



WEIBEL CDS AG
Container Closure Device System Solutions

RECONSTYRINGE®: FULL INTEGRATION OF ALL FUNCTIONS & PARTS, FULLY AUTOMATED RECONSTITUTION

Featuring for the first time in ONdrugDelivery Magazine, Ludwig Weibel, Chief Executive Officer, and Hans Peter Manser, Business Director, both of Weibel CDS AG, introduce the Reconstyringe® system, which offers a fully automated reconstitution of lyophilised drugs.

Safer, easier and faster drug delivery – Weibel CDS AG, Switzerland, develops and produces innovative, user-friendly, application-oriented primary packaging and devices.

The SuperCapSyringe® product family upgrades your vial practically to a prefilled syringe. Based on a modular design, the syringe is fully adaptable to your application needs. It is supplied in different sizes and, as a new offering, with staked needles including a passive safety device.

Following our mission to support safer, easier and faster preparation and administration of injections, all functions and parts needed for a specific drug application are integrated into one product. The user only opens one package and the complete handling is done in a closed system in order to reduce contamination, handling errors and needle-stick injuries, whilst also saving time.

Drug Delivery Systems of Weibel CDS AG are ready to use, no longer requiring the patient to transfer the drug into the system. Based on the MiniBagSystems concept, a unique pump system as well as needle insertion, the device is available for SC and IV injections making the life of patients as well as healthcare professionals much safer and easier. Thanks to a disposable and a re-usable unit the economic footprint is much smaller as the drive unit, controller and batteries are re-used and not discarded once the injection is completed. The final design is according to your specific needs from a functional as well as design perspective.

THE RECONSTYRINGE® CONCEPT

Our Reconstyringe® product family is first in offering a fully automated recon-

stitution of lyophilised drugs. This product line is presented in detail in this article.

TODAY'S SITUATION

One-third of parenteral drugs sold in vials are lyophilised. Especially for cytostatic drugs, the procedure the healthcare professional is required to go through can be not only cumbersome but also requires special attention as often the reconstitution needs to take place under laminar flow. Today, conventional reconstitution and administration of lyophilised drugs requires as many as 22 individual steps (see Figure 1). Not only are these 22 steps and associated handling time inconvenient, but there is also substantial potential for contaminations as well as handling errors including needle-stick injuries, as single-use syringes are not commonly available with a passive safety system.

Despite numerous solutions available to facilitate reconstitution, none of these concepts is significantly changing the process itself. In contrast, we believe in full integration of all functions and parts, plus full automation of the reconstitution process.

RECONSTITUTION – LISTENING TO THE MARKET

Market feedback is suggesting that a new approach is required and is asking for a “Swiss watch” approach. In response to numerous experts in the industry as well as hospitals, Weibel CDS AG has developed an innovative reconstitution system including the features of the SuperCapSyringe®, combined with the MiniBagSystem (described



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RECONSTITUTION: TODAY

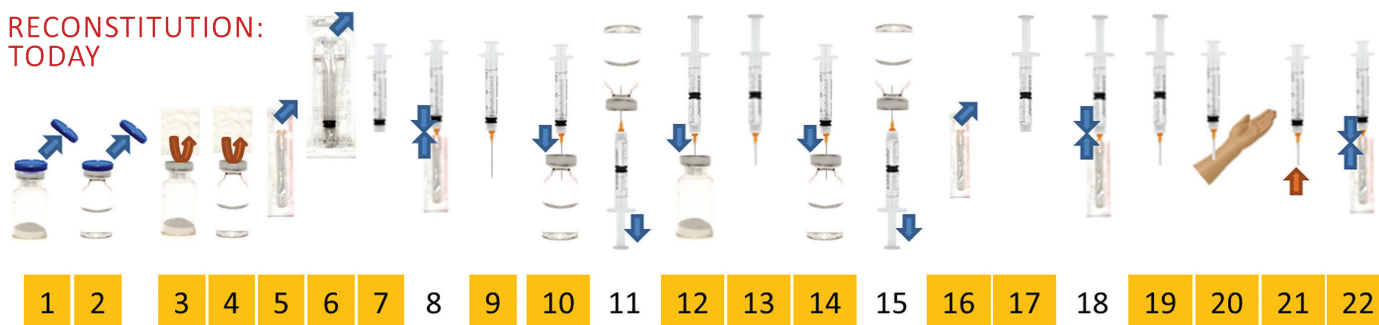
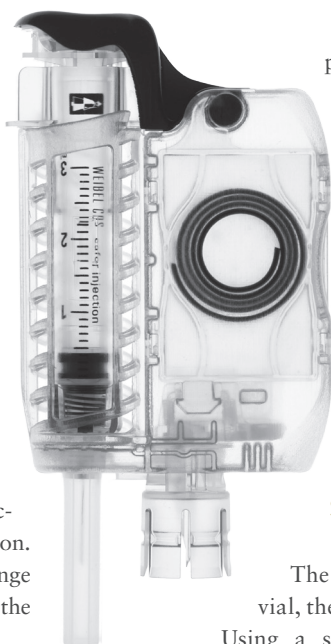


Figure 1: Conventional reconstitution and administration of lyophilised drugs requires as many as 22 individual steps.

Figure 2: Diagram showing the internal mechanism of the Reconstryng® including the holding plates and spring.

below) to hold the solvent, and an innovative technique to automate the reconstitution procedure. The design is such that no batteries or drives are required and the complexity is reduced to a minimum thus reducing the risk of malfunction. Most importantly, no change is required with regards to the formulation of the drug.



port to enable filling and discharging limiting overfill to an absolute minimum. Multilayer foils have been chosen as base material to provide lowest levels of gas and water vapour permeability close to glass. Inside the Reconstryng®, the MiniBagSystem holds the solvent.

AUTOMATED RECONSTITUTION: ONLY EIGHT INTUITIVE STEPS

The drug is contained in its original vial, the solvent in our MiniBagSystem. Using a spring mechanism and holder plates (visible in Figure 2) the content of the MiniBagSystem is emptied into the vial. With the precision of a Swiss watch, the system runs through the full reconstitution cycle. Finally, the drug is drawn into a SuperCapSyringe® for injection (see Figure 3).

After withdrawal of the syringe, a passive safety system slides over the needle, providing the highest levels of protection against needle-stick injuries.

Reconstryng® is available in 1 mL, 3 mL, 5 mL and 10 mL versions, all remaining in a very compact format of single-use syringes including the one-piece safety device.

Reconstryng® offers full integration of all functions and parts plus full automation of the reconstitution process. The advantages for the end user are:

- Reduction in contamination
- Reduction in handling errors
- reduction in needle-stick injuries
- and a gain of time.

Reconstryng® allows pharma companies both to pass on these benefits to the end user and differentiate themselves from competition.

Weibel CDS has several international patents pending for Reconstryng®.

SuperCapSyringe® and Reconstryng® are registered trademarks of Weibel CDS AG, Switzerland.

MINIBAGSYSTEMS

Weibel's MiniBagSystem represents a revolutionary concept providing a platform for various drug delivery systems. MiniBagSystems are designed with a unique

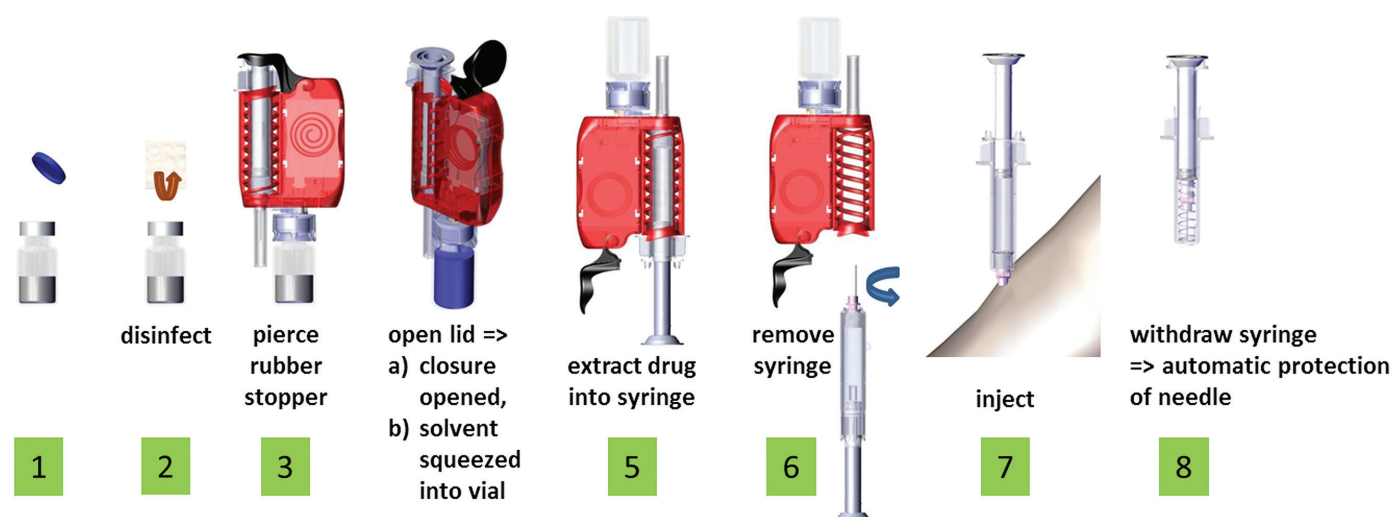


Figure 3: The Reconstryng® runs through the entire reconstitution cycle, reducing the injection procedure down from as many as 22 steps to just eight intuitive steps.

RECONSTYRINGE®



Our **Reconstyringe®** product family is first in offering a fully automated reconstitution of lyophilised drugs. The drug is contained in the original vial, the solvent in our MiniBag. Like a Swiss watch, it runs through the full reconstitution cycle. Finally, the drug is drawn into a **SuperCapSyringe®** for injection.

**safer, easier and faster
drug delivery**

Reconstyringe® and **SuperCapSyringe®** are registered trademarks of Weibel CDS AG



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