

COMPANY PROFILE: ZAHORANSKY AG SYSTEMS TECHNOLOGIES



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As automation systems supplier for drug delivery devices, ZAHORANSKY provides the Z.BLIZZARD system for the glueless production of staked-needle prefilled syringes (PFS). This system combines complete needle isolation, injection mould and automation into a single unit.

The new Z.BLIZZARD system (Figure 1) for the production of staked-needle syringes is an integrated automation solution in module design, allowing the isolation and glueless sheathing of cannulas. The Z.BLIZZARD system features both the needle feeding system, Z.NFS (see Figure 2), and the injection moulding machine (Figure 3) with tool. 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 piercing aids in various lengths and diameters. Optionally, even needles and cannulas with grinded or shaped sections can so be aligned automatically and then carried to downstream processing.



Figure 1: The Z.Blizzard full-range automation system.

One invaluable advantage of plastic syringes compared with glass syringes is that there is almost no risk of breakage during handling, storage and transport. Another benefit compared with the conventional way of making PFS from glass is in the much greater design freedom for the components to be made. Technical function features can be designed and added directly to the plastic part. With optimised construction, this results in highly cost-effective overall systems. These may be design-related, technical or safety features which are integrated directly onto or into the syringe body. Every conceivable freedom in design is possible in line with the customers' ideas and specifications, with the ultimate solution in terms of design and functionality found in the dialogue among the pharma company, the plastic processor and the filler. Fillers should ensure, however, that existing filling systems can cope with new products.

THE COMPANY

For more than 110 years, the name ZAHORANSKY has stood for reliability, precision and fully evolved engineering for machines for automation, mainly in the production of brushes. Today, ZAHORANSKY AG is a full-range supplier in mechanical engineering, sophisticated, innovative injection moulds and automation equipment. The company's Systems Technology division is based in Freiburg (see Figure 4) and operates with more than 600 associates at production sites in Germany, Spain, China, India and the US.

ZAHORANSKY offers across-the-board systems and solutions for the whole process chain, including the integration of tools and moulds, packaging engineering, handling, programming and robotics in the production of fully automated production and assembly plants. Automation systems are made for the industrial sectors Oral Care, Medical Engineering, Cosmetics, Consumer Goods, Household and Industrial Brushes, and Packaging. Systems for medical are available in medical classes 1 to 3.

GLUELESS PRODUCTION OF DISPOSABLE SYRINGES

First, the needles to be sheathed are taken or isolated from a magazine (see Figure 5), using the first-in-first-out principle. The components to be sheathed are then brought together and provided at a defined handover



Figure 3: View into injection moulder.



Figure 2: The Z.NFS needle feeding system.



Figure 4: Zahoransky AG, Systems Technology plant in Freiburg, Germany.

point between the Z.NFS and the further downstream automation. In the process step, the components are placed by a gripper system developed in-house into the injection mould also developed and patented by ZAHORANSKY. The full hot-runner valve gate injection mould is an integral and essential part of the value added chain. 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 needles are aligned and transferred to a handling system which first checks whether they are in place and in correct position. Using a numeric controlled axis robot, the needles are then placed in a parting line of the injection mould. Suitable devices hold the needles in the correct position. Parallel to equipping the needles, the finished parts are removed out of the second parting line by a six-axis robot. This reduces the cycle time to a substantial degree, because feed-in and removal take place almost simultaneously. After feed-in the needles and removal of the finished parts, the mould closes again. All open cavities and areas, in particular those of the needle bore, are closed by the appropriate functions of the injection mould. Plastic material is then injected into the cavities of the injection mould.

The high-grade technical polymer used is, for example, Zeonex cyclo-olefin-polymer (COP) from Zeon, or cyclo-olefin-copolymer (COC) from Ticona or similar alternatives. When using the glass-like COP, processing recommendations instructions say that the screw feed-in of the injection moulding machine should be nitrogen flooded to ensure that almost no so-called black spots or defects come up at the plastic parts. Using full hot-runner valve gate moulds means that there is no, or only very little, particle contamination, caused by a mass guidance system in the production area. To keep the particle contamination on the surface of the plastic part as low as pos-

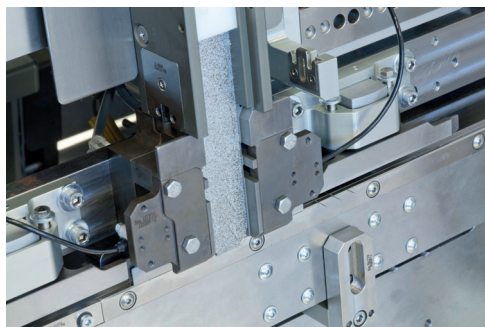


Figure 5: Detailed view of needle isolation.

sible, it is recommended to cover the area of the injection zone (the mould) and maybe also the handling and downstream automation system with one or several additional laminar flow units.

OPTIONS FOR SUBSEQUENT PROCESSING

After removing the staked-needle syringes (Figure 6) with a suitable removal system (in this case a Kuka s-axis robot), the parts are placed on a sight or transport line to prepare them for further processing. Some of these subsequent processing steps can be, for instance, a visual inspection, siliconisation, various checks and inspections for best possible patient use, plugging on a sealing cap and handing over to standardised trays (100/160) as carrier system for further processing or filling the PFS. To ensure that no silicone seeps in or contaminates the injection moulding area during subsequent processing, these areas are separated from each other by the above-mentioned sight or transport lines. Visual inspections and siliconisation are possible in the downstream

automation independent from the actual injection moulding process. Other options are also feasible between the pick-up from the sight line and placing the parts in the standardised 100 or 160 trays. Options are for example, covering and sealing the disposable syringes (PFS) with a fleece and a covering film, an optical camera control of the needles in the sheathed zone, siliconising the needles, an lubrication check

of the needles, if necessary, siliconising the inside of the barrel and maybe one more quality check. There is also the option to use a plunger to be able to generate a so-called zero-bubble filling situation.

OUTLOOK – WHAT'S NEXT?

In the future, ZAHORANSKY will build more in-house downstream automation units on a modular platform (Z.MISTRAL). Basically, this automation platform relies on a larger number of approved components, allowing the customer to build up a total automation concept from a range of standardised function units. From the range of ZAHORANSKY AG there will also be a tray loader (Z.LODOS), as interface to a downstream automation. Tray loaders are used to place parts in industry trays that are usable for automation or in trays for staked needle syringes, for example.

The glueless production of prefillable syringes is relatively new and already enjoys a high level of acceptance. But, according to ZAHORANSKY's investigations, well over 95% of all cannulas are still being glued in Europe. If new developments and interrelations of all parties consider design, engineering and technical safety features, the future will certainly belong to glueless plastic syringes.



Figure 6: Plastic staked-needle prefillable syringes.

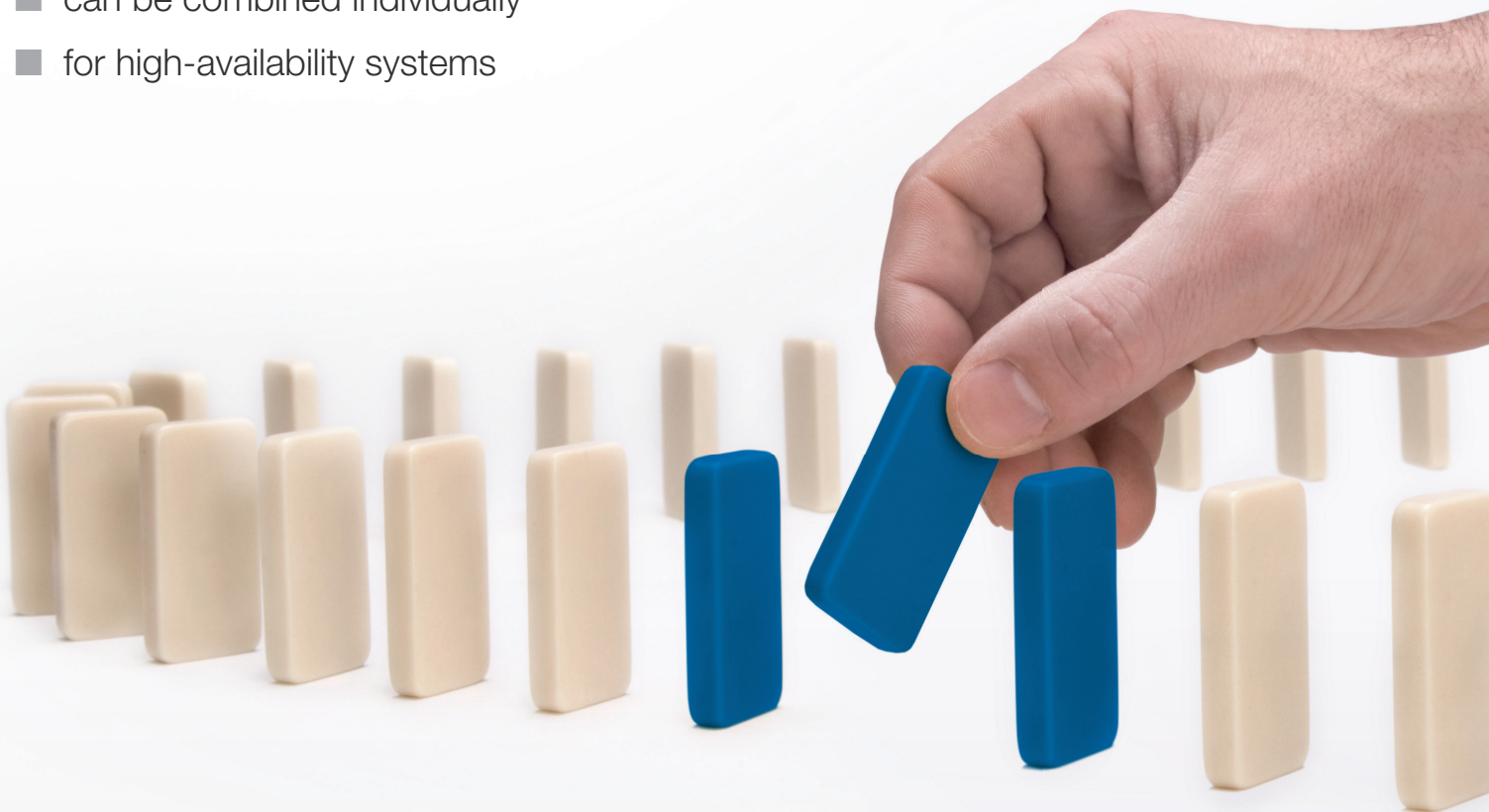
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Automation solutions from the **toolkit**

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



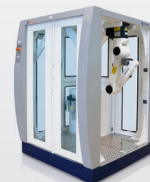
Z.NFS



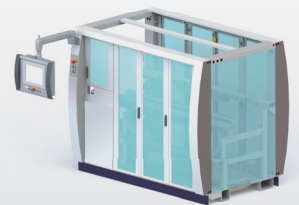
Z.BLIZZARD



Z.ZYKLON



Z.SIROC



Z.MISTRAL

Starting from a toolkit of preconfigured automation modules, we work with you to develop a flexible solution for manufacturing your plastic products for industry, consumer goods, and medical technology. Efficient, and cost-effective.

We will be happy to advise you. zsys@zahoransky.com



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