



WEIBEL CDS AG

safer, easier and faster drug delivery

LYCAJECT: AUTOMATIC RECONSTITUTION PATCH INJECTOR

Here, Hans Peter Manser, Chief Executive Officer; Christoph Egloff, Chief Technology Officer; and Martin C King, Head of Quality & Regulatory; all of Weibel CDS, introduce the LyCaJect Patch Injector, the company's offering in the field of wearable injectors, with automatic reconstitution as a headline feature.

LYCAJECT

Following its mission to support safer, easier and faster preparation and administration of drugs, Weibel CDS has developed the LyCaJect Patch Injector, a wearable drug delivery platform with all functions and parts needed for a specific drug administration integrated into a single

"The LyCaJect Patch Injector platform is a cartridge-based system and is designed to be ideal for self-use in a non-clinical environment."

product (Figure 1). The user only opens one package and the complete handling of the drug is done wholly in a closed system, reducing the risk of contamination, handling errors and needlestick injuries, as well as proving to be a time-saving and convenient product.

LyCaJect features:

- Drug product integrated during final assembly, never touched by the user
- Automatic reconstitution of lyophilised drugs
- Safe, automatic needle insertion system.

The LyCaJect Patch Injector platform is a cartridge-based system and is designed to be ideal for self-use in a non-clinical environment. It includes a system for safe, automatic reconstitution of lyophilised drugs, independent of the device's orientation and not requiring the patient or caregiver to perform any handling steps (Figure 2).

LyCaJect is operated by a spring-loaded mechanism and includes a proprietary automatic needle insertion system (ANIS) for subcutaneous injections. The device uses a 27 gauge steel cannula, which is immediately retracted after the injection, leaving only the soft cannula in the



Hans Peter Manser
Chief Executive Officer
T: +41 71 351 73 22
E: sales@weibelcds.com



Christoph Egloff
Chief Technology Officer
T: +41 71 351 73 23



Martin C King
Head of Quality & Regulatory
T: +41 71 351 73 23

Weibel CDS AG
Urnäscherstrasse 51
CH-9104 Waldstatt
Switzerland

www.weibelcds.com



Figure 1: Weibel CDS' LyCaJect Patch Injector.

"The user unpacks the device, which automatically starts the drug reconstitution process. After the patch is adhered to the body, on the thigh, abdomen or upper arm, the injection is executed by simply pressing a button."

tissue offering controlled, painless skin penetration and improved comfort during delivery of the drug. The design is very safe with respect to needlestick injuries, drug reconstitution and dosage accuracy. Additionally, the soft cannula provides maximum wearing comfort.

The slow injection technology used by LyCaJect offers painless drug administration to patients. The injection mechanism is completely mechanical by design, but electronic monitoring sensors provide status information and a display guides the patient through the three steps required for successful administration of the injection.

As LyCaJect is intended for use in both emergency situations and homecare, it was established early on that handling the device needed to be intuitive and all functions, including drug reconstitution, should be fully automatic and handled by the device itself, not requiring any further input from the patient.

In practice, the user unpacks the device, which automatically starts the drug reconstitution process. After the patch is adhered to the body, on the thigh, abdomen or upper arm, the injection is executed by simply pressing a button.

The fluid path, designed for manufacture using gamma sterilisation and combined with a unique sterility concept, assures the full integrity of this combination product throughout its lifespan. As well as the reconstitution of lyophilised products, LyCaJect is capable of performing liquid-liquid mixture too.

The LyCaJect Patch Injector facilitates product differentiation, meeting the current needs and requirements of clients, including improved patient adherence via a holistic user experience. The final design can be customised according to a client's specific needs from

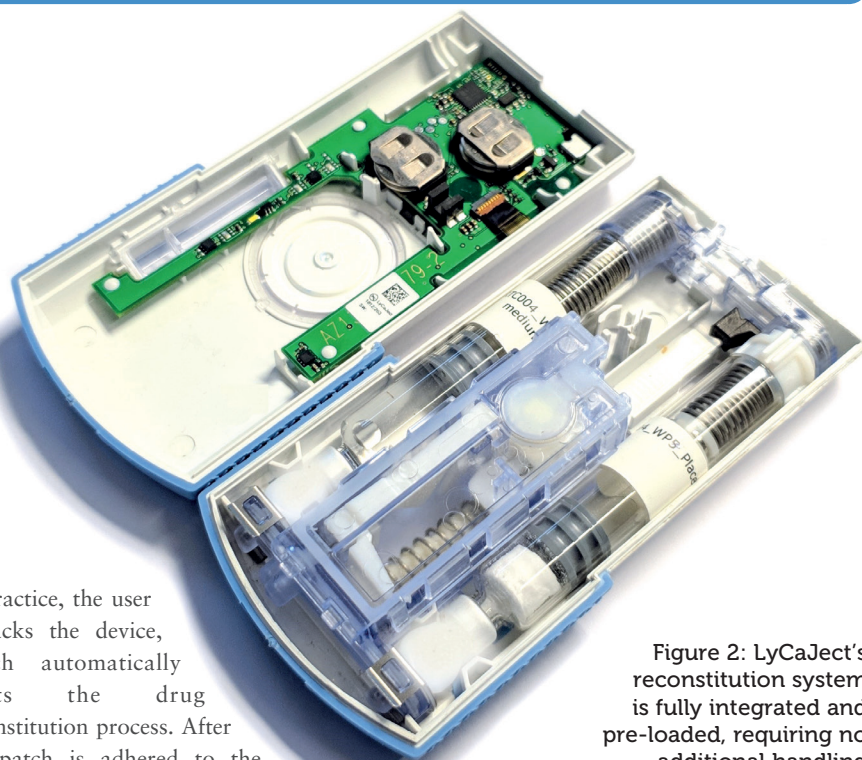


Figure 2: LyCaJect's reconstitution system is fully integrated and pre-loaded, requiring no additional handling steps by the user.

"The LyCaJect Patch Injector facilitates product differentiation, meeting the current needs and requirements of clients, including improved patient adherence."

functional, drug-related and design perspectives (Figure 3).

For liquid drugs, a less complex version is available using a standard 3 mL cartridge, providing a true alternative to conventional autoinjectors. LyCaJect makes the whole self-injection procedure simpler and safer for patients and guarantees a high level of compliance.

WEIBEL CDS PORTFOLIO

Alongside LyCaJect, Weibel CDS offers the following drug delivery systems:

- Large-volume, high-viscosity DRUGDELIVERYSYSTEMS (LVDs) based on Weibel CDS' MiniBagSystem for micro infusion of up to 50 mL.
- Squeezer based on the MiniBagSystem, enabling fast and easy stability and preclinical testing.
- Standard cartridge-based DRUGDELIVERYSYSTEMS.

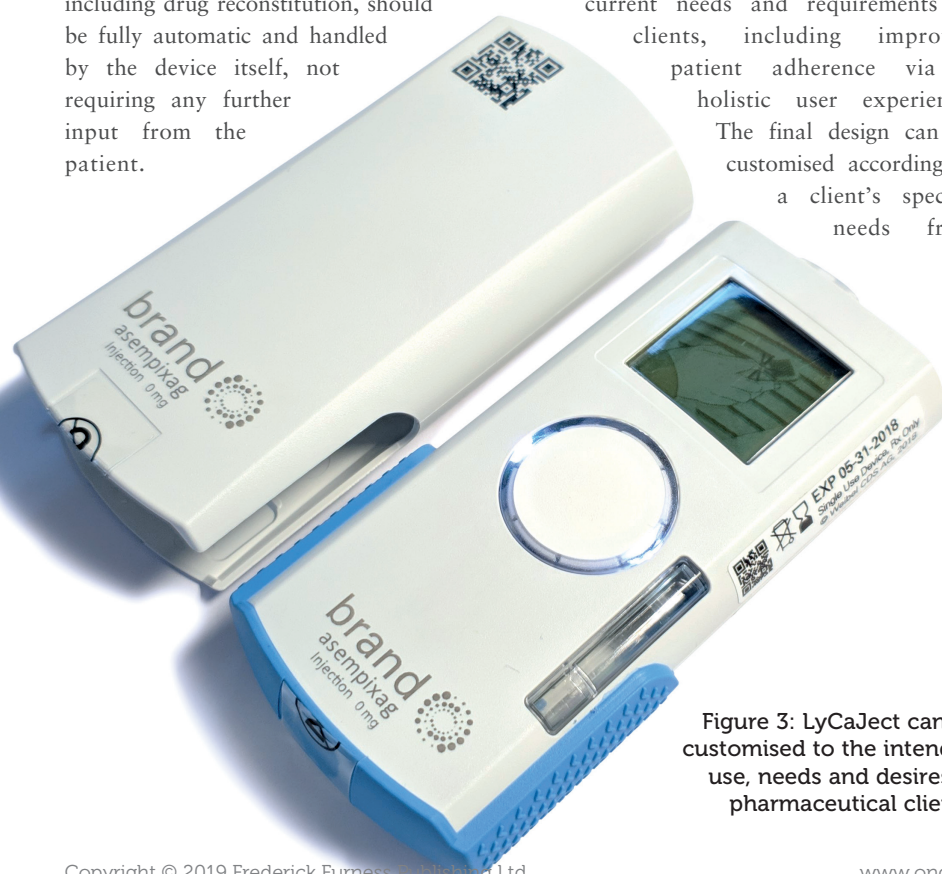


Figure 3: LyCaJect can be customised to the intended use, needs and desires of pharmaceutical clients.

- The SuperCapSyringe® product family for upgrading a vial practically to a prefilled syringe. Based on a modular design, the syringe is fully adaptable to the needs of a given application. It is supplied in different sizes and with staked needles, including a passive safety device.
- The Reconstryinge® product family is first in offering a fully automated reconstitution system for lyophilised drugs. The drug is contained in its original vial and the solvent in Weibel CDS' MiniBagSystem. Using a spring mechanism and holder plates, the contents of the MiniBagSystem is emptied into the vial. Like a Swiss watch, it reliably runs through the full reconstitution cycle. Finally, the drug is drawn into the SuperCapSyringe® for injection.

Weibel CDS AG is holder of numerous international patents. SuperCapSyringe® and Reconstryinge® are registered trademarks of Weibel CDS AG, Switzerland

ABOUT THE COMPANY

Weibel is a privately owned Swiss medical technology company, founded in 2010 and headquartered in Waldstatt, Switzerland.

BOX 1: LYCAJECT SPECIFICATIONS

DIMENSIONS

- Approx. 158 x 75 x 30 mm

WEIGHT

- Full device with medication: approx. 170 g

CASING

- Biocompatible materials
- Shock resistant
- Resistant to pharmaceuticals
- All edges rounded

IP54

- Protected from limited dust ingress
- Protected from water spray from any direction, limited ingress protection

TEMPERATURE RANGES

(dependent on pharmaceutical)

- During operation: 5–40°C
- Storage in shipping case: 5–45°C
- During transport: 2–50°C

AIR HUMIDITY (Relative Humidity)

- During operation: 20–90%
- Storage in shipping case: 5–85%
- During transport: 5–95%

MAXIMUM DELIVERY PRESSURE

- 400 kPa (4.0 bar)

FLOW (Delivery Rate)

- Built in Cartridge size 2 x 3 mL
- Dead Volume 0.2 mL

The company is specialised in customer-funded research and development of affordable, innovative, user-friendly injection systems and devices to ensure safer, easier and faster delivery of parenteral drugs for home, point-of-care and clinical users.

In 2018, the company opened a technology centre in Schaffhausen

specialising in the development, manufacturing and supply of modern parenteral drug delivery solutions serving an international customer base. Weibel CDS is part of a unique medtech cluster in Switzerland that benefits from a high density of precision industry-specialised suppliers with significant medtech know-how.

ABOUT THE AUTHORS

Hans Peter Manser is the Chief Executive Officer at Weibel CDS, holds a diploma in Business Administration and Applied Technical Management. After perennial stays in the UK, Australia, US, France and Germany, he assumed sales management and executive functions in the communications industry with global responsibilities. Mr Manser transitioned to the pharmaceutical packaging industry in 2001 and subsequently joined Weibel CDS in May 2011 as Business Director, responsible for setting up and management of all administrative and commercial aspects of the company, taking over the overall responsibility of the company in October 2016.

Christoph Egloff is the Chief Technology Officer at Weibel CDS. His role covers innovation, technical design, management of the engineering department and project management. Mr Egloff worked on the manufacturing, installation and qualification of SuperCapSyringe®, and development, testing and production for the LyCaJect project.

Martin C King is Head of Quality and Regulatory at Weibel CDS. He has extensive experience in the fields of international medical device development and pharmaceutical management, encompassing all aspects of quality management and regulatory affairs. Mr King has served as a Deputy Swissmedic Responsible Person and Certified Lead Auditor under ISO 13485:2016, with specific expertise in ISO 62304, ISO 14971, 21 CFR 820 and MDSAP.



**We know
drug delivery**
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LyCaJect



Automatic Reconstitution Patch Injector

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International patents pending



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Urnäscherstrasse 51 | CH-9104 Waldstatt

+41 71 351 73 22 | www.weibelcds.ch