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(71) Applicant (for all designated States except US): UN-
OMEDICAL A/S [DK/DK]; Birkerød Kongevej 2,
DK-3460 Birkerød (DK).

(72) Inventor; and

(75) Inventor/Applicant (for US only): HASTED, Søren,
Bo [DK/DK]; Rosenvængets Allé 27A, 2. tv., DK-2100
København Ø (DK).

(74) Agent: ZACCO DENMARK A/S; Hans Bekkevolds Allé
7, DK-2900 Hellerup (DK).

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(54) Title: CANNULA INSERTION DEVICE WITH AUTOMATIC NEEDLE RETRACTION COMPRISING ONLY ONE SPRING

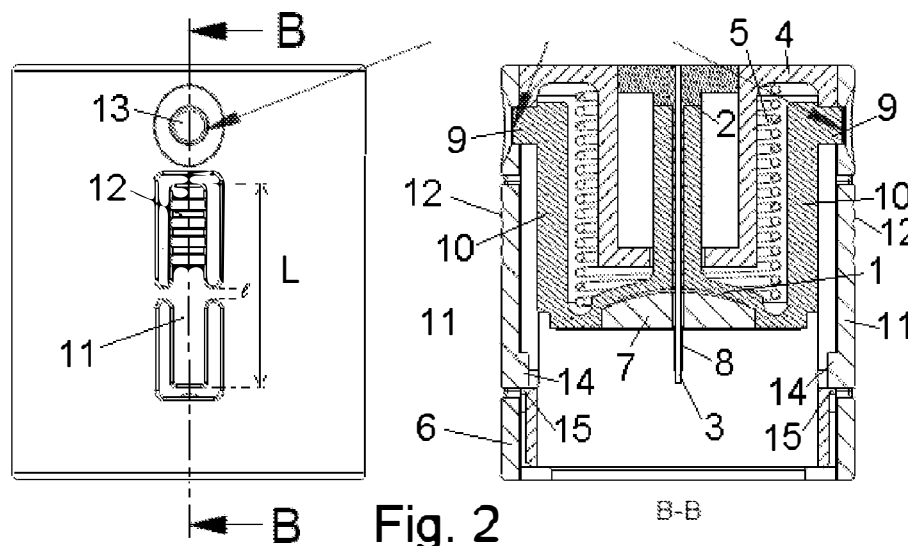


Fig. 2

(57) Abstract: The inserter for an infusion set comprises an insertion needle and a spring unit assuring automatic insertion and automatic retraction of the insertion needle. The inserter for a medical device comprises - a housing (6), - a first body (1) which is movable relative to the housing and comprising penetrating means (3) pointing in the direction of insertion, - a second body (4) which is also movable relative to the housing (6) and - driving means (5) which move respectively the first body (1) and the second body (4) relative to the housing (6) wherein the driving means (5) moves the first body (1) in the direction of insertion and moves the second body (4) in a direction different from the insertion direction.

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The invention relates to an inserter for a medical device e.g. an infusion set for intermittent or continuous administration of a therapeutical substance,
5 such as e.g. insulin. The inserter comprises an insertion needle and a spring unit assuring automatic insertion and automatic retraction of the insertion needle.

Background of the invention

10 It is known to construct inserters for infusion sets which hides and protects the insertion needle before insertion and which retracts the insertion needle after penetration of the patients skin and thereafter hides and protects the insertion needle.

Such a device is known from EP 1.762.259. The inserter according to this
15 document comprises a needle hub comprising an insertion needle and two spring units assuring automatic insertion and automatic retraction of the insertion needle. Although the design of the device is compact and user friendly the mechanism is relatively complex as two spring units are used in order to make the device work correctly.

20 The present invention provides both protection of the insertion needle before insertion and after retraction and at the same time the inserter device is of a simple construction which only needs one spring unit.

Description of invention

25 The object of the invention is to provide a simple, non-expensive inserter for an infusion device which inserter would be easy and safe for the user to handle during use and safe to dispose of after use.

The invention concerns an inserter for inserting a medical device comprising a housing, a first body which is movable relative to the housing and comprising penetrating means pointing in the direction of insertion, a second body which is also movable relative to the housing and driving means which
5 move respectively the first body and the second body relative to the housing wherein the driving means moves the first body in the direction of insertion and moves the second body in a direction different from the insertion direction.

10 In one embodiment the driving means first move the first body in the direction of insertion and then moves the second body in the direction different from the insertion direction. The driving means can comprise a single spring unit which could be a cluster of several springs or a single spring unit, e.g. a
15 coiled spring. The spring unit of this one embodiment can work by first expanding in the insertion direction and then expanding in the direction different from the insertion direction. This direction different from the insertion direction can be in an angle of $180^\circ \pm 5^\circ$ to the insertion direction.

In one embodiment the inserter device can be provided with first locking
20 means which locking means can keep the first body in a chosen retracted position in relation to the housing while the driving means are biased i.e. the driving means posses stored or potential energy. These first locking means can comprise a protruding part on the first body which interacts with an opening in the housing.

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In one embodiment the inserter is provided with second locking means which second locking means can keep the second body in a chosen forward
30 position in relation to the housing while the driving means are biased i.e. the driving means posses potential energy, e.g. the second locking means comprises an inwardly protruding part of the housing which interacts with a distally turned surface of the second body.

According to one embodiment the inserter comprises means for locking the penetrating means to the second body while the second body is moving from a forward to a retracted position in relation to the housing.

5

The medical device used with the inserter device can be e.g. an infusion part for administrating medication or a sensor device for measuring values e.g. of the blood or a simple port/gateway for administering medication by a syringe or the like.

10

The invention also relates to a process for positioning a medical device on the skin of a patient which process comprises the following steps:

- a) removing any packing and preparing the skin adhesion of the medical device;
- 15 b) placing the proximal end of the inserter against the skin of the patient or against a pre-positioned pad;.
- c) unreleasing a first set of locking means (9) which will bring a first body (1) to reach a forward position and cause a proximal surface of the medical device to reach the surface it is to be placed on;
- 20 d) unreleasing a second set of locking means (11) which will result in that a second body (4) including parts locked to the second body (4) are distanced from the medical device which is left on the patients skin;
- e) removing the inserter from the position while the medical device is left in the position.

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Description of the drawings

The invention is explained in greater detail below with reference to the accompanying drawings wherein preferred embodiments of the invention is shown.

Fig. 1 shows a cut-through view of an embodiment of a device according to the invention. The embodiment is in a first state where the penetrating member is retracted and the spring unit is tightened.

Fig. 2 shows the same embodiment as fig. 1 in the same state but in a view which is perpendicular to the view of fig. 1.

Fig. 3 shows the same embodiment as fig. 1 and 2 in a second state where the penetrating member is in a forward position and the spring unit in a semi-tightened state.

Fig. 4 shows the same embodiment as the previous figures in a third state where the penetrating member is in a retracted position; the medical device is left on the skin of the patient and the spring unit in a non-tightened state.

Fig. 5 shows an exploded view of the same embodiment as the previous figures.

15 The device illustrated in fig. 1 comprises a carrier body 1 for a medical device to be inserted, a needle hub 2 comprising a penetrating member 3, a movable part 4, a spring unit 5 and a housing 6. The spring unit 5 is tightened or biased in the

20 The medical device can be all sorts of devices which for some reason needs to be placed sub- or transcutaneously on a patient for a shorter or longer time. In the embodiment illustrated in fig. 1-5 the medical device is a port-device. A port-device is a device which is placed on a user's skin for a period of upto three days and replaces numerous injections normally made by a
25 syringe. The medical device could instead be an infusion part which device is also normally situated on the patient for several days and an infusion part has means for connecting it to a delivery device e.g. for delivering insulin. An infusion part can e.g. provide an optimized administration of a therapeutic substance as it allows very small doses to be transferred often. The medical
30 device can also be a sensor device provided with a subcutaneously placed

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