

Published: 2013/12/11

— with international search report (Art. 21(3))
DRUG DELIVERY DEVICE WITH INTEGRATED SHIELD

The present invention generally relates to medical delivery devices adapted for transcutaneous delivery of an amount of drug.

BACKGROUND OF THE INVENTION

In the disclosure of the present invention reference is mostly made to the treatment of diabetes by delivery of insulin, however, this is only an exemplary use of the present invention.

Drug Injection devices have greatly improved the lives of patients who must self-administer drugs and biological agents. Drug Injection devices may take many forms, including simple disposable devices that are little more than an ampoule with an injection means or they may be highly sophisticated electronically controlled instruments with numerous functions. Regardless of their form, they have proven to be great aids in assisting patients to self-administer injectable drugs and biological agents. They also greatly assist care givers in administering injectable medicines to those incapable of performing self-injections.

In particular pen-style injection devices have proven to provide an accurate, convenient, and often discrete, way to administer drugs and biological agents, such as insulin. Modern devices have become more sophisticated and often include diverse and robust functions, such as memories for remembering time and amount of last dose, as well as, in the case of insulin devices, blood glucose monitors. While pen-style injection devices are typically cylindrically shaped with a needle protruding from the most distal portion of one end of the device, some devices have other shapes with the needle no longer protruding from the most distal part of an end of the device, e.g. Innovo® and InnoLet® from Novo Nordisk A/S, Bagsvaerd, Denmark.

Typically, injection devices use a pre-filled cartridge containing the medication of interest, e.g. 1.5 or 3.0 ml of insulin or growth hormone. The cartridge is typically in the form of a generally cylindrical transparent ampoule with a needle pierceable septum at one end and an opposed piston designed to be moved by the dosing mechanism of the injection device. The injection devices generally are of two types: "Durable" devices and "disposable" devices. A durable device is designed to allow a user to replace one cartridge with another cartridge, typically a new cartridge in place of an empty cartridge. In contrast, a disposable device is provided with an integrated cartridge which cannot be replaced by the user; when the cartridge is empty the entire device is discarded. Most injection devices are provided with a re-
leasable pen cap covering and protecting the cartridge, the needle mount portion with the
pierceable septum, and, as may be the case, a mounted needle. To protect the needle it is
normally provided with an inner needle cap.

Often injection devices are provided as a system or family of devices containing different
types of drugs, e.g. as known from WO 2004/069314. This application discloses a system of
substantially identical injection devices, each individual injection device comprising a housing
accommodating an ampoule containing drug sufficient for a number of injections and a dose
setting mechanism by which a predetermined dose size can be set, and wherein each of the
plurality of injection devices has a different predetermined dose size. The difference in the
predetermined dose sizes can in one embodiment be based on the drug in the devices hav-
ing different strength.

People suffering from diabetes are often treated with multiple daily injections in a regimen
comprising one or two daily injections of long acting insulin to cover the basal requirement
supplemented by bolus injections of short or rapid acting insulin to cover requirements relat-
ed to meals.

A user will therefore often require two different injection devices, one containing the long act-
ing insulin and another containing the short or rapid acting insulin. Often these injection de-
VICES have different colour indications to inform the user of the kind of insulin contained in the
injection device. For example, the FlexPen® system offered by Novo Nordisk comprises
pens for long and short acting insulins as well as for mixed insulin, the bodies and caps being
identical with colour markings on the main body to differentiate the two types of insulin. In the
SoloStar® system offered by Sanofi-Aventis the pens for long and short acting insulins have
differently coloured bodies as well as caps. In addition these injection devices can be provid-
ed with tactile means such as a mechanical coding informing the user of the kind of insulin
contained in the injection device.

Although the prior art discloses a number of solutions of how to differentiate similar or other-
wise identical drug delivery devices containing different kinds of drugs, there is still a need for
a drug delivery devices which in a simple and effective manner provides a strong identifica-
tion of the kind of drug contained in a specific pen, this reducing the risk of a user inadvert-
ently taking the incorrect kind of drug.
Having regard to the above, it is an object of the present invention to provide a drug delivery device which in a simple and cost-effective manner reduces the likelihood of a user taking the wrong kind of drug. The device should be simple, safe and convenient to use. A further object of the invention is to provide a drug delivery which is convenient as well as safe in use.

**DISCLOSURE OF THE INVENTION**

In the disclosure of the present invention, embodiments and aspects will be described which will address one or more of the above objects or which will address objects apparent from the below disclosure as well as from the description of exemplary embodiments.

Thus, in accordance with a first aspect a drug delivery system is provided comprising a drug delivery device with a main part and a shield, the main part comprising a drug reservoir or means for receiving and holding a drug reservoir, the drug reservoir having a distal outlet, and drug expelling means for expelling drug from the reservoir. The shield is moveably mounted to the main part and is displaceable by a user between a shielding and a non-shielding position, the shield comprising an opening, and closure means for closing the opening, the closure means being reversible actuable between a closed state and an open state. In such a system the shield in the shielding position, with the closure means in the closed state, covers the distal outlet of a mounted reservoir or the distal end of the means for receiving and holding a drug reservoir, whereas the shield in the non-shielding position, with the closure means in the open state, allows the distal outlet of a mounted drug reservoir or the distal end of the means for receiving and holding a drug reservoir to protrude through the opening. The means for receiving and holding a drug reservoir may be in the form of a cartridge holder.

By providing a system in which the traditional detachable cap has been replaced with a retractable shield the shield can be used to safely identify the drug content of a given drug delivery device without the risk of a user mounting a given cap on a non-corresponding device main part with the possible risk of taking the wrong medication, e.g. mounting a cap indicating short acting insulin on a main device portion containing long acting insulin.

Further, by replacing the traditional detachable cap with a retractable shield, a drug delivery device which is simple and convenient in use is provided, e.g. having no loose parts which can be displaced or lost. The reversible operatable closure means allows that a mounted
needle assembly or the reservoir outlet can be well protected against dust and dirt, thereby providing the same functionality as a traditional removable cap.

Although not related to the issue of reducing the likelihood of a user taking the wrong kind of drug, US 5,360,408 and WO 2011/007178 disclose safety shields which will cover a needle tip after having been actuated, however, in accordance with the purpose of the shields they are adapted to permanently close an opening.

In exemplary embodiments, the closure means is actuated automatically from the closed to the open state when the shield is moved from the shielding to the non-shielding position, and from the open to the closed state when the shield is moved from the non-shielding to the shielding position. Alternatively, the closure means may be operated manually by a user.

The drug delivery device may be provided with a needle mount associated with the distal outlet of a mounted reservoir or the distal end of the means for receiving and holding a drug reservoir, the needle mount being adapted to allow a needle assembly to be mounted in fluid communication with the reservoir, wherein the shield in the shielding position, with the closure means in the closed state, covers the needle mount.

The drug delivery system may further comprise a needle assembly comprising a needle hub adapted to be mounted on the main portion needle mount, and a hollow needle mounted in the needle hub and comprising a distal pointed end and a proximal end, the proximal end being adapted to be arranged in fluid communication with the reservoir when the hub is mounted on the main portion needle mount, wherein the shield in the shielding position, with the closure means in the closed state, covers the distal pointed end of a mounted needle assembly.

The needle assembly may be provided with a needle cap adapted to be mounted on the needle hub to cover the distal pointed end, wherein the shield in the shielding position, with the closure means in the closed state, covers the needle cap of a mounted needle assembly.

The main part may define a general longitudinal axis, the shield being axially slideable relative to the main part between the shielding and non-shielding positions. Further, the shield may be moved between the shielding and non-shielding positions by at least in part a helical movement relative to the main part.
The shield may in the shielding position circumferentially fully cover the distal outlet of a mounted reservoir or the distal end of the means for receiving and holding a drug reservoir. Alternatively, the shield may be partially open circumferentially, e.g. for technical design reasons, however, such a partially open shield should be designed to prevent user access to the shielded structure to a high degree.

The closure means may in the closed position axially fully cover the distal outlet of a mounted reservoir or the distal end of the means for receiving and holding a drug reservoir. Alternatively, the closure means may be partially open axially, e.g. for technical design reasons, however, such a partially open closure means should be designed to prevent user access to the shielded structure to a high degree.

To further improve handling and convenience the shield may be provided with one or more inspection openings or windows allowing a user to inspect at least a portion of a mounted reservoir or needle assembly. In this way a user does not have to remove the cap to check if a needle assembly is mounted or to check the reservoir.

Correspondingly, the main portion may be provided with a user-inspectable portion adapted to be covered by the shield, the shield being provided with one or more inspection openings or windows allowing a user to inspect at least a portion of the user-inspectable portion.

For example, the user-inspectable portion may comprise a transparent reservoir portion allowing a user to inspect drug contained in the reservoir or the position of a piston located in the reservoir. For easier inspection of the transparent reservoir the shield may be provided with a second set of inspection openings or windows arranged generally opposite the first set, this allowing light to travel through the reservoir.

The shield may be generally non-transparent and be provided with one or more transparent windows, the transparent windows comprising means for reducing transmission of light detrimental to drug contained in the reservoir, e.g. a UV filter.

In the above described embodiments the main part of the drug delivery device comprises a reservoir, however, in alternative versions the different embodiments may be adapted to re-
receive a replaceable reservoir, e.g. a cartridge to be used in combination with a durable type injection device.

As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a cannula or hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs include pharmaceuticals such as peptides (e.g. insulins, insulin containing drugs, GLP-1 containing drugs as well as derivates thereof), proteins, and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. In the description of the exemplary embodiments reference will be made to the use of insulin containing drugs.

**BRIEF DESCRIPTION OF THE DRAWINGS**

In the following the invention will be further described with reference to the drawings, wherein

fig. 1 shows an embodiment of a drug delivery device with a shield in a shielding position,
fig. 2 shows the device of fig. 1 with the shield in a non-shielding position,
fig. 3 shows an exploded view of the device of fig. 1,
fig. 4 shows a cross-sectional view of the device of fig. 1,
fig. 5 shows a cross-sectional view of the device of fig. 2 and
fig. 6 shows a side view of the device of fig. 1.

In the figures like structures are mainly identified by like reference numerals.

**DESCRIPTION OF EXEMPLARY EMBODIMENTS**

When in the following terms such as "upper" and "lower", "right" and "left", "horizontal" and "vertical" or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as their relative dimensions are intended to serve illustrative purposes only. When the term member is used for a given component it generally indicates that in the described embodiment the component is a unitary component, however, the same member may alternatively comprise a number of sub-components just as two or more of the described components could be provided as unitary components, e.g. manufactured as a single injection moulded part.
Referring to figs. 1 and 2 a drug delivery device 1 will be described. The device comprises a main (or body) part 10 on which a retractable but non-removable shield 20 is mounted. In the shown embodiment the main part defines a general longitudinal axis. The main part comprises (see fig. 3) a drug-filled reservoir (or cartridge) 30 with an axially displaceable piston 31 and a distal outlet 32 with an associated needle mount 35 adapted to allow a needle assembly to be mounted in fluid communication with the reservoir. The needle mount may be part of either the cartridge or the structure for holding the cartridge. The main part further comprises a drug expelling means (not shown) for moving the piston distally to thereby expel a user-settable dose of drug from the reservoir. The mounted needle assembly 40 comprises a needle hub 41 adapted to be mounted on the needle mount, a hollow needle 42 mounted in the needle hub and comprising a distal pointed end and a proximal end, the proximal end being adapted to be arranged in fluid communication with the reservoir when the hub is mounted on the main part needle mount. An inner cap (not shown) may be mounted on the needle hub to cover the distal portion of the needle. The shield is moveably mounted to the main part and is displaceable by a user between a shielding and a non-shielding position, the shield comprising a shield main part 21 with a distal opening 22 sized to allow a mounted needle assembly to move there through, and a closure member 25 for closing the opening. The closure member is reversible actuable between a closed state and an open state and is associated with an actuation member 26 serving to both actuate the closure member and move the shield main part back and forth between a distal shielding position (see fig. 1) and a retracted proximal non-shielding position (see fig. 2).

Thus, when the shield is in the shielding position it covers the distal pointed end of a mounted needle assembly with the closure member in its closed stat, and when the shield is in the non-shielding position with the closure means in its open state it allows the distal pointed end of a mounted needle assembly to protrude from the opening and thus to be inserted subcutaneously. In this position it is also possible to remove and mount a needle assembly. The closure means is actuated from the closed to the open state when the shield is moved from the shielding to the non-shielding position, and actuated from the open to the closed state when the shield is moved from the non-shielding to the shielding position.

As appears from the figures, in the exemplary embodiment the shield in the shielding position circumferentially fully covers the distal outlet of the mounted reservoir, just as the closure means in the closed position axially fully covers the distal outlet of the mounted reservoir.
Fig. 3 shows in an exploded view the parts making up the shield 20, i.e. the shield main part 21 with the distal opening 22, the closure member 25 formed as the distal portion of a flexible strip member 24, and the actuation member 26. The drug delivery device main part 10 is shown with a cartridge holder 16 without a mounted cartridge. In the shown embodiment the cartridge holder and a therein mounted cartridge are arranged corresponding to general longitudinal axis of the main part.

Figs. 4 and 5 show the drug delivery device 1 of figs. 1 and 2 in cross-sectional views with mainly the features relevant for the present invention shown in detail. Correspondingly, the device body portion is shown with a cartridge 30 mounted in a cartridge holder 15 having an opening 16 allowing a portion of the cartridge to be inspected, the piston rod for moving the cartridge piston 31 and the drug expelling means for driving the piston rod not being shown. These parts of the device may be of any suitable design, either manual or motorized. An example of a manual expelling mechanism which would be suitable for use in a drug delivery device having the shown boxy "doser" configuration is disclosed in US 6,796,970 hereby incorporated by reference. A motorized electronically controlled device may be provided with a display 19 providing a user with relevant information, e.g. showing size and time values for a log of expelled amounts of drug.

The actuation member 26 is mounted non-releasably in a cut-out in the shield main part and moveable in a guided relationship with the shield main part via the slider portion 27 between a distal and a proximal position. The flexible strip member is mounted non-releasably to the actuation member and moveable in a guided relationship with the shield main part between a distal position in which the distal portion 25 serves as the actual closure member to close the opening 22.

To ensure proper operation the shield is provided with means, e.g. detents, serving to ensure that when the actuation member is moved proximally with the shield in its shielding position and the opening closed, the flexible member is retraced proximally to open the opening before the shield main part is retracted. The other way round, when the actuation member is moved distally with the shield in its non-shielding position and the opening open, the shield main portion is moved to the shielding position before the flexible member is moved distally to close the opening. In the shown embodiment the device main part and the shield main part are provided with corresponding detents 18, 28 serving as locking means to lock and hold
the shield in its shielding respectively non-shielding position. These detents may also serve to assure proper order of operation as described above.

In case the drug delivery device is of the durable type and thus adapted for exchange of an empty cartridge, the shield may be adapted to be removed from the device main part to allow for (easy) insertion of a new cartridge in the cartridge holder, e.g. by pulling the detent 18 out of engagement with the device main part. The cartridge holder may be adapted to be removed from the main part during cartridge exchange, or it may be actutable, e.g. by sliding or pivoting movement, between an open cartridge receiving state and a closed state.

The shield may be generally non-transparent and be provided with one or more transparent windows 29, the transparent windows comprising means for reducing transmission of light detrimental to drug contained in the reservoir, e.g. a UV filter. Such a window may also allow a user to easily check whether or not a needle assembly is mounted, see fig. 6.

In the above-described embodiment the shield is arranged axially slideable relative to the main part between the shielding and non-shielding positions, such a movement being the most relevant for a drug delivery device having a box-shaped configuration. However, for a traditional pen-formed drug delivery device the shield could be actuated by rotation and moved between the shielding and non-shielding positions by a fully or partly helical movement relative to the main part.

For example, for a pen-formed drug delivery device, e.g. a FlexTouch® or a FlexPen® from Novo Nordisk, see e.g. US 6,004,297 which is hereby incorporated by reference, the shield may have a generally cylindrical configuration with a distal opening. For such a configuration the closure means arranged to close the opening could be actuated between a closed and open state by an initial pure rotation of the shield relative to the main part, e.g. 15 degrees, after which further rotation of the shield, e.g. 90 degrees, results in the shield being retracted to its non-shielding position by a helical movement. Indeed, the axial movement could also be a pure axial movement. The closure means could e.g. be of the aperture type or comprise one or more hinged doors being moved outwards when actuated. The latter type of closure means may be actuated by axial movement of the shield.

In the above description of the preferred embodiments, the different structures and means providing the described functionality for the different components have been described to a
degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

*****
CLAIMS

1. A drug delivery system, comprising:

(a) a main portion (10) comprising:
- a drug reservoir (30) or means for receiving and holding a drug reservoir, the drug reservoir having a distal outlet, and
- drug expelling means for expelling drug from the reservoir,

(b) a shield (20) moveably mounted to the main portion and being displaceable by a user between a shielding and a non-shielding position, comprising:
- an opening (22), and
- closure means (25) for closing the opening, the closure means being actuable between a closed state and an open state,

- wherein the shield in the shielding position, with the closure means in the closed state, covers the distal outlet (32) of a mounted reservoir or the distal end of the means for receiving and holding a drug reservoir,
- wherein the shield in the non-shielding position, with the closure means in the open state, allows the distal outlet of a mounted drug reservoir or the distal end of the means for receiving and holding a drug reservoir to protrude through the opening, and

- wherein the closure means is reversible actuable between the closed state and the open state.

2. A drug delivery system as in claim 1,

- wherein the closure means is actuated from the closed to the open state when the shield is moved from the shielding to the non-shielding position, and
- wherein the closure means is actuated from the open to the closed state when the shield is moved from the non-shielding to the shielding position.

3. A drug delivery system as in claim 1 or 2, the main portion further comprising:
- a needle mount (35) associated with the distal outlet of a mounted reservoir or the distal end of the means for receiving and holding a drug reservoir, the needle mount being adapted to allow a needle assembly to be mounted in fluid communication with the reservoir,
- wherein the shield in the shielding position, with the closure means in the closed state, covers the needle mount.

4. A drug delivery system as in claim 3, further comprising:
   (c) a needle assembly (40) comprising:
      - a needle hub (41) adapted to be mounted on the main portion needle mount,
      - a hollow needle (42) mounted in the needle hub and comprising a distal pointed end and a proximal end, the proximal end being adapted to be arranged in fluid communication with the reservoir when the hub is mounted on the main portion needle mount,

   - wherein the shield in the shielding position, with the closure means in the closed state, covers the distal pointed end of a mounted needle assembly.

5. A drug delivery system as in claim 4, the needle assembly further comprising:
   - a needle cap adapted to be mounted on the needle hub to cover the distal pointed end,
   - wherein the shield in the shielding position, with the closure means in the closed state, covers the needle cap of a mounted needle assembly.

6. A drug delivery system as in any of the previous claims, wherein the shield in the shielding position circumferentially fully covers the distal outlet (32) of a mounted reservoir or the distal end of the means for receiving and holding a drug reservoir.

7. A drug delivery system as in any of the previous claims, wherein the closure means in the closed position axially fully covers the distal outlet (32) of a mounted reservoir or the distal end of the means for receiving and holding a drug reservoir.

8. A drug delivery system as in any of the previous claims, wherein the main part defines a general longitudinal axis, the shield being axially slideable relative to the main part between the shielding and non-shielding positions.

9. A drug delivery system as in any of the previous claims, wherein the shield is moved between the shielding and non-shielding positions by at least in part a helical movement relative to the main part.
### INTERNATIONAL SEARCH REPORT

**International application No**
PCT/EP2013/073466

**A. CLASSIFICATION OF SUBJECT MATTER**

**INV.** A61M5/32

**ADD.**

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
</table>

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

- **X** document defining the general state of the art which is not considered to be of particular relevance
- **E** earlier application or patent but published on or after the international filing date
- **L** document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- **O** document referring to an oral disclosure, use, exhibition or other means
- **P** document published prior to the international filing date but later than the priority date claimed
- **T** later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- **X** document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- **Y** document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- **A** document member of the same patent family

**Date of the actual completion of the international search**

3 February 2014

**Date of mailing of the international search report**

11/02/2014

**Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Riviswijk Tel: (+31-70) 340-2040, Fax: (+31-70) 340-3016**

**Authorized officer**

Tiirkavci, Levent
<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent document cited in search report</td>
<td>Publication date</td>
<td>Patent family member(s)</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-----------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>US 565,1774 A</td>
<td>29-07-1997</td>
<td>NON E</td>
</tr>
<tr>
<td>US 2012/130,277 AI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WO 2011/007,178 A2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>US 536,0408 A</td>
<td>01-11-1994</td>
<td>NON E</td>
</tr>
<tr>
<td>US 2005/17,1483 AI</td>
<td>04-08-2005</td>
<td>NON E</td>
</tr>
</tbody>
</table>