



A LARGE-VOLUME SC DELIVERY SYSTEM MUST ADJUST TO DRUG & PATIENT NEEDS ... NOT VICE VERSA

Here, Gerhard Mayer, PhD, Vice-President Business Development North America; Sandra de Haan, Head of Business Development outside North America; and Helmut Thiemer, Head of Technology; all of Sensile Medical, describe the SenseCore micro pump and, in particular, relate aspects of its mechanism to specific advantages when applied in the area of large volume injection devices.

As your new drug moves from the early stages of dose finding and clinical trials through commercialisation, there will be a number of unknowns that the drug developer and their “customers” in marketing may have to deal with:

- What will the drug formulation be in the end? Viscosity? Flow rates?
- What will be the need for dosage accuracy?
- Is the primary packaging clearly defined? Vial or cartridge? Would cartridge development potentially endanger the targeted launch date?
- How and where will drug delivery take place? Are there special requirements dictated by therapy or patient needs?
- When and to what extent will the needs be in clinicals?

Sensile Medical has developed a wearable large volume injector (also known as a patch pump) that can be adjusted to meet the needs of your drug and potential patients – while enabling meaningful product differentiation for the marketing team.

For the drug development and drug delivery specialists at pharmaceutical companies, this article provides broad detail on the options and capabilities provided by Sensile Medical's large volume injector technology.

THE HEART OF SENSILE'S LARGE VOLUME INJECTORS

Sensile has developed a novel micro pump concept called SenseCore, which lies at the heart of its large volume injectors.

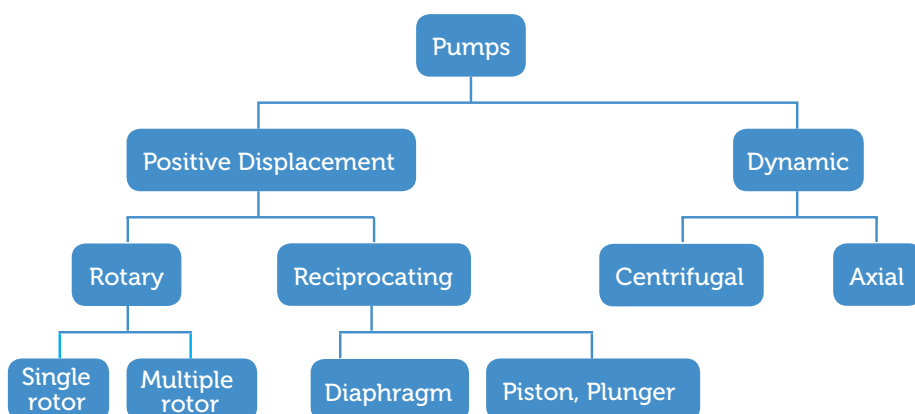


Figure 1: Classification chart for types of pumps. SenseCore is a reciprocating-type positive displacement pump.



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Medical devices based on this concept offer a wide range of advantages and are superior in many aspects over narrowly defined drug delivery systems or even syringe pumps, which may be used in clinical trials.

This article lists some key features and advantages.

CLASSIFICATION / PRINCIPLE

Within the classification scheme of pumps (Figure 1), SenseCore is a reciprocating-type positive displacement pump. Specifically, it is a piston pump (as well known in pharmaceutical filling technology) with a ring shaped piston area.

The rotating piston, together with an injection moulded valve structure, mechanically drives intake and outlet valves and additionally generates the correct pumping stroke derived from the primary rotation.

The design is flexible and can operate bidirectionally by defining the pump direction just by selecting the appropriate sense of rotation of its pump drive.

As is typical of piston pumps, each pumping cycle:

- generates a good suction pressure
- intakes a well-defined volume of drug
- accurately delivers a nominal pump volume at a defined delivery pressure and time.

SCALABILITY

The nominal delivery volume can easily be designed to the required optimum delivery volume per stroke, typically ranging (but not limited to) from less than 1 μL to 25 μL per cycle. Taking advantage of the active piston area being a ring, the delivery volume is defined by the ratio of the two diameters of the stepped piston (Figure 2). Even at very small delivery increments, the parts allow for tight tolerances as well as a very robust product.

MATERIALS

The two pump elements – the pump housing and the shaft (piston) – can be chosen from a variety of materials. For the housing, all suitable outer-shell materials can be chosen as long as they allow adherence of the inner soft component, which is injection-moulded into the shell using a two-shot moulding concept.

For the inner soft component (forming the valve structure) typically thermoplastic elastomers (TPE) are used, allowing for low

cost, while also liquid silicone rubber (LSR) is available and can be used.

For the piston the material of choice is injection moulded plastics just by the obvious cost advantages in large scale production.

Alternatively, shafts from stainless steel or ceramic can be used depending on needs.

DRUGS AND DRUG FORMULATIONS

As a piston pump, SenseCore handles liquids as well as gases and liquid gas mixtures. While liquids are delivered exact to the designed volume, just defined by the pump's displacement, with gases, on account of their compressibility, the delivered volumes are only defined if the pressure conditions are taken into consideration.

Still SenseCore does pump gases. With its compression ratio of typically 1:1, it is absolutely self-priming and generates a suction pressured of 0.5 bar at standard atmospheric conditions (MSL).

Sensile works on projects where a SenseCore pump is intentionally delivering gas. By its chosen design and working principle it further does not accumulate air



Figure 2: The delivery volume is defined by the ratio of the diameters of the stepped piston.

DOSAGE ACCURACY

As a positive displacement pump with its incremental delivery, SenseCore offers large improvements when judged via the trumpet curve, which represents the maximum percentage deviation from the expected dose for a given time interval.

Unlike syringe pumps (even being equipped with a high-precision, linear drive) where the elasticity and varying break-loose forces of the plunger first under deliver and then, after some time, overshoot, SenseCore delivers one nominal pump volume per each and every stroke to the patient.

By its design and specific concept, the accuracy achieved with SenseCore, consisting of only two precision plastic parts, holds at $\pm 5\%$ over large scale production.

All parameters influencing the delivery accuracy are injection moulded in one shot into a single part, the piston. As shrinkage influences both of the relevant piston diameters in common mode, the difference remains nearly unchanged,

"A standard vial can be combined with an internal device reservoir, potentially eliminating the need for costly and time-consuming development of a prefilled cartridge"

bubbles but instead passes such microbubbles through.

On the drug viscosity the limiting factor is not the pump itself, but more generically the throttling effects occurring on the suction / intake side, and the counter pressure generated by the downstream side of the fluidics path. Typically this is determined mainly by the gauge of the injection needle. Sensile carefully considers the relevant conditions when defining an application-specific device, by aligning needed flow rate, planned needle size and given drug viscosity to stay safely within the specified performance data for suction and delivery pressure.

generating only a negligible effect on the resulting ring type piston, assuring low delivery-volume changes.

OPTION TO USE STANDARD VIAL AS PRIMARY PACKAGING

As a piston pump, it provides for very good suction capabilities. This combined with the bidirectional capability allows new device concepts that use a standard vial as primary packaging (see Figure 3, overleaf).

A standard vial can be combined with an internal device reservoir, potentially eliminating the need for costly and time-consuming development of a prefilled cartridge.

"Occlusion on the downstream side is monitored using contactless sensors"

MEETING SPECIAL DRUG AND PATIENT NEEDS

Delivery patterns can be programmed to meet potential daily basal profiles, specific drug delivery rates, a high flow constancy performance, or fast bolus delivery. These are easily achieved by running the drive at a different speed and/or combining this with an On-Off pattern. Furthermore, SenseCore technology allows for methods that Sensile has developed to stretch out delivery increment for the sake of flow consistency or to realise extremely low flow rates, for example in neonatal applications.

SAFETY

With the SenseCore, functional principle is inherently safe. This is due to mechanically and actively driven valves, a mechanically defined angular relation between valve elements, and (again mechanically) a fixed relation between valve elements and intake as well as expel stroke.

The valves are defined by mechanical design that ensures at any given time only one valve can be open. In an angular position where the pump is parked (inactive), both valves are closed at the same time. This feature allows for double safety against free flow.

SenseCore technology monitors the pump's angular position, sense of rotation and rotational and axial speed. In addition, occlusion on the downstream side is monitored using contactless sensors. These sensors are part of the reusable subsystem of the device and monitor the relevant elements in the disposable portion.

Figure 3: SenseTrial, a patch pump designed to be used in clinical studies for subcutaneous drug delivery, uses a vial as its primary packaging. This is possible because of SenseCore's good suction and bidirectional capability.



For additional monitoring requirements, magnetic or optical sensors can also be selected.

BASIC DEVICE CONCEPTS

For many applications, semi-disposable product concepts may be preferred. The disposable portion contains all parts in contact with the drug or the patient: the pump, fluidic channels, and patient interfacing elements like the needle and the adhesive. Drug delivery systems of the patch pump variety are often affixed to the patient with an adhesive and with an integrated needle that deploys and retracts automatically.

The reusable portion of the device includes electronics, sensors, drive, rechargeable battery and the simple user interface.

ABOUT SENSILE MEDICAL

Sensile Medical AG is a leader in the area of advanced micro pump technology, developing a broad range of customer-specific delivery and dosing solutions. Its pumps are increasingly being used to enable, for instance, 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. They are increasingly used in drug delivery, medical and consumer applications. Founded in 2004, Sensile Medical is located in Hagendorf, Switzerland. For further information consult www.sensile-medical.com.



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