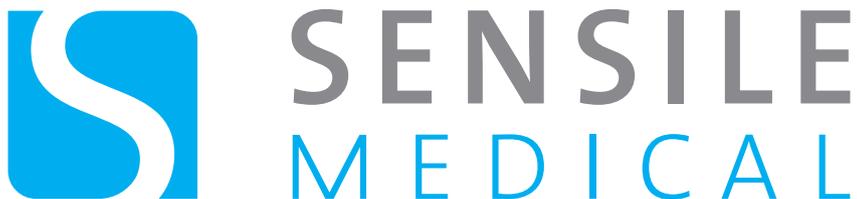


GETTING TO KNOW...



In 2004 Sensile Medical started developing its micro pump, and patented the SenseCore technology (Figure 1) that powers it. Compatible with many different types of medicines, SenseCore is small, precise, flexible and, since it is composed of just two plastic parts, affordable. SenseCore provides the core functionality for other pump platforms like SenseFlex (belt-worn pump) and SensePatch (body-worn patch pump).

SensePatch (Figure 2), complete with its own adhesive, has an integrated auto needle inserter, which makes its subcutaneous needle not only simple to use but also discrete – a big help for those patients who are afraid of needles. SensePatch is suitable for volumes up to 20 mL. The SenseLyo (Figure 3) is an automated reconstitution device, compatible with a variety of reservoirs.

In 2007, the company moved to Haegendorf in Switzerland's Solothurn canton. Lying in the centre of German-speaking Switzerland, Haegendorf is not only accessible for more clients, but also for new employees. In 2015, the SenseCore technology won the Swiss Technology Award – the most important award of its kind in Switzerland.

The company has recently moved again, to a new facility (pictured on Page 11) offering more space for larger laboratories and more employees, since much more will be done in-house. In Autumn 2016, Sensile had 65 employees. One year later, it has more than 100, and by the end of 2017, the company is expected to employ 120 people. Multiple projects are under development. Sensile is confident that with the further development of biotech the demand for devices like the ones Sensile produces will rise.

That's as good a reason as any to look back at the last ten years of Sensile Medical. Chief Executive Officer Derek Brandt and three of his colleagues – Christoph Lüdi, Head of Systems Engineering, Alex Perrier, Senior Technology Manager, and Marco Drüssel, Mechanical Engineering Manager – have all been a part of the company for the past ten years, so are in a good position to reflect on the company's past and discuss the future.

Q Which position did you start in at Sensile?

DB: I came to Sensile in 2007 and started as Chief Executive Officer.

CL: In the summer of 2007, I came to Sensile Medical as Head of Software with the goal of building up the software department for our pumps. At that point, there was no development for the device available. Even though I had

experience, the beginning, and especially the build-up phase, went very slowly.

AP: I started as Project Leader at Sensile Medical. I was especially interested in development work.

MD: Right after I got my degree, I began to work at Sensile as a testing engineer.

Q Has your job changed over the past ten years?

DB: Back then, three to four people worked in our offices at Baar, Switzerland. Pretty soon we moved, and our employee count rose quickly. At that point, everyone was involved in everything, from the creation of quality processes to picking out furniture. In the meantime, I needed to learn how to delegate some of my responsibilities to new coworkers – it was a mutual learning experience.

CL: For the past three years, I've been the Head Systems Engineer. Systems engineering is fundamentally different from software engineering, but we use similar approaches to solving problems. Our job is to develop the architecture for the device, keeping in mind all the components that comprise the whole. Without considering the whole, each part functions less efficiently – especially the software. As a systems engineer you become a sort of middleman, in the sense that you're in constant contact with other departments. The entire project needs to work together if it wants to implement its solutions efficiently.

AP: I quickly and unofficially began leading mechanical engineering. It was important to me that we work in a structured manner. So I

"Finding a device for a therapy and then bringing them together is almost like marriage, in the sense that you are constantly dependent on the other."



Sensile Medical's new facility in Olten, Switzerland offers more space for larger laboratories and more employees, enabling much more work to be done in-house.

made checklists, established a clear drawing number definition, and set up tolerance analyses. I focused about 60% of my attention on being Project Leader and then devoted the rest to the fundamental development of our organisational structure. For a while, I separated myself from the materials (plastics). Since mid-2014, I've worked solely as Project Leader, but I'm still heavily involved in the mechanical side of development, especially with our pump. For this reason, I joined the Technology group in September 2016.

MD: After a few years in the workshop and after university, I transferred into mechanical development. As of the beginning of this year, I'm still a partial Project Leader. Structurally, we needed to adapt to the number of new employees coming each month—the company is growing rapidly. My job has changed in the sense that I'm not doing hands-on development anymore, but instead I'm focusing on documentation, requests and analyses.

Q Which milestones has Sensile reached in the last ten years?

DB: Ten years ago, we were still a start-up. I wouldn't call us that today, because we survived the critical portion of a start-up's life – 80% of start-ups go

out of business in the first ten years. We managed to beat the trend, thanks to Sensile's fantastic employees and thanks to our investors, who stood by us through every setback.

Q How have the demands of customers and the industry changed?

DB: The regulatory aspect of doing business in the medical devices industry has become fundamentally stricter. Of course, in this industry, this is normal. What is also changing is the quality expectations from our pharma clients. Quality audits are today more comprehensive than ever before. Finding a device for a therapy and then bringing them together is almost like marriage, in the sense that you are constantly dependent on the other. Given the demands of the industry, companies on both ends want to make sure that the marriage is solid before anything is signed.

CL: New technologies like the iPhone also bring with them new expectations. For example, connectivity is a huge challenge for a small business like Sensile: naturally, a client would prefer it if our device connected with a smartphone. Building in functionality like that means a lot of time spent in the development phase, reworking parts of the device.



Figure 1: The SenseCore pump technology.

"I generally believe that the demand for pumps that patients can use easily by themselves will rise quickly. The therapies that make this possible are also growing quickly. The old kinds of pumps, that aren't reusable or disposable, have become far less lucrative for manufacturers to produce."

AP: For me, in principle nothing has changed. The environment built itself up. There is one difference: today, there is an insulin patch pump on the market that stands as a benchmark. Ten years ago, that was not the case.

MD: The biggest change occurred in the organisation overall, when we began to focus more on developing a product rather than developing a technology. There are always new technologies we could implement in our project. The question then becomes to which degree and for which reason do we implement them.

Q Has digitalisation made things simpler?

CL: In my area digitalisation has a lot to do with the theme of "requirement management", which really started coming up around 10 to 15 years ago,



Figure 2: The SensePatch body worn pump is suitable for volumes up to 20 mL.

and today is "state of the art". In 2012, we introduced a tool to answer this. Without this programme, our work wouldn't be efficient; each component and interface needs to develop and follow its own requirements. It also means, though, more time spent, since traversing this extensive database isn't trivial. Maintenance is needed and people need to be trained to use it – it demands a different way of working.

AP: These changes are visible in many different areas. You always have access to the workplace, even from home. It makes work both faster and easier. I see the cost more in insecurity than in documentation, in the sense that, to do everything correctly, you have to fundamentally alter existing processes. Also, our paper filing system couldn't keep pace with our digital one. Today, you can send a manufacturer an electronic CAD model, which might be correct only in the sense that it could be manufactured, and you can get a finished part back – that's a big advantage.

MD: In the medical technologies sector, we have always had to deal with lots of documentation. There are new tools that do so much and open up so many opportunities. For example, now it's not just physical models, but also simulations. Today, work goes faster. On the other hand, doing everything on the computer generates massive amounts of data, and that brings with it its own questions – for example, how to handle the data and make it easily accessible.

Q How has your field changed in the past few years?

CL: At Sensile Medical, systems engineering is a new development. This work demanded a change in the previous development process. Originally, our approach stemmed from one used in the aerospace sector, but it works well



Figure 3: The SenseLyo automated reconstitution device is compatible with a variety of reservoirs.

for our devices, too – fundamentally because both approaches try to create synergy in a system with an incredibly diverse set of interdependencies. It also helps strengthen workplace synergy – each coworker helps in the development of our device architecture. It's a joint effort, but with this system, everyone knows exactly what he or she is responsible for.

AP: In my opinion, leading a project focuses more on co-ordinating jobs. The project leader lets teams work independently for the most part, since teams should have the ability and experience to do so. As far as my experience goes, this isn't always the case – often, the project leaders are more experienced than their coworkers. I think this is because five years ago employers demanded more expertise from their project leaders.

"One clear trend is the move towards digital health or smart devices that can transmit information to the patient and/or the patient's doctor so that the correct medicine can be given."

MD: Fundamental research was the first thing we did. The technology itself stood in the foreground, and we really only produced sample pieces of our technology until we got our first project. Then, all of a sudden, with the first project the focus changed from technology to adaptation of the technology in terms of how it applies to a device. Now as Sensile receives even more projects, this transformation – from a company that produces a technology to a company that produces a product – affects Sensile at all levels.

Q In which direction do you see your industry moving in the future?

DB: One clear trend is the move towards digital health or smart devices that can transmit information to the patient and/or the patient's doctor so that the correct medicine can be given. The theme of connectivity will develop further, and we need to make certain that we keep up with it.

AP: I generally believe that the demand for pumps that patients can use easily by themselves will rise quickly. The therapies that make this possible are also growing quickly. The old kinds of pumps, that aren't reusable or disposable, have become far less lucrative for manufacturers to produce. I'm convinced that we have a great concept for our pump – both our reusable and disposable unit.

MD: The medical technologies sector doesn't change quickly, since in a highly regulated industry everything takes so much time. There is a trend, though, that devices need to meet a certain set of requirements: that they get smaller and that they look more stylish, so that they stop being recognised as a medical device and start being seen more as a gadget or lifestyle product. Of course, the influences on the industry are myriad. What would happen if someone invented an insulin pill? Would we still need a pump? And what if ObamaCare is repealed?

Q What has kept you at Sensile for ten years?

DB: My motivation comes in principle from improving the lives of patients. To create the right product for a therapy and then to bring that product to the patients – all of that motivates me. The road from start to finish is such an interesting one. My coworkers at Sensile are also great; each one is really an integral part of the entire process.

CL: I saw the chance to build something here, and I accepted that that would be a longer-term project. Looking back, the development has been very positive, especially considering that we started at nothing and have already achieved so much. The best part – nothing has been boring at Sensile. And the experience I've had here is not something I could have got anywhere else.

MD: I like my job. There are always new challenges and new opportunities. Sometimes, you have to develop something new and then, looking back, you realise you should have done it that way all along. Processes always need to be adapted, which can be a little tiresome. Still, I find it positive, the sort of insight I've got here and the lessons I've learned. Not just in my sector, either – I've also had the chance to apply that to other branches of the company when I support their efforts.

AP: There are few undertakings that combine so many disciplines and technologies in one product. We have the opportunity to be a pioneer in our field and to build a product from the ground up. We are a very agile company; whatever the customers need, we can adapt to meet their demands. In my case, I appreciate the scope of our business a lot. I'm very involved in development but am also in constant contact with manufacturers, suppliers and clients. It's a rich environment with inexhaustible possibility, and in a field like that, there is never a dull day.



Derek Brandt
Chief Executive Officer
T: +41 62 209 71 00
E: derek.brandt@sensile-medical.com



Christoph Lüdi
Head of Systems Engineering



Alex Perrier
Senior Technology Manager



Marco Drüssel
Mechanical Engineering Manager

Sensile Medical Ltd
Solothurnerstrasse 235
4600 Olten
Switzerland

www.sensile-medical.com



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