**BEST PRACTICE BEST PRACTICE** 

# ANEW KIND OF FREEDOM

With their unique mealtime insulin patch Simplicity™, the Swiss company CeQur could be changing the lives of millions of type 2 diabetes patients. The device is amazingly simple to use but highly complex in design. Just like the giant production line that Harro Höfliger developed for this product.

casual meal with friends, an after-work drink served with appetizers, a quick stop at a snack bar: Most people take it for granted. For type 2 diabetes patients who in addition to long-acting sustained-release insulin also require mealtime insulin, it is often a challenge. Especially for these patients the new mealtime insulin patch CeQur Simplicity™ is expected to make life easier in the future. It is thin and invisible under clothes. It is lightweight and you hardly feel that it is there. Once attached to your body, it stays securely and discreetly in place, covering your mealtime insulin needs for around three days. While eating, a short click is all it takes and two doses of rapid-acting insulin enter the body via a soft and flexible cannula. The 2-button dosing mechanism prevents accidental dispensing of the drug. An audible and perceptible "click" gives wearers the assurance

a few minutes.'

that the dose was administered correctly. "This device is unique. There is nothing comparable on the market," enthuses Douglas Gunthardt, Executive Vice President at CeQur. "And it is so easy to use that patients can handle it within

### SUDDEN HALT ON THE HOME STRETCH

The idea for this trend setting solution has been existing for a long time. Originally developed by a startup, a global healthcare player acquired that company in 2012 and invested in the device's Design for Manufacturing. It also conducted one of the most extensive clinical trials at that time for a diabetes med-tech product, with 278 patients. After FDA approval, the company commissioned Harro Höfliger to build a semi-automatic pilot production line. In Puerto Rico the group initially installed the pilot line capable of producing devices for up to 10,000 patients. A high-volume line to supply treatment for 80,000 patients was already under design and construction at Harro Höfliger and another machine manufacturer when in 2018 the customer decided to divest themselves from their entire diabetes medtech business. The project came to a standstill and, for the time being, the gigantic, almost completed machine slumbered, a true Sleeping Beauty.

"In the US alone, there are about 27 million people diagnosed with diabetes."

Douglas Gunthardt Executive Vice President, CeQui

> An innovative lighting concept provides an overview of the huge system; machine components illuminated in green are working properly, red indicates a need for action, and unlit



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# **BEST PRACTICE** But psychological reasons also speak in favor of CeQur

# **NEW HOPE FOR MILLIONS**

CeQur, a start-up founded in 2008 with headquarters in Horw, Switzerland, recognized the opportunity that the patch offered. In mid-2018 the company secured the worldwide license for this product. "A look at the figures in the US shows the potential of this solution," explains Douglas Gunthardt: "In the US alone, there are about 27 million people diagnosed with diabetes and the number is rising. Approximately 24.5 million people suffer from type 2 diabetes and about two million need to provide mealtime insulin to their bodies in addition to long-acting insulin." When Bradley Paddock joined CeQur mid-2019 as CEO, he quickly focused all the company's efforts on bringing this product to market.

Simplicity™, as the patch is called. "Unlike type 1 patients whose bodies cannot produce insulin due to a genetic predisposition or a disease, the cause in type 2 patients can be a poor diet, being overweight and lack of exercise in addition to hereditary predisposition," explains Gunthardt and continues: "These patients often find it difficult to deal openly with their disease. Wearing a pump or handling syringes and pens when having meals is therefore often met with skepticism and rejection by those affected." As a result, more than half of the patients admit that they regularly skip insulin doses for a variety of reasons, which can lead to serious health complications. "This gap is filled by Simplicity™. It is so discreet that patients quickly learn to embrace it," says Gunthardt. The pilot launch of CeQur Simplicity™ in three US states already showed that 95 percent of users were very satisfied with the patch and 93 percent prefer it to pens and syringes.

The flat patch disappears discreetly under clothing and stays in place for up to three days.

## A PRODUCTION SYSTEM OF SUPERLATIVES

In 2021, CeQur gave Harro Höfliger the go-ahead for the completion of the stored, fully automatic highvolume line. It comprises a grouping of 30 machines, 28 are from Harro Höfliger. A blister forming and punching machine and a leak test machine come from two partner companies.

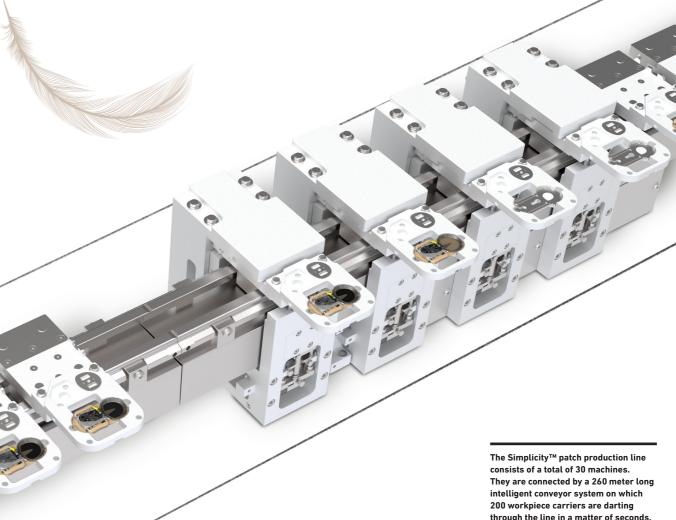
"In addition to its size, a special feature of the line is the intelligent conveyor belt system," explains Gunthardt. "It advances the workpiece carriers through the line at two meters per second and enables the production of up to 40 devices per minute."

The 30 machines are connected by a conveyor line measuring more than 260 m, on which 200 workpiece carriers are individually actuated and processed. "This requires precision in every detail," says Gunthardt and adds: "Every device consists of 39 individual components. Feeding the individual components, providing the logistic processes and ensuring positioning accuracy of the workpiece carriers were just some of the challenges that Harro Höfliger's experts have overcome brilliantly."

Some of the processes were deliberately implemented redundantly so that the line can continue production in case of a partial failure or during maintenance activities. In addition, space capacities have been provided so that the system can be expanded to 80 devices per minute.

### A CHALLENGING RELOCATION

Handling of the giga line is a demanding task too: The first validation and startup operations took place at the Harro Höfliger production site in Satteldorf. In the next step, the complete line will be disassembled and shipped to the USA. At the CeQur production site in Columbia, South Carolina, the grouping of machines will be assembled again and, after another validation, put into operation presumably at the beginning of 2023. "All this would not be feasible without a partner like Harro Höfliger," says Douglas Gunthardt and affirms: "Not only does Harro Höfliger bring along machine and process expertise, their project and quality management is also world-class."



through the line in a matter of seconds.