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☑ Description : paged ....1.... to paged ....8.....
☑ Claim(s) : paged ....1.... to paged ..10.....
☑ Drawing(s) : paged ....1/3.... to paged ..3/3.....
☑ Abstract : paged ..1.... to paged ....
DATE OF RECEIPT .....

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Injection Device

The invention relates to a device for introducing an active substance solution into a patient with means for fastening the device to the body surface and with a cannula for insertion into the skin or into the tissue underlying it and for introducing the active substance solution.

During the preparation of a patient for an operation etc. it is now customary to create a venous access to which injection appliances can be connected in case of need. However, in the area of after-care, therapy and prevention, this method is frequently associated with disadvantages, of which the most serious may be mentioned. The insertion of cannulas may be performed only by trained medical staff. Patients themselves are in most cases not capable of this, so that self-medication is not possible in the case of medicines which are injected. On the other hand, the insertion of a cannula results, especially in the case of long-term therapy, in an injury with an increased danger of infection. The danger of injury when handling used cannulas represents an additional risk. The said disadvantages lead to the subcutaneous or intradermal injection route frequently being chosen for cost and safety reasons.

Devices which can be worn on the body and which represent a combination of cannula and reservoir for the active substance solution have been developed for the patient's convenience, specifically to facilitate self-medication. For example, EP-A-272 530 discloses a wearable device for subcutaneous or intradermal injection of a liquid active substance formulation, which consists of a storage container, an injection needle to be connected to the latter, a pump unit for emptying the container through the injection needle and fastening means, the needle being propelled by means of a drive device into the skin of the patient.

Devices of this type which have an active substance reservoir as an integral component have the disadvantage that a separate device is necessary for each active substance formulation. In addition, the limitation

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of the volume of active substance in these devices prevents their use for a number of applications.

The object on which the invention is based is therefore to provide a device which offers great convenience to the patient and, at the same time, the maximum possible flexibility and safety for intradermal and subcutaneous injections.

This is achieved according to the invention by a device of the type specified earlier, which is distinguished by an advancer unit to propel the cannula into the skin, a connecting element which is arranged on the outside of the device for connection to a conveying unit for the active substance solution, a connection channel, which is open in the inserted state of the cannula, between the connecting element and the cannula, and fastening means for fastening the device to the patient's skin.

According to a further embodiment of the invention, the said advancer unit is designed in such a way that the cannula can, after the infusion is complete, be returned to a protected initial position.

Exemplary embodiments of the invention are described hereinafter by means of the appended drawings.

Figures 1-5 show various embodiments of injection units, in each case in section.

The device shown in Fig. 1 has an approximately frustoconical housing 1 with a concentric bore 2 which consists of four regions with diameters increasing in each case from the bottom to the top. The base of the housing has a concentric projection 3. The part of the base which surrounds the projection 3 is provided with an adhesive layer 4 for fastening the device to a site on a patient's body, the material and thickness of which are selected in particular with a view to wearing convenience and secure retention of the device. From this viewpoint, a so-called adhesive foam was selected for the layer 4. The face of the projection 3 is likewise provided with an adhesive layer 5 which serves in particular for reliable immobilization of the skin. For this purpose, the adhesive layer 5 consists of a thinner, relatively vigorously adhesive material. However, it is perfectly possible for adhesive layers 4 and 5 to consist of the same material.

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A Luer attachment 6 is located at a site on the housing and serves to connect the device to a delivery pump for an active substance solution and, via the latter, to a reservoir. A narrow channel 7 leads from the Luer attachment to the central bore. Above and below the opening of the channel 7 into the bore, O rings 8 are inserted into corresponding annular grooves in the inner wall of the bore.

A thin steel capillary of about 200 m diameter with a bevelled insertion end serves as cannula 9. The cannula is held in a cannula holder 10. The cannula holder 10 is an element which is arranged to be concentrically and axially displaceable in the bore 2 and which is shown in its upper terminal position. In its lower terminal position, the lower face of the cannula holder lies on the stop formed by the junction between the narrowest region of the bore 2 and the next larger one thereof. The cannula 9 then extends through the narrowest region, serving as passage for the needle, of the bore 2 and through the adhesive layer 5, for example into the tissue of the adjoining skin of a patient.

A channel 11 leads from the cylindrical side of the cannula holder 10 and widens in the interior thereof. The end of the cannula 9 opposite to the bevelled tip thereof opens into the widening of the channel 11. In the lower position of the cannula holder, the channel 11 is opposite to channel 7 in the housing 1.

The cannula holder has a guide flange 12 with a diameter corresponding to the internal diameter of the third region of the bore. On its upper surface the cannula holder 10 has a hollow cylindrical wall 13 which is provided on its inside directly adjacent to its upper end with an encircling beading. The wall 13 with the beading cooperates with the retaining and releasing mechanism 14 which will be described hereinafter.

A retaining and releasing mechanism 14 is inserted into the topmost region of the bore 2 with the largest diameter and retains the cannula holder 10 in the resting state in its upper terminal position and, by releasing, permits its displacement into the lower terminal position. Between the cannula holder 10 and the retaining and releasing mechanism 14 there is a coil spring which pushes the cannula holder 10 downwards.

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The retaining and releasing mechanism 14 consists of two parts which can be displaced axially towards one another and of which the lower consists of an annular plate 15 and wall segments 16 which project downwards on the central opening of the latter and essentially form a hollow cylindrical shape. The plate 15 is firmly connected to the housing, that is to say screwed, welded etc. It forms the upper abutment of the spring 17 and must therefore be designed to be relatively rigid.

The wall segments 16 have on their outer surfaces a conical shoulder which forms the junction between an upper smaller and a lower larger axial distance. The beading of the wall 13 lies on this shoulder, which retains the cannula holder 10 in its upper terminal position. The wall segments 16 likewise have on their inside a shoulder in which a bracing flange 19, which will be described hereinafter, engages.

The upper part of the retaining and releasing mechanism 14 consists of an approximately mushroom-shaped releasing trigger 18 on the lower end of which the said bracing flange 19 is located. The releasing trigger is retained in the upper position shown by a disc spring 20. The bracing flange 19 prevents the inward movement of the elastic wall segments 16 and thus the releasing of the downward movement of the cannula holder 10.

The retaining and releasing mechanism 14 accordingly represents in the present embodiment a spring-loaded catch with lock. Removal of the lock automatically releases the spring-loaded catch as a result of the pressure of the spring 17.

If the device is now attached, that is to say stuck, to a suitable site on a patient's body, and is connected to a conveying unit for an active substance solution, and if the injection is to be triggered, the patient pushes the trigger 18 downwards against the pressure of the spring 20. This pushes the bracing flange 19 out of its seating in the interior of the wall segments 16. The wall segments escape inwards from the pressure exerted on the shoulder by the coil spring 17 via the beading, and the cannula holder 10 together with the cannula 9 is pushed downwards with high acceleration by the spring 17. The cannula 9 is projected through the adhesive layer 5 into the patient's tissue. The high acceleration means that the penetration of the needle takes place so quickly that the patient feels no pain.

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The embodiment shown in Fig. 2 has a number of functional elements identical to those shown in Fig. 1. Some of the elements merely have a different shape, while other elements are assigned different or additional functions.

A housing 21 has a bore 22 which, in the present case, has only one gradation of its diameter, namely the constriction at its lower end to form an orifice for an injection cannula 29. The housing is likewise provided on its underside with an adhesive layer 24 which in this case is designed to be continuous. A Luer attachment 26 is located in an extension 23 attached on the side of the housing and is connected via a channel 27 to the bore 22. Two O rings 28 lie in corresponding annular grooves above and below the opening of the channel 27 into the bore 22.

The cannula 29 is also in this case seated in a cannula holder 30 which is designed to be essentially cylindrical and has a channel 31 for connecting the rear of the cannula to the bore 22. Its outer surface has a conical shoulder formed by an upward widening of the cross section. The cannula holder 30 is firmly connected via an annular, glass-clear viewing element 33 to a cap 38 which encloses the entire mechanism and which can be moved downwards from the upper position shown in the Figure and serves as a releasing head. The cap 38 has a viewing window 39 in its centre.

Wall segments 36 are located on the housing surface and arranged around the edge of the bore 22, and are provided on their upper edge with projections which are directed towards the axis and which grip under the conical shoulder of the cannula holder 30. The wall segments 36 are elastic and form together with the conical shoulder of the cannula holder a retaining and releasing mechanism 34. Finger pressure on the cap 38 bends them outwards until, when the pressure is sufficient, they release the cannula holder 30. Owing to the finger pressure necessary to overcome the retaining force, when the cannula holder 30 is released the needle is forced into the patient's skin. The upper end of the cannula holder 30 has a conical taper and is designed so that the elastic wall elements 36 exert a pressure directed downwards onto the cannula holder, which holds the needle in the lower insertion position after pushing in.

The outer surface of the cap 38 is shaped so that it can be gripped by the fingers and pulled back again to its initial position. On its lower edge the

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cap is provided with a projection 37 which is directed inwards and which, together with a corresponding shoulder 35 on the housing, prevents the cap being pulled out beyond the initial position. The result of this is that the cannula can be pulled back completely into the housing again after the infusion is complete.

In the lower terminal position of cap 38 and cannula holder 30, the projections on the wall segments 36 are at the level of the viewing element 33 and are in contact with it. The wall segments 36 are picked out in colour so that they are readily visible in this position through the viewing window 39 and thus indicate that the cannula 29 has been inserted. A visual check of this type is often advantageous because the patient does not feel the prick.

Fig. 3a shows a device in which the housing 41 has a design very similar to that in Fig. 1 with bore 42, projection 43, adhesive layers 44 and 45 and with Luer attachment 46, channel 47 and O rings 48 in the wall of the bore 42. The cannula holder 50 with cannula 49 and connection channel 51 and the wall segments 56 retaining it are the same as in the device shown in Fig. 2. The cap 57, which also has a viewing window 59 in this case, is provided with a crossbar 58 by which it can be rotated. It additionally has a plurality of fingers 60 which project downwards from its underside and which in turn are provided with toes 61 which are directed radially outwards. These toes 61 slide in grooves provided in the wall of the upper region of the bore and of which one is shown in Fig. 3b. The groove has an arm 62 which runs vertically downwards and an arm 63 which is inclined like a ramp. The two arms are connected at the bottom by a short horizontal piece 64. A horizontal groove piece 65, 66 is attached at each of their upper ends. The horizontal groove piece 65 on the right in the drawing, which is located at the top of the vertical arm 62, defines the resting position before use of the device. The other horizontal groove piece 66 at the top of the inclined arm 63 defines the position after use of the device. The cannula holder 50 and injection cannula 49 are pulled back into this position by rotating the crossbar 58 before the device is taken off the patient. This pulling back of the cannula prevents both possible injury to the patient due to tilting of the cannula on taking off, and injuries and thus infections of the medical assistants owing to the projecting cannula.

The device shown in Figure 4 has no release of the cannula advance to be actuated manually by the patient. The housing 71 is very flat, only about

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10 mm high, and is closed at the top and has a concentric chamber 72 open at the bottom. It is additionally in two parts and has a part 73 which is inserted in the base and simultaneously forms a projecting part, surrounding the orifice, of the base. A protective film 74 is located between the main part of the housing 71 and the inserted part 73 and encloses the chamber formed between the two parts. A Luer attachment 76 is located in the upper part of the housing and is connected by a channel 77 to the chamber 72.

An O ring 78 is inserted into a corresponding encircling groove on a concentric projection projecting from above into the chamber.

A cannula 79 is seated in a cannula holder 80 which essentially matches the shape of the chamber 72. The cannula holder 80 has on its lower edge an encircling projection which engages in a corresponding annular groove in the housing and forms together with the groove a spring-loaded catch 81. The latter retains the cannula holder firmly in the position shown in the resting state.

Near the upper edge of its cylindrical outer surface, the cannula holder has an encircling annular groove into which an O ring 82 is inserted. An annular enclosed space is produced by the two O rings 78 and 82 between the cannula holder and the upper face of the chamber and is connected to the Luer attachment 76 only through the channel 77.

The cannula holder furthermore has on its lower edge two pins 83 which project radially outwards. The end pieces of two torsion springs 84 engage these. The latter have an initial tension such that they convey the cannula holder downwards as soon as it is released.

This embodiment functions in the following way:

When the device is fastened to a site on the patient's body, the connection to the conveying unit for the active substance solution (not shown) is set up via the Luer attachment. The delivery pump generates a pressure in the upper region of the chamber 72. The force acting thereby on the cannula holder 80 is added to the force of the springs 84. As soon as the added force exceeds the retaining power of the spring-loaded catch 81, the cannula holder moves downwards. The springs 84 now take over the

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propulsion of the cannula holder. After an initial short distance has been covered, the inner upper rim of the cannula holder has passed below the O ring 78 and thus opens the way for the active substance solution to the upper end of the cannula 79. The active substance solution is able to reach the patient's skin through the cannula 79.

The device shown in Figure 5 is depicted in two mutually perpendicular cross-sections in order to make the details clearer. The aim of this device was to reduce the height of the construction even further. The housing 91 is very flat, that is to say it has a height of less than 10 mm. A chamber 92 which is centrally located in the housing is once again open at the bottom and closed at the top. The housing is in two parts for assembly. The lower part 93 forms a central, concentric projection which projects beyond the face of the housing. Protective films 94 are located between the lower part 93 and the main part of the housing 91 and seal the cavity produced between the two housing parts. A Luer attachment 96 is again located in the upper housing part 91 and is connected by a channel 97 to the chamber 92.

A cannula 99 is inserted in a cannula holder 100 but otherwise moves freely in an elastic seal 101 located in the lower part of the chamber.

The cannula holder 100 essentially consists only of a U-shaped element on the upper ends of whose arms there are located attachment points for the transmission of force from torsion springs 102. The springs 102 have an initial tension such that they drive the cannula holder with the cannula 99 downwards as soon as they are released.

The cannula holder 100 is retained in the upper resting position shown in Figure 5 by a slide 103. When the slide 103 is moved to the right, it releases the cannula holder 100, and the spring 102 is able to move the cannula holder 100 together with cannula 99 downwards and thus insert the cannula 99 into the patient's skin.

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Claims

1. A device for introducing an active substance solution into a patient with means for fastening the device to the body surface and with a cannula for insertion into the skin and for introducing the active substance solution, said device comprising

- an advancer unit (14, 34) to propel the cannula (9, 29, 49, 79, 99) into the skin

- a connecting element (6, 26, 46) which is arranged on the outside of the device for connection to a conveying unit for the active substance solution and

- a connection channel (7, 11; 27, 31; 77; 97), which is open in the inserted state of the cannula, between the connecting element and the cannula.

2. A device according to claim 1, wherein the advancer unit has a retaining and releasing mechanism (14) which is formed by a spring-loaded catch (13, 16) with lock 19 and a spring 17.

3. A device according to claim 2, wherein the retaining and releasing mechanism (34) has a releasing button with a viewing window (39) to check the position of the cannula holder.

4. A device according to claim 1, wherein means for withdrawing the cannula holder (30, 50) and the cannula (29, 49) are present.

5. A device according to claim 4, wherein the cannula holder (50) is provided with toes (61) on the side which are guided in a groove (62-66) of the housing (41).

6. A device according to claim 1, wherein means (78, 82) for advancing the cannula holder (80) on the basis of the pressure of the active substance solution are present.

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7. A device according to claim 1, wherein the cannula (9, 29, 49, 79, 99) is isolated from the outside in its upper position by a protective film (74).

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