Process expertise plays a crucial role in the sealing of microfluidic structures in medical technology

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Hermetically sealing micro-channels is considered one of the main challenges in developing diagnostic systems in medical technology. The seals have to be mechanically stable, resistant to chemicals, optically clear and cost-effective. Gerresheimer, a leading medical technology supplier, has extensive process expertise when it comes to sealing microfluidic structures. During the development and industrialization phase, the company supports its customers in selecting and implementing a suitable joining method.

Choosing the right joining method depends on multiple factors. The requirements of the application and of the specific material properties of the mating partners have to be aligned with economic considerations.

Standard joining methods include laser welding, ultrasound welding, PSA (pressure-sensitive adhesives), heat-sealing and solvent bonding. Each of these methods has specific advantages and disadvantages that have to be carefully considered.
(see pages 8 – 9)

Selecting the joining method

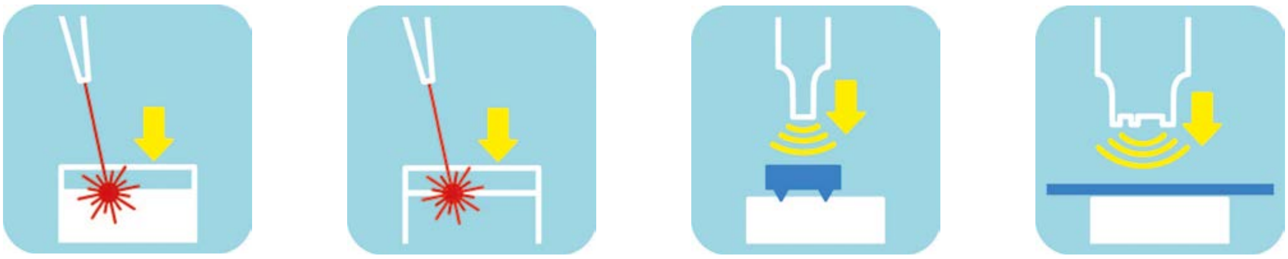
To meet the requirements of the application, a concept rating compares and weighs the advantages and disadvantages of possible methods. Additional preliminary tests closely examine the suitable joining method to make a final selection. In product development, the selected concept is then examined in detail and all necessary influencing factors and parameter definitions are described.

Identification of a suitable joining method is only possible with prior selection and application of suitable test methods. This is the only way to ensure that the seal actually meets the specific requirements of the application. The standard test methods include pressure loss testing, fluid testing, visual inspections, process parameter testing and destructive testing of the mating partner pull-out force. However, each of these methods has its own advantages and disadvantages.

During pressure loss testing, compressed air is applied to the sealed unit to test tightness. A defined pressure loss over a specified period of time must not be exceeded. Fluid testing can be performed similarly. This is a visual test checking whether fluids escape at leaks.

Visual inspections are also suitable for assessing the sealed seam width and quality. Process parameter tests monitor temperature, pressure and time during sealing. Finally, for the mating partner pull-out force, the adhesion force is determined as part of destructive testing to test the strength of the bond.

Bonding

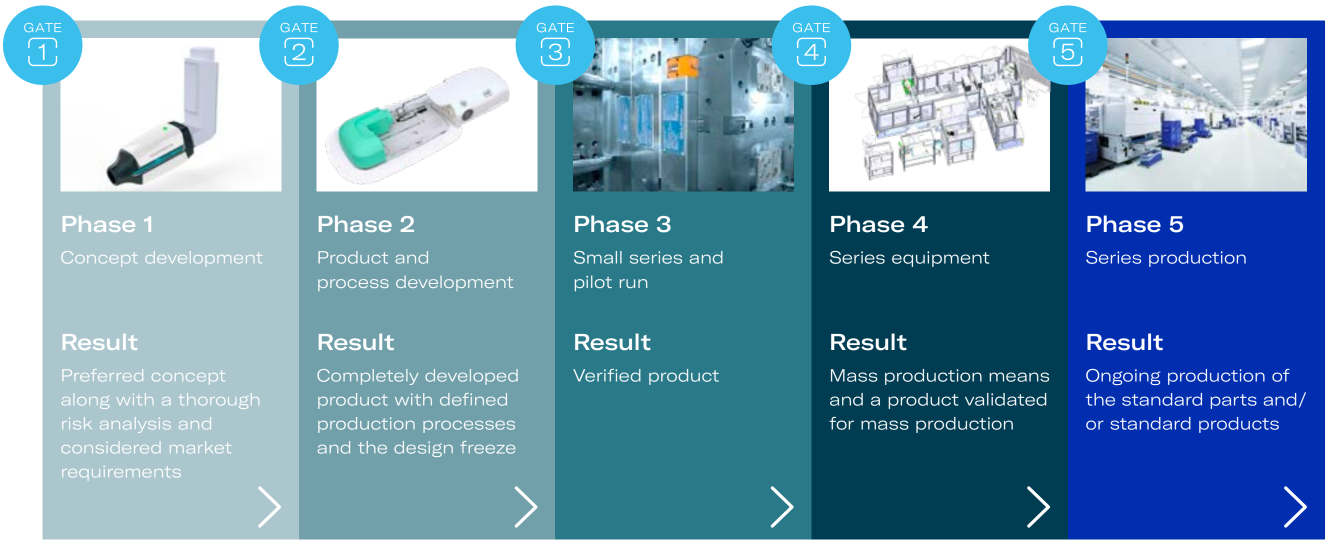


In principle, there are numerous technical options for joining multiple mating partners.
Graphic: Gerresheimer

Integration into the Gx phase model

Gerresheimer integrates the selection and testing of the joining methods into its Gx phase model, achieving a standardized workflow.

Gerresheimer Development Process

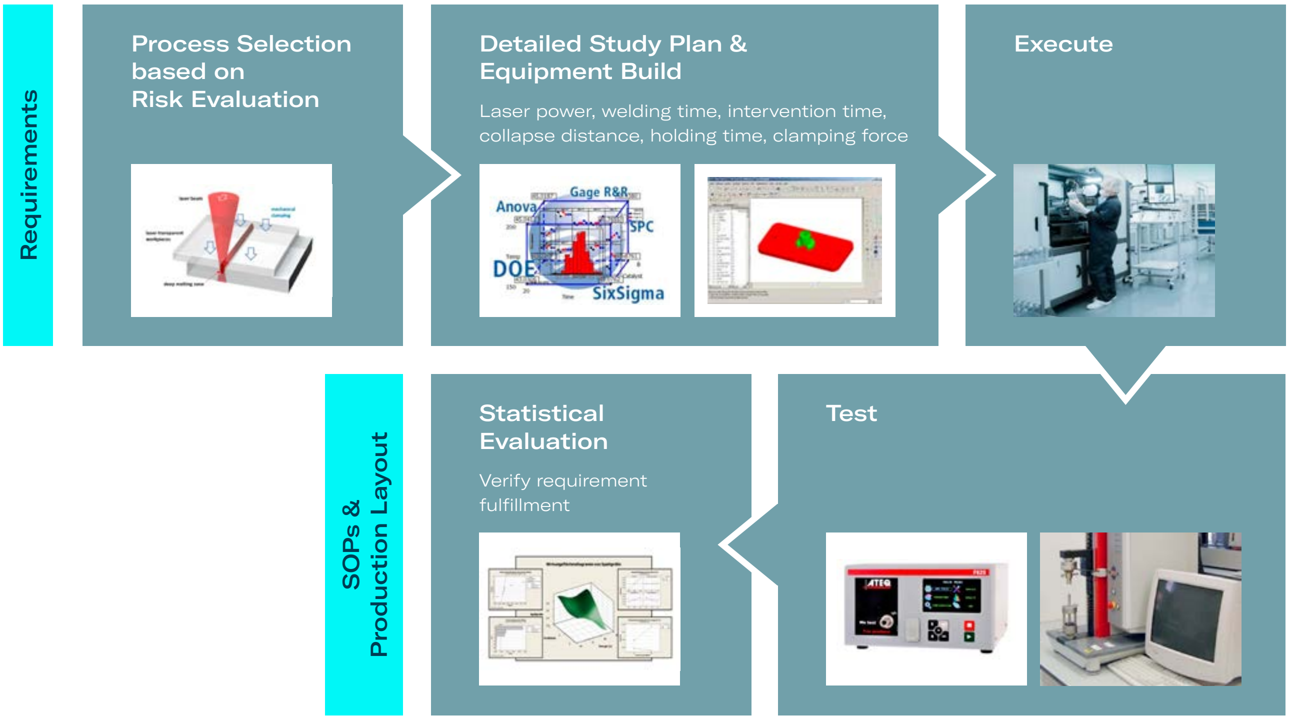


Structured product engineering process for methodical risk minimization and greatest degree of flexibility

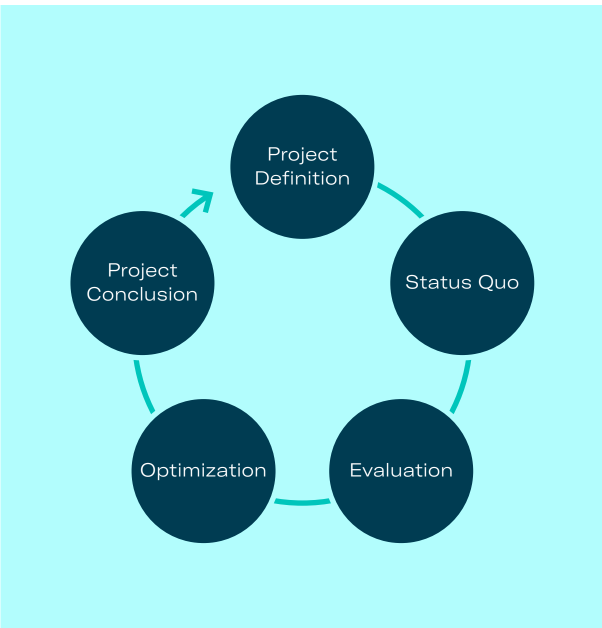
Integration into the Gx phase model

In the concept phase, different bonding technologies are compared based on a concept rating. Critical sub-processes are examined and the feasibility or options for practical implementation are assessed.

After a process is selected, the second phase focuses on detailing the joining method by means of design of experiments (DoEs) and engineering tests, all the way to design freeze.



Workflow in phase 2

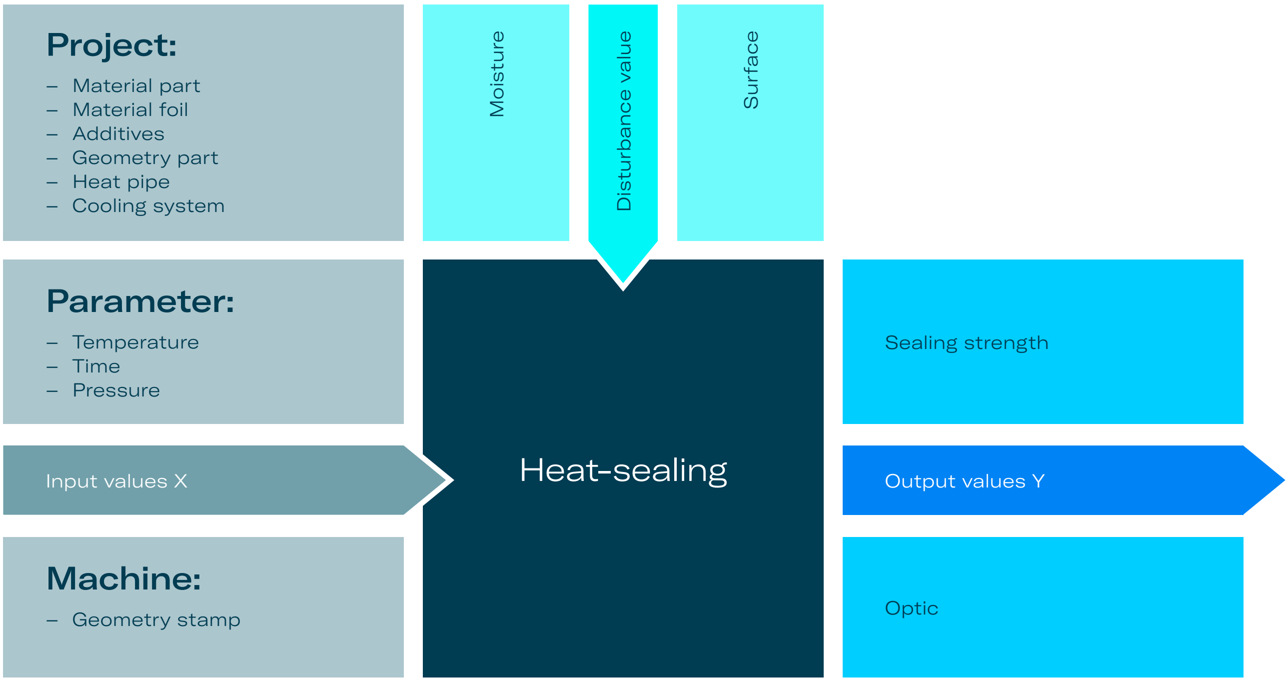


Phase 3, the final phase, includes design verification with qualified equipment and planning of subsequent production based on ramp-up figures.

Graphic presenting the process development workflow.
Grafik: Gerresheimer

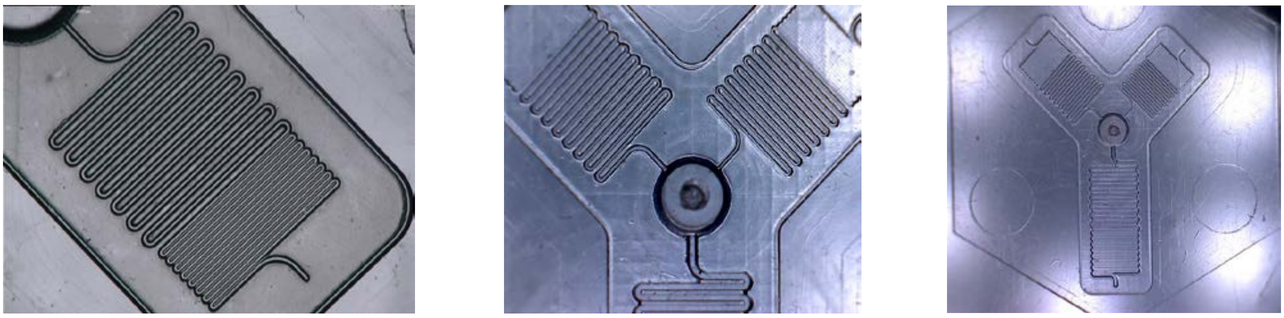
Real-world examples

Gerresheimer has many years of experience in conceptualizing and implementing development projects in the area of diagnostics, already successfully realizing numerous orders.



Considering all the requirements, in this case heat-sealing emerged as the most suitable joining method.
Graphic: Gerresheimer

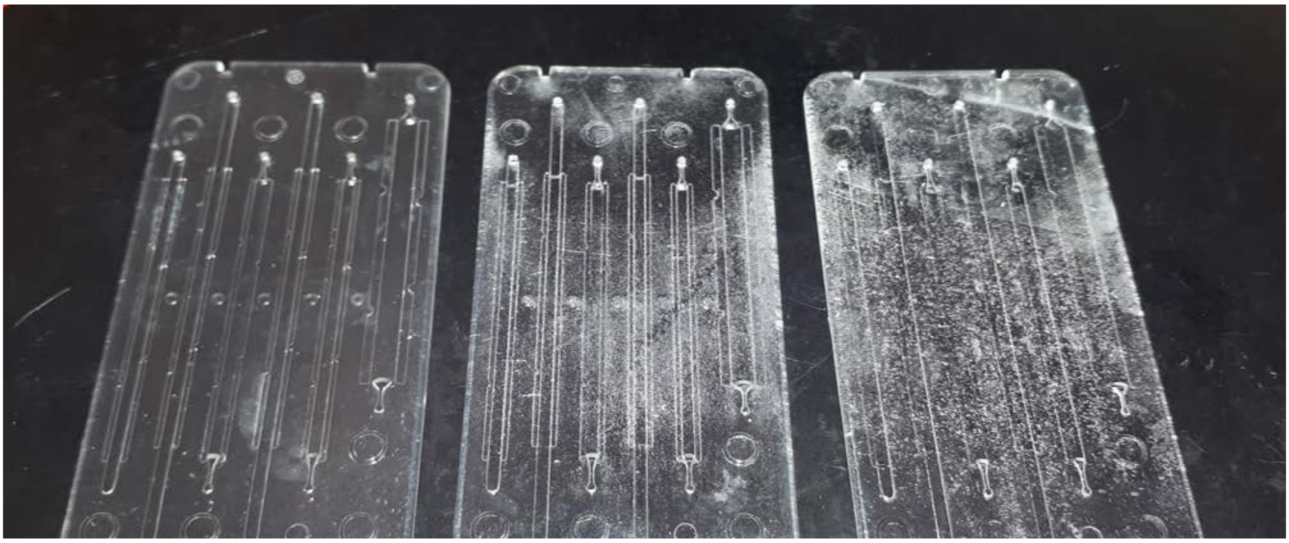
An example from the recent past: For a heat-sealing bonding application, the development experts from Gerresheimer analyzed different plastic materials to be able to meet the desired product requirements. Test chips made of different materials with different channel designs were produced to professionally evaluate their suitability.



The test chips provide valuable insights to perfect the joining method.
Photo: Gerresheimer

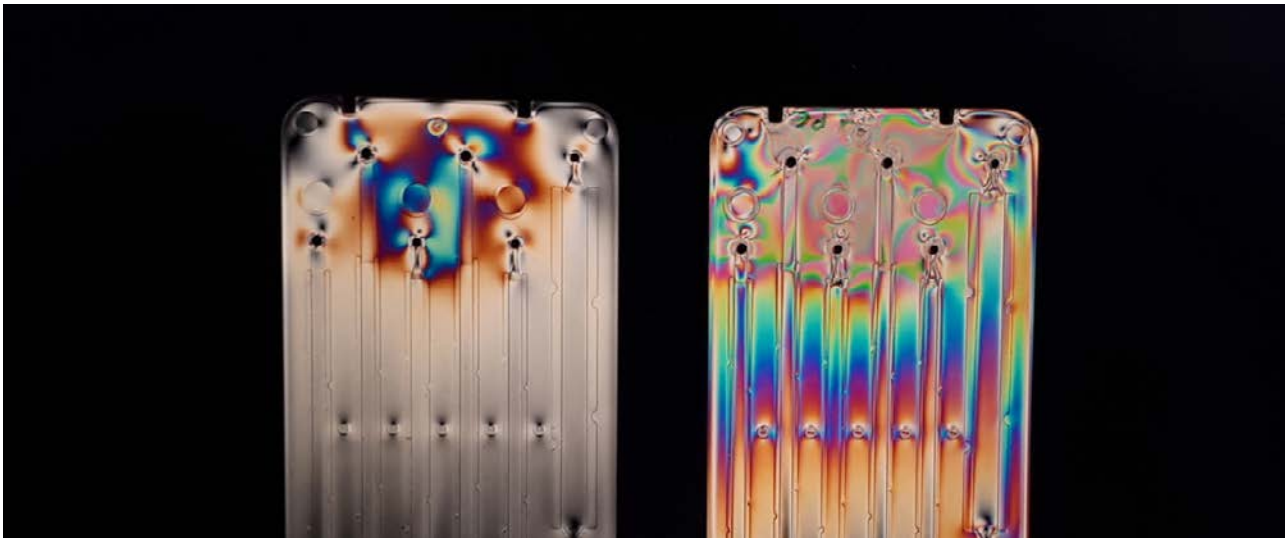
Real-world examples

The quality of the plastic parts plays a crucial role in the subsequent strength of the joint. Only parts with minimal distortion and low stress levels are suitable for reliable seals. That is why the influence of internal stress was carefully examined. Next, the influences of different heat-sealing process parameters on the bonding quality were analyzed. The fluidic performance of the test cartridges was also tested.



50% Hex, 30sec | 100% Hex, 30sec | 100% Hex, 60sec

Stress cracks caused intentionally by solvent reveal weak spots.
Photos: Gerresheimer



COC | PC

Polarized light

Real-world examples

Sealing

Foil heat sealing equipment for process development

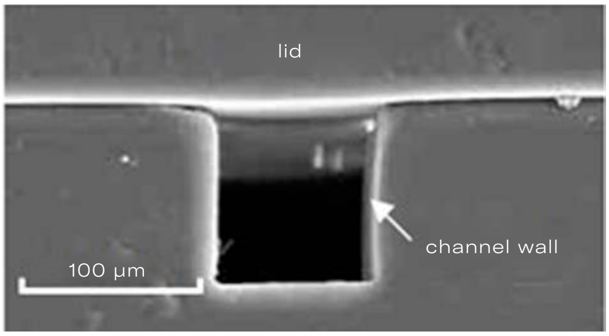
Seal Testing

Air Leakage testing

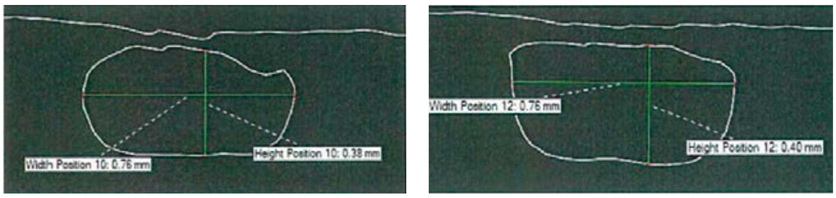
Water Leakage testing

Cartridge Sealing & Testing

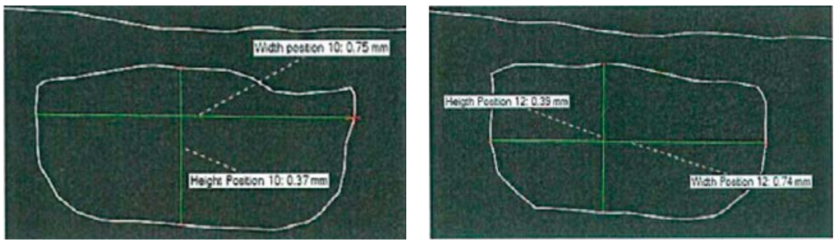
Finally, the parts underwent optical measurement and a CT scan to test the cross-section profiles of the joints and ensure the integrity of the seals.



The channel cross-section was measured.
Photos: Gerresheimer

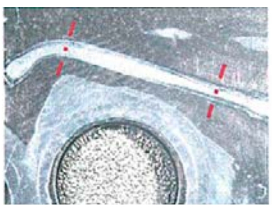


CT scan
foil sealing 1

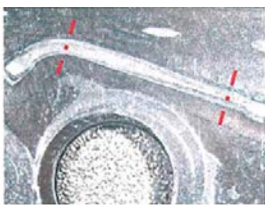


CT scan
foil sealing 2

unsealed channel



foil sealing 1



foil sealing 2

The bottom line

The process of selecting a suitable joining technology for microfluidic systems in medical technology is complex and requires a thorough, systematic analysis of the specific requirements of every application. Gerresheimer offers extensive expertise, providing support throughout all phases, from conceptualization to production. Careful selection and testing of the joining method ensures that the diagnostic systems are not only functional and reliable, but that they also meet technical, regulatory and economic requirements.

Overview of possible joining methods and their advantages and disadvantages

Laser welding

With this method, a laser beam melts and welds the materials to be bonded. One major advantage of laser welding is that no additional adhesives are required, which increases the purity of the joint and eliminates the possibility of chemical interactions with the fluid to be transported. The method is also low-particle, which is especially important in medical technology. It also enables the bonding of films and fixed caps and offers high joining forces. Besides the high price of the systems, one disadvantage of laser welding is the limited selection of materials, as not all materials are suitable for this method. One of the two mating partners also has to be transparent for the laser beam to allow the beam to pass through. In addition, the material absorbing the laser may melt, which can affect the design of micro-channels.

Overview of possible joining methods and their advantages and disadvantages

Ultrasound welding

This method uses high-frequency sound waves to fuse the mating partners. Like with laser welding, no adhesives are required, which makes the method clean and efficient. It is also very fast and is suitable for both films and fixed caps. The joining forces are relatively high. However, ultrasound welding requires a defined joint design and may cause particle abrasion depending on the material. Furthermore, there is also a risk of melting here.

PSA (pressure sensitive adhesives)

PSA uses pressure-sensitive adhesives to join materials. This method is inexpensive and does not require any specific joint design. It also enables multi-layer setups of films to be bonded without melting. The main disadvantage of PSA is the lower joint strength compared to other methods. In addition, the adhesive films may react with the fluids being transported, which could have a negative impact on the long-term stability of the joint. Handling the adhesive films (feeding and cutting) also presents a challenge, especially with high production volumes.

Heat-sealing

During heat-sealing, the mating partners are heated and then pressed together. This method is very fast and does not require any additional adhesives. It is particularly well suited for multi-layer setups. One disadvantage is that films are the only possible mating partner and melting may occur. The method also requires a high heat input, which rules out temperature-sensitive materials.

Solvent bonding

This method uses solvent to solvate and bond the surfaces of the mating partners. The advantage is the wider range of possible mating partner materials and the fact that no specific joint design is necessary. Even so, adhesives can interact with the transported fluids, which limits the possible applications. In addition, the method may not be suitable for mass production, as it is more complex than other methods.

The authors

Andreas Knie
Global Head of Sales Engineering

Andreas Knie studied process engineering at Georg Simon Ohm Technical University in Nuremberg and completed his studies with a Diplom degree in 1997.

He got his start as a development engineer for drug delivery devices and for diagnostic and medical products at Gerresheimer Regensburg GmbH. Since 2011, he has headed up the global Sales Engineering Team and provides the Gerresheimer Medical Systems Sales Team with support regarding technical issues during the request phase.

Together with his team, he is responsible for the technical evaluation of requests for offers, the development of technical solutions for internal calculations and the performance of project team cost estimations. All technical analyses are conducted across the entire product portfolio of the Medical Systems Business Unit and for Gerresheimer sales and development centers across the globe.

Michael Dehling
Sales Engineer

Michael Dehling completed his studies as an industrial engineer at Weiden Technical College with a Diplom degree in 2004. He then began his professional career as a simulation engineer with a focus on injection molding simulation and structural mechanics simulation (statics and dynamics). Four years later, he became managing development engineer for a complex drug delivery service. Following the completion of this project, he assumed the role of sales engineer for all products and sites within the Gerresheimer Medical Systems Business Unit.

In 2014, he expatriated to the US for two years, where he established sales engineering expertise directly at the Gerresheimer Medical Systems Unit at the Gerresheimer site in Peachtree City, Georgia.

Following his return to Germany, he became part of the Global Sales Engineering Team located in Wackersdorf.

Mareike Wiebe
Global Head of Process Development

Mareike Wiebe graduated in Mechanical Engineering at TU Berlin and added a Master of Biomedical Engineering with focus on development of new biomedical products.

In 2016 she joined Gerresheimer as a process engineer, where she developed and implemented several manufacturing processes into different production settings, ranging from protoype manufacturing to automated high volume manufacturing.

Since 2021 she heads the global process development department. Her team is responsible for the initial development and the serial implementation of all kinds of plastics processing (welding, gluing, coating, heat staking, etc.) and glass processing (glass forming, glass cutting, RTF processing, etc.) for biomedical products.

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