallest possible number of single components, ease of use, and efficient production. The electronics and liquid also have to be sealed against each other according to the IP protection classification. An on/off button was integrated into the upper shell. For Koch, the prime directive was: "Incorporate as much functionality as possible with just one cycle." That is why Paritec works closely with Kraiburg TPE starting in a very early development phase in order to jointly discuss geometries, flow paths, and material formulations.

In contrast to 99 % of Paritec's plastic components, the housing of the Velox is not made of PP but ABS as the hard component (Fig. 5). Its adhesion to TPE was one of the main project issues from the outset, Steiner reports. In order to obtain a good connection between the two materials, TPE normally melts the ABS slightly when it contacts the surface. This causes the macromolecules to link, creating a physical connection.

With the Velox housing however, the shot weight and the contact surface between the TPE and ABS were so small that the surface was not sufficiently heated. This resulted in poor adhesion of the materials. The connection was not

An efficient production cycle starts with the right material recipe

simple, both in terms of the formulation and regarding the processing parameters, Schmidt says, and adds with a smile, "a really tricky task." Naturally a TPE version with very high flowability was used from the outset, Schmidt emphasizes, "but you will not get anywhere with a run-of-the-mill formulation for such a high quality product." He therefore utilized existing adhesion systems and modified them especially for the component. Schmidt and Steiner were at the machine together and refined the parameters until they were optimal for the material, machine, and product. That was the only way to achieve a thermal transition state between hard and soft components with the given geometries in the end.



Fig. 5. Exterior and interior view of the ABS upper shell of the Velox housing with control unit. TPE serves as the seal and button in one, and is distributed to the inside and outside via sophisticated flow paths from a single injection point

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Seal and Button in One Cycle

Everyone agrees that the interplay of the material formulation, machine parameters, and tool is always crucial. What this meant for the Velox upper shell: a lot of adhesion modifier, a heated tool (50 °C for ABS and 30-40 °C for TPE), and rapid injection with a hot runner. Among other things, the supply for the main and secondary components was switched so the TPE as secondary component has the shorter flow path and is as hot as possible when it gets into the tool and onto the ABS.

In Velox, TPE serves both as a seal and as a functional element. This is illustrated in particular by the on/off button. It had to be mechanically actuated, back lit, and sealed against moisture. "An ABS button would not have given any feedback, a separately inserted button would have produced a gap with a capillary effect for liquids," Koch explains. Now this can be realized in just one 2-component injection molding cycle due to well-chosen flow channels and a translucent thermoplast-M type from Kraiburg TPE. The additional circumferential TPE seal is not visible to the naked eye. Only by pressing lightly with a finger can the soft component be detected. Kraiburg TPE dyes the selected compound exactly to the color of the hard ABS component.

It took about a year from the first components to the Velox pilot series. In the meantime, it has found its way to the market. The mobile inhaler has a medical device number for statutory health insurance and is eligible for reimbursement.

Digitalization of SMEs

The fully modernized manufacturing facility allows Michael Koch to check the current production parameters via the smartphone even during external

appointments. As with many other SMEs, his thoughts are currently revolving around digitalization. While he is convinced that manufacturing can be made far more efficient and effective with data and production networks, he has to be highly selective in the use of his resources. "You are not going to find any robots moving goods around in our operation," he says, "this is still something for the greats in the industry at the moment." According to Koch, an economic advantage for SMEs is realized when an MES can be omitted. "If I merely have data that do not control anything, I might as well skip it," is how he sums it up. Instead, an intelligent machine should send data to a cloud-based information platform that in turn generates control commands. In-house production data are no secret to him, quite to the contrary: "I have respect for anyone who can produce components exactly like these here based on our machine and process data," Koch says with self-confidence. ■

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