



SENSILE MEDICAL

EFFICIENT RESULTS FROM A PARTNERSHIP THAT WORKS – THE DRIVE UNIT OF THE PATCH PUMP

Sensile Medical needed a better motor for a new micro-pump application, and they selected Buehler Motor (Nuremberg, Germany) as their partner. Here, Gerhard Mayer, PhD, Vice-President Business Development North America; and Sandra de Haan, Head of Business Development outside North America, both of Sensile Medical, describe how, together with their pharmaceutical partner scPharmaceuticals (Lexington, MA, US) and Buehler Motor, developed the drive mechanism for a new, soon-to-be launched patch pump.

Sensile Medical has developed a novel micro pump which is the heart of the patch pump for scPharmaceuticals. This patch pump offers a wide range of advantages and is superior in many aspects over narrowly-defined drug delivery systems. The patch pump consists of two main components: an activator, which is reusable up to 300 times, and a single-use cartridge. In April 2016 scPharmaceuticals initiated clinical trials with the patch pump.

BASIC DEVICE CONCEPT

For many applications, semi-disposable product concepts may be preferred. The overall objective for the development of the complete patch pump was to offer the most advanced features for safety and convenience, with the cost and utility of a disposable product.

The disposable part contains all components that come into contact with the drug or the patient: the core pumping mechanism, fluidic channels and patient interfacing elements like the needle and the adhesive. The reusable part of the patch pump includes electronics, sensors, drive unit, rechargeable battery and the simple user interface.

As a “patch pump”, this drug delivery system is affixed to the patient with an adhesive. An integrated needle is deployed prior to the injection and retracts automatically after the injection.

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ADVANTAGES OF THE PUMP SYSTEM

These pumps are increasingly being used to enable large-volume subcutaneous delivery of modern pharmaceutical and biotech products for self-administration by patients. Due to Sensile’s SenseCore technology the products are highly cost-efficient, accurate and safe.



Dr Gerhard Mayer
Vice-President Business Development
North America
T: +41 62 209 71 00
E: gerhard.mayer@
sensile-medical.com



Sandra de Haan
Head Business Development outside
North America
T: +41 62 209 71 00
E: sandra.dehaan@
sensile-medical.com

Sensile Medical AG
Fabrikstrasse 10
CH-4614 Hagendorf
Switzerland

www.sensile-medical.com



Figure 1: The device with its motor.

These easy-to-use, safe and discrete devices enable better therapies while improving the daily lives of patients. At the same time, by taking the therapy out of a clinical setting and allowing patients to self-administer their medication, healthcare costs are reduced significantly.

CHOOSING THE RIGHT DRIVE UNIT

The project with scPharmaceuticals involved choosing a drive unit where key criteria included:

1 Optimisation of sound and space

Special care was given to minimise the noise levels of the planetary gear train, providing discretion for patients during use. Due to the small available space inside the reusable part of the device, an additional focus was also given to the size of the gear motor.

2 Drive unit customisation

The integration of the clutch into the motor unit allowed for power consumption optimisation. Additionally, the permanent axial load towards the gear motor had to be addressed.

3 Fast prototype availability

Time was short. A working prototype was urgently required.

4 Initial production in small quantities but high quality

ISO 13485 requires that production processes for the patch pump are mapped out. Despite small initial production levels, rapid transition to efficient, high-volume production was targeted.

FINDING A PARTNER TO PROVIDE THE DRIVE MECHANISM

Sensile Medical chose Buehler Motor, a specialist in micro-drive mechanisms, to be the partner for scPharmaceuticals' pump.

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Disposable part



Reusable part

Figure 2: The device with the vial shown in situ (Investigational Device – Not Approved for Sale).

Buehler Motor started with humble beginnings as a clock-making company more than 160 years ago in Germany's Black Forest. Since then, it has transitioned into an international supplier of high-tech drive solutions for automotive, healthcare and industrial applications. Innovation, change, new developments and continuous improvements have all made an impact on what the company can now deliver.

Buehler Motor can provide system solutions from a single source. Quick and flexible implementation of complete



Figure 3: The patch pump is affixed to the patient with an adhesive.

customer-specific solutions – from prototype to series production – is only possible in combination with Buehler’s in-house system capability, in-house development competence, in-house production expertise and in-house quality commitment.

Development proficiency is the strong foundation upon which Buehler Motor is built. An extremely high process capability in developing motors and gearing, along with hardware and software, is one of Buehler’s exceptional strengths. This expansive knowledge allows Buehler to provide a complete solution independently.

THE INITIAL CHALLENGES

1 Meeting industry standards

Medical industry norms EN 60601-1 and EN ISO 13485 guide the development for the pump and motor. The final product had to meet stringent criteria for temperature, mechanical stress, as well as low noise levels. This included, not only the core motor, but also components such as the gear train, transmission and clutch.

2 Creating the custom drive unit

The drive mechanism has to perform three

functions: transfer the medication from a vial to the internal pump reservoir, insert the needle into the subcutaneous tissue and deliver the medication. This drove the use of a Snap-Fit connection and a custom-designed clutch between the motor’s core pumping components. The clutch and the output shaft of the gear were designed in a very smart way to decouple the planetary gear train from the permanent axial load, as well as reduce the short-term stress during drop off.

3 Constructing the prototypes

The prototypes required construction in a clean-room environment. The development of such a small, highly-precise drive mechanism required a unique solution for a lubricant-dosing system, while implementing the process within the confines of an existing production area.

4 Production

A small-scale production line, for clinical trial units, was set up at Buehler’s headquarters and development centre in Nuremberg, Germany. A dedicated clean-room was constructed that mimicked the processes of the planned, future large-scale

production in Mexico. The same team that developed and implemented the prototype production in Germany also led the efforts to build the production line in Mexico.

CONCLUSION

The partnership between Buehler Motor and Sensile Medical worked well. Employees from both companies established an efficient team to implement a good solution to meet scPharmaceuticals’ specific needs. Highly-efficient communication between all involved parties was key for the successful development in a very short time frame.

ABOUT SENSILE MEDICAL

Sensile Medical is a leading company in the area of advanced micro pump technology developing a broad range of customer-specific delivery and dosing solutions. Sensile Medical is a full-service provider of pump-based drug delivery solutions, with in-house specialists for engineering, electro mechanics, software development and more. Our partners include well-known pharmaceutical companies and research organisations.



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T: +41 62 209 71 00
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