WEIBEL CDS AG
Container Closure Device System Solutions

DRUGDELIVERYSYSTEMS: READY TO USE FOR HIGHEST PATIENT COMFORT

Micro-infusion – a new trend in drug delivery? This and other questions are discussed by Ludwig Weibel, Chief Executive Officer, and Hans Peter Manser, Business Director, both of Weibel CDS AG. A novel and innovative approach is presented offering all stakeholders – pharmaceutical companies, healthcare personnel as well as patients – numerous advantages.

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

INJECTABLE DRUG ADMINISTRATION – MARKET VIEW

Only one third of injectable drugs are injected, whereas all others are administered by infusion. These two thirds of the cake are traditionally infused via infusion bags and sets (see Figure 1). Not only is the handling of infusions time-consuming and cumbersome, patients often also lose mobility and are usually confined to bed.

Valuable time of healthcare personnel, as well as high costs for time spent in hospitals, is outweighing the actual cost of drugs by far, thus increasing the total cost of treatment dramatically.

Alternatively, drugs are administered by infusion pumps. Here two different solutions are available. Hospitalised patients are given their treatment via infusion pumps based on 50 mL syringes with the same effect on mobility and confinement to bed as for infusion bags. Mobile patients use small pumps which are either carried in a special holster on a belt or patched to the body. In rare cases the pump may even be implanted.

The most familiar use of this latter category is for insulin, where pump systems are widely accepted. Unfortunately, all systems available today require patients to transfer the drug from a container (for example, a vial) into the pump by using a syringe. Self-medication is heavily dependent on the ability of the patients to prepare and manipulate the injection device. For any patients with reduced manual dexterity, such as those with Parkinson's disease and requiring apomorphine, this can be a major issue.

> "Weibel CDS has developed DrugDeliverySystems, which are ready to use, and no longer require the patient to transfer the drug into the system"

New systems are being developed, but most still rely on a tube as a connection between pump and catheter.

Figure 1: Traditional infusion sets.

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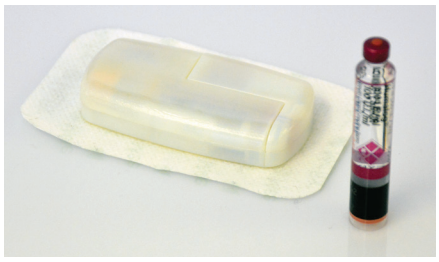

Figure 2: Small yet incorporating all functions.

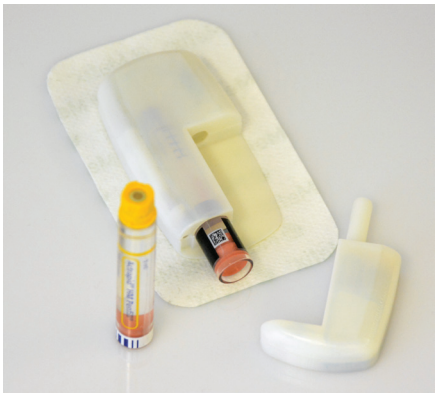

Figure 3: Available for all 3 mL cartridges.

Figure 4: The MiniBagSystems-based DrugDelivery System.

MICRO-INFUSION – A NEW TREND IN DRUG DELIVERY?

Subcutaneous Infusion

The positive feedback from diabetics in using micro-infusion pumps subcutaneously has prompted the pharmaceutical industry to evaluate such systems for other drugs requiring repeated daily or even hourly SC injections, such as apomorphine for Parkinson's disease, or interferon beta for multiple sclerosis. But also for diabetics the end of the rope has not been reached as one of the major elements still need to be implemented – ready to use, prefilled systems are required to really mark a break through.

> "Ready to use, prefilled drug delivery systems are required to open up a new era in drug administration"

Intravenous Infusion

Patient mobility and changes in drug administration will require new drug delivery systems that allow for total freedom to move as well as long-term treatment. Studies suggest in some cases a better drug acceptance and, more importantly, improved long term results if cytostatic drugs, for example, are administered starting with a bolus injection at the hospital followed by a long-term basal injection. The big challenge for such systems is again to be ready to use as well as prefilled, since handling by the patient may lead to dangerous situations due to the toxicity of the drug. In addition the container size may no longer be adequate if only around 1-3 mL. Large-volume containers up to 30 mL will be needed creating a huge challenge as the size of the device itself should still be small. Especially as glass containers holding 30 mL have diameters of up to 30 mm.

NOVEL DRUGDELIVERYSYSTEMS BY WEIBEL CDS AG

Weibel CDS has developed DrugDeliverySystems, which are ready to use, and no longer require the patient to transfer the drug into the system. Two versions are available, one for standard 3 mL cartridges as well as one using Weibel's MiniBagSystems, scalable from 1-30 mL.

CARTRIDGE-BASED DRUGDELIVERYSYSTEMS

Designed to accept standard 3 mL insulin cartridges of all insulin manufacturers, the cartridge-based DrugDeliverySystems are barely larger than the cartridge itself (see Figure 2). The system is extremely small yet still incorporates all functions including a unique pump system, a needle insertion system, a battery, a drive and an electronic control unit. The pump system is powerful, guaranteeing that it will overcome the break-loose forces and maintain the smooth gliding of the rubber stopper throughout the injection.

The cartridge may be pre-assembled by the pharmaceutical company or alternatively a solution is available offering the patient the option to choose the insulin supplier themselves (Figure 3).

The device is patched to the body, often the abdomen, and may be operated via an external control unit allowing the patient discreet use.

MINIBAGSYSTEMS-BASED DRUGDELIVERYSYSTEMS

Weibel's MiniBagSystems are a revolutionary concept providing a platform for various drug delivery systems (Figure 4). MiniBagSystems are designed with a unique port to enable filling and discharging, thus limiting overdosing to an absolute minimum. Multilayer foil has been chosen as the base material to provide the lowest levels of gas (including water vapour) permeability, close to those of glass. Long-term stability studies with protein-based drugs have shown positive results at >1.5 years, and still ongoing.

Size is a big advantage of MiniBagSystems as they remain flat, even for versions holding 30 mL (Figure 5). Combined with a unique pump system, a needle insertion system, a battery, a drive and an electronic control unit, the device is available for subcutaneous infusions. The automatic needle insertion system includes a soft cannula and the steel needle is permanently withdrawn.

For intravenous infusion, replacing today's gravimetric systems and larger pump systems, the device is available with a tube and cannula. Again patched to the body, the system offers patients total freedom to move.

RE-USABLE VERSUS FULLY INTEGRATED SOLUTIONS

A re-usable unit containing the drive, battery and the electronic parts allow for a highly economic footprint. Yet, as these parts will be used for one year or

Figure 5: Size comparison up to 30 mL.

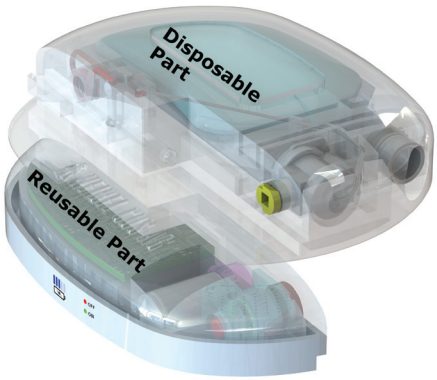

Figure 6: Re-usable and disposable parts.

more and are not discarded after every infusion, more durable and expensive components can be chosen. Additional components, such as a pressure sensor, can be added to offer controlled and guaranteed system reliability.

The disposable part includes the drug container, pump and the needle insertion system as all parts in contact with the drug or blood need to be discarded (Figure 6). Thanks to the soft cannula and retracted steel needle the risk of needle stick injuries is eliminated.

Market acceptance, however, may demand for a fully integrated solution. For such components are available with a guaranteed life time over e.g. a certain number of turns as for the drive.

Weibel CDS offers all DrugDeliverySystems in re-usable / disposable or fully integrated versions as finally the market and individual customers will decide on the solution chosen – re-usable / disposable or fully integrated.

Besides **DrugDeliverySystems**, Weibel CDS supplies injection devices such as:

- The **SuperCapSyringe®** product family upgrades your vial practically to a pre-filled syringe. Based on a modular design, the syringe is fully adaptable to your application needs. It is supplied in different sizes and, as a novelty, with staked needles including a passive safety device.
- The **Reconstyringe®** product family is first in offering a fully automated reconstitution of lyophilised drugs. The drug is contained in its original vial, the solvent in the MiniBagSystem. With a spring mechanism and holder plates the content of the MiniBagSystem is emptied into the vial. Like a Swiss watch, it runs through the full reconstitution cycle. Finally, the drug is drawn into the SuperCapSyringe® for injection.

(Both the **SuperCapSyringe®** and the **Reconstyringe®** were discussed in greater detail in ONdrugDelivery Magazine, 2015, Issue 55, pp 66-67.)

International patents pending. SuperCapSyringe® and Reconstyringe® are registered trademarks of Weibel CDS AG, Switzerland.

> "The system is extremely small yet still incorporates all functions including a unique pump system, a needle insertion system, a battery, a drive and an electronic control unit."

DrugDeliverySystem

DrugDeliverySystems of Weibel CDS AG are ready to use and prefilled – available for standard 3 ml cartridges as well as with MiniBagsSystems scalable from 1 to 30 ml

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International patents pending

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