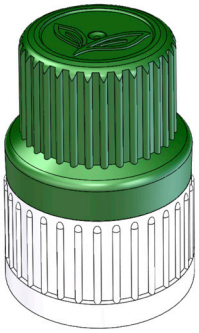
heinlein
PLASTIK-TECHNIK

HEINLEIN INDIVIDUAL

THE PERFECT PACKAGING FOR YOUR PRODUCT

Before:
OV1-18.282/UNI-2.02



Now:
SO3-18.100/012/Z-1020
SV-18.284/UNI-2.02

LIMITATION AS A CHALLENGE

New combination of active ingredients – new packaging: Heinlein Plastik-Technik once again demonstrated its comprehensive development expertise in redesigning a closure system for a herbal medicinal product.

Its a customer of Heinlein Plastik-Technik for over twenty years now. With the increasing number of closure and dosing units that Heinlein supplies to the company for filling its pharmaceutical products, the extent and intensity of the business relationship has also developed steadily over this period.

Until 2019 the customers requirements were solely focused on standard products – mainly GL 18 screw closures and universal droppers – which also featured the manufacturer's logo on the closures of the preparations. However, soon after the introduction of a new combination of active ingredients for the gastrointestinal medicine, it became apparent that when used with the tried-and-tested standard dropper, the shelf life of the new medicine declined significantly. "Some of the active ingredients in the liquid medicine were migrating through the polymeric plastic material, changing the active ingredient composition of the liquid in the bottle. This, in turn, caused a reduction in its stability and therefore the shelf life of the medicine."

After identifying and analysing this problem, turned to its long-standing partner. The enquiry: Could Heinlein develop a closure system able to marry the proven technical specifications with the usual guaranteed shelf life and storage periods?

Specifically, the main challenge was to separate the dropper insert from the liquid in the bottle in order to prevent excessive diffusion with consequent impairment of the medicinal product's shelf life. The following demands were imposed on the new product being developed:

- **In terms of size, design and material, the dropper was to be identical to the standard model used previously.**
- **The dosing insert had to be physically separated from contact with the pharmaceutical liquid.**
- **It should be easy to integrate the new system under development into the existing production line.**
- **It should be just as easy as with the previous solution to screw the closure system onto the bottle at the end of the line.**

Picture 1 / top:
Acceptance by company Teamtechnik
Picture 2 / below:
Machine MM 65

An on-site visit by the Heinlein team – consisting of machine and mould makers, system technicians as well as service and sales staff – once again emphasised the essential requirements and parameters in the customer's production process.

It quickly became evident that compliance with the existing available space dimensions was the decisive aspect for successfully developing a new solution. The height of available space in particular proved to be a limiting factor.

According to Heinlein's Head of Research and Development: **"Since the new closure was meant to be based on the existing standard solution, but at the same time the dropper had to be physically separated from contact with the actual liquid, it was especially the specified maximum overall height that placed tight limits on the new solutions being developed."**

In the end, the pivotal idea for successful implementation was the design of a multi-part closure. It was based on the connection of two closures via a plug-in adapter in which a single-piece tamper-evident closure was fitted. The fitted screw closure includes the standard dropper (UNI-2.02). The first time it is used, it can be unscrewed from the adapter without applying too much force and then screwed into the bottle. The main "separating element" is the disc glued into it. Its properties as a barrier separate the liquid in the bottle from the dropper, allowing it to significantly prolong the shelf life of the medicinal product.

The basic idea for this new closure concept came about quickly: Just a few weeks after the enquiry in January 2019, the Heinlein development team had already completed the initial computer draft design.

Following the first rounds of consultation at the customer's premises, an initial, basically functional 3D design prototype was made available to the customer within a few weeks. The functionality of the sample parts could then be further optimised.

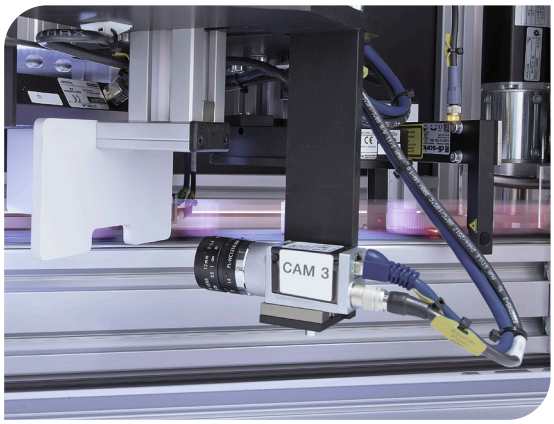
The primary aim was to reduce the force required for the initial opening and for unscrewing and screwing in the parts of the closure to ensure consistently easy handling by the user. The end of this phase resulted in the first batch of one hundred hand-assembled closure systems combining near full functionality with perfectly balanced force. "From this point on," according to the Head of Development, "we actually only made improvements to the appearance."

During the first phase of developing the new closure system, was able to benefit not only from Heinlein's technical expertise but also from its highly flexible and "permeable" internal organisation.
"We were particularly impressed by the powerful presence of our partner during this development period," sums up.

"The company's flat hierarchy and close cooperation between individual departments such as development, mould making and mechanical engineering as well as in the area of application technology were all factors that ensured that the success of our joint project was kept at the forefront at an early stage."

Thanks to the timely coordination with the mould making department, the requirements regarding mould size and cavities were able to be specified at a very early stage and the sample moulds produced for development – this was made possible by close cooperation in tightly scheduled stages with a correspondingly high degree of implementation precision. Early collaboration between the development department and Heinlein's internal mechanical engineering department, on the other hand, ensures at an early stage whether the machine parts required for subsequent production can be assembled, integrated and sorted, and finally whether they can be adapted.

In the subsequent phase, the new solution was finally put through its paces. Could the implementation of all the functions be guaranteed when dealing with the two-part closure? Can a permanent high level of tightness be ensured by the barrier disc? Are the specifications defi ned by the customer actually being met, particularly with regard to the dimensioning of the parts?



Heinlein developed and configured a camera system to establish complete quality assurance.

Using the test samples, it was ultimately possible to check the defect characteristics during assembly and injection moulding.

Following successful “fine-tuning”, sampling with the aim of achieving the optimal execution of the individual solution components and subsequent approval by the customer, the first hundred thousand units of the newly developed closure systems were produced using small tools at the beginning of 2020.

In this phase, the main task was to test the production of the parts on a larger scale and ultimately consolidate their production in the assembly process. With the construction of the required large injection moulds and a completely new assembly machine, another milestone was passed in spring 2020 with the transition to series production. Since the beginning of 2021, the newly developed closures from Heinlein has been produced for the market in quantities numbering in the tens of millions per annum!

This was an excerpt from a joint project for a new primary packaging solution. We also look forward to receiving your inquiry to find an individual solution for your product. Please do not hesitate to contact us.

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