Sophisticated Geometry – and Hermetically Tight

Welding instead of Gluing for Sophisticated Medical Engineering Function Components

The cleanroom production of a biochip system made of semi-crystalline plastic presented a great challenge for the manufacturer. The upper part with test chamber must be assembled with the support layer in an absolutely tight manner. After all gluing trials had failed, the methodical approach in the weld process saved the project.

Fig. 1. The test strip for diagnosis is difficult to produce: Rida-Chip FoodGuide for determination of food intolerances (© R-Biopharm)

R-Biopharm AG from Darmstadt, Germany (**see box p. 26**) had invested three years into research and development to design their Rida-Chip FoodGuide (**Fig. 1**) for detection of food intolerances from blood samples. A particularly complex issue was joining of the upper part and the support layer of the biochip system. The required tightness could not be achieved using glue. Eventually, the developing engineers encountered a more promising joining technology for this type of application: ultrasonic welding. Ultrasonic welding is not only fast and clean but, in contrast to solvent-containing glues, it does not impair the biological components of the test equipment, such as enzymes.

However, the road to success was not easy with this method, either: the feasibility tests revealed that the relatively recently developed, clear plastic reacted well to the ultrasonic waves, i.e. it was easy to be welded. Notwithstanding, the geometry of the biochip was still a great challenge. The FoodGuide consists of a support layer with 24 openings; the parts to be welded on are three test strips with eight test chambers, each (**Fig. 2**). All in all, a joint length of 670 mm, divided to 24 chambers with a weld depth of as little as 0.25 mm, needed tight welding.

The process development for tight welding took almost 24 months, required several visits of the R-Biopharm developers at the ultrasonic lab of Herrmann »

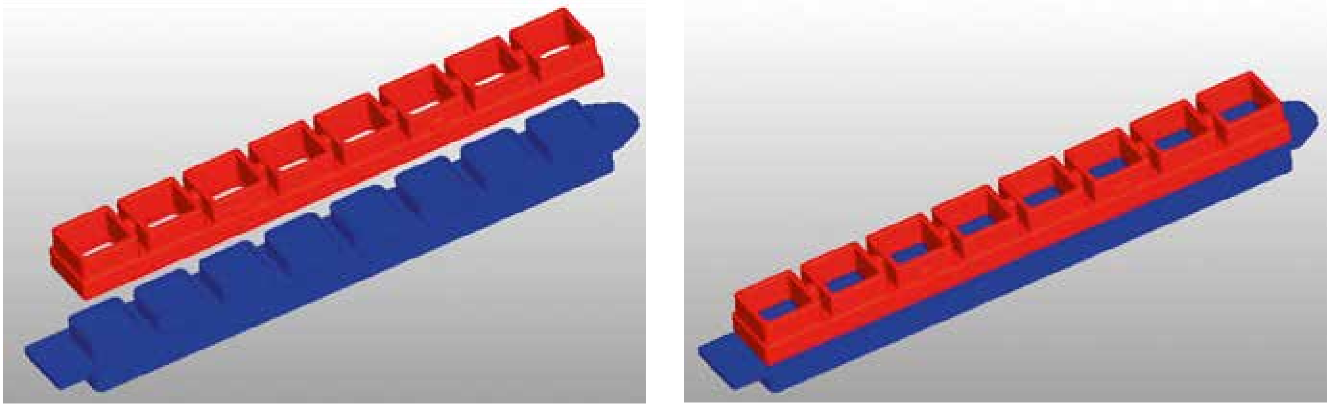

Fig. 2. Biochip system: bottom tray and chamber part must be tightly welded to one another (© Herrmann Ultraschall)

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Company Profile

R-Biopharm AG was founded in 1988 as a subsidiary of Röhm GmbH in Darmstadt, Germany. They develop products for clinical diagnostics, as well as food and feedstuffs analysis. Since January 2000, the company has held the globally exclusive rights of sale for enzymatic bioanalytics by Roche Diagnostics (previously Boehringer Mannheim).

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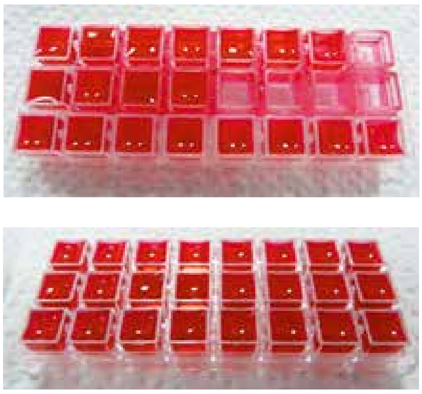

Fig. 3. Tightness test by means of rhodamine dye. Above: a leaking component during the test cycles, bottom: a tight component at the end of application development (© Herrmann Ultraschall)

Ultraschalltechnik in Karlsbad, Germany, and a great number of test and trial cycles (**Fig. 3**).

The cooling behavior of the plastic used played an important role in parameter development: for production, the recommendation eventually was to produce the components in advance so that the material would be available for welding in completely crystallized condition. Otherwise, welding may cause distortion or "trapped" stress inside the component and thus result in leakage.

Design of Energy Directors and the Sonotrode

With regard to design of the joining areas, the customer was given the advice to include the missing energy director. For that purpose, the injection mold did not have to be re-designed but merely required subsequent modification: It was eroded and re-worked mechanically. Joint design with the help of energy directors is required for reliable process management. For injection-molded parts energy directors are weld geometries including spikes or ridges inside the joining area. They focus the ultrasonic and define the exact location of melt formation. In this way, the component transmits the ultrasonic waves to the joining area.

Another issue was the contact surface for the weld tool, referred to as sonotrode. The sonotrode makes contact with the grid walls between the chambers during joining. Often, in ultrasonic welding tools with recesses in the surface are used, which means that through protruding contours above the weld joints precise sonic exposure is ensured. Due to the geometrically flat face of the component, the sonotrode also needed to form flat contact. Thus, the requirement was to design the contact pattern of the sonotrode with the component such that no incor-

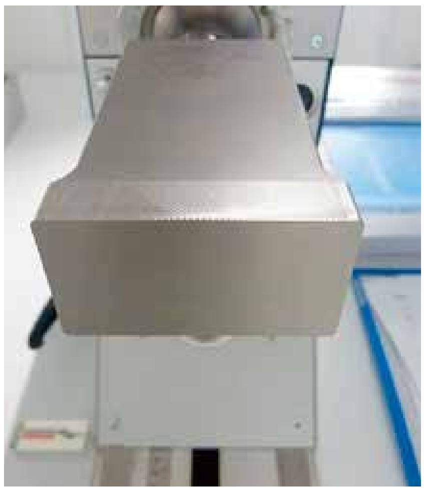

Fig. 4. The surface of the weld tool (sonotrode) needs to be finely polished to prevent unwanted melting (© Herrmann Ultraschall)

Fig. 5. The cut image at the beginning of the tests reveals that the component is not yet correctly centered and that further modification of the injection molding tool is required (© Herrmann Ultraschall)

rect melts were generated and the desired visual appearance was not impaired. It had to be ensured that only the energy directors at a distance of 3.8 mm off the sonotrode would melt but not the thin ridges of the chamber walls that would come directly in contact with the sonotrode. These ridges are actually too narrow and do not comply with the general rule that the contact surface needs to be at least three times as wide as the energy director.

Fig. 6. Component centering through centering nubs: view of the inside of the chamber (© Herrmann Ultraschall)

Normally, sonotrode surfaces are milled, but with such delicate geometries there was a risk of the milling scores to act as unwanted energy directors and generate melt or particle formation directly at the tool surface. This effect can be prevented by grinding and polishing the tool surface (**Fig. 4**). Finally, to ensure dimensional accuracy, the fixtures were made of cleanroom-compatible stainless steel; and what is more, they were made in one piece.

Component Centering through Cut Image Measurement

Centering of the component in process set-up was also a challenge that presented many difficulties, but was indispensable for tight welding. During the test and trial cycles, detailed 3D measurement of the cut image revealed that the clearances between the components were still too big and yet another reworking of the injection molding tool was required to modify the energy directors (**Fig. 5**).

Another measure for centering the components within the required tolerance limits were centering nubs inside the chambers (**Fig. 6**). They ensure positioning of the components relative to one another and thus a correct production course.

Assessment of the joining quality through the light microscope at the end of the development work in the laboratory, confirmed the weld quality (**Fig. 7**).

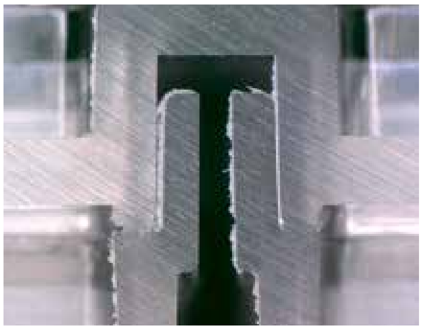

Fig. 7. Final assessment in the light microscope: centered homogeneous joining result (© Herrmann Ultraschall)

Conclusion

Solving such a challenging application takes a long R&D period and numerous tests and trials in a well-equipped ultrasonic lab. In this project, the welding parameters were determined through the DoE method during tests of almost 40 hours duration. Correct interpretation of the characteristics and analysis results was particularly important. This means that expertise and a methodical approach in application development play a great role, particularly when developments are at stake, as was the case in this project. ■