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Medical-Grade Spool Maker Launches Cleanroom Production

A manufacturer of thermoplastic spools, Hafner & Krullmann GmbH (Leopoldshöhe, Germany) has set up its first cleanroom to manufacture medical-grade spools. Made from impact-resistant acrylonitrile-butadiene-styrene, the spools are designed for winding capillaries and flexible tubes used in permanent venous catheters, among other applications.

“We decided to invest in cleanroom production in order to meet the product requirements from B. Braun Melsungen,” says general manager Jan Hafner. “In the long run, however, we believe that we can add value for [all] our customers with our competence in developing, designing, and producing spools and other products under cleanroom conditions.”

Hafner’s new cleanroom is equipped with an injection moulding machine that has a locking force of 3500 kN, a maximum shot weight of about 1650 g, and a maximum 710 × 1000 mm tool size. To minimize human contact and the risk of contamination, a five-axis robot takes the parts out of the mould and stacks them prior to packaging. All key process control systems are located outside the cleanroom to further reduce the risk of contamination. Quality systems inside the Class 8 cleanroom follow US FDA’s CGMP guidelines.

In the future, the company wants to intensify its production under cleanroom conditions. Aside



Spools manufactured under cleanroom conditions by Hafner & Krullmann GmbH are supplied to B. Braun Melsungen AG for permanent venous catheter applications (pictured).

from making its own products such as spools, the company offers contract services to medical device manufacturers seeking a partner with these types of production capabilities. “The project can either be a single moulded part or a product with several pieces requiring automated or manual assembly,” says Hafner.

For more information about the firm’s contract services capabilities, contact Hafner & Krullmann GmbH, Krentrufer Strasse 7-15, 33818 Leopoldshöhe, Germany; phone: +49 5208 70040; fax: +49 5208 7004118; e-mail: info@hafner-spools.com; Internet: www.hafner-spools.com.