Kit for and method of assembling an applicator for inserting an implant

The invention relates to a kit for assembling a disposable applicator for inserting an implant, in particular a rod-like implant containing an active substance, under the skin of a human or animal. The invention further relates to a method of assembling an applicator.

US 4,820,267 relates to a device for subcutaneous implantation of single and plural elongated medicament pellets comprising a single dosage where magazine feeding is not applicable because considerations of sterility and cross-contamination require a fresh needle and obturator for each patient. The device includes a cannula supported at a proximal end thereof by a hub which slides within a tubular barrel, the barrel supporting an obturator which selectively penetrates the cannula to maintain an implanted pellet in position as the cannula is withdrawn. For single pellet dosages, the pellet is carried in the fore part of the cannula, while in the case of multiple pellet dosages, the additional pellets, prior to loading, are carried in open-ended cylindrical tubes engageable with a proximal end of the hub whereby the obturator may be employed to transfer the pellet to the cannula from the sleeve which is discarded. Repositioning of the hub within the sleeve is then accomplished without disengagement of the distal end of the cannula from the tissues of the patient and additional implantations may then be performed.

US 3,016,895 relates to injectors, and more particularly to a veterinarian's injector of the type designed for subcutaneous implantation of solids in animals. US 3,016,895 discloses a device wherein a longitudinally bored pellet receiving and loading unit is hingedly mounted so that it may be misaligned with the body of the injector,

so that a solid pellet may be easily inserted therein, for convenient loading of the injector.

WO 2004/089458 relates to a device for inserting implantable objects beneath the skin of a patient, including a handle for grasping the device and a base connected to the handle. The base comprises a post, a cannula, and a flexible actuator positioned in an angled track. The cannula is positioned coaxially around and is longitudinally slidable over the post from an extended position, where an implantable object is retained in the cannula, to a retracted position, where the implantable object is released from the cannula. In operation the implanting device may be loaded with an implantable object either manually or with a cartridge. One embodiment of the device according to WO 2004/089458 is a kit which may include additional parts along with an implanting device which may be combined together to implant therapeutics, pharmaceuticals, or microencapsulated sensors into a patient. The kit may include the implanter in a first compartment. A second compartment may include a syringe, needles, scalpel, and any other instruments needed. A third compartment may include gloves, drapes, wound dressings and other procedural supplies for maintaining sterility of the implanting process, as well as an instruction booklet. A fourth compartment may include additional cannula and posts.

WO 01/68168 relates to a disposable device for inserting one or several implants, said device comprising a tubular cannula (10) provided with a tip (11), said cannula also serving as a container for the implants, a plunger (20) and a handle (30) having a first end (31) directed towards the cannula (10), and a second end (32) directed away from the cannula. The plunger (20) and the handle (30) are attached or attachable to each other in a fixed manner, and the cannula (10) is arranged to be movable in the longitudinal direction, so that the plunger (20) is placed therein. The device in WO 01/68168 is characterized in that i) the cannula (10) can, after inserting the implant or implants, be drawn on top of the plunger (20) so far, that

the tip (11) of the cannula (10) becomes covered by the handle (30) or by a piece connected to the handle (30), and/or that ii) the cannula (10) is, when drawn to its extreme position, towards the second end (32) of the handle (30), arranged to be irretrievably locked in relation to the plunger (20).

EP 1 300 173 relates to a hand held implanter for containing and depositing a subcutaneous implant beneath the skin of a patient. Figures 11 to 13 illustrate one preferred method for loading the implant (18) into the implanter (110) in the case where the implanter is not preloaded by employing an implant containing vial (90). The vial (90) maintains the implant in a sterile condition during transportation, storage, and loading.

US 2001/0031940 relates to a device for administering implants. The device is a syringe-like device having a plunger, an injection cannula, and an active substance container therebetween. The active substance container includes two retaining elements for preventing inadvertent dispensing of an implant. The retaining elements are flexible, and may be O-rings.

WO 98/58698 discloses an implantation device (1) comprising a hollow needle (2), preferably of the type having a chamfered tip profile, and a body (3) adjoining the needle part comprising a plunger (5), preferably having a chamfered tip profile capable of blending with the needle tip profile. The device is made preloadable by being provided with a chamber (7) capable of holding an implant (8), which chamber is positioned radially outside the periphery of the plunger (5) and has a directly or indirectly open connection to a channel (6) surrounding the plunger. The plunger is capable of closing off and opening up the chamber by being displaced.

It is an object of the present invention to provide a kit in accordance with the opening paragraph which reduces the risk of damaging the, often delicate, implant during (automated) introduction of the implant into a cannula and/or a cannula holder and which facilitates such

introduction at a late stage of assembly of the applicator, even if the applicator comprises intricate design features to enhance e.g. ergonomics and/or operation safety.

To this end, the kit according to the present invention comprises a first component, in turn comprising a main housing part providing a handle for grasping and manoeuvring the applicator, a cannula, preferably extending from the housing, and a cannula holder mounted, preferably slidably, in the main housing part, the main housing part having an opening which allows introduction of an implant into the proximal end of the cannula and/or the cannula holder, and,

separate from the first component,

a second component for closing said opening, in turn comprising a second housing part at least partially complementary in shape to the main housing part and a rod attached to or forming an integral whole with the second housing part and mountable inside the cannula and/or the cannula holder.

Thus, the implant can be introduced into the proximal end of the cannula and/or the cannula holder avoiding contact with the tip of the cannula and such introduction can be postponed until just before the applicator is completed.

It is preferred that the first and second components are provided with complementary features for irreversibly attaching, e.g. snap fitting, one part to the other.

To facilitate proper alignment between the cannula and the implant during introduction, even if the implant is slightly curved due to storage on a reel, it is preferred that the distance between the opening in the main housing part, in particular the edge of the opening, and the proximal end of the lumen of the cannula and/or the cannula holder is less than the length of the implant to be used, preferably less than 20 mm, more preferably less than 10 mm or even less than 5mm.

In a further embodiment the handle extends above at least 30%, preferably at least 50%, more preferably at least 80% or all of the length of the cannula extending from the first component.

The invention further pertains to a method of assembling a disposable applicator comprising the steps of subsequently

- providing a first component comprising a main housing part providing a handle for grasping and manoeuvring the applicator, a cannula, preferably extending from the housing, and a cannula holder mounted, preferably slidably, in the main housing part, the main housing part having an opening which allows introduction of an implant into the proximal end of the cannula and/or the cannula holder, and, separate from the first component,

a second component for closing the opening in the main housing part, in turn comprising a second housing part at least partially complementary in shape to the main housing part and a rod attached to or forming an integral whole with the second housing part,

- introducing an implant through the opening and into the proximal end of the cannula and/or the cannula holder,

- mounting the rod inside the cannula and/or the cannula holder and closing the opening by attaching, preferably irreversibly, one housing part to the other.

Finally, the invention relates to a disposable applicator obtained with this method, which applicator is contained inside a sterile package.

The invention will now be explained in more detail with reference to the drawings, which schematically show a preferred embodiment according to the present invention.

Figures 1 and 2 are perspective views of a kit in accordance with the present invention.

Figure 3 is a perspective view of an applicator.

Figure 4 is a cross-sectional side view of the applicator of Figure 3.

Figure 5 is an exploded view of the applicator of Figure 3.

Figures 1 and 2 show a kit 1 in accordance with the present invention for assembling a disposable applicator 2 (shown in assembled condition in Figures 3 and 4) for inserting an implant 3, in particular a rod-like implant containing an active substance, such as a contraceptive, under the skin of a human.

The kit 1 comprises a first component 4, in turn comprising a main housing part consisting of two half-shells 5, 6, welded together ultrasonically, and providing a handle 7 for grasping and manoeuvring the applicator 2 (once assembled) and an open rear (proximal) section, and a second component 8, in turn comprising a second housing part consisting of a rear shell 9, complementary in shape to the main housing part 5, 6 and spanning at least 20% of the surface of the applicator 1 (once assembled), and a rod 10 attached to or forming an integral whole with the second housing part 9.

With reference also to Figures 3 to 5, which show the assembled applicator (respectively an exploded view of the applicator), the first component 4 comprises a metal cannula 11 accommodating the implant 3, a protective cover 12 comprising a pin 13 extending into the tip of the cannula 11 to restrict the freedom of movement of the implant 3, and an actuator 14 for retracting the cannula 11 into the housing 5, 6, 9. The cannula 11 is fixed to a cannula holder 15, which is slidably received inside the housing 5, 6. To this end, the inner walls of the half-shells 5, 6 and the rear shell 9 are provided with parallel and longitudinal guides 16 and the cannula holder 15 is provided with corresponding longitudinal grooves 17 (Figure 5). The cannula holder 15 is connected to the actuator 14 by means of a flexible element 18, which, in this example, forms an integral whole with the cannula holder 15 and the actuator 14. Depending on the configuration of the applicator, it may be more advantageous to employ a rigid element and/or a separate actuator, flexible element, and cannula holder,

which are connected upon assembly of the applicator. The flexible element 18 comprises on either side and preferably just below the actuator 14 lateral protrusions 19 (Figure 5). The inner wall of the main housing part 5, 6 in turn comprises two corresponding stops 20 (Figure 4), which prevent the protrusions 19 from passing and hence the actuator 14 from being pulled rearwards unintentionally. The lateral protrusions 19 and stops 20 also prevent the cannula holder 15 and the cannula 11 from being pushed rearwards during insertion.

On top of the handle 17, a track 21 is provided for guiding the actuator 14. A guide 22 is included just below the track 21, which is shaped to provide sufficient room below the actuator 14 to enable it to flex sufficiently far downwards to allow the lateral protrusions 19 to pass the stops 20, upon pushing the actuator 14 down. Retracting the cannula 11 thus can be performed in one flowing movement, i.e. upon applying pressure to the actuator 14, typically with an index finger, the actuator 14 flexes downwards, clearing the stops 20, and subsequently rearwards to the retracted position.

Also, two resilient lips 23 are provided on the rear (proximal) end of the cannula holder 15. The inner sidewalls of the main housing part 5, 6 in turn comprise two corresponding stops (not shown) that block rearward motion of the lips 23 and hence define the longitudinal position of the cannula holder 15 in rearward direction. It is preferred that this mechanism urges the cannula holder 15 into its most forward position, so as to prevent the implant 3 from extending from the cannula 11. Upon actuation, the lips 23 will flex inwards and past the stops.

A lever 24 is pivotally connected to the front end of the handle 7. The lever 24 is gently biased towards the cannula 11 by means of a spring 25 extending between the lever 24 and an inner wall of the handle 7. In the present example, the lever 24 interacts with the protective cover 12 and the implant 3. To this end, the lever 24 comprises a

first protrusion 26 (Figure 4) on its lower wall and a pair of lateral protrusions 27 (Figure 5) on its upper rim.

The protective cover 12 (see in particular Figure 5) on its inner walls comprises a pair of ridges 28 which, in combination with corresponding slots 29 on the outside of the half-shells 5, 6, impose sliding engagement between the cover 12 and the main housing part. The cover 12 further comprises, on its upper rim, a pair of keys 30, each interrupted by a notch 31.

The cannula 11 in turn comprises an opening 32 which allows the protrusion 26 to engage the implant 3 and thus to gently urge the implant 3 against the inner wall of the cannula 11.

With the protective cover 12 in place, the lateral protrusions 27 of the lever 24 are supported by the keys 30 and the first protrusion 26 is just clear of the implant 3.

If the protective cover 12 is removed, i.e. slid in longitudinal direction and away from the main housing part, the keys 30 will slide under the lateral protrusions 27. If no implant 3 is present inside the cannula 11, the protrusion 26 on the lever 24 is free to enter the cannula 11 through the opening 32. I.e., the lever 24 will drop when the lateral protrusions 27 reach the notches 31, thus blocking further movement of the cover 12, preventing the same from being removed and preventing the applicator from being used any further. If an implant 3 is present, the lever 24 will be lowered only very slightly, with the lateral protrusions 27 still clear of the notches 31, and yet causing the first protrusion 26 to rest, through the opening 32, on the implant 3, thus, on the one hand, allowing the cover 12 to be removed and, on the other, gently urging the implant 3 towards the inner wall of the cannula 11, i.e. securing the implant 3 inside the cannula 11.

The cover 12 further comprises, on its inner bottom wall, a stay 33 preferably having, in its top surface, a V-shaped groove extending in the longitudinal direction of the applicator 2. Upon placing the protective cover 12 onto the

main housing part 5, 6, the stay 33 slightly lifts the cannula 11 and reproducibly defines the lateral position and height of the tip of the cannula 11 with respect to the pin 13, thus preventing contact between the tip of the cannula and the inner walls of the cover 12.

Finally, the main housing part 5, 6 comprises, preferably at the rear, at least one, e.g. two guides 34, and/or at least one, e.g. two resilient hooks 34A, for cooperation with corresponding features of the second housing part.

The second component 8 of the kit comprises a bracket 35, which has been inserted in and snap-fitted to the rear shell 9 by means of two resilient fingers 36, 37, each provided with a protrusion 36A, 37A. The lower finger 37 comprises, near its end, a second, preferably wedge-shaped, protrusion 38, which serves to lock the cannula holder 15 in its retracted position. The bracket 35 carries the aforementioned rod 10.

In this example, the length of the rod 10 is adjusted to the length of the lumen of the cannula holder 15 and the cannula 11 and the length of the implant 3, such that when the applicator is assembled and the cannula 11 is in the extended position, the implant 3 is fully contained inside the cannula 11 and typically abuts the distal end of the rod 10. When the cannula 11 is in the retracted position, the implant 3 is completely expelled from the cannula 11 and the distal end of the rod 10 extends from the distal end of the (retracted) cannula 11.

Finally, the rear shell 9 comprises at least one, e.g. two guides 39 for slidingly mounting the rear shell 9 onto the main housing part 5, 6 (in particular guides 34), and/or at least one feature, e.g. two ridges 39A, for snap-fitting the shell to the main housing 5, 6.

As will be clear from the explanations above, the main housing part comprises several sophisticated features that enhance ergonomics and/or safety of operation. Accordingly, it may occur, more frequently than in the case of more straightforward designs, that during production some

applicators do not pass quality tests and are rejected. In such cases, the relatively expensive implant contained in the applicator is also lost.

With the kit according to the present invention, the implant can be introduced into the proximal end of the cannula and/or cannula holder after the first and second components have been approved and only just before the applicator is completed. Further, contact with the tip of the cannula during introduction of the implant can be avoided effectively.

To facilitate automated introduction of an implant, the proximal end of the lumen of the cannula 11 and/or cannula holder 15 is provided with a funnel-shaped entrance 40. To prevent the implant from contacting the upper rim of the cannula and hence to further reduce the risk of damaging the implant during insertion into the cannula, the diameter of the narrowest portion of the funnel-shaped entrance is equal to or smaller than the inner diameter of the cannula.

Also, the first component 4, in particular the main housing parts, can comprise features to enhance interaction with one or more tools. In this example, the main housing part 5, 6 comprises, in the edge of the open rear section, notches 41 to provide sufficient room for proper alignment of a tool for introducing the implant 3 into the cannula holder 15.

In this example, the kit 2 is produced by means of the following steps:

introducing at least the proximal end of the cannula 11 in a mould and moulding the cannula holder 15 about the proximal end, thus providing accurate alignment of entrance 40 of the cannula holder 15 and the cannula 11;

positioning the cannula holder 15, the cannula 11, the actuator 14, the lever 24, and the spring 25 inside the half-shells 5, 6, and welding the same together ultrasonically;

placing the cover 12 onto the main housing part 5, 6;

attaching the rod 10 to the rear shell 9 and inspecting the thus obtained first and second components for compliance with production specifications.

The kit is now ready to receive an implant, either at the same facilities or elsewhere e.g. at the facilities where the implant is produced.

The implant 3, which, in this example, is supplied in the form of a fibre wound on a large diameter reel, is introduced into the applicator 2 by means of the following steps:

taking the end of the fibre from a reel and cutting the implant 3 to size; inspecting the implant 3; introducing the implant 3 through the open rear section of the first component 4 into the proximal end of the cannula 11 and/or the cannula holder 15;

mounting the rod 10 inside the cannula 11 and/or the cannula holder 15 and closing the opening by snap fitting the second component 8 to the first component 4; and

sterilizing and packaging the applicator 2.

The kit according to the present invention is especially suitable for use with delicate implants, in particular implants that slowly release an active substance over an extended period of time. A preferred example of such an implant is a single-rod contraceptive implant that provides protection against pregnancy for an extended period of time, e.g. 3 years. It consists of a non-biodegradable rod measuring 40 mm in length and 2 mm in diameter. After insertion, the rod slowly releases a progestogenic hormone, viz. etonogestrel.

The invention is not restricted to the above-described embodiments, which can be varied in a number of ways within the scope of the claims. For instance, in one embodiment at least the main and second housing parts, the cannula holder, and the rod are made of a synthetic material, for instance by means of injection moulding.

CLAIMS

1. Kit (1) for assembling a disposable applicator (2) for inserting an implant (3), in particular a rod-like implant containing an active substance, under the skin of a human or animal, the kit (1) comprising

a first component (4), in turn comprising a main housing part (5,6) providing a handle (7) for grasping and manoeuvring the applicator (2), a cannula (11), and a cannula holder (15) mounted in the main housing part (5,6), the main housing part (5,6) having an opening which allows introduction of an implant (3) into the proximal end of the cannula (11) and/or the cannula holder (15), and,

separate from the first component (4),

a second component (8) for closing said opening, in turn comprising a second housing part (9) at least partially complementary in shape to the main housing part (5,6) and a rod (10) attached to or forming an integral whole with the second housing part (9) and mountable inside the cannula (11) and/or the cannula holder (15).

2. Kit (1) according to claim 1, wherein the first and second components (4,8) are provided with complementary features (34,39) for irreversibly attaching one part to the other.

3. Kit (1) according to claim 1 or 2, wherein the distance between the opening and the proximal end of the lumen of the cannula (11) and/or the cannula holder (15) is less than the length of the implant (3) to be used and preferably less than 20 mm, more preferably less than 10 mm.

4. Kit (1) according to any one of the preceding claims, wherein the proximal end of the lumen of the cannula (11) and/or the cannula holder (15) is provided with a funnel-shaped entrance (40).

5. Kit (1) according to claim 4, wherein the diameter of the narrowest portion of the funnel-shaped entrance (40) is equal to or smaller than the inner diameter of the cannula (11).

6. Kit (1) according to any one of the preceding claims, wherein the main housing part comprises two half-shells (5,6) and the second housing part comprises a further shell (9), the shells (5,6,9) forming, once assembled, a hollow and substantially closed housing.

7. Kit (1) according to any one of the preceding claims, wherein the first component (4) comprises an actuator (14), which is connected to the cannula holder (15) so as to enable, once assembled, retracting the cannula (11) and the cannula holder (15) over the rod (10).

8. Kit (1) according to any one of the preceding claims, wherein the handle (7) extends above at least 30%, preferably at least 50%, more preferably at least 80% or all of the length of the cannula (11) extending from the first component (4).

9. Kit (1) according to any one of the preceding claims, wherein the first component (4) comprises a mechanism having a lever (24) extending along at least part of the cannula (11), which lever (24) is rotatable and/or slidable and/or flexible between a first position, wherein the implant (3) is secured inside the cannula (11) and/or the cannula holder (15), and a second position, wherein the implant (3) is disengaged.

10. Method of assembling a disposable applicator (2) comprising the steps of subsequently

- providing

a first component (4) comprising a main housing part (5,6) providing a handle (7) for grasping and manoeuvring the applicator (2), a cannula (11), and a cannula holder (15) mounted in the main housing part (5,6), the main housing part (5,6) having an opening which allows introduction of an implant (3) into the proximal end of the cannula (11) and/or the cannula holder (15), and, separate from the first component (4),

a second component (8) for closing said opening, in turn comprising a second housing part (9) at least partially complementary in shape to the main housing

part (5,6) and a rod (10) attached to or forming an integral whole with the second housing part (9),

- introducing an implant (3) through the opening and into the proximal end of the cannula (11) and/or the cannula holder (15),

- mounting the rod (10) inside the cannula (11) and/or the cannula holder (15) and closing the opening by attaching one housing part to the other.

11. Method according to claim 10, wherein the implant (3) is taken from a reel and cut to size prior to introducing the implant (3) into the proximal end of the cannula (11) and/or the cannula holder (15).

12. Method according to claim 10 or 11, wherein the cannula holder (15) is manufactured by introducing at least the proximal end of the cannula (11) in a mould and moulding the cannula holder (15) about the proximal end.

13. Method according to any one of claims 10-12, wherein at least the first component (4) is inspected for compliance with production specifications prior to introduction of the implant (3).

14. Disposable applicator (2) obtained with the method according to any one of claims 10 to 13, which applicator (2) is contained inside a sterile package.