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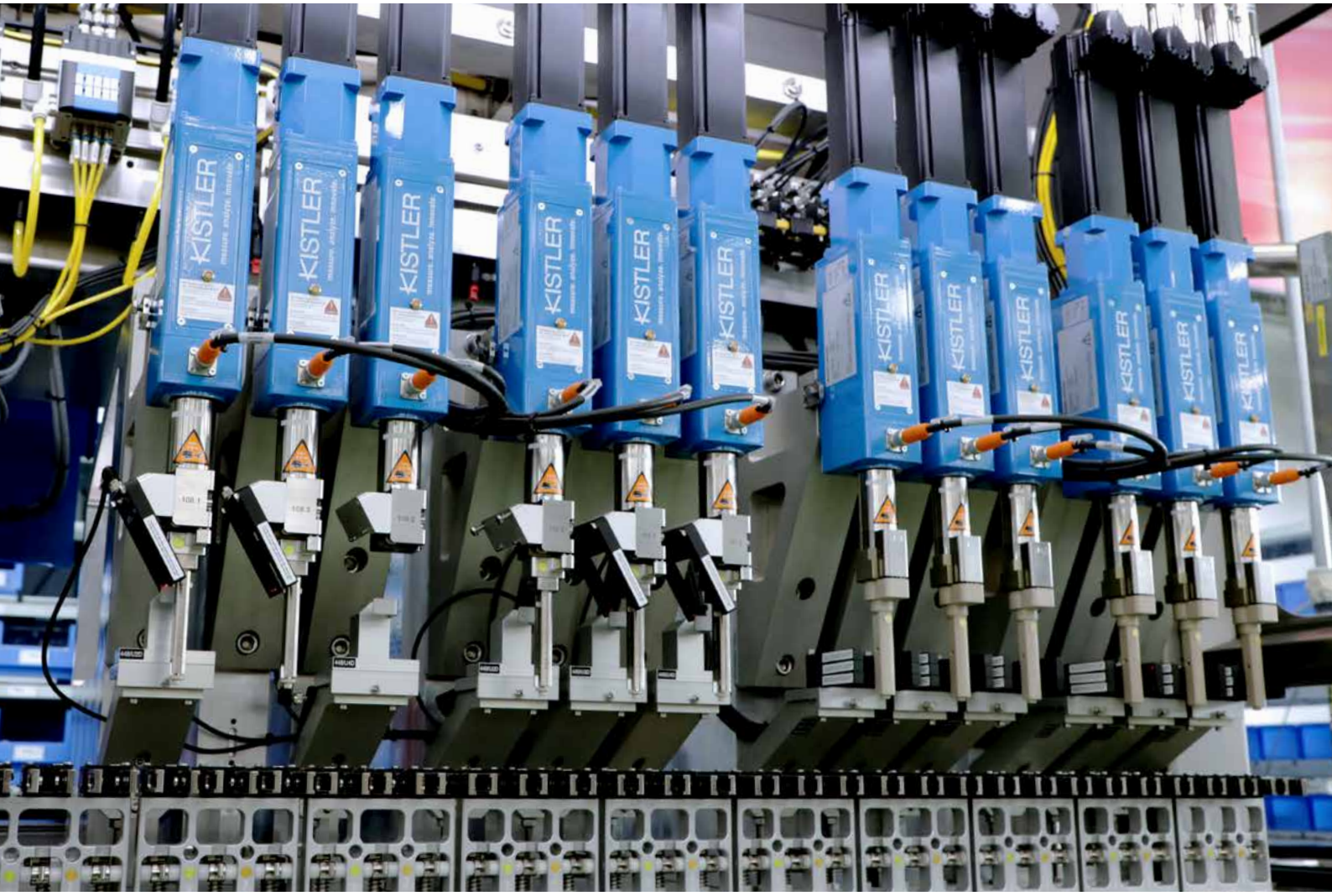

In complete control

Kistler supports Mikron Automation with joining systems for medical device manufacturing

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As a specialist in engineering complex assembly cells for the medtech and pharma sectors, Mikron Automation relies on electromechanical joining systems from Kistler.

Mikron Switzerland AG has designed a complex assembly line for autoinjectors that involves two different assembly cells – and no less than 18 NCFT electromechanical joining modules from Kistler. Together with integrated maXYmos process monitoring systems, the modules support automated assembly, including force-displacement control as well as real-time data transmission and process transparency.

Located in Boudry, a small town on the shore of Lake Neuchâtel in Switzerland's French-speaking region, Mikron Switzerland AG, Boudry is the headquarters of the Mikron Automation division. Now renowned worldwide as a specialist in the design of assembly solutions integrating complex manufacturing processes, Mikron can look back on a lengthy tradition in the micromechanics industry. With over 700 employees at sites in Denver (USA), Kaunas (Lithuania), Singapore and Shanghai, Mikron has already supplied more than 3,800 assembly solutions to its customers. Every day, Mikron assembly solutions are used to manufacture around 150 million products – ranging from pen and auto-injectors, inhalers, safety syringes and point of care testing to airbag parts, relays and connectors: the list could go on.

Jean François Bauer is Head of Marketing & Business Development at Mikron Automation. As he explains, recent years have seen the automation sector developing at a very dynamic pace: "Our assembly solutions focus on small products – you can hold them in your hand, and very often involve complex processes and also more and more data management." As an industry expert, Mikron supplies high-performance, scalable and customized assembly solutions to the pharma/medtech, automotive, electrical/industrial and consumer goods sectors.

"Pharma and medtech have gained enormous momentum in the last ten to fifteen years. That's where we generate the lion's share of our sales. As well as high-volume solutions with throughput rates of several hundred parts per minute, we also supply scalable systems for very low or medium production output. This is because clinical studies and assembly tests have to be carried out in various stages before a medical device is launched on the market and mass production can really get going." To ensure maximum flexibility and efficiency, Mikron Automation opts for a modular platform approach, following the example of the automotive industry: standardized base machines are designed and specified to suit each customer's requirements and every application.

High-precision assembly, including process documentation

In a project currently in progress for a major pharmaceutical company, Mikron is using electromechanical joining systems from Kistler integrated into two manufacturing cells. Jörg Besold has been a project manager at Mikron Switzerland AG, Boudry for almost five years. Together with a core team of about ten people, he is responsible for all the steps in the design and development process – from project kick-off through to final acceptance at the customer's site. This is how he describes the requirements: "To assemble an autoinjector, several plastic parts and a syringe have to be assembled together in a process that must be accurate and controlled. We're using twelve servo presses from Kistler for one cell, and six more for the other cell. That allows us to triple the steps needed so we can achieve the desired volume of over 100 parts per minute."

> "It's not by chance that Kistler has a reputation for high precision: these joining systems provide excellent process control for our complex assembly operations, and that's why we'll certainly continue using them in the future. And it was also thanks to the systems from Kistler that we achieved very high levels of quality assurance and traceability in this project."
>
> Jörg Besold, Project Manager at Mikron Switzerland AG, Boudry

The NCFT joining module from Kistler (see box) is an electromechanical servo press that was specifically designed for small forces in a wide measuring range from 0.05 to 1.5 kN. It can be combined with the maXYmos NC process monitoring system to achieve complete control of all movements and forces, including detailed process documentation based on piezoelectric force measurement.

"We already had some previous experience of using force-displacement sensor technology from Kistler combined with the maXYmos system," Besold recalls. "But in view of the demanding requirements for this project, we opted for the high-end solution. It provides control of forces and positions at every point in time, as well as comprehensive process data for every product. Because the modules are integrated directly into the automation environment via OPC UA, we're able to manufacture two product variants simultaneously. The machine control sends the different parameter sets to the maXYmos NC units that control the joining modules." All the production data and quality parameters are stored in a database, and a matrix code engraved into every product guarantees 100 percent traceability for the end customer. Mikron has also integrated quality testing for each individual step into both assembly cells – an additional feature that ensures a very high standard of quality, for the benefit of the patients who will use the device.

Customized design meets challenging requirements

"We're highly satisfied not only with the solutions from Kistler, but also with the valuable support they give us. With project lead times of nine to twelve months or more, we need a reliable, professional partner who can support us throughout the various phases," Besold points out. As this was the first time that Mikron had used the NC joining systems, a joint workshop was staged at Kistler's headquarters in Winterthur. Besold continues: "Even though the maXYmos systems are simple to integrate, it was especially useful for our software engineers to learn how the entire joining process is synchronized with the machine and optimized."

Project Manager Jörg Besold, the engineer responsible for this project at Mikron Switzerland AG, Boudry, is favorably impressed by the electromechanical joining systems from Kistler.

Resource-efficient joining for small-force assembly processes

The NCFT joining module from Kistler (Type 2157B) for low compression forces up to 1.5 kN is available in two versions: straight (with a stroke of 100 mm) and a compact angular variant (stroke: 250 mm).

The NCFT is one of six electromechanical joining modules from Kistler used to automate assembly processes and integrate force displacement monitoring. Its key features:

- High-precision piezoelectric force measurement (via telemetry)
- Certified for ISO 14644-1 class 8 cleanroom use (class 7 possible)
- Very wide measuring range from 0.05 to 1.5 kN
- Very short cycle times thanks to high velocity
- Sensor has high overload capacity

The NCFT joining module from Kistler (Type 2157B) is available in two versions: straight (with a stroke of 100 mm) and a compact angular variant (stroke: 250 mm). Both versions can be combined with the maXYmos NC process monitoring system to provide a state-of-the art joining system.

Given that the solution is intended for use in medical environments, additional adaptations were implemented to meet the relevant requirements. André Signer, Sales Engineer at Kistler, explains: "First, we integrated a functionality to track and back up all user changes to the system – this is what's known as an audit trail, and it's absolutely essential for medtech applications. Then we prepared our NCFT system for production in class 7 cleanrooms. And finally, we had to replace the lubricants in all the modules to ensure compliance with the requirements."

Following a successful assembly test and release by the end customer, the automation solutions from Mikron are being handed over and mass production can start. Jörg Besold sums up: "It's not by chance that Kistler has a reputation for high precision: these joining systems provide excellent process control for our complex assembly operations, and that's why we'll certainly continue using them in the future. And it was also thanks to the systems from Kistler that we achieved very high levels of quality assurance and traceability in this project."

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