ZAHORANSKY
PERFECTLY DIFFERENT

DRUG DELIVERY SYSTEM BY ZAHORANSKY WITH OWN AUTOMATIC NEEDLE FEEDING & AUTOMATED PRODUCTION OF READY-TO-FILL PREFILLABLE SYRINGES

In this article, Harry Pruner, Freelance Journalist, Pruner Marketing Services, describes the automated assembly equipment offered by ZAHORANSKY AG for the production of ready-to-fill, prefillable syringes.

As a supplier of automation equipment for drug delivery systems, ZAHORANSKY provides the Z.BLIZZARD (Figure 1) system for the glueless production of staked needle syringes (Figure 2). It combines complete needle isolation, the injection mould and the downstream automation into a single unit.

The Z.BLIZZARD system for the production of staked needle syringes is an integrated automation solution in a modular design, allowing the isolation and glueless overmoulding of cannulas. The Z.BLIZZARD system features both the Needle Feeding System (Z.NFS) as shown in Figure 3, and the injection moulding machine with mould (Figure 4) to produce hybrid components.

The integrated Z.NFS is also modular in structure, with the effect that different design variations of cannulas can be processed within the specification. The Z.NFS is capable of handling needles, cannulas and lancet devices in various lengths and diameters. Optionally, even needles and cannulas with ground or shaped sections can so be aligned automatically and then carried to downstream processing.

ZAHORANSKY offers needle isolation systems (Figure 5) capable of singularising between four and currently 32 needles or cannulas with as much as 12 cycles per minute. Diameters range from 0.2 mm upwards, lengths of as much as 40 mm are handled properly. There are plans for more model sizes to enlarge the delivery range.

Z.NFS SYSTEM, IDEAL NEEDLE ISOLATION FOR MEDIUM BATCH SIZES

The market already offers a number of different solutions for needle isolation, but many of these systems have been designed for producing very large unit quantities. With its new Z.NFS unit, ZAHORANSKY closes the downward gap for delivering as many as 400 cannulas per minute, covering the general tendency in the industry toward smaller batch sizes and higher redundancies and toward multiple units for smaller volumes.

The new Z.NFS system allows the quick conversion to similar products or the flexible production in the event of breakdowns without causing delivery delays or keeping stocks high as a safeguard. The new Z.NFS system has been designed such that it can be used smoothly for inserting needles in automation equipment, moulds or injection moulding machines.

FIVE STEPS TO NEEDLE ISOLATION

Generally speaking, the full function sequence of the isolation process right

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Figure 1: The Z.BLIZZARD system for the glueless production of staked-needle syringes.

through to overmoulding can be divided into five steps. The first step involves mounting the filled magazine, followed by splitting off and separating the needles from the magazine by gripping or vacuum pickup. The next step is the visual check for "all needles available". Finally, the needles are fed for overmoulding or further processing using a gripper head with a linear robot or an alternative automation component of the injection moulding machine or a downstream automation device.

The five steps in detail are:

1. Filling Needle Magazines

There are several options for filling the compact and transport-safe magazines. Either customers themselves fill the magazine or they have it filled by their needle supplier. The magazine is used internally or externally as a reusable transport unit, with the design of the magazine guaranteeing the safe transport of the needles to the point of processing.

Keeping a second ready-filled magazine in stock in the Z.NFS unit is another advantage, allowing the fast mechanical or manual changeover. The ideal variant – virtually without any downtimes – is ZAHORANSKY's optional automatic magazine changing device where as many as two ready-filled magazines are installed additionally in the Z.NFS system that are changed automatically. This has the added advantage that the operator does not touch the needles, with the effect that contact contamination by personnel is largely ruled out.

2. Needle Isolation

To isolate the needles, a so-called partition slide equipped with the desired number of notches matching the design and size of the needles passes underneath the loaded magazine by means of a left-right movement, placing a needle in every notch. This movement is servo-electrical and can therefore be controlled with SPC device.

Once the final position is reached, the needles are either taken by mechanical grippers or released for vacuuming through stainless steel tubes. The isolation process is now repeated by the partition slide moving in the opposite direction until it is located in front of the second vacuuming or gripper station. Isolation from the magazine follows the first-in-first-out principle (FIFO) which ensures the best possible batch processing of the needles. This would be a substantial advantage if the batch needed to be tracked at some point in time later. Production in medical category 1 and 2, but also in category 3 is possible.

Figure 2: Staked needle syringes produced by the Z.BLIZZARD system.

3. Visual Completion Check

Sensors mounted to the left and right of the feeder magazine check the needles in transit to ensure that they are complete. While moving in the direction of the final position, it also checks if the required number of needles is available. Once the partition slide moves back, a check is made to ensure that all the needles have been duly removed for further processing.

4. Transporting Isolated Needles

There are two equivalent options for carrying to the syringes' cavities – rearward suction or mechanically gripping the separated cannulas.

The needles separated by the partition slide are vacuumed off at the same time. To do so, a transfer station with the tubes leading to the gripper head or the transfer unit docks against the separated needles. For the vacuuming process, a gripper head docks at the other end of the tube, triggers a suction impulse and sucks up the needles without damaging the tips or the grinded section. The resulting vacuum positions the needles against the corresponding stop in the gripper head. The cannulas are gripped directly at the partition slide, with one gripper head located at each end position of the partition slide removing the cannulas and taking these to the transfer position required for further processing, from where they are taken off aligned in the proper position. Every part making contact with the product is subject to the stringent US FDA and GMP regulations and is corrosion-resistant and designed compatible with the product.

5. Handover of Loaded Gripper Head into the Injection Mould

Before insertion, checks are carried out at various points to make sure that the following injection moulding process proceeds without any rejects. In line with the number of cavities in the injection mould, the cannulas are aligned and transferred to a handling system which first checks whether they are in place and in the correct position.

A two-axes linear unit hands over the cannulas placed on a holding plate into the mould cavities on the ejector side. There, they are already exactly positioned matching the mould inserts. Parallel to the insertion phase in the mould half on the closing side, the already injected parts are at the same time removed on the nozzle side mould half via a six-axes robot. This

substantially reduces the cycle time, as feed-in and removal take place at the same time.

The injection mould used is a ZAHORANSKY-patented Stack Mould System. The special features of this patented system are the two parting lines, allowing cannulas to be inserted and to remove ready overmolded cannulas at the same time.

Injection is performed by a Ewikon (Frankenberg, Germany) Hot Runner System with needle valve gate. The material used is a high-grade technical polymer, mostly cyclo-olefin copolymer (COC) or cyclo-olefin polymer (COP).

The cavity inserts are heated, while the rest of the mould is cooled normally. To do so, the inserts are thermally separated from the mould in order to minimise the energy loss and quickly accomplish a thermal equilibrium in the system.

EASY PRODUCTION CHANGEOVER

The engineers also focused on easy, quick and cost-effective refitting during a production changeover. During a product change, essential components of the Z.NFS system can be used again for a later use. Especially in the production of smaller and medium batch sizes, this flexibility offers substantial cost benefits compared with rigid systems designed only for a single product.

SUMMARY AND OUTLOOK

Additional external automation equipment makes the system even more convenient. After the isolated cannulas are handed over to a gripper head, the needles are delivered either to an injection moulding machine for direct machining or to another automation equipment item.

A system for bending the needles for higher retention forces, beading the blunt end for better piercing strength, or aligning the grinded cannula tips, for example, are conceivable downstream processing steps.

Depending on application, the machined needles are servo-motor removed, fed in and placed back in position either by a six-axes robot or a linear handling unit. If the needles are carried into the injection mould directly for overmolding, a linear axis is used. Before being transported further into the downstream unit – in most cases an injection moulding machine – the needles are normally checked for completeness. If the insertion gripper is not completely filled, the machine operator or the previously specified procedures in the system control unit decide whether the missing needle should be replenished or whether the complete content of the gripper head should be discarded. Another option involves an intermediate station to make the fully automated orientation of the polished needles.

Laser devices check both the feed-in of the needles and the overmoulded needles for completeness. The finished syringe bodies can then be siliconised in an integrated follow-up station to improve the sliding property of the needles.

Other operational steps could possibly include placing a protective cap on top or a subsequent X-ray test to ensure that the integrity of the tip of the syringe is guaranteed and that the overmoulded zone complies with requirements. This step is followed by automatic packaging in standard or customer-specific trays, ensuring that particle contamination caused by hand contact is prevented or at least minimised throughout the whole of the process chain.

Figure 3: The Z.NFS – ZAHORANSKY Needle Feeding System.

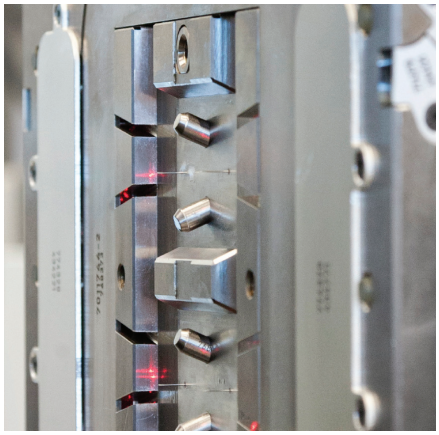


Figure 4: Cannula mounted in b-side of injection mould.

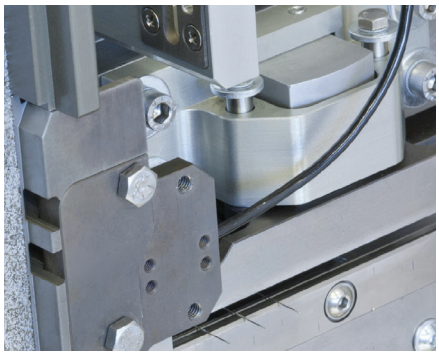


Figure 5: Detailed view of needle isolation.

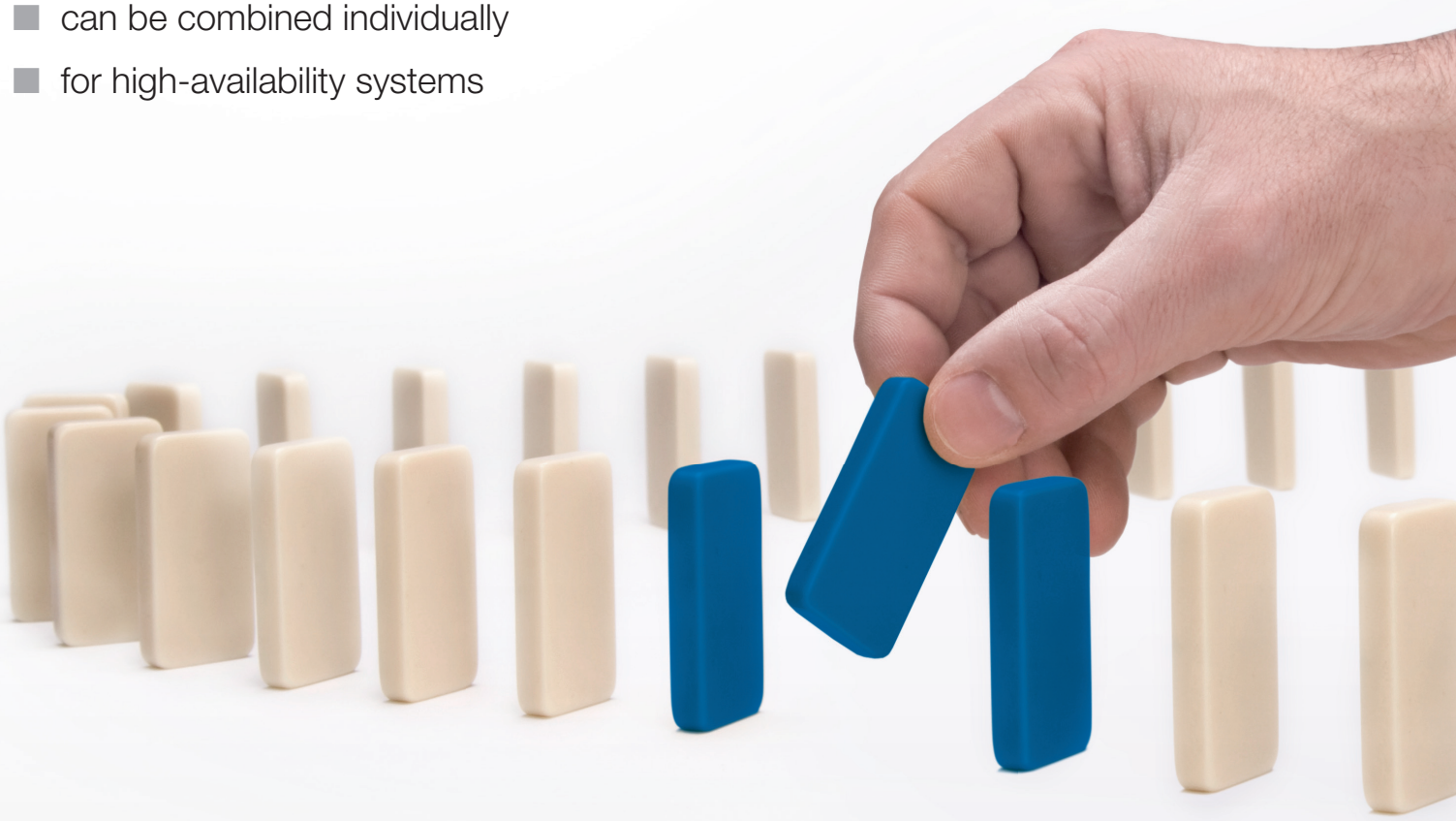
ABOUT THE COMPANY

ZAHORANSKY AG is a full-range supplier in machinery and production lines, sophisticated, innovative injection moulds and automation equipment. The company operates with over 700 associates at production sites in Germany, Spain, China, India and the US.

System Technology offers across-system solutions for the injection-related automation. These systems are based on injection moulds by ZAHORANSKY Automation & Molds GmbH and on established systems from different modules of automation. Intelligent and injection-related automation solutions can be composed with these modules. ZAHORANSKY Automation & Molds GmbH serves the areas Industrial Automation and Medical Devices, with pre-configured solutions provided for medical engineering. Z.BLIZZARD, for example, is an integral solution for making ready- to-fill prefillable syringes as primary medical packaging.

Automation solutions from the **toolkit**

- System modules for automating manufacturing processes around injection molding
- can be combined individually
- for high-availability systems

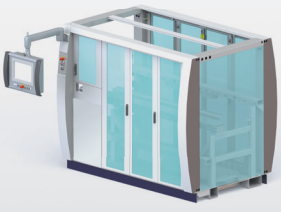


Z.NFS

Z.BLIZZARD

Z.ZYKLON

Z.SIROC



Z.MISTRAL

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