



Equipment designed for production and filling of infusion bags in a cleanroom environment (photos: Kiefel)

IV Bags Filled In-Line

Cleanroom. Suppliers of plants for the production and filling of infusion bags must consider very high requirements. No matter if in thermocontact or high frequency welding, or when processing flat or blown films – the utmost quality standards of precision and sterility will always apply.

Kiefel GmbH in Freilassing, Germany, has introduced its IV-Express, a new plant designed for the production and filling of infusion bags at cleanroom conditions. Kiefel is a specialist in welding technology and producer of thermoforming plants and, according to company information, this new development is perfectly tailored to meet the requirements of the market. The compact machine is made of stainless

steel and can achieve extraordinarily high output rates at minimum footprint. The plant moreover offers a high level of flexibility in production: For instance, different sizes of IV (intravenous) bags can

be flexibly produced in 2, 4 and 6-up configuration – as can be multi-chamber bags with peel-open seals. The manufacturer claims that users can achieve high productivity with a minimum of retooling, because the system offers high process safety while operating on short cycles.

The filling station is integrated into the system and a high-precision dosing unit ensures accurate filling. Oxygen or other gases can be supplied. Monitoring and testing units can be used in accordance with the corresponding application. Of course, a printing station for hot emboss-

i More on this Topic

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ing or laser application can be integrated into the system. Another benefit is the fact that only very little film waste is produced.

Facts indicate the plant's high performance: the IV-Express machine uses the thermocontact welding technique to manufacture up to 4,800 infusion bags per hour, in a 4-up configuration. At a footprint of merely 18 m², this means an output of approx. 270 articles per square meter and hour.

Compact Design in a Cleanroom

To protect manufacturing unit and products from environmental soiling, production takes place under cleanroom conditions, as with most pharmaceutical products.

Machine equipment is required here to fulfill the highest demands of cleanroom production. In addition, the cleanroom should not be larger than required by the plant. The target of cleanroom production is thus the establishment of well-considered and graduated cleanroom sectors with favorable oper-



An infusion bag produced on an IV-Express plant

ating conditions. The IV-Express' compact stainless steel design corresponds to GMP class C requirements concerning cleanliness, while demanding little space.

As one option, the machine is available with a stationary cleanroom cabin: the compact cabin is designed in compliance with the principle of turbulent mixing

ventilation according to GMP class C "at rest" corresponding to ISO 14644-1, class 7, as well as according to US. Fed. Standard 209e, class 10,000, respectively. It also complies with GMP class C "in operation" according to ISO 14644-1, class 8. To safeguard optimum conditions, the clean air units operate at 0.45 m/s air speed.

Integrated Filling

Some of the infusion bags to be filled are dimensionally instable, thus posing extraordinary requirements to gripper and handling.

The IV-Express machine features an integrated station for exact, automated filling and closing of the bags. The filling tolerance is +/-1 %. A robot precisely closes the filled infusion bags. Another benefit is the fact that various closure systems are possible. As a major component, the system also has an integrated CIP/SIP system for cleaning and sterilizing the pipe and device system, which exists in any type of quality oriented production of pharmaceutical products. ■

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Detail of the filling station