

COMPANY SHOWCASE: Sensile Medical



A Gerresheimer Company

Sensile Medical has achieved a lot since its acquisition by Gerresheimer last year. Here we provide an update on two recent projects: the recent market launch of our first micropump, an infusion pump for Parkinson's disease patients; and our latest project with SQ Innovation for a 3 mL furosemide patch pump. With these tangible results and achievements, we demonstrate our world-class capabilities in the development of large- and small-volume wearable injection devices.

ONCE-A-DAY SET-UP OF A FULL DAY'S TREATMENT

The first micropump from Sensile Medical is now available on the market. It may give Parkinson's patients more autonomy in their day-to-day lives by enabling once-a-day set-up for a full day's treatment.



Figure 1: 20 mL wearable platform has recently been launched in Europe with apomorphine for advanced Parkinson's disease.

"For most patients a full day's treatment can be set up just once a day, giving them more autonomy in their daily lives."

Developed by Sensile Medical especially for EVER Pharma (Unterach, Austria) under the brand name *D-mine*[®] Pump, this 20 mL wearable infusion device with a micropump (Figure 1) recently received European CE certification and has already been launched in several European countries. The compact, patient-friendly infusion pump is used for the continuous subcutaneous administration of apomorphine to treat the advanced stages of Parkinson's disease.

Looking at currently available treatments, patients often have to swallow multiple oral dosage forms while adhering to a strict schedule. Additionally, one or more self-injections of medicine were required. All this compromised their quality of life. In order to ease the control of the disease, a continuous infusion using the pump offers a beneficial option. For most patients a full day's treatment can be set up just once a day, giving them more autonomy in their daily lives.

A Perfect Fit: Modular and Flexible Components

Sensile's modular and flexible system, providing a multi-use reusable module containing the software and electronics as well as motor, feedback elements and power source, together with the single-use disposable component that is exchanged with every new drug filling, are a perfect answer for this specific therapy.

Considering the impairments caused by the disease, it was crucial to develop a device which is safe and easy to handle for those having difficulties co-ordinating their movements. Small, discreet and easy to carry portable

were further goals which were achieved from a device look and feel perspective.

Fully Patient Centric – Basal and Bolus Fit to Each Individual Patient's Needs

It was mandatory to have built-in automated drug transfer from the vial to the device. A minimal number of buttons and a multicolour screen interface allow adjustment of the pump according to every single patient's needs for basal and bolus drug flow, as well as adapting the dose whenever needed. Plain text menus improve usability. With Sensile's micropump technology these features and settings are an integral part assuring precise and accurate dosing.

The integrated software and electronics, fully adapted to the specific therapy, allowed us to integrate multiple languages supporting launch in various countries. Patients have



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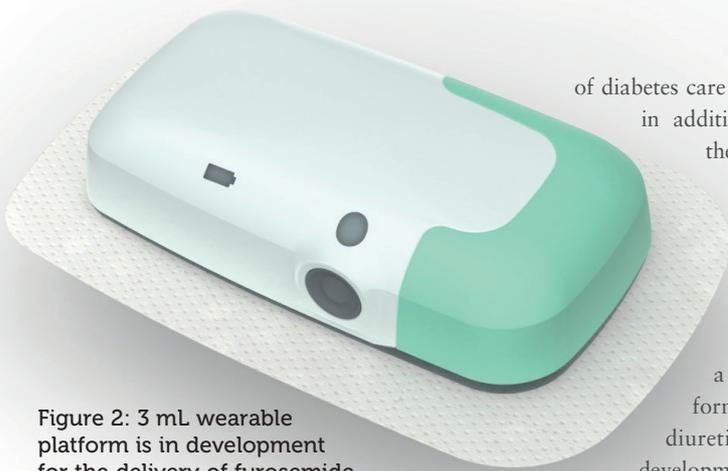


Figure 2: 3 mL wearable platform is in development for the delivery of furosemide.

the freedom to choose their language of choice. To avoid complicated flow-rate calculations for this specific treatment the device flow rate was set to mg instead of ml/h for delivery. Data history can be looked up and supports better management options to healthcare professionals with no additional daily paperwork for the patient.

Based on its excellent dedicated team, technology and experience Sensile Medical has delivered an ambitious 20 mL infusion pump with highly innovative user requirements fully customised to the patient and pharma company's needs and the pump has successfully entered the market.

3 ML MICROPUMP FOR CONCENTRATED FUROSEMIDE – A NEW TREATMENT OPTION

Sensile Medical is in the advanced stages of development of a 3 mL micropump (Figure 2) providing extremely accurate dosing over time. The most obvious therapeutic application for such a pump is in the area

of diabetes care with insulin. However, in addition to insulin therapy, the 3 mL pump platform is being developed for multiple other therapeutic applications. One of these is for ultra-accurate delivery of a novel concentrated formulation of the loop diuretic furosemide under development by SQ Innovation (Zug, Switzerland) for the treatment of oedema in heart failure.

In partnership with SQ Innovation, Sensile is utilising its 3 mL platform, based on a standard 3 mL cartridge, to enable a cost-effective drug delivery solution that will help improve outcomes and reduce costs in the treatment of heart failure. The device design comprises reusable motorised component and disposable cartridge, which minimises waste and creates cost-effective treatment options across therapy areas.

Heart failure is a common, complex and serious condition affecting approximately 6.2 million people in the US and 26 million people worldwide. Many patients with heart failure experience episodes of worsening symptoms due to fluid overload (oedema). Current therapy options for these episodes include an increase in oral medication or, when oral treatment is not sufficiently effective, intravenous (IV) treatment, typically delivered in an emergency room or other clinical setting. Subcutaneous infusion by means of a mini pump adhered to the skin may offer a solution for patients who

otherwise do not require hospital care.

Fluid overload in heart failure is responsible for approximately US\$14 billion (£11.5 billion) in Medicare spending, or approximately 3.9% of the Medicare budget, making it one of the most expensive therapies for the elderly. The high spending is attributable to in-patient care for diuretic treatment which accounts for approximately 7% of Medicare hospital admissions. In addition, a hospital stay is associated with risks of adverse outcomes due to rapid muscle loss and functional decline experienced by many elderly patients during their hospital stay and recovery.

“A heart failure patient should not have to be in hospital to receive effective diuretic therapy for fluid overload,” said Bertram Pitt, MD, Professor of Medicine (*emeritus*) at the University of Michigan School of Medicine (Ann Arbor, MI, US). “A treatment option that provides IV strength diuresis without the need for venous access would enable the development of novel strategies, which could reduce hospitalisations with a resultant improvement in quality of life and a reduction in healthcare costs.”

Sensile Medical is proud to be involved at the centre of exactly such a treatment option.

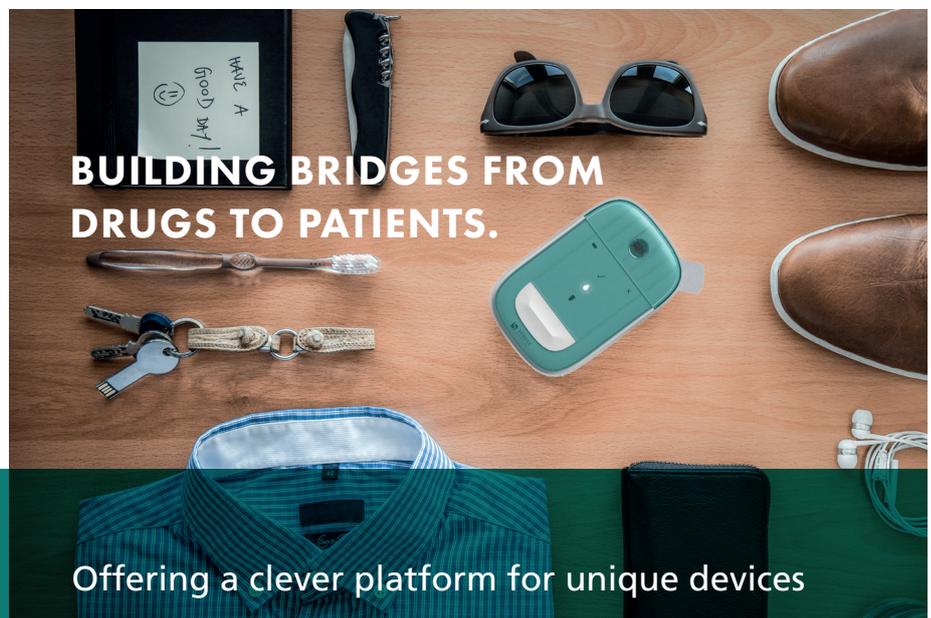
CONCLUSION

The interest in small- and large-volume patches, and off-body worn devices, is constantly growing in the industry. Modular and flexible platforms support individual requirements in various treatment areas. Sensile Medical is the right partner building bridges from drugs to patients.

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**We are Swiss pioneers
in Large Volume
Injector Devices**

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