PHARMAPACK
Drug Delivery & Packaging

INNOVATION GALLERY eBOOK

2021

Patient / User Safety

Ease of Use

Eco-friendly

Patient Adherence

Cost Effective

#PharmapackEU

For further info please contact: salesoperations@informa.com
www.pharmapackeurope.com

informa markets

INDEX 2021

EXHIBITOR INNOVATIONS

SYCARE

2021

Company name: Althena Medical

Country: Italy

Product name: Sycare

Product type: pre-fillable syringe

Date of launch: 04/12/21

Current development phase: Commercialization

Patent: Ongoing

Target markets: Europe, North America

Target clients: Pharmaceutical Companies

Business model: Direct Sales

FACT SHEET

PRODUCT DESCRIPTION

Sycare is a pre-fillable syringe made of COP designed to offer solutions to some fundamental issues that relate to pre-fillable syringes. First and foremost, guaranteeing the integrity of the product it contains for a period that is at least equal to that of the stability of the medicine or of the substance-based medical device, i.e. 3 years. In fact, studies have shown that pre-fillable syringes do not always maintain their sealing power over time. Small quantities of air may penetrate the inside of the barrel, causing the substance it contains to deteriorate, potentially harming the health of the patient, either locally at the injection site, or systemically to the patient's body.

Sycare has been subsequently studied and designed to:

- guarantee the transparency of the barrel even following sterilisation in autoclave;
- the absence of cracks and breakage in the Luer lock area;
- smoother movement of the plunger rod inside the barrel, thus enabling the injection of viscous and ultra viscous substances.

Studies, performed both internally - in accordance with ISO standards - and in external laboratories, confirm that the sealing power of the Sycare syringe remains unchanged even 3 years after it has been filled and that the force required to slide the plunger is significantly lower than the current standards. These studies are available to all, on request.Product description

APPLICATION AREAS

- aesthetic and regenerative medicine, dermatology, orthopaedics, ophthalmology;
- delivery of high viscosity treatment drugs, vaccines.Supporting evidenceApplication areas

KEY FEATURES

- very low sliding force of the plunger in the barrel;
- sturdy and reliable design: prevents the formation of cracks and breakage;
- tested in autoclave up to 3.5 bar;
- remains transparent even after being sterilised in an autoclave;
- available in the following volumes: 0.5 ml, 1ml, 1.0 ml long, 3ml, 5 ml, 6.5 ml, and soon 20 ml and 30 ml;
- screw cap made of transparent COP;
- 100% customisable;
- patented screw cap;
- guaranteed sealing power even 3 years after the syringe has been filled;
- excellent quality/price ratio;
- possibility to customise the finger grip with a logo;
- also available in COC version.

Website: https://www.althenamedical.it/prodotti/

INTEGRATED PATIENT ALERT CARD

2021

Company name: AR Packaging

Country: Sweden

Product name: Integrated Patient Alert Card

Product type: Secondary Packaging

Date of launch: 07/01/21

Current development phase: On the market

Patent: Pending

Target markets: Worldwide

Target clients: Pharmaceutical companies

Business model: Direct sales

FACT SHEET

PRODUCT DESCRIPTION

The Integrated Patient Alert Card unlocks a new level of high line efficiency for secondary packaging with additional information cards. More and more, they are a mandatory part of packaging for some special medicine, to emphasise that patients should not combine intake with other pharmaceutical agents and risk life-threatening interactions. As the cards should be kept close in a wallet, they should be easily detachable from the packaging. Our integrated patient alert card is part of the blank and runs through a uniquely advanced folding and gluing process. For maximised efficiency no separate step is necessary in the packing line. Reverse side printing in one run fully uses the space available to include all language versions. And the small folding style (up to 8 panels) adds convenience for the patient.

APPLICATION AREAS

These kinds of cards are requested more and more – for different products and topics, e.g. organ donor cards, patient alert cards. But until now, the existing solutions reach their limits when it comes to efficiency. They have to be either glued in or dispensed in an extra step.

Our integrated patient alert card provides enough space for all the necessary information for the patient and thus ensures patient safety.

When opening the secondary packaging, the perforation easily tears apart the patient alert card from the packaging. It is simple to use for the customer and with the small folding type, the patient can carry the card conveniently in his pocket all day every day.

KEY FEATURES

The innovative structural design and advanced production process are perfectly co-ordinated with each other to achieve maximum packaging efficiency.

- Structural design is reduced to only one piece: Integration of the card on the 4th flap of the blank - without additional steps for gluing or dispensing
- Efficient manufacturing through inline printing & refined converting process: With inline reverse printing and an advanced process to assemble the blank, the solution enables space for 8 pages for information and multiple language versions
- Facilitates further machineability & handling: Smart folding type of the patient alert card supports smooth dispensing of tablet blisters and leaflets

Website: https://www.ar-packaging.com/en/solutions/integrated-patient-alert-card

OR2PACK®

2021

Company name: ARAYMONDLIFE SASU

Country: France

Product name: OR2pack®

Product type: Primary Packaging

Date of launch: Q4 2021

Current development phase: Industrialization

Patent: Patented 1125-FR

Target markets: Worldwide

Target clients: Implant manufacturers

Business model: Direct sales

FACT SHEET

PRODUCT DESCRIPTION

OR2pack® is an innovative concept for the packaging of sterile implants. Maintaining sterility and traceability of implants during surgery is an absolute necessity to preserve the safety and health of the patient. OR2Pack is a patented solution from ARaymondlife using 2 air-tight square tubes thus allowing staff to transfer implants safely from the non-sterile area to the sterile area in the operating room. Once in the sterile area, this inner packaging guarantees sterile and touchless handling of the implant.

The innovative design of the packaging makes it intuitive and easy to use.

Based on customer feedbacks, a square section for the packaging was designed, not only to avoid tubes rolling and falling from the table, but also to maximize the internal space available to store implants and provide flat surfaces for labelling (thus preventing the need for addition heat shrunk sealing).

The packaging can easily be color coded in 3 different ways to facilitate quick and clear identification of implant and find the right one at a glance. Manufactured in an ISO 5 clean room, this packaging is suitable for different types of implants and available in several sizes.

OR2Pack® packaging concept is a class I medical devices.

APPLICATION AREAS

- Orthopedics
- Extremities
- Spinal and trauma surgery

OR2Pack® is an innovative solution for the packaging of implants (bone screw systems) that provides a double sterile barrier, thus enabling a safe transfer by the surgical staff from the non-sterile to the sterile area of the operating room.

Once in the sterile area, the inner packaging guarantees sterile and touchless handling of the implant.

KEY FEATURES

OR2Pack® is a true innovation for the packaging of implants that simplifies the handling in the operating room and assures full implant traceability.

Developed to comply with ISO 11607 and EN 868 standards for sterile medical device packaging, OR2Pack® is a bi-material part consisting of a rigid square tube with a soft pusher. Both materials are USP Class VI, phthalate and latex free. The product is validated for gamma sterilization.

DOUBLE AIRTIGHT PACKAGING
- Secure
- Tamper evident closure
- Guarantee of product integrity

2 SQUARE TUBES INSERTED INTO EACH OTHER
- Optimized packaging internal volume
- Stable packaging does not roll or fall
- 4 flat sides maximize product labelling

Website: https://www.araymond-life.com/en/customized-solutions

BD Libertas™ Wearable Injector

2021

Company name: BD

Country: Global

Product name: BD Libertas™ Wearable Injector

Product type: Subcutaneous Wearable Injector

Date of launch: Development samples available on request

Current development phase: Design Verification

Patent: Available Upon Request

Target markets: Global

Target clients: Pharma, CDMO, Consultant

Business model: Combi Product Partner

FACT SHEET

PRODUCT DESCRIPTION

The BD Libertas™ Wearable Injector is a hands-free injection system designed to deliver high-volume and/or highly viscous* biologics subcutaneously, at home or in clinical settings. The fully mechanical device design is a pre-fillable drug delivery system for combination products that requires no patient filling or assembly.
*2-10 mL and up to 50cP
BD Libertas™ Wearable Injector is a product in development; some statements are forward looking and are subject to a variety of risks and uncertainties. BD Libertas™ Wearable Injector is a device component intended for drug-device combination products and not subject to FDA 510(k) clearance or separate EU CE mark certification.

APPLICATION AREAS

BD Libertas™ Wearable Injector is designed to deliver subcutaneous injections of large volume (2-5 mL or 5-10 mL) and/or high viscosity (up to 50 cP) fixed dose biologics for applications where handheld autoinjectors may not be feasible or preferred.

REFERENCES

- Woodley, et al. Clinical Evaluation of Large Volume Subcutaneous Injection Tissue Effects, Pain, and Acceptability in Healthy Adults. Clin Transl Sci. 2021 Jul 16. doi: 10.1111/cts.13109.
- Woodley, et al. (2020) Clinical Evaluation of an Investigational 5ml Wearable Injector in Healthy Human Subjects, Clin Transl Sci (2021) 14, 859-869; doi: 10.1111/cts.12946

KEY FEATURES

BD Libertas™ Wearable Injector with Peel, Stick & Click™ feature

The design and development of the BD Libertas™ Wearable Injector is informed by over 50 BD pre-clinical and clinical studies.

- Ready-to-use design requires no patient filling or assembly
- Patented sterile fluid pathway design, supported by testing and validation
- 100% mechanical spring-based power source
  - no battery or heavy metals disposal concerns
  - no software or electronics supplier management and revision controls required
- 2-5 mL device performance and acceptance demonstrated in a clinical study published in a peer reviewed journal

Website: drugdeliverysystems.bd.com/

Intuity® Spray

2021

Company name: EVEON

Country: France

Product name: Intuity® Spray

Product type: Medical device

Date of launch: 01/01/23

Current development phase: Prototype

Patent: WO2021/156573 + WO2021/156574

Target markets: Pharma

Target clients: North America - Europe

Business model: out-license

FACT SHEET

PRODUCT DESCRIPTION

Intuity® Spray is a medical device that allows easy and precise spray or mist delivery of various drugs. This innovative medical device offers a very accurate airless spray or mist delivery for a large range of liquids and gels dedicated to specific applications such as respiratory, dermatology and oral.
Thanks to its fluidic and electronic features, Intuity® Spray is a custom-made solution that provides a safe and efficient solution for precise spray or mist delivery with optimum results.
Intuity® Spray is composed of a reusable device, and disposable and sterile spray nozzle. In addition, digital and connectivity features such as data tracking, data sharing and drug recognition can be added.

APPLICATION AREAS

Respiratory, Dermatology, Oral

KEY FEATURES

- Accurate dosage: control of flow rate and dosage, precise delivery of small dose on large surface area
- Safe: non-contact delivery, non-invasive solution, airless / propellant free, soft and gentle spray or mist
- Easy-to-use: automated or assisted delivery for pratictionner, and delivery to limited access area to improve treatment
- Compact and universal: adapted to standard primary containers (pre-filled syringes, cartridges) for unidose or multidose delivery.

ADDITIONAL RESOURCES

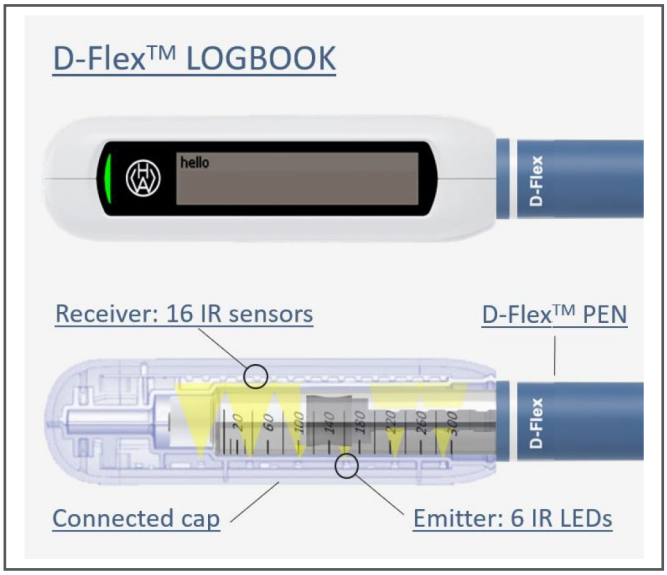
Product Overview: https://www.eveon.eu/images/leaflets/202105-EVEON-Intuity-Spray.pdf

Case Study: https://www.eveon.eu/images/Cases-studies/202108-EVEON-CaseStudy-IntuitySpray.pdf

Website: www.eveon.eu

D-Flex™ LOGBOOK

2021



Company name: Haselmeier GmbH

Country: Germany

Product name: D-Flex™ LOGBOOK

Product type: Connected drug delivery solution

Date of launch: 01/06/22

Current development phase: Clinical studies

Patent: Filed

Target markets: Global

Target clients: Biopharmaceutical comp.

Business model: out-license

FACT SHEET

PRODUCT DESCRIPTION

- The D-Flex™ LOGBOOK is a smart drug delivery system.
- It consists of the fixed dose D-Flex™ Injection Pen and a smart cap, replacing the standard cap.
- It automatically collects treatment data at the point of care.

APPLICATION AREAS

The D-Flex™ LOGBOOK covers your needs from clinical testing to commercial launch. It allows utilization of a commercially viable injection pen already during dose ranging trials. Its Dose Selector Technology enables quick adoption to different dose settings and once reaching commercial launch there is no need for additional human factor or equivalence studies. Furthermore, its connectivity allows you to collect real world evidence at the point of care, complementing your clinical outcome data.

ADDITIONAL RESOURCES

A previous version of the D-Flex™ LOGBOOK has already successfully been tested in a clinical trial with 75 patients.

Publication in Diabetes Care 2019; 42:1129–1131

https://doi.org/10.2337/dc18-1631

KEY FEATURES

- Fixed dose pen, significantly reducing the number of incorrect doses available.
- Dose Selector Technology enables fast pen adoption to therapy changes during clinical trials by reengineering just one single pen component.
- Patient controlled injection time and speed.
- Build-in spring support reduces necessary push force.
- Automatically logs expelled injection dose, temperature and time after each patient injection.
- Stores up to 1000 injection events.
- Independent solution without the need for a patient app.

Website: https://haselmeier.com

FLIPDROPPER

2021

Company name: HEINLEIN Plastik-Technik GmbH

Country: Germany

Product name: Flipdropper (TE Flip top cap with integrated drip function)

Product type: Primary Packaging

Date of launch: 01/01/21

Current development phase: commercialization

Patent: patented

Target markets: worldwide

Target clients: Pharmacy,Medicine,Lifestyle

Business model: Direct sales

FACT SHEET

PRODUCT DESCRIPTION

As an innovative manufacturer of reliable primary packaging solutions, we have developed a new product: The Flipdropper - Its a single-piece flip top cap with tamper-evidence and integrated drip function. The flip top cap can be opened in one easy step after which the contents can be dispensed. Cumbersome unscrewing is now a thing of the past. Upon initial opening, the seal falls into a pocket provided for this purpose. The integrated universal drip function starts dripping as soon as the bottle is turned down. After dosing the liquid can be securely resealed regarding the intuitive push- and pull mechanism. With the Flipdropper you will have a perfect dosage with residue-free product return. Furthermore it offers a quick product access and also a ideal product protection.

APPLICATION AREAS

Pharmacy

Medicine

Food Supplements

Lifestyle Products, like essential oils

ADDITIONAL RESOURCES

Please find more details about the Flipdropper and the product range of Heinlein Plastik-Technik at
https://catalogue.heinlein-plastik.de

Demo Video:
https://www.heinlein-plastik.de/en/innovations#flip-drop-cap

KEY FEATURES

First, the single-piece flip top cap is made out of pharma grade material and is therefore suitable for the pharmaceutical, medicine and also for lifestyle products.

With the GL 18 thread it fits on a wide range of standard bottles in glass or plastic. The Flipdropper is only one piece. This requires a very intelligent tool concept. These flip top cap is a tamper evident closure with double protection between bottle and closure and with a small seal on the flip-top lid, which only breaks when first used. The flip-top cap is very easy to open, even with only one hand. So it s perfect for elderly people. “Flipdropper” pours out liquids with different viscosity and with residue-free product return. So everything stay clean and hygienic. With an elegant and timeless design “Flipdropper” fits to a wide range of bottle shapes. These cap can be processed on all commonly encountered sealing machines.

Website: www.heinlein-plastik.de/en/innovations#flip-drop-cap

Polyfoil® Mono-Material Barrier Tube

2021

Company name: Hoffmann Neopac AG

Country: Switzerland

Product name: Polyfoil® mono-material barrier tube designed for recyclability

Product type: Primary packaging / tubes

Date of launch: 01/09/21

Current development phase: Commercialization

Patent: WO2021/037347A1

Target markets: Europe, North America

Target clients: Pharmaceutical companies

Business model: Direct sales

FACT SHEET

PRODUCT DESCRIPTION

The Polyfoil® Mono-Material Barrier tube (MMB) is a high-performance tube, offering SUPERIOR PROTECTION to pharma formulas and is RECYCLABLE! Due to the application of innovative oriented and combined barrier technologies as well as pharma grade contact layers, the tubes provide excellent product compatibility and maintain premium product protection while keeping the known aesthetic characteristics of Neopac's conventional Polyfoil® tubes.

Combined with HDPE screw and hinge closures, the tube is ready for recycling in the PE rigid streams.

APPLICATION AREAS

Polyfoil® MMB tubes are particularly relevant to the oral care and pharmaceutical sectors, as they sustainably yet responsibly house both consumer items like toothpastes and cosmetics and pharma products in the dermatological or pain-relief sectors.

The new MMB Polyfoil® mono-material barrier tubes provide exemplary product protection while being fully compatible with existing HDPE recycling processes.

Incorporating a novel mono-directional-oriented (MDO) barrier film technology, Neopac's Polyfoil® MMB tubes can reduce tube body weight by as much as 50% compared to the company's conventional Polyfoil® technology. Our goal is to create tubes that simplify recycling – a crucial aspect of next-level sustainability practices. Eco-conscious advancements in the ways plastics are designed and produced are a must as it's demanded by both industry and consumers.

Website: https://www.neopac.com/de/tuben/recylable-polyfoil-mono-material-barrier-tube

Polyfoil® Mono-Material Barrier Tube

KEY FEATURES

• Polyfoil® Mono-Material Barrier tube (MMB) is a high-performance tube, offering superior protection to pharma formulas and is recyclable! Due to the application of innovative oriented and combined barrier technologies as well as pharma grade contact layers, the tubes provide excellent product compatibility and maintain premium product protection while keeping the known aesthetic characteristics of Neopac's conventional Polyfoil® tubes.

Combined with HDPE screw and hinge closures, the tube is ready for recycling in the PE rigid streams.

• **Recyclass Approval**

First Mono-Material Barrier Tubes with HDPE Caps to Receive Full RecyClass Technology & Product Approval

• **AAA rating from cyclos-HTP institute**

Fully printed Polyfoil® MMB tubes with HDPE caps have also obtained the AAA rating from Germany-based testing lab cyclos-HTP, Institute of Recyclability and Product Responsibility, which certifies that the product has a recyclability rate of more than 95%.

• **Reduced product carbon footprint**

The LCA study performed from an independent laboratory according to ISO 14.040/44 resp. ISO/TS 14.067 demonstrates that the "cradle to grave" carbon footprint of Polyfoil® MMB tubes is reduced up to 35% compared to Al barrier-containing Polyfoil® tubes, depending on the wall thickness and end-of-line scenario selected.

ADDITIONAL RESOURCES

Demo Video: https://youtu.be/Q2FCe3aW7Kw

Aclar Edge™ Bottles

2021

Company name: Honeywell International, Inc.

Country: Global

Product name: Acar Edge™

Product type: High barrier polymer bottles

Date of launch: 02/05/20

Current development phase: Prototype

Patent: United States

Target markets: Oral liquids, lab, animal

Target clients: Pharma & Biopharma

Business model: Direct

FACT SHEET

PRODUCT DESCRIPTION

Honeywell Aclar® film has set the standard for high-barrier blister packaging in pharmaceuticals. Now we are transforming the industry with new Aclar Edge™ bottles and vials produced with innovative technology. They have ultra-low moisture weight loss comparable to glass. Aclar Edge™ bottles and vials are lightweight with excellent impact resistance. Order your sample today and see the difference.

APPLICATION AREAS

-Oral liquids
-Animal health
-Vaccines & biologics
-Labware
-Pediatric & formulations
-Custom applications

ADDITIONAL RESOURCES

Aclar Edge Webinar

KEY FEATURES

- Eliminates glass particulates
- Minimizes product loss resulting from glass breakage
- Improved handling safety
- Improved manufacturing efficiency**
- Reduced shipping costs***

** Eliminates glass cleaning and depyrogenation for sterile vials

***Due to lighter weight compared to glass

Website: https://lifesciences.honeywell.com/us/en/products/barrier-packaging/ultra-high-barrier-bottles-and-vials

Nexium Mups

2021

Company name: Körber's Packaging Materials

Country: Switzerland

Product name: Nexium Mups

Product type: Cardboard wallet solution

Date of launch: 01/11/20

Current development phase: On Market

Patent: tbd

Target markets: Pharmaceutical

Target clients: Pharma/Biotech

Business model: B2B

FACT SHEET

PRODUCT DESCRIPTION

Körber is developing a patient-friendly, resealable alternative for wallet packaging. The packaging machine has a smaller floor plan with a significantly higher output; the packaging offers a tamper-evident seal without adhesive strips.

In 2018, Grünenthal, a global pharmaceutical company with headquarters in Aachen (D) and specializing in the indications of pain and related diseases, acquired the European pharmaceutical rights for the gastric drug Nexium® from Astra Zeneca. In the future, 20 million packaging units of the blockbuster are to be produced and packaged every year. The appearance of the packaging must not change under any circumstances in order not to endanger the recognition of the patient and thus the trust in the new manufacturer and the drug. A wallet, a cardboard box folded into a booklet with a glued-in blister, should also serve as packaging. In order to ensure the planned annual production, the packaging system must produce at least 200 wallets per minute. In search of an alternative to the only wallet machine with this performance available on the market, Grünenthal, who has not yet been a Körber customer, approached the packaging specialists in the Pharmaceuticals Business Area.

APPLICATION AREAS

With the combination of a new packaging process and matching packaging, Körber has succeeded in combining the advantages of sleeves - which are mainly used in the food and cosmetics industries - with those of a wallet. Without a folding process and without applying an adhesive strip, a secure secondary packaging is created that shows the tamper-evident seal that is indispensable in the pharmaceutical industry and at the same time can be conveniently reclosed. The ten percent higher machine output outweighs the 100,000 euros higher material costs per year due to the pre-folded, glued packaging.

Website: https://www.koerber-pharma.com/solutions/verpackungsmaterial/wallet-verpackungen

Nexium Mups

KEY FEATURES

Challenge:

Grünenthal plans an annual production of 20 million pieces of the blockbuster Nexium®. The wallet packaging system available on the market, which Astra Zeneca also used for the production of the gastric remedy, achieves the 200 cycles per minute required for this. Due to the high investment costs, Grünenthal is looking for an alternative and is ready to rely on a new development despite the greater risk.

The actual available wallet solution can only offer a performance of 50 wallets per minute and therefore below the requirements. No optical changes may be made to the secondary packaging, different types of packaging are generally out of the question.

Körber is looking for a completely new solution, consisting of a combination of packaging machine, process and packaging material, which is developed around the 'look and feel' of secondary packaging.

Solution:

In close cooperation, the Körber specialists for packaging machines and packaging materials are developing a new packaging process: for sleeves. These are once glued wallets open to the side, in which a blister is glued. The blisters are loaded, sealed and then folded in a thermoforming machine. A robot turns the blisters by 180 °. The pre-glued sleeves are fed to the specially developed packaging machine. This places the blister with glue on the side of the sleeves and presses them on. The sleeves are then assembled in the cartoning machine.

Reliable tamper evident protection:

thanks to pre-perforated sleeves and without additional adhesive tape.

Smaller floor plan:

by eliminating the hemming process. The area of the Körber packaging line is significantly smaller than that of wallet machines.

Resealability:

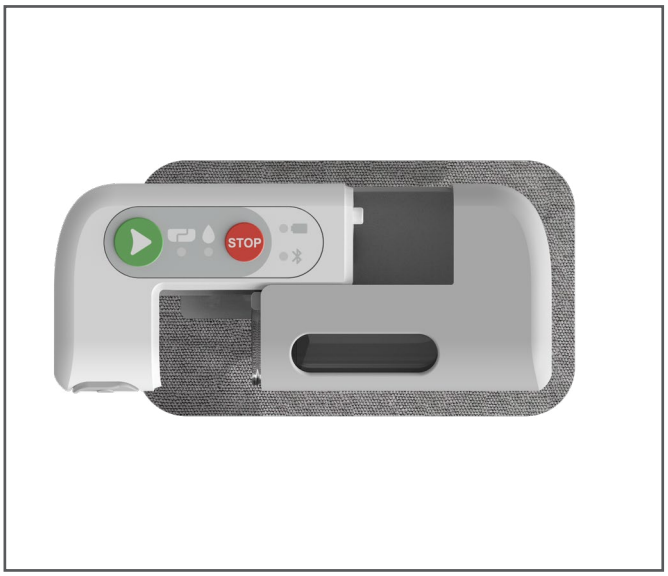
thanks to a flap. Unlike a wallet, the sleeve can be securely closed again and again.

Dismantling to a blister system:

if blisters are to be packed at a later point in time.

Symbioze

2021



Company name: Nemera

Country: France

Product name: Symbioze

Product type: Wearables

Date of launch: 30/09/21

Current development phase: Prototype

Patent: Ongoing

Target markets: North America, Europe

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Nemera's smart on-body injector platform, Symbioze, is an innovative, user-friendly and sustainable solution to self-inject a medication at home. Its unique positioning consists of delivering large volume drugs, especially biologics, in combination with a multiple-use approach, thanks to its reusable and disposable parts. It is suitable for various drug platform and compatible with market-proven cartridges, as well as standard manufacturing process. The cartridge is prefilled and preloaded in the disposable part for patient safety and ready-to-use feature. Symbioze is specifically designed to accommodate large volume injection (20 ml), with flexibility for adjustment to different volumes, flowrates, and viscosities. It also includes connectivity feature, to improve patients' adherence and compliance. To foster patient injection experience, our on-body injector offers a safe and reliable injection thanks to the state-of-the-art engineering, including automatic needle insertion and hidden needle.

APPLICATION AREAS

A rising number of pipelines in biologics and biosimilars requires adequate drug delivery device solutions to accommodate sensitive drugs for safe self-administration. In the Covid-19 pandemic context, patients wish for independence and convenience in managing their drug regimen with reassurance at home, without having to worry about being exposed to the virus at the healthcare facilities. Moreover, the switch from intravenous to subcutaneous drug administration in a home-care therapy setting is emerging, and requiring a robust, reliable drug delivery device to administer high volume and viscosity. To cater to these needs, our smart on-body injector, Symbioze, answers the needs for digital health to foster patient adherence and injection experience.

Our wearable platform is designed for flexibility to be adjusted to any pathology, targeted patient population and drug posology. It is sustainable and cost-efficient for multiple use, thanks to its reusable electronic and disposable parts. Thanks to its connectivity feature, patients and their healthcare professionals could stay in touch and better manage the treatment.

Symbioze offers a highly engineered solution and smart design with unique drug delivery system including following benefits:

- Adaptable to several drug volumes and viscosities
- Adjustable flowrate
- Flowrate control & Failure mode control
- Fully integrated in reusable

Our innovative design enables drug/device assembly in a non-aseptic environment with an embedded sterile connection between the drug container and the delivery system.

Website: https://www.nemera.net/products/parenteral/wearables/

Symbioze

KEY FEATURES

Key features:

- Sustainable and cost-efficient thanks to its reusable electronic and disposable parts
- Enables large volume injection (20 ml with flexibility for adjustments upon needs)
- Ready-to-use: prefilled and preloaded cartridge for patient safety
- Compatible with market-proven cartridges and standard manufacturing process

Key Benefits:

- Architecture can be tailored to match any drug specifications (dose volume, viscosity, flowrate...) which is particularly relevant to biologics drugs
- Secured injection with automatic needle insertion and hidden needle
- Recognition system between reusable and disposable parts for verification and locking
- Ergonomic needle safety cap removal and user-friendly adhesive liner removal
- Possible connectivity feature to improve patient compliance and adherence

DOSEA SMART LABEL

2021

Company name: Neutroplast

Country: Portugal

Product name: DOSEA Smart Label

Product type: Medication Adherence Smart Label

Date of launch: 01/06/22

Current development phase: In Development

Patent: 20211000019816

Target markets: Clinical Trials, Healthcare

Target clients: Chronic Patients, Hospitals

Business model: Manufacturer

FACT SHEET

PRODUCT DESCRIPTION

The DOSEA Smart Label, developed by Neutroplast and Beyondevices together with CeNTI, consists of ultrathin labels with communication and alarm systems integrating printed electronic circuits, adaptable to different types of pharma packaging. The basic system's functionality is a programmable alarm that ensures that medication doses are taken on time by the patients, optimizing medical treatments and clinical trials. Three versions are being developed, to meet different market needs: i. DOSEA BASIC, which through a low-cost printed system, with resistive tracks printed on the label, enables simple programming through button loading on the label itself and ultra-thin battery power supply, ensuring the lowest cost; ii. DOSEA +, integrates an additional E-ink screen that allows the display of the programming status, induction rechargeable battery, and the possibility of being programmed directly by a dedicated mobile app, through NFC; iii. DOSEA Omni, an upgraded version of DOSEA +, integrates a capacitive level sensor attached that allows the validation of liquid or powder medication intake, and also has an induction charging base that indicates the storage conditions of the medication bottles, through measurements of the environment parameters. With the 3 solutions, the DOSEA Dosing Sensor & Alarm project is the most adaptable solution to the market needs, serving lower cost and also more complex solutions, thus ensuring adaptability to different medical treatments. This work was developed in the scope of national project DOSEA (n. 33664), which was co-financed by Portugal 2020, under the Operational Program for Competitiveness and Internationalization (COMPETE 2020) through the European Regional Development Fund (ERDF).

Website: neutroplast.com/projects

DOSEA SMART LABEL

APPLICATION AREAS

Smart Packaging is a recent concept that has been increasingly adopted in the food, cosmetics, and pharmaceutical industries. This concept is based on enabling the packaging to have communication interfaces with the product and the customer, allowing a new range of possibilities and functionalities. In the pharmaceutical universe, one of the main smart packaging applications is the optimization of medical treatments and clinical studies, by validating the improvement of medication adherence by patients.

In hospital environments, medication management for the numerous patients is also a challenge that carries a high cost. In this scope the use of Smart Packaging technologies allows for a more simplified manipulation and control of medication vials by autonomous systems, allowing the identification of which medication should be directed to which patient. The use of these systems more efficiently is also linked to the need for a platform that unifies this data, allowing the interconnection of systems in a standardized and organized way.

An alarm system integrated with a flexible, low-cost and highly autonomous electronic component can help patients with chronic diseases not to miss the time to take their medication dose. Elderly patients (and their caregivers) also benefit greatly from this kind of technology, helping them to manage the doses of medications they normally have to take at different times of the day. A light or audible warning directly on the bottle avoids the need to use a smartphone or smartwatch, which elderly patients may find difficult to adopt to this type of newer technology.

Linking the data with other individual patient data available on other platforms, such as hospital platforms, is another important aspect. With the aggregation of information, behavioral trends and correlation of other variables (geographic, social) with medication adherence can be established, thus being a powerful tool for the validation of clinical trials and drug efficacy for specific patient profiles.

KEY FEATURES

The DOSEA Smart Labels are devices for medication control and management that can be used in a home or professional environment. Different versions with different degrees of complexity and integrated functionalities are being developed: DOSEA Basic, DOSEA + and DOSEA Omni.

The DOSEA Basic version is a single-use label that features the lowest cost and greatest simplicity. Using printed buttons, the user sets the total duration of treatment and the interval set for taking his medication in an extremely simple way. The system has 3 pre-defined durations and 3 intervals based on research conducted with health care entities, in order to be adaptable to most of the treatments performed today.

Through an integrated alarm system, the tag emits a light signal at the programmed time, alerting the patient to the time to take his medication. The system is powered by an ultra-thin battery, designed to meet product specifications and ensure the tag functions during the intended treatment. In this way, with a low-cost system, it is possible to improve adherence and ensure the effectiveness of a single treatment.

The DOSEA+ version has similar functionalities to the Basic version, with the advantage of being a reconfigurable system with a rechargeable battery which allows usage in several treatments, ensuring greater cost-effectiveness for patients who depend on recurring drug treatments. This version has an integrated screen, which allows you to view more information regarding medication taking. This version can be managed through a mobile application, which allows you to program the tag via NFC with the times of medication intake and collect data on prescription adherence.

DOSEA Omni is the version with the most features, since in addition to having all the features of DOSEA +, it also has a printed level sensor attached to the label. This sensor will allow the automatic validation of the medication intake. The DOSEA Omni version also features the Omni Station, a base for charging and monitoring ambient conditions. The Omni Station will be particularly oriented to multimedication, allowing the loading of more than one smart label simultaneously (through a technology that allows the union of several bases) and will include an information management system and humidity and temperature sensors to monitor storage conditions. Through the loading base it will also be possible to perform data transfer between the labels and the base, so that the system is data-oriented and integrated into a single treatment management platform.

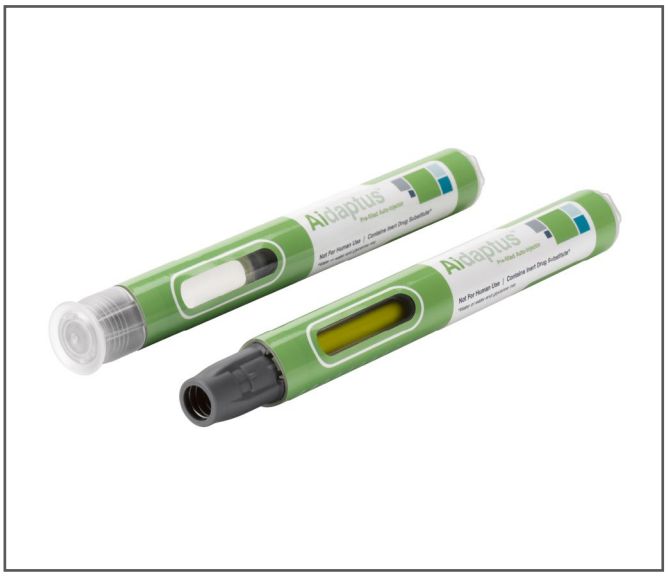
ADDITIONAL RESOURCES

Product Overview: https://www.centi.pt/projetos/saude-bem-estar/dosea

Neutroplast Projects: https://www.neutroplast.com/projects/pt

Aidaptus® 2-step single use auto-injector

2021



Company name: Owen Mumford Ltd

Country: UK

Product name: Aidaptus 2-step single use auto-injector

Product type: Disposable Auto-injector

Date of launch: 01/09/21

Current development phase: Production

Patent: PCT/EP2019/075402 and others

Target markets: Global

Target clients: Pharmaceutical & Biotech

Business model: B2B

FACT SHEET

PRODUCT DESCRIPTION

Aidaptus is a 2-step single use auto-injector platform with a versatile design and intuitive drug delivery.

Aidaptus accommodates both 1mL and 2.25mL glass syringes in the same device, and readily adapts to different fill volumes with no changed parts.

Aidaptus is suitable for reducing risk during drug development and life-cycle management, if the drug formulation has to change this device does not as it is designed to be flexible.

APPLICATION AREAS

Aidaptus is a platform disposable auto-injector for the subcutaneous administration of drugs. The product is designed for use by a patient, carer or healthcare professional. Aidaptus has undergone thorough Human Factors testing to ensure it is suitable for use by a wide variety of patient demographics and therapy areas as well as healthcare professionals. This also includes patients across a range of ages and those with dexterity challenges.

Aidaptus automatically provides needle shielding before, during and after use and so protects the user from needle-stick injuries and also complies with needle-stick prevention regulations. The concealed needle also provides confidence for those patients who are needle phobic.

Aidaptus is designed to accommodate both 1mL and 2.25mL primary container syringes in the same device with only minimal change parts and so is suitable for a range of formulations including biologics. Aidaptus also readily adapts to a range of different drug fill volumes with no changed parts, using a self-adjusting plunger.

Aidaptus is designed so that it is simple & intuitive to use with minimal user steps. It has both visual and audible indicators to guide the patient successfully through the drug delivery procedure and help achieve therapy compliance. The device provides user confidence that the injection has been successfully completed, by a ‘click’ at the start and end. A bright yellow plunger rod is also visible though a large window to confirm the end of injection. The device is small, lightweight and discreet for easy storage and use.

Aidaptus is suitable for a variety of therapy areas including Rheumatoid arthritis, Crohns’ disease and multiple sclerosis.

Website: https://www.ompharmaservices.com/

Aidaptus® 2-step single use auto-injector

2021

KEY FEATURES

Aidaptus disposable auto-injector can be used with both 1mL and 2.25mL standard syringes in the same device with minimal change parts. It also readily adapts to different fill volumes with a self adjusting plunger, with no change parts required. A choice of delivery springs allows options for higher viscosity formulations such as biologics. This provides flexibility for pharmaceutical companies during drug development and also for life cycle management, when varying formulations may be required.

Aidaptus features automatic needle insertion, enabling consistency of injection experience. In addition the 2-phase independent needle insertion and dose delivery helps to prevent device related wet injections and drug wastage & also limits impact forces on the syringe, which reduces the risk of syringe breakage. This helps to ensure that the patient always receives the full dose for their treatment.

Aidaptus has audible 'click' notifications to provide clear feedback to the user after needle insertion and once the drug delivery is complete. There is visual confirmation with a bright yellow plunger rod at the end of dose delivery. This helps to provide the patient with reassurance that they have successfully completed their drug administration.

Aidaptus is available in two base platform options: a clear outer body or opaque solid housing. Custom designs can be added via an outer wrap or choice of colour. This provides versatility for branding and options for market segmentation and life cycle management.

Patented technology in Aidaptus provides true platform benefits in robustness and reduced time to market, cost and risk.

ADDITIONAL RESOURCES

Product Website: https://www.ompharmaservices.com/explore-aidaptus/

Case Study: https://www.ompharmaservices.com/wp-content/uploads/2020/10/Posters-Delivering_a_True_Platform_Autoinjector_%E2%80%93_Customisable_vs_Configurable_vs_Adaptive-_A_Case_Study.pdf

Product Poster: https://www.ompharmaservices.com/wp-content/uploads/2020/10/Poster-Stopper_Movement_During_High_Altitude_Shipping-A_Novel_Solution.pdf

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Sanner Dropper Cap

2021

Company name: Sanner GmbH

Country: Germany

Product name: Sanner Dropper Cap

Product type: Dropper cap for glass bottles

Date of launch: 01.02.2023

Current development phase: Prototype

Patent: None

Target markets: Europe, North America

Target clients: Pharma companies

Business model: CDMO

FACT SHEET

PRODUCT DESCRIPTION

The Sanner Dropper has a convenient FlipTop Cap for easy opening and intuitive re-closing. The 2-part concept consists of an upper part of the cap with an integrated dropper, which pierces a sealing when the dosing function is opened for the first time, so the liquid drug inside doesn't get into contact with the plastic cap. This is crucial especially concerning aggressive substances in the drug and the achievement of a defined shelf-life. The lower part of the closure remains permanently screwed to the bottle for more patient's safety. The cap is defined for the standard bottleneck (PP28). Finally the dosing accuracy of the dropper has to be designed according to the viscosity of the drug. So adaptions are essential when it comes to commercialization. According to the bottled liquid drug use-stability can be determined. It starts when the sealing is pierced when the dosing function is activated for the first time. Naturally, the Sanner Dropper Cap as also a guaranty function in form of a tamper evident band. The tamper evident band is optically and haptically differentiated from the cap design itself. It is designed glossy whereas the Sanner dropper cap is matt. This haptic and optic difference enlarges the consumer safety also for persons with a visual impairment. On the head plate of the dropper cap you can either integrate a company logo for branding reasons or numbers to illustrate the initial application. It is also possible, as it is a two-part dropper cap, that the parts are manufactured in different colors, for example according to the brand corporate colors.

Website: sanner-group.com

Sanner Dropper Cap

KEY FEATURES

The Sanner Dropper Cap remains firmly on the bottle, unscrewing is not possible, so the patient cannot screw off and bypass the medication which leads to a better patient adherence and prevents the contents from being taken over- or under-dosed. Additionally the dropper cap has a tamper evident function which guarantees the first opening by the patient. The flip-top function of the cap enables dosing with one hand, it is easy to open with a defined opening force and enables an intuitive re-closing with a click sound and is so very consumer friendly. It is an active and modern design with a good touch and feel, also with the design options, for example a two-color cap and logo corresponding to the corporate identity of the pharmacist and the glossy-matt design.

The Sanner Dropper Cap has beside the convenient functions also extraordinary technical features. The 2-part concept consists of an upper part of the cap with an integrated dropper, which pierces a sealing when the dosing function is opened for the first time. The lower part remains permanently screwed to the bottle.

The sealing makes a 2-year shelf-life possible also for aggressive substances in the liquid. The dropper cap has to be activated by the patient. A simple and intuitive handling enables activation with little effort and an audible end position. The design of the dosing geometry is perfectly suitable for the exact dosing and dripping speed, cleanliness and residual emptying is guaranteed. Dosage can be adjusted to pharmacopoeia (Ph. Eur. 0672) depending on the viscosity of the liquid drug. The FlipTop has a verifiable 250 opening cycles.

APPLICATION AREAS

The Sanner Dropper Cap is designed for the standard bottle neck of glass bottles (PP28), so the pharmacist has the possibility to purchase standard glass bottles. This facilitates the market entry. After filling the Sanner Dropper Cap has to be screwed on the glass bottle and is separated from the content by an integrated sealing. This enlarges the shelf-life of the drug especially if we talk about natural substances which might engage with plastic materials. So here the pharmacist has the possibility to pack also critical liquids. Critical concerning the shelf-life because of sensitivity of oxygen as well as critical concerning the engagement of the liquid with the plastic cap. In this respect, an additional advantage is the facilitation of the logistic chain, especially if we talk about transportation to other continents. Of course, also the Sanner Dropper Cap can be used for all other liquid drugs as well. The user-friendly features, like the flip-top cap with one-hand opening and the exact dosage. Beside these application features the cap guarantees an exact dosage of the content without an extra measuring cap and prevents the patient from unscrewing and bypassing the medication which is also essential for certain critical liquids. The Sanner Dropper Cap has a guaranty function in form of a tamper evident band and ensures first opening by the patient. The tamper evident band is optically and haptically differentiated from the cap design itself. It is designed glossy whereas the Sanner dropper cap is matt. This haptic and optic difference enlarges the consumer safety also for persons with a visual impairment. This is supported by the possibility to mold haptic numbers on the head plate. The numbers describe the different application steps while the first-opening.

ADDITIONAL RESOURCES

Product Overview: https://www.sanner-group.com/en/engineered-product-solutions/primary-packaging

SG Alina®

2021

Company name: Stevanato Group

Country: Italy

Product name: SG Alina®

Product type: Pen Injector

Date of launch: 2021

Current development phase: Engineering Verification

Patent: Licenced IP

Target markets: Worldwide Pen Injector

Target clients: Pharma companies

Business model: Off-the shelf platform with customization option

FACT SHEET

PRODUCT DESCRIPTION

SG Alina® is a user-friendly disposable pen injector for diabetes care, based on proven technology. The variable-dose pen injector is under development at Stevanato Group in collaboration with Cambridge Design Partnership. It is based on Axis-D intellectual property exclusively licensed from pen injector device expert Haselmeier.

The pen injector features an appealing and functional design, including an easy-to-dial mechanism, optimized injection force for patient comfort, and a user-friendly readable display. This platform pen-injector offers a range of customization options from dosing configurations and color selection to a more customized industrial design, depending on the specific needs of the pharmaceutical client.

The pen injector will be manufactured at Stevanato Group's FDA-audited facility in Germany as an-off-the-shelf product, whereby the installed production line offers clients a cost-effective and minimized time-to-market. Dedicated production tooling and lines are also available if requested due to customization considerations or to support overall risk mitigation strategies.

APPLICATION AREAS

Insulin:
SG Alina® is a customizable injection pen that helps type 1 and type 2 diabetes patients to self-administer insulin, promoting better compliance and more effective treatment.

GLP-1:
SG Alina® can support safe and efficient self-injection of GLP-1, helping diabetes patients to manage their condition, and so aiding efforts to reduce costs and improve quality of care.

KEY FEATURES

Stevanato Group is offering a pen injector that can be integrated with all standard 3mL glass cartridges. In addition, SG Alina® enables flexibility with respect to assembled cartridges, in that through the innovative final assembly procedure, the pen injector can accept assembled cartridges with a range of assembled dimensions, and so from a range of fill-finish procedures. This will benefit not only the manufacturer but also the patient by bringing the device to market faster.

Other key features are:

Flexibility: Our platform design still allows for customization of the dosing requirements of different drug products

Readability: Accurate dose reading is enhanced with sliding window design

Safety: Patient safety has been considered carefully in the design of this device. For example, having dose correction available to avoid injection errors.

Convenience: A simple and easy-to-use disposable pen injector.

Customization: We have options available to customize the pen injector to better suit your client needs in terms of color, appearance and more. Feedback: Visual, audible and tactile feedbacks for dose setting, correction and injection

Compatibility: SG Alina is compatible with standard pen needles

Quality: This disposable pen injector is produced to exacting quality requirements at our ISO13485 facilities.

Website: https://www.stevanatogroup.com/en/offering/drug-delivery-systems/proprietary-and-licensed-devices/sg-alina/

YpsoDose

2021

Company name: Ypsomed Delivery Systems

Country: Switzerland

Product name: YpsoDose

Product type: Wearable injector

Date of launch: Dependent on customer filing strategy

Current development phase: Clinical development

Patent: Proprietary patented technology

Target markets: Global

Target clients: Pharmaceutical companies

Business model: Platform product

FACT SHEET

PRODUCT DESCRIPTION

The YpsoDose single-use injector is an electromechanical pre-filled and preassembled patch device compatible with 10 mL glass cartridges. Needle insertion, injection, end of injection feedback and needle safety steps are all performed automatically. The needle remains hidden at all times and made safe after injection and device removal.

APPLICATION AREAS

For patch injector platforms, simplicity and safety is key. The main drug candidates for large volume injectable drugs are antibody-based treatments for autoimmune diseases including orphan and rare diseases. Looking into the future, patch injector demand will increase further to cover the subcutaneous delivery of immuno-oncology drugs. Therefore, the potential range of indications covers both clinical and home settings from young to elderly patients with varying degrees of symptoms and disabilities. Patch injectors are dosed subcutaneously every 2 weeks, monthly or even less frequently. The number of use steps and thus complexity must be minimised to ensure that all users will remember the correct handling even with a longer timespan between injections. Accordingly, simplicity and safety is a key requirement for a patch injector and is reflected in the design of YpsoDose. The patch injector is prefilled and preassembled, therefore reducing the handling to two simple steps: patch and inject. The digital user interface ensures clear and unambiguous communication of the device status to the user. The integrated skin sensing patch guarantees needle safety even in case of false manipulations by the user, like early activation of the start button or premature removal of the device from the skin.

ADDITIONAL RESOURCES

Video: **https://www.youtube.com/watch?v=JTCK94oF8DY**

ONdrugDelivery article: **https://ondrugdelivery.com/simplifying-large-volume-patch-injection-for-pharma-and-patients/**

KEY FEATURES

Developing and designing a wearable patch injector is demanding and requires a broad range of technology and medical device competencies. Ideally, the infrequently used patch injector should be as easy if not easier to use as a disposable 2-step autoinjector, which is why the prefilled YpsoDose format incorporates the following key technical features and benefits:

- Pre-filled and fully disposable to remove any need to assemble or fill the drug reservoir and device.
- Adheres to the skin during injection and is easy to remove after injection.
- A capacitive sensing patch, which only allows initiation of the injection after the skin sensor, has confirmed skin contact.
- Automatic needle insertion at the start and retraction at the end of the injection process. The needle is also retracted if the device is removed from the skin before the end of injection.
- An electromechanical drive accommodates a range of fill volumes and viscosities and provides a programmable and reproducible injection time and volumes for each drug.
- Audible and visual feedback to clearly communicate with the user before, during and after the injection.
- The integrated electronics allow wireless connectivity to provide additional smart services.

Website: **https://yds.ypsomed.com/en/products/wearable-injectors/ypsodose.html**