



# RAUMEDIC®

— Lifeline to Health —

## INSERT. WEAR. INJECT. DISPOSABLE UNITS FOR WEARABLE DRUG DELIVERY DEVICES

Mobile drug delivery pumps can significantly improve patients' quality of life, however they require highly advanced disposable components to ensure that patients receive the exact dose required. Here, Claudia Fink, Senior Product Manager Marketing & Sales at Raumedic AG, reviews how the components are produced and which secondary processing techniques are required. She then looks at how partnering with Sensile Medical has helped with the development of the disposable units for a modern drug delivery system.

Worn discreetly on the body, mobile drug delivery pumps are simplifying the lives of many patients who need regular medication. With the help of a patch, they can simply affix the pump to their skin. The medication can then be administered regardless of time or place, without the need to travel frequently to hospital, which significantly improves their quality of life.

The core elements of such wearable drug delivery devices are a reusable electronic activator and a pump module for one-time use. To create these customised disposable units, Raumedic has used its expertise to produce high-precision moulded parts and micro-tubing (via extrusion processes) from a number of different medical-grade plastics.

### PRODUCING THE THERMOPLASTIC AND SILICONE COMPONENTS

The fluidic outlet alone – comprised of four components – requires extensive knowledge to make, both in terms of production

systems and secondary processing (Figure 1). The transparent slider and the tube clamp are injection moulded, whereas the tubing is produced in a coextrusion process. The manufacturer-specific Rauinert technology almost completely eliminates the possibility of interactions between the pharmaceutical and the material as the two thermoplastics are coextruded in a single step. The outer layer, made of polyurethane (PUR), ensures that the tubing can be optimally glued and sterilised. The inner layer is made of polyethylene (PE), which is an inert material that is very medication compatible. It is imperative that any materials used in pharmaceutical applications that come into direct contact with drugs are very carefully selected.

When patients self-medicate at home, they must be able to expect that the pharmaceutical will be delivered in the exact dosage. Therefore, the reservoir requires a syringe plunger with excellent sliding properties. To ensure that this component



Figure 1: As a component group of wearable patch pumps, the fluidic outlet is primarily responsible for the subcutaneous injection.



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slides smoothly through the syringe barrel with little effort, medical-grade silicone is shaped into the desired form during an injection-moulding process. The syringe plunger, as well as all other required plastic elements, is produced under clean-room conditions on the basis of ISO Class 7.

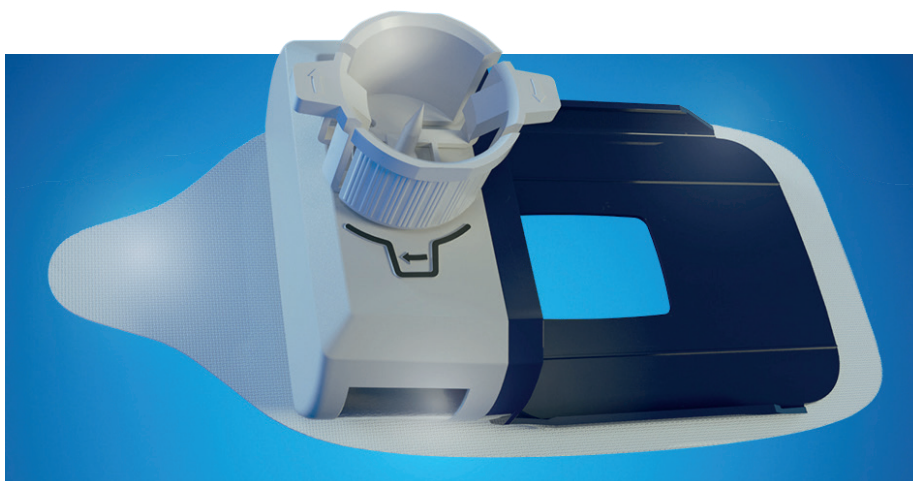
## SECONDARY PROCESSING

The secondary processing of individual components plays an important role, too: the micro-tubing and tube clamp are glued together with the help of UV bonding. To minimise the pain felt by the patient during a subcutaneous injection, the hypodermic needle must be siliconised. The medication reservoir receives similar treatment, but always with one principle in mind: the process should only use as much silicone oil as required for an even application. In addition, the desired graduated scale is stamped onto the reservoir, made of polypropylene (PP), in a pad-printing process. The serial number and instructions about the correct placement of the vial adaptor on the pump housing must be abrasion-resistant so a laser-marking process is used for these labels (Figure 2).

“Our polymer and secondary processing go hand in hand,” said Thorsten Kellner, the senior engineer responsible for injection and dosing systems at Raumedic. He added that this relationship was a key consideration for business partners in the medical and pharmaceutical industry, “When all fundamental production and assembly steps are done under one roof, our customers have fewer external contact points, something that gives them greater process security.”

## WORKING WITH A PARTNER COMPANY TO DEVELOP DISPOSABLE UNITS

Since 2014, Raumedic has been working with the Swiss pump manufacturer Sensile Medical on the development and production of disposable units for modern drug delivery systems. Derek Brandt, CEO at Sensile Medical, summed up the partnership, “We needed a strong manufacturer who could turn our SenseCore micro-pump technology into a cutting-edge drug delivery device. We found in Raumedic a partner that could meet all of our requirements: a single point of contact for all necessary production steps, proven expertise in a range of manufacturing technologies and an understanding of the special needs of the pharmaceutical industry.”



**Figure 2: Manufacturers of state-of-the-art medication pumps require the broadest range of production and secondary-processing techniques, including two-component injection moulding and laser marking.**

Many challenges had to be overcome in this multi-year project. “The end product consists of many components, some of which are complex, and they have to function on a system level,” said Mr Kellner, “One of the most work-intensive steps we faced was developing an optimal design in terms of feasibility.” One other wide-ranging task was the design validation that was done as part of a clinical trial.

In addition, leak-tightness, flow and 100%-inline function tests were conducted for the individual component groups. Finally, the finished product was packed in blisters and sterilised in accordance with customer requirements.

## CONCLUSION

“We are certain that compact drug delivery devices still have a lot of untapped potential,” Mr Kellner said in describing the company’s view of the future. The constant stream of new products being developed by the pharmaceutical industry will ensure that the number of approved drugs for self-medication purposes will continue to rise.

“And the application fields for large-volume wearable injectors in the home-care area are becoming broader and broader,” he added.

## ABOUT THE COMPANY

Human health is at the core of Raumedic Group’s business. The company, which has a global workforce of 700 people, specialises in processing medical-grade thermoplastic polymers and silicones at five production sites in Germany and the US. As a partner of the international medical technology and pharmaceutical industry, the polymer specialist develops and produces customised components for customers, including tubing, catheters and moulded parts as well as complex groups of components and systems for diagnostic and therapeutic uses. With 70 years of experience in the areas of extrusion, injection moulding and assembly, the company turns customer ideas into mature products. The foundation of this work is formed by a quality management system based on ISO 13485 and clean room manufacturing on an area of 10,000 m<sup>2</sup> based on ISO 14644 (Class 7).

## ABOUT THE AUTHOR

**Claudia Fink** has been working at Raumedic since February 2011. At the headquarters in Helmbrechts, Germany, she is responsible for the strategic orientation of the Injection/Dosing product segment in the Systems Business Unit. In this position, she works closely with sales and application technology. As Senior Product Manager, she primarily handles commercial and operational tasks. Participating in trade fairs, meeting clients and constant market monitoring are also included. Claudia Fink was involved in all critical steps of the development project with Sensile Medical: from drafting the offer through coordinating the production of samples to order processing, the Product Manager assisted in all core processes. Before joining the company, Claudia Fink studied Business Spanish and lived in Spain for a year.