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HIGH-PRECISION INJECTION MOULDS FOR INHALERS: CHALLENGES AND SOLUTIONS

In this article, Rob Doorakkers, Chief Innovation Officer, and Erwin van Huijksloot, Senior Sales Manager, both at IGS GeboJagama, discuss the challenges and solutions of engineering and manufacturing high-precision injection moulds for inhalers.

The goal of an inhaler is simple: to reliably and efficiently deliver medicine. Efficient drug delivery makes treatments more effective and thus allows patients to extract more successful dosages from a single canister.

Whether inhalers accurately deliver drugs is largely determined by the precision of the moulded actuator. Small differences in the geometry of the actuator can drastically change the medicine's spray behaviour, also known as bloom. The bloom determines where the medicine is applied in the mouth, which is an important factor in how effective a drug is. For example, some drugs

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are most effective when administered to the roof of the mouth, while others should reach the back of the throat to be inhaled deep into the lungs (Figure 1).

IGS GeboJagama has engineered and manufactured injection moulds for inhalers for more than 20 years. In fact, the first inhaler mould the Eindhoven company delivered is still active today. In this article,



Figure 1: Some drugs must be administered through the roof of the mouth, while others must reach the back of the throat.



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Figure 2: More than 20 years of experience.

the authors will discuss the challenges in realising the required degree of precision, as well as some of the most effective solutions developed by the IGS GeboJagama engineering team (Figure 2).

CRITICAL COMPONENTS: THE STEM FIT AND THE ORIFICE

To understand the challenges in manufacturing inhalers, it is first necessary to take a closer look at how these devices are constructed. The device has a right-angled design. The canister is placed in the body of the device, while the medicine is administered through the mouthpiece (Figure 3).

Two components are absolutely critical for accurate drug delivery: the stem fit and the orifice. The stem fit is where the medicine canister and the plastic device connect. The orifice is the opening through which the medicine is sprayed into the patient's mouth.

The geometry of the stem fit and orifice determine the device's bloom. Consequently, this is where all IGS GeboJagama's injection mould expertise can be found. For example, during the validation phase, the IGS GeboJagama team extensively tests the bloom of different device dimensions. Ink is placed in the device, which is then sprayed at a "dartboard" to confirm that the drug will reach the correct location in the mouth (Figure 4).

Having determined which device dimensions are necessary for accurate drug delivery, the next step is to create an injection mould for the device. Over the past two decades, IGS GeboJagama has developed a range of solutions for common challenges and client requirements in this process.

UNIT ORIENTATION

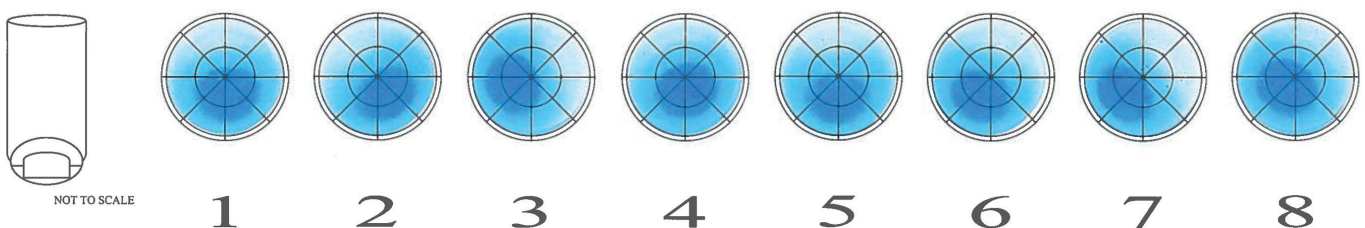


Figure 4: The tests of the bloom during the validation phase.

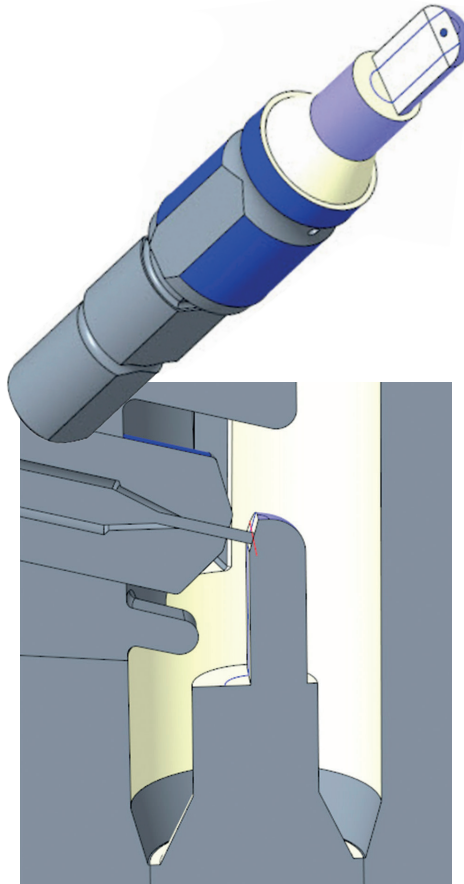


Figure 3: The stem fit.

1. Fast Stem Fit Variations for Optimal Uptime and Higher Mould Output

The stem fit is of vital importance for accurate drug delivery. It must be perfectly in line with the body and mouthpiece to create the optimum spray direction. If this is not the case, the "aim" will be off and medicine will be unnecessarily lost. Moreover, the geometry of the stem fit affects the bloom of the medicine. So, by using a different stem fit, a different bloom can be realised.

During the injection-moulding process, a stem fit insert is used to mould this part of the plastic product. In what could be called the standard injection mould for inhalers, it is possible to change the stem fit insert. However, the process is time consuming, as the mould must first be removed from the moulding machine. For contract manufacturing organisations (CMOs) that produce limited variations of their product, this is not an issue.

"Applying too much pressure on the orifice pin will cause it to deform."

But for medical device manufacturers that need to produce many different variations, a better solution is necessary.

For these clients, the engineering team at IGS GeboJagama created a solution where the stem fit insert can be removed while the mould is still on the machine. Via the side of the mould, a system can be activated to remove or mount the stem fit insert. This easy system saves a lot of time and improves the uptime of the mould, which allows for higher mould output.

2. Orifice Precision to Avoid Flash in the Shut-Off Area

The orifice is the opening in the mouthpiece through which the medicine passes. It is, of course, essential that this opening remains perfectly "clean". For example, no plastic film (also known as "flash") must be left behind in the orifice. IGS GeboJagama has developed a special technique to mould the orifice. In its moulds, a spring keeps sufficient pressure on an "orifice pin" in order to realise a clean "shut-off area": the area where the stem fit insert and the orifice pin meet. This prevents flash in the orifice, which could otherwise potentially be inhaled by the patient.

This technique requires a high degree of precision. Applying too much pressure on the orifice pin will cause it to deform and result in a "mushroom effect". Moreover, placing too much pressure on the orifice pin will also create an indent on the stem fit insert, which can also create flash. As a solution, in the past, hard materials were used for this component. But, as these hard materials proved susceptible to breakage, today IGS GeboJagama uses a tough steel-grade component with a carbide centre in the shut-off area.

3. Flexible Orifice Moulds for Improved Uptime and Mould Output

As discussed, the bloom of an inhaler can be modified by changing the stem fit. However, for some devices it is necessary to change the orifice as well, as different drugs require a different orifice length and diameter. For these projects, IGS GeboJagama has implemented a quick-change system that allows replacement of the orifice pin while the mould is mounted on the injection-moulding machine. As with the system to quickly change stem fit inserts, this saves time and improves the uptime of the mould – and thus optimises mould output. For even more switching speed, the engineering team at IGS GeboJagama developed a second solution, which gives CMOs the option to adjust the jet length of the orifice in seconds using a control built into the mould.

4. Long-Life Orifice Pins for Highly Reliable Product Quality

The orifice diameter is usually between 0.2 and 0.5 mm. The orifice tends to have a length between 0.2 and 1 mm. That means the orifice pin required to mould this component will be very thin as well. Considering the large amount of pressure placed upon the orifice pin during the moulding process, it should be no surprise that these pins are at risk of bending or breaking over time. The bending of the pin is a particularly pernicious problem, as it can slowly affect the accuracy of the actuator and thus the bloom. Considering the trend of orifice diameters becoming smaller and smaller, this could become a more prevalent issue for medical device manufacturers if no countermeasures are taken.

The root cause of these problems is the force released when the injection mould closes and opens again. This force causes the orifice pin to move slightly which, over time, can cause the issues described above. To prevent this, IGS GeboJagama developed a solution where a servo-driven

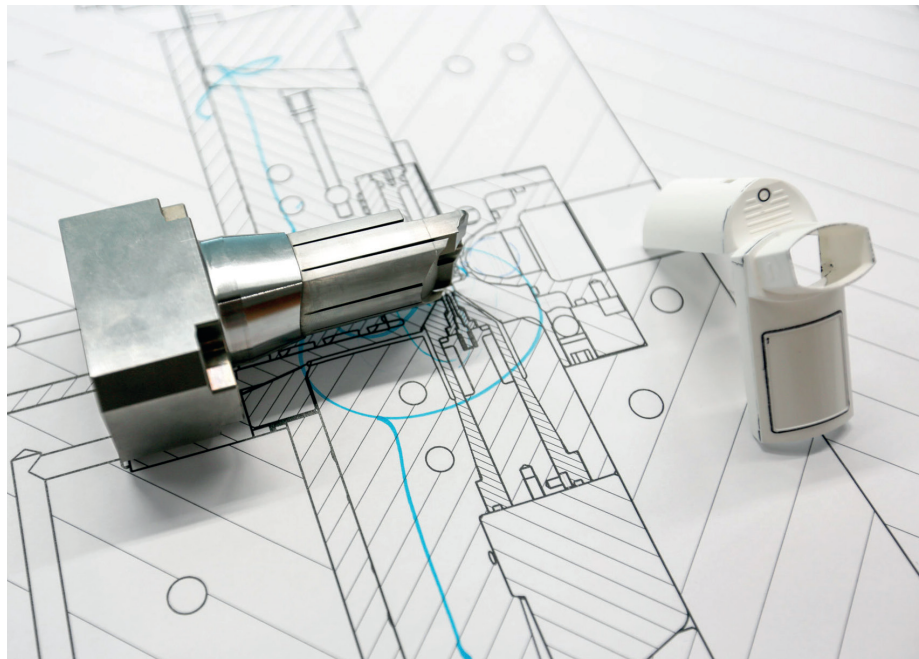


Figure 5: Innovation through passion.

“The ideal mould design depends on a project’s exact requirements.”

system retracts the orifice pin to a safe position before the clamp is released and the mould is opened. The system then returns the orifice pin to its original position once the mould is closed again and the clamp force has already been applied. This solution extends the lifetime of the pin and prevents bending and breaking problems.

A PASSION FOR PRECISION

This article has presented several solutions that the engineering team at IGS GeboJagama has developed over the past two decades. Of course, the ideal mould design depends on a project’s exact requirements. The mould features described in this article can help

to meet those project requirements through greater uptime, fewer problems and a lower total cost of ownership (Figure 5).

Through smart technical solutions, moulds can minimise loss of medicine in the device. It allows patients to rest assured that exactly the right amount of medicine is being administered. It is just one example of how IGS GeboJagama’s passion for precision touches billions of lives every day.

ABOUT THE COMPANY

IGS GeboJagama is a high-precision mould maker, headquartered in the Netherlands. The company designs, manufactures, validates and maintains moulds for products where extreme precision is vital: from glasses and contact lenses to asthma inhalers, insulin pens and blood diagnostic devices. IGS GeboJagama specialises in collaborating with medical original equipment manufacturers early in the product lifecycle, allowing its engineering team to develop innovative moulding solutions.

ABOUT THE AUTHORS

Rob Doorackers is Chief Innovation Officer at IGS GeboJagama, where he focuses on optimising production processes, continuously improving product quality and finding innovative solutions to solve the most challenging technical challenges. Mr Doorackers has over 30 years of experience in the injection moulding and manufacturing industry.

Erwin van Huijksloot is Senior Sales Manager at IGS GeboJagama, responsible for the commercial relationship with healthcare customers, with a focus on partnership and long-term customer relations. He has more than 20 years of experience in sales in the injection-moulding industry and has worked for IGS GeboJagama since 2010.

High Precision Moulds

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300+ MOULDS MANUFACTURED ANNUALLY

When it comes to people's health, nothing but the very highest standards will do. That's what drives IGS GeboJagama to push the envelope every single day. Based in the heart of the most prominent technology hub of Europe, we have assembled a team of world-class engineers. Through their ambition and creativity, we develop cutting-edge and highly reliable moulding solutions for the healthcare market.

IGS GeboJagama combines unrivalled technical expertise, smart innovations and rigorous testing with the latest technology and the highest specifications of materials. By working closely with medical OEMs early in the product life cycle, we allow our clients to take full advantage of our engineering power. It's how we deliver unique, innovative solutions that give our clients an edge over their competitors.

Let's innovate together

Join us in creating the future of injection moulding and discover how our team can make your production easier, faster and less expensive.

