



STEVANATO GROUP AND EITAN MEDICAL BRING NEXT-GENERATION WEARABLE DRUG DELIVERY SOLUTIONS TO MARKET

In this article, Chiara Mussoi, Product Manager for the Cartridge Platform, and Riccardo Prete, Product Manager for the Vial Platform, both of Stevanato Group; and Mindy Katz, Vice-President, Marketing and Alliance Management – Pharmaceutical Solutions at Eitan Medical, outline the benefits of collaboration when it comes to bringing wearable drug delivery solutions to market.

The collaboration between Stevanato Group and Eitan Medical (developer of the Sorrel wearable injection device platform) is founded on the principal aim of bringing to market wearable injection solutions for the simple and efficient subcutaneous administration of large-volume and high-viscosity medications that serve the interests of both patients and pharmaceutical companies. As a leading producer of primary packaging and integrated capabilities for drug delivery systems, Stevanato Group plays a key role in the optimisation of primary containers – both cartridges and vials – for integration into large-volume wearable injectors.

The collaboration began with the development of cartridges to serve as primary drug reservoirs for Eitan Medical's Sorrel wearable device line, later expanding to include the supply of glass containers for vial-based configurations of the device. Sorrel devices are, by design, primary-container agnostic, being able to accommodate a variety of different container types in a range of volumes and dimensions. Although not tied to a specific primary container manufacturer or proprietary design, the unique collaboration leverages the core strengths of both

companies: Stevanato Group's extensive experience in the design and testing of glass primary containers and its position as a leading provider of containment solutions combined with Eitan Medical's development expertise in the area of smart, electromechanical drug delivery and infusion devices.

Both companies are united in their commitment to improve the self-administration experience and outcomes for patients, while helping pharmaceutical partners mitigate risks and minimise time to market with proven technical, regulatory and manufacturing expertise.

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Figure 1: Primary containers to wearables.



"The Sorrel platform's proprietary technology provides a distinctive solution for drawing medication directly from a vial, while still enabling a prefilled and preloaded configuration."

THE SORREL WEARABLE DRUG DELIVERY DEVICE PLATFORM

The Sorrel wearable drug delivery device platform is designed to provide both a patient-centric and partner-focused solution for the self-administration of large-volume and high-viscosity medications. The prefilled and preloaded configuration encourages adherence to treatment therapies while reducing the risk of medication errors. The incorporation of multiple smart sensors and indicators further guarantees patients a successful self-administration experience (Figure 1).

Because the platform is primary-container agnostic, pharmaceutical companies working with the Sorrel platform enjoy the flexibility to use the primary container of their choice, thus enabling Eitan Medical to collaborate with multiple pharmaceutical partners across a wide range of molecules, volumes and indications. Additionally, the Sorrel platform's proprietary technology provides a distinctive solution for drawing medication directly from a vial, while still enabling a prefilled and preloaded configuration, presenting several advantages to customers. Pharmaceutical partners can thereby save considerable time and risk

by commercialising a combination product with the device constituent being a Sorrel vial-based wearable injector.

Eitan Medical's decision to introduce a vial-based configuration for its Sorrel wearable platform provides a number of key benefits for pharmaceutical partners. Glass vials constitute the most versatile primary packaging containment solution, as almost all pharmaceutical companies already possess internal vial filling capabilities. This can help to ensure compatibility with a wearable drug delivery platform from the initial development stages of new drug formulations, while also enhancing the lifecycle management of those products already on the market with established supply chains.

OPTIMISING GLASS CONTAINMENT SOLUTIONS

Stevanato Group's contribution to the development of the Sorrel wearable devices surpasses the mere provision of glass primary packaging to include technical, analytical and project management competencies that provide fully integrated containment solutions for wearable drug delivery devices. The customised package comprises several key components, primarily high-quality primary packaging in the form of Stevanato Group's SG EZ-fill format. Also included is the identification of the most suitable add-on components according to

the final application and the filling process, leveraging Stevanato Group's proficiency and long history of collaboration with leading closure manufacturers of rubber plunger stoppers, lined caps, front caps and aluminium crimps for cartridges, as well as front caps and aluminium crimps for vials.

Stevanato Group can additionally provide standard and ad-hoc testing of drug-container and container-device interaction within the company's ISO/IEC 17025 certified internal laboratory. Additionally, project management support enables partners to focus their energies on core activities while Stevanato Group co-ordinates parties to provide container closure systems that are ideally suited for the device platform. Internally developed glass converting technologies, scalable and flexible assembly solutions and sterilisation processes allow the company to strictly control all manufacturing parameters relating to drug product quality and safety.

SG EZ-FILL FOR ASEPTIC MANUFACTURING

Stevanato Group's EZ-fill platform provides a fully integrated pre-sterilised solution for aseptic manufacturing, developed in close collaboration with equipment manufacturers in response to the growing demand for increased operational flexibility. Available in a double secondary packaging

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Areas of cosmetic inspection - Vials



Figure 2: Cosmetic controls on Stevanato Group vials.

configuration (nest-and-tub and tray), SG EZ-fill provides an optimal solution for both small-batch and industrial-scale production.

Close collaboration with key providers of ready-to-use closures and add-on components has enabled Stevanato Group to offer systems fully compliant with international regulations. Pharmaceutical companies can therefore easily address specific concerns – such as breakages, cosmetic issues and particle generation – enabling them to devote greater energy to core activities, such as new drug development. Additionally, by using proven packaging, SG EZ-fill is able to maximise filling efficiency by allowing for different filling nozzle combinations. Every aspect of the filling process can therefore be streamlined, from incoming material to final product shipment.

The use of a nest-and-tub configuration confers further key benefits to the SG EZ-fill platform, minimising glass-to-glass contact, increasing cosmetic quality and reducing particles, which results in a lower risk of rejection and waste of drug products, along with higher mechanical resistance, thus reducing the risk of container breakage and further drug loss.

PRIMARY CONTAINER CONSIDERATIONS FOR OPTIMISATION INTO LARGE-VOLUME WEARABLE DEVICES

Using the SG EZ-fill format enables Stevanato Group to provide large-volume primary cartridges ranging from 5 mL to

20 mL that can be integrated into wearable delivery systems suitable for treatment of chronic illnesses. With complete control of the forming conditions, and through continuous product improvement, Stevanato Group can optimise the internal shape of the primary container, thus maximising dosing accuracy. Furthermore, every aspect of the drug reservoir – length, diameter, volume, neck size, flange design and closure – can be customised according to a specific device's technical needs.

With the aim of obtaining a homogenous silicone layer in terms of thickness and distribution, the proper and optimised silicone recipe for each format is defined by a tailored design of experiment study.

Using proprietary siliconisation technology and automatic camera controls guarantees optimal results for gliding profile and good cosmetic appearance.

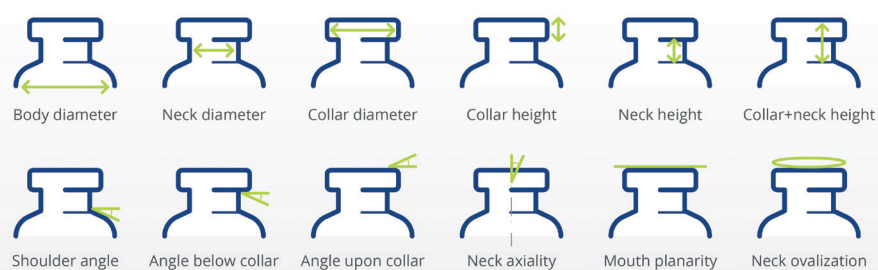
As a full solution provider, Stevanato Group is further able to support plunger development to reduce the dead volume and optimise “glideability” by using the partner's preferred rubber manufacturer, formulation and coating. Moreover, Stevanato Group can pre-assemble cartridges with the customer's closure of choice (for example, a front stopper with or without flip-off) from all major closure manufacturers. Specific in-line cameras are dedicated to control the quality of the crimping to improve container closure integrity.

EVOLUTION OF A PROVEN VIAL SOLUTION FOR INTEGRATION IN WEARABLE DEVICES

Stevanato Group has developed rigorous inspection protocols to ensure compliance with the strictest partner requirements in terms of both dimensional and cosmetic parameters. Dimensional conformance is integral to ensuring compatibility between primary containers and drug delivery devices, while maintaining cosmetic standards reduces the risk of non-quality rejection in fill-and-finish lines, avoiding wastage of valuable drugs (Figure 2).

Dimensional and cosmetic quality of the vials is maintained through automated inspection systems installed in production lines. Cameras positioned before the packing station detect scratches, deformations, bubbles, pressure marks, airlines,

Inspection Controls on the Neck Profile



Internal Controls

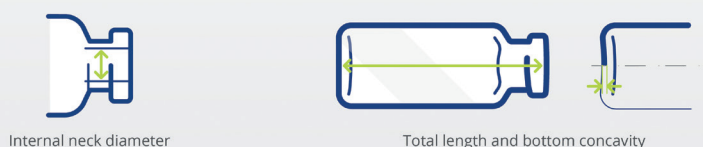


Figure 3: Dimensional controls on Stevanato Group vials.



Figure 4: Sorrel testing of new primary containers in process.

chips and cracks. Manual controls are performed before, during and after both the production process and the SG EZ-fill process. Using specially designed techniques and instruments, quality control teams ensure that all products fully meet both customers' and regulators' quality and dimensional requirements (Figure 3).

SORREL DEVICE ASSESSMENT PROTOCOLS

In addition to the inspection protocols performed by Stevanato Group, once received by Eitan Medical a thorough testing regime is conducted by the verification and validation teams, ensuring that the Sorrel device and the relevant primary container and closure components work together seamlessly.

General dose accuracy testing is performed with any new primary container and components to determine overall device performance and functionality. Needle penetration force and depth measurements are taken for each new device/container/component configuration, optimising the depth to which the needle penetrates the septum to ensure it always clears the rubber partition to enter and draw medication from the primary container.

To ensure proper mechanical fit of the primary container within the Sorrel device, Eitan Medical can easily customise the device's plastic casing to adapt to different dimensions of a primary container. Certain device configurations include an internal adapter that can be employed to allow smaller primary containers to use the same device for testing purposes. For example, the Sorrel fully functional 20R vial-based wearable injector can easily be configured to accommodate 10R vials, allowing pharmaceutical companies to test different vial sizes with just a quick insertion of an adapter in the device assembly line. This is yet another example of how pharmaceutical companies can test products more quickly, and kick off development projects faster, with the platform approach of a medical device manufacturer (Figure 4).

Hold-up volumes of both vial and cartridge primary containers are measured alongside the dead volume within needles to provide an overall understanding of the hold-up volume of the entire wearable system. This allows for primary container fill volumes to be further adjusted as needed to guarantee optimal performance.

To overcome the inherent challenge of maintaining sterility in preloaded devices, the Sorrel devices use UV-C LED technology for

disinfection at the point of care, disinfecting the point of engagement between the primary container and the device's fluid path. Intensive UV disinfection validations are therefore performed on every rubber septum to conform to the six-log bacteria reduction as stipulated by the US FDA for low-level disinfection.

THREE-WAY COLLABORATION FROM THE OUTSET

The collaboration between Eitan Medical and Stevanato Group has resulted in the ability to offer a full portfolio of subcutaneous wearable drug delivery solutions, in both vial and cartridge configurations and across a range of different sizes, that are able to meet any drug development phase, from preclinical studies to lifecycle management, and can be easily adapted to the maturity of a project.

However, when looking to introduce drug delivery combination products to market, it is imperative that all participants – the device manufacturer, primary container manufacturer and drug developer – are brought into play and that collaboration is established as early in the process as possible. As activities are often intertwined, early engagement will ensure

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that interdependencies are considered, and timelines aligned to streamline the entire process. This early co-operation can thus expedite the introduction of new drug delivery systems for the benefit of all parties – the device manufacturer, container provider, pharmaceutical developer and, ultimately and most importantly, the patient.

ABOUT THE COMPANIES

Established in 1949, **Stevanato Group** is the world's largest privately-owned designer and producer of glass primary packaging for the pharmaceutical industry. From its outset, the group has developed its own glass converting technology to ensure the highest

standards of quality. The group comprises a wide set of capabilities dedicated to serving the biopharmaceutical and diagnostic industries: from glass containers with its historical brand Ompi, to high-precision plastic diagnostic and medical components, to contract manufacturing for drug delivery devices, to vision inspection systems, assembly and packaging equipment. Stevanato Group also provides analytical and testing services to study container closure integrity and integration into drug delivery devices, streamlining the drug development process.

Eitan Medical is reimagining drug delivery, with reliable innovations that put patients at the centre of care, making drug delivery easier and safer than ever before. Patient safety and care are only the starting point, as Eitan Medical goes beyond – delivering connected, intuitive drug delivery and infusion solutions that are designed to improve patient and clinician quality of life across the continuum of care, including hospital, ambulatory and home-care environments. For over a decade, Eitan Medical has provided safe, intuitive and flexible solutions that meet evolving drug delivery needs.

Eitan Medical's product lines include the Sapphire infusion platform*, providing connected infusion therapy systems in hospital and ambulatory settings; the Sorrel wearable drug delivery platform**, the patient-centric on-body injector for delivery of biologic treatments; and Avoset***, connected infusion systems for the home-care market.

* Q Core Medical Ltd is the legal manufacturer of the Sapphire infusion pump.

**Sorrel Medical Ltd is the legal manufacturer of the Sorrel wearable drug delivery platform (FDA investigational device).

***Avoset devices are currently under development.

ABOUT THE AUTHORS

Chiara Mussoi is the Product Manager for the Cartridge Platform at Stevanato Group. She is responsible for the development and definition of the go-to-market strategy of glass cartridges (ready-to-use and bulk). After studying Economics and Business Administration at Udine University (Italy) and Copenhagen Business School (Frederiksberg, Denmark), she accumulated extensive knowledge working as a Product Manager for medical devices for injectable products. Since joining Stevanato Group in 2016, Ms Mussoi has been in charge of evaluating and promoting new products that meet customers' needs and expectations

Riccardo Prete is currently part of the Product Management team of Stevanato Group, overseeing the sterile and bulk glass vials business. With a background in Economics and a Master's degree in Business Administration from Ca' Foscari University of Venice (Italy), he joined Stevanato Group in 2017 as a Product Specialist for glass bulk products.

Mindy Katz is Vice-President, Marketing and Alliance Management at Eitan Medical where she heads the company's alliance management, marketing and product management activities for the Pharmaceutical Solutions business unit. Ms Katz's involvement in the company's early days influenced Eitan Medical's decision to pursue the wearable drug delivery market, resulting in the development of the Sorrel wearable drug delivery platform. To date, Ms Katz has held a number of positions within the group, including serving as Vice-President of Marketing and Director of Product at Sorrel Medical, and prior to that as Program Manager at Q Core Medical, where she worked across multidisciplinary teams to build structured and collaborative partnerships between companies in the world of drug delivery. She holds a BSc in Biomedical Engineering from the Technion – Israel Institute of Technology.

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Integrated solutions for pharma & healthcare

Stevanato Group integrates products, technologies and services, providing value-added solutions to improve patients' lives

**Eitan Medical partners with
pharmaceutical & biotech companies**
to bring to market drug delivery and infusion
solutions across the continuum of care –
from the hospital to the home.



We believe in developing tailored solutions to meet the needs of our pharmaceutical partners, with a platform of software-controlled and highly versatile smart infusion pumps and wearable injectors

Dr. Andrei Yosef, General Manager, Pharmaceutical Solutions at Eitan Medical

**Contact our business development team to explore partnership opportunities:
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