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CUSTOMISED SOLUTIONS FOR LARGE VOLUME INJECTORS

In this article, Paul Senn, PhD, Vice-President of Business Development, Sensile Medical, discusses the products and philosophy of Sensile Medical, a developer of large volume injection devices utilising a patented micro pump technology.

When it comes to wearable injectors, customisation is key. Since every patient group and therapy has its own specific needs, the device must correspond to match. It has to be flexible and fulfil 100% of the specific requirements of the target patient group. Sensile Medical's products show that pump devices are very flexible by design and work in a safe, efficient and simple way (Figure 1). Characterised by modularity and flexibility, Sensile's new range of devices seeks to deliver patient

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safety and comfort through reliable drug delivery products.

A drug delivery device is mainly defined by the drug to be administered, the treatment regime and the patient. Opinions of patient groups and healthcare providers, the patient's physical condition, the place of administration and other similar factors are taken into account during early handling studies in order to address all stakeholder needs. No matter which patient group receives the device – paediatrics, adults or geriatrics; mobile or immobile patients – Sensile Medical's



Figure 1: Sensile's small volume, on-body patch pump.



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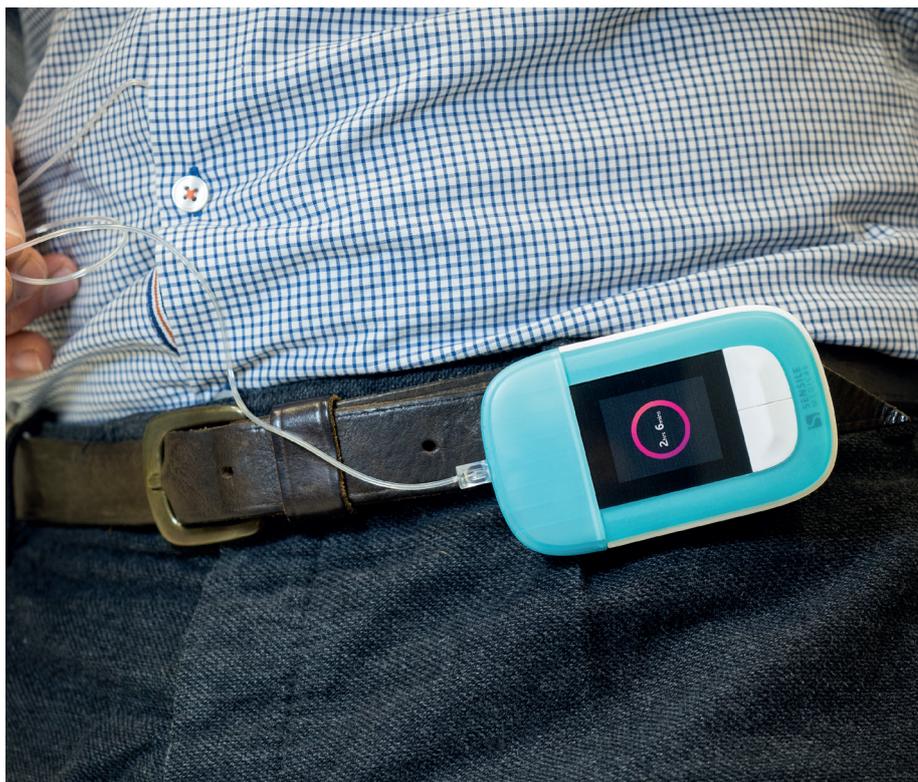


Figure 2: Sensile's belt-worn infusion pump.

“All Sensile devices consist of a reusable and a disposable part, which are connected prior to use .”

FLEXIBILITY FOR SPECIFIC NEEDS

In addition to wearable patch pumps, Sensile also offers a large volume injector that is worn off-body, for example attached to a belt (Figure 2). The device has a standard Luer Lock connection for use with most commercially available infusion sets. The patient interface can also be varied, for example it can be controlled by an easy user interface with a start/stop button and a limited number of LEDs that indicate the status of the device. Alternatively, the device may be controlled by a more sophisticated user interface, using control buttons and a screen to display the status of the device, as well as further functionalities. These additional functions can include independent infusion rates or various bolus options.

COST EFFICIENT AND ENVIRONMENTALLY FRIENDLY

All Sensile devices consist of a reusable and a disposable part, which are connected prior to use. The reusable unit contains a rechargeable battery, a motor, a gear drive and the electronics with the control software. Depending on the treatment regime, the reusable unit can be recharged and re-used hundreds of times. The sterile disposable part, containing the entire fluidic path with the drug reservoir, the pump and the needle, is only used once and can be safely disposed of after the delivery of the drug. The disposable unit is locked after use in order to prevent multiple uses. This design reduces waste and protects the environment.

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devices are tailored and customised for the individual patient group. Sensile also addresses the increasing demand for technologies for eHealth applications and is working on connectivity solutions and sensor technologies as an additional option for device flexibility.

SAFETY FIRST

Sensile's on-body wearable devices have a mechanism that enables automated needle insertion before, and retraction after, administration of the drug. This feature greatly reduces the risk of needlestick injuries and contamination before or after administration. Sensile also offers a number of other technologies and sensors to actively monitor the status of the device and the administration of the drug. The core design at the heart of all Sensile devices – a micro piston pump – is used to monitor if an occlusion is present in the system which might inhibit the delivery of the drug to the patient. If an occlusion is detected, the patient is alerted and can take appropriate measures and actions depending on the indication and treatment regime.



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ACCURATE DOSE DELIVERY

SenseCore, Sensile's proprietary two-part micro rotary-piston pump is flexible in delivery volume and in flow rates, ranging from below 1 µL up to 6 mL per minute. It can pump up to 50 mL from an external primary container into an internal reservoir. The micro piston pump is able to pump and dose water-like liquids or viscous solutions accurately, in increments down to 1 µL. Thanks to Sensile's flexible solutions, it is not necessary for customers to modify the primary packaging, regardless of whether the drug solution is in a 1.5 mL or 3 mL cartridge, a syringe with 5–10 mL or a standard vial with up to 50 mL of content. Since the drug is transferred from the existing primary container to the device prior to injection, the drug does not have to be reformulated in a new specific container, reducing the risk and cost of development. Also, there is no need to invest in new dedicated filling lines.

DIVERSITY AND CONVENIENCE

Based on the same micro rotary-piston pump technology, Sensile also offers a drug reconstitution device that enables fully automated reconstitution of lyophilised drugs with an aqueous solution, as well as transfer to a container for subsequent injection.

Another form of administration is the pen bolus injector, which can inject multiple drug products simultaneously or sequentially, with independently programmable delivery rates and injection times. This may replace the use of multiple conventional syringes and therefore reduce the number of injections necessary for patients with complex, multi-drug regimes.

All Sensile's devices – both small and large volume – are indication independent and tailored to the specific needs of the target therapy. Sensile's products can be used for a wide variety of treatments, including those where drug infusion must be done by a healthcare provider or for an application where the patient can self-inject the drug at home.

ABOUT THE COMPANY

Sensile Medical Ltd is a globally-active Swiss-based medical technology company in the field of large volume injectors. In close corporation with pharma and biotech companies, Sensile develops devices for liquid drug delivery. The core of its system is the patented SenseCore technology, a micro pump that is cost-efficient to produce and provides very accurate dosage. Sensile's designs are characterised by modularity and flexibility to meet patient needs in the best way possible. Sensile Medical employs about 120 employees at its the headquarter in Olten, Switzerland.

ABOUT THE AUTHOR

Paul Senn has been VP Business Development of Sensile Medical AG since January 2017. Prior to Sensile, Dr Senn held several management positions with increasing responsibilities in pharmaceutical and medical device companies in business development, marketing and development of drug products and design of medical devices. He holds a Master's degree in Chemistry and a PhD in Physical Chemistry from the University of Basel (Basel, Switzerland) and received a management education at the International Institute for Management Development (Lausanne, Switzerland).

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