

# Balda

HEALTHCARE



## OMPI EZ-FILL® INTEGRATED TIP CAP: PRODUCTIVE SUPPLY CHAIN SYNERGIES BETWEEN OMPI & BALDA

In March 2016, Stevanato Group, specialising in glass pharmaceutical primary packaging, glass converting machines, visual inspection systems, assembling and packaging machines for the pharmaceutical industry, acquired the operating units of Balda Group. The German group specialises in high quality and high precision plastic solutions for the healthcare segment and medical device applications. In this article, Alessandro Artioli, Core Team Leader, and Alessandro Morandotti, EZ-fill Syringes Product Manager, both of Ompi, and Paul Wismer, Business Development Manager at Balda, look at the first example of integration between the two companies: the Ompi EZ-fill® Integrated Tip Cap.

The Ompi EZ-fill® Integrated Tip Cap (ITC) is the first product created by moving from a glass component to the integrated system for pharmaceutical use. Technical studies and tests on torque force and pull force have led to a perfect fit between the glass components of Ompi, and Balda plastic components.

“What if you can combine the glass/syringe expertise together with injection moulding as well as device technology to provide complete solutions or even solution platforms, to help patients in their daily lives?”

It incorporates a twist-off closure system for Luer lock cone syringes. With an easy twist-off functionality, it provides improved usability for final users without compromising the integrity of the prefilled syringe itself. The ITC is the result of a rubber component (Tip Cap, rubber

formulations: 7025, 7028, FM27, FM30) inserted in a rigid plastic cap, screwed onto a Luer lock adaptor and then pre-assembled on the Ompi EZ-fill® Syringe. Its functional performances in terms of torque force and pull force are determined by the Luer lock adaptor, in particular, by the inner hole diameter, as well as the length and thickness of the ribs.



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		Vaccines	Hyaluronic Acid	Other Viscous	Biotech Drugs
	1ml std	●			●
	1ml long		●	●	●
	1.5ml	●			●
	2.25ml		●	●	●
	3.00ml		●	●	●
	5.00ml		●		

Figure 1: Comparison between Ompi Luer Lock Tip Caps.

Luer Lock Adapter (LLA)	Originalitäts Verschluss Spritze (OVS)	Ompi EZ-fill® Integrated Tip Cap (ITC)
<ul style="list-style-type: none"> <li>Original Luer lock option introduced to the market.</li> </ul>	<ul style="list-style-type: none"> <li>Tamper evident Luer Lock solution offered as an alternative to a twisting system.</li> </ul>	<ul style="list-style-type: none"> <li>Luer Lock twisting system</li> </ul>
<ul style="list-style-type: none"> <li>It is still wide-spread for some applications, but above all, it is used in specific countries.</li> </ul>	<ul style="list-style-type: none"> <li>Less wide-spread than the twisting solution but it was introduced in case the company wants to differentiate from the Ompi EZ-fill® Integrated Tip Cap (ITC)</li> </ul>	<ul style="list-style-type: none"> <li>Worldwide use due to the intuitive opening movement</li> </ul>
<ul style="list-style-type: none"> <li>LLA is less common for the vaccines market and it is used for diluent and water liquid products.</li> </ul>	<ul style="list-style-type: none"> <li>Different applications: diluent, vaccines, HA and Biotech</li> </ul>	<ul style="list-style-type: none"> <li>Different applications: diluent, vaccines, HA and biotech</li> </ul>
<ul style="list-style-type: none"> <li>Compatible with existing needle hubs</li> </ul>	<ul style="list-style-type: none"> <li>Compatible with existing needle hubs</li> </ul>	<ul style="list-style-type: none"> <li>Compatible with existing needle hubs</li> </ul>

Table 1: Ompi EZ-fill Integrated Tip Cap (ITC) typical application.

With its screw functionality, Ompi EZ-fill® ITC is a revolution in the Ompi EZ-fill® Syringes world. Its optimised design on the glass cone has been developed in order to assure the best match possible with our glass prefillable syringes. At the same time our offer provides more options to pharmaceutical companies. As shown in Table 1, Ompi EZ-fill® ITC has been developed for different syringes sizes: 1 mL std, 1 mL long, 1.5 mL, 2.25 mL, 3 mL, 5 mL. In the future, Ompi plans to offer Ompi EZ-fill® ITC in an even wider range of syringe sizes.

The target markets for the Ompi EZ-fill® ITC are: vaccines, hyaluronic acid and biotech drugs. Comparing with other suppliers' tip caps, the absence of ceramic coating on the cone avoids the Ompi EZ-fill® ITC rotation and this is a clear advantage as ceramic coatings create lots of particles. As regards the customisation, Ompi EZ-fill® ITC is available with coloured rigid caps according to customer needs, but the translucent plastic parts will be the standard.

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#### DIFFERENCES BETWEEN LOCK TIP CAPS

There are several differences between Ompi EZ-fill® ITC and the other Ompi Luer lock tip caps, as shown in Figure 1.

Thanks to the collaboration between Ompi and Balda, the Ompi EZ-fill® ITC solution focuses on many different aspects, above all on cone breakage. Thanks to the twisting system and the torque- and de-torque forces, the cone of the syringe doesn't need to be broken any more which means better safety for patients by avoiding the risk of scattering glass pieces into drug.

#### BALDA'S ROLE IN THE OMPI EZ-FILL ITC PROJECT

What if you can combine glass/syringe expertise together with injection moulding as well as device technology to provide complete solutions or even solution platforms, to help patients in their daily lives? That is exactly what Stevanato had in mind when acquiring the operating units of Balda earlier this year. Balda brings decades of experience with hand-held devices and consumables made of plastic, serving various customers in the healthcare markets.

Balda is a “one-stop” player in the contract development and manufacturing organisation (CDMO) landscape, providing everything from idea generation to prototyping, to high-volume manufacturing to logistics solutions; and this all throughout the lifecycle of a medical product. The core competency is injection moulded polymer plastics, but Balda has surrounded this core with a myriad of other services. Assembly, often fully automated, completes the manufacturing process. This can be done in clean-room conditions as strict as ISO5, thus meeting the demands of many pharmaceutical projects. Balda, with operations in Germany and California, can serve a global base of customers and provide the needed regulatory support for both FDA- and EU-regulated markets. Balda possesses the relevant certifications, such as ISO 13485, in order to serve the high level of quality demanded by international healthcare clients.

However, projects often start in the idea stage. Here Balda conducts an innovation workshop with, and does necessary freedom-to-operate research for, its clients. After completion of this step, actual product development will start, i.e. once the idea (or ideas) exist. Balda then uses modern proven methods in this all-important stage: design-to-cost, design-for-manufacture, design-for-quality and even design-for-disposal to address the ever-increasing demand to reduce the environmental footprint, are all part of the DNA of



Figure 2: Ompi EZ-fill® Integrated Tip Cap (ITC).

Balda. Using 3D or rapid prototyping, the first look and feel of the product can be presented to the client and modifications developed before moving to more rigorous testing or even clinical phases.

Once full industrialisation and production is to start, Balda can deploy its high-precision capabilities on over 200 state-of-the-art injection moulding machines. Based upon over 60 years of experience, Balda is ready to meet the most demanding of specifications of any client project. Whether two- or three-component moulding, over moulding or metal substrates, Balda engineers can come up with the best solution at the highest level of quality. Manufacturing/assembly can be done with 100% control, using modern laser, camera or other electronic monitoring systems. Needless to say, a 100% traceability is designed into the process, which is another critical customer demand that must be met.



Figure 3: Ompi EZ-fill® ITC Nest&Tub.

Finally, a product can only help patients if it gets to the right place at the right time. Warehousing, safety stock holding and distribution to our clients' worldwide logistics hubs, or even directly to their sales chain, are all services Balda provides. Via integration into a customer's enterprise resource planning (ERP) system, quick and error-free management of the logistics process is made easy.

“Ompi's lead in glass primary packaging for pharmaceutical use and Balda's specialisation in plastics and delivery devices, the synergies between them as well as the integration of the two “know-hows” permit the creation of high-quality, fully integrated products.”

Ompi and Balda put together a teamwork of expertise that, working hand-in-hand, provides the best solution for Stevanato Group clients, such as the Ompi EZ-fill® ITC system.

Ompi EZ-fill® ITC is a new component to add to the current offer of EZ-fill® syringes that will play a key role into the expansion of the EZ-fill® line in the

market (Figure 2). For this reason, it has its own dedicated nest and tub (Figure 3). However, the process of filling and finishing will not be subject to changes in those lines.

### PHASES OF THE INTEGRATED TIP CAP PROCESS

In the EZ-fill® environment, the Ompi EZ-fill® ITC process is the same as for syringes and can be described in the following phases:

- **Incoming materials:** syringes are supplied to the EZ-fill® area (ISO7 and ISO5 under laminar flow).
- **Washing:** in the washing machine using water for injection (WFI).
- **Siliconisation:** syringes are siliconised with a high-performance layer distribution process.
- **Packaging:** the final steps place the syringes into Nest&Tub packaging solutions, which is then sealed with a Tyvek® lid and finally packaged in steribags and case-pack allowing for sterilisation. As much attention is given to the cleanliness of the packaging components as to the production of the glass container itself. Final configuration includes packaging in pallets.
- **Final sterilisation:** filled tubs/tray in steribags are sterilised by Ethylene Oxide (EtO). EtO sterilisation is mainly used to sterilise medical and pharmaceutical products that cannot support conventional high-temperature steam sterilisation. This process is completed by aeration. (Further developments/validation of alternative terminal sterilisation methods are ongoing, as requested from most of the top pharmaceutical companies.)

### CONCLUSION

Balda, joining Stevanato Group and closely collaborating with Ompi, is leveraging value for pharmaceutical and healthcare customers. This allows the development of a wider, more integrated and more efficient value proposition. Considering Ompi's lead in glass primary packaging for pharmaceutical use and Balda's specialisation in plastics and delivery devices, the synergies between them as well as the integration of the two “know-hows” permit the creation of high-quality, fully integrated products.



## Integrated Tip Cap (ITC)

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A twist-off  
closure system  
for prefilled  
syringes

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