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(71) Applicant *(for all designated States except US)*: **UNOMEDICAL A/S** [DK/DK]; Engmosen 1, DK-3540 Lynge (DK).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **MOGENSEN, Lasse, Wesseltoft** [DK/DK]; Jacob Bulls Allé 100, DK-2860 Søborg (DK). **GÖRANSSON, Magnus, Walter** [SE/SE]; Folkungagatan 11, S-411 02 Göteborg (SE).

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

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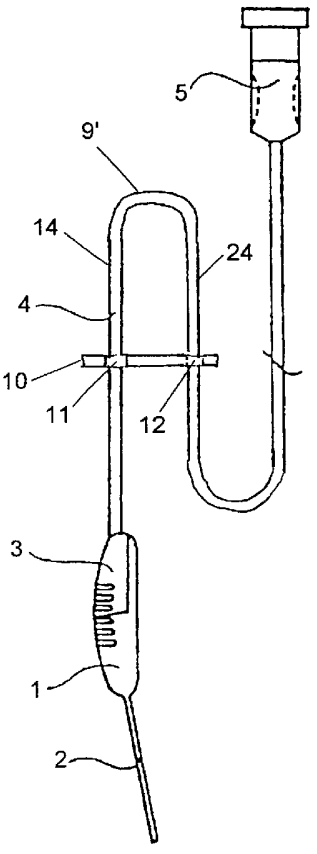
(54) Title: A DEVICE FOR SUBCUTANEOUS ADMINISTRATION OF A MEDICAMENT TO A PATIENT



(57) Abstract: The invention relates to a device for subcutaneous administration of a medicament to a patient, comprising a cannula housing (1) with an interior chamber, a cannula (2) connected to said cannula housing (1) and being in flow communication with the interior chamber, a flexible tubing (4) having a first end (4') and a second end (4''), wherein the tubing (4) is, at the first end (4'), coupled to the cannula housing (1) such that the tubing (4) is in flow communication with the interior chamber, and wherein, at its other end (4''), the tubing carries a source coupling (5), whereby the tubing (4) can be coupled to a source for said medicament. The invention is characterised in that the tubing (4) is, between the first and the second end (4', 4''), folded (9, 9') for forming a configuration with at least two essentially parallel courses (14, 24, 34) of tubing, that the tubing (4) is secured in said configuration by means of a first holder device (10) arranged between the first and second end (4', 4'') of the tubing; and that the tubing (4) can be displaced in relation to said first holder device (10) for varying the length of said courses (14, 24, 34) of tubing.

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A device for subcutaneous administration of a medicament to a patient

The present invention relates to a device for subcutaneous administration of a medicament to a patient, comprising a cannula housing with an interior chamber, a cannula connected to said cannula housing and being in flow communication with the interior chamber, and a flexible tubing having a first end and a second end, wherein the tubing is, at the first end, coupled to the cannula housing such that the tubing is in flow communication with the interior chamber, and wherein, at its second end, the tubing carries a source coupling by which the tubing can be coupled to a source for said medicament; and wherein, between its first and its second end, the tubing is folded for forming a controlled configuration of the tubing with essentially parallel courses of tubing.

US patent No. 5,522,803, being now as a reference deemed to constitute a part of the present text, shows in Figures 1 and 2 a cannula housing to be adhered to the skin of the patient so as to enable continuous administration of a drug to the patient via a plastics needle introduced into the skin of the patient. At its one end a tubing features a coupling that is releasably secured to the cannula housing, whereby the tubing can be released from the cannula housing, eg when the patient is in the bath. At its other end the tubing features a a source coupling by which the tubing can be coupled to a source, such as a pump, thereby enabling the drug to be fed to the cannula housing through the tubing.

In some situations, eg when the patient is asleep it is necessary to have a relatively long distance between the cannula housing and the source of the drug to enable the source of drug to sit on a table next to the patient. Thus there is a need for a comparatively long tubing, eg a tubing having a length of about 1.1 m. Conversely, a short tubing is typically desired when the patient is up and about, ie when the source of drug is carried by the patient, eg in a

pocket in his clothes. To overcome this problem, it is an option to change tubing as day turns into night. This, however, may lead to waste of the usually very expensive medicament located in the long tubing.

It is previously been attempted to solve this problem by providing the source of drug with a winder mechanism for the tubing, see international patent application No. WO 96/35472. The winder mechanism described therein, however, cannot be manufactured at low costs and there is a risk of the winder mechanism getting stuck.

It is the object of the present invention to provide a device for subcutaneous administration of a drug to a patient that can be be manufactured at low costs and that enables variations in the distance between the source of drug and the cannula housing.

This is accomplished in that, in order to secure the tubing in said configuration, it is received in guides in a first holder device arranged between the first and the second end of the tubing and in guides in a second holder device arranged at the first or second end of the tubing or between the first and the second end of the tubing; and that the first holder device can be displaced along the tubing in a direction towards the second holder device by movement of the tubing along said guides in the first holder device. Hereby it is possible to vary the effective distance between the cannula housing and the source of drug between approximately the length of the tubing and a distance determined by the number of folds on the tubing and the position of the holder device; and to adequately control the courses of tubing and adequately support the tubing in the area around the folds. The second holder device may be an integral part of the cannula housing or the source coupling, or it may be configured in the same manner as the first holder device and may be arranged on the tubing as a separate component that is capable of being displaced along the tubing.

In the latter case, the effective distance between the cannula housing and the source of drug can be increased by manually displacing the holder devices towards each other along the tubing, ie along the respective courses of tubing, and then sort out the requisite length of tubing. Depending on the frictional resistance between the tubing and the holder device, said effective distance may alternatively be increased by merely applying a pull in the two ends of the tubing. The distance can subsequently be reduced by manually pulling the holder devices away from each other.

It is preferred that at least the first holder device is provided with guides for the tubing, preferably in the form of bores, ie closed channels, and these guides can be rectilinear or they can be curved and hence receive the fold(s) of the tubing and provide a certain protection of the tubing in these areas. Particular advantages from the point of view of mounting can be accomplished by configuring the one or both of the holder devices as a two-piece housing, thereby facilitating the mounting of the holder devices on the tubing.

In the present context, the term "parallel courses of tubing" is intended to designate one or two lengths of the tubing that has/have – apart from the folding area – courses that are mutually entirely parallel or converge towards each other within an angle interval of a very few degrees, eg 1-5°, so as to allow the courses of tubing to extend relatively close to each other irrespective of the position of the holder device along the tubing. Also, the term "folded" is intended to designate a state in which the tubing continues to be able to convey medicament from the one end of the tubing to the other.

The invention also relates to a tubing as recited in claim 12 that is suitable for being mounted on an existing system for subcutaneous administration of a medicament.

The invention will now be explained in further detail with reference to the drawing.

Figure 1 is a schematic view of a number of the elements necessary for subcutaneous administration of a medicament to a patient;

Figure 2 shows, in schematic outline, a sectional view of a first embodiment of the invention;

Figure 3 schematically shows a sectional view of an alternative embodiment of the invention, wherein the cannula housing and source coupling are omitted;

Figures 4a, 4b and 4c show a variant of the embodiment of Figure 3, wherein the cannula housing and source coupling are omitted.

Figures 5, 6a and 6b are alternative embodiments, wherein the second holder device is configured as an integral part of the coupling to the cannula housing; and

Figure 7 shows an embodiment in which the second holder device is configured as an integral part of the source coupling.

Figure 1 shows a part of a flexible tubing 4 having a first end 4' and a second end 4''. At its first end 4' the tubing 4 is provided with a coupling 3 configured for being, in a releasable manner, able to be secured to a cannula housing 1. The cannula housing 1 has an interior chamber that communicates with the tubing 4 and with a cannula 2 that protrudes from the cannula housing 1 which is preferably flexible and of plastics and intended for being introduced through the surface of the skin of a patient by means of a not shown insertion

needle. The interior chamber is not shown, but its configuration may like the one shown in US patent No. 5,522,803.

A source coupling 5 secured to the second end 4" of the tubing 4 makes it possible to releasably couple the tubing to a source for a drug. The term 'source' in this context is intended to designate a receptacle for the drug, a pump preferably being introduced between the receptacle and the coupling that, said pump supplying the drug to the patient via the tubing 4 in a predetermined dosage. The source coupling 5 is configured for being able to co-operate with a complementary coupling on said drug receptacle or on a tubing connected to the receptacle or pump. Preferably the tubing 4 is made of a plastics material and has such properties that, to a wide extent, the tubing 4 is able to prevent a local occlusion of the flow of the drug if the tubing 4 is folded sharply.

Figure 2 shows a first embodiment of the invention, wherein a holder device 10 in the form of a sheet element with two through-going guides or passages 11, 12 is mounted on the tubing 4. The holder device 10 secures the tubing 4 in a folded state so as to provide a controlled configuration with two courses 14, 24 of tubing extending approximately in parallel with each other between the fold 9 and the holder device 10. Conveyance of the holder device 10 to a position in which the courses 14, 24 of tubing have a length corresponding to approximately half of the length of the tubing 4, ie downwards in Figure 2, it is possible to accomplish improved control of the tubing 4 when, in combination with the cannula housing 1 and the source of medicament, the tubing is to be worn by the patient. It is preferred to configure the passages 11, 12 with such clearance width that the tubing 4 can be secured by means of a certain friction force. The shown solution is suitable in particular in situations where the holder device is mounted on the tubing 4 before the tubing 4 is provided with the couplings 3, 5.

Figure 3 shows an alternative embodiment of the invention, wherein – in order to impart to the tubing the desired, controlled configuration – a further, second holder device 20 is used which is also located between the ends 4', 4'' of the tubing. As will appear, the two holder devices 10, 20 are used for providing a configuration with three courses, 14, 24, 34 of tubing that extend between the holder devices 10, 20. Alternatively, it is certainly an option to configure the holder devices 10, 20 to form five courses of tubing.

The holder devices 10, 20 are shown in Figure 3 in a schematic sectional view and each of the holder devices 10, 20 comprises an internal semicircular guide 11 and an internal rectilinear guide 12, respectively. The semi-circular guide 11 serves to receive the fold 9, 9' of the tubing, while the rectilinear guide 12 conveys the tubing 4 into the area between the two holder devices 10, 20. The width of the guides 11, 12 are adapted to the diameter of the tubing 4, such that the tubing 4 is able to slide in the guides 11, 12 with a desired minimum friction. In order to increase the distance between the cannula housing and the source coupling, a pull is merely exerted in the tubing 4 at its ends 4', 4'', whereby the length of the individual courses of tubing is reduced, while simultaneously the holder devices 10, 20 move towards each other. Conversely, to increase the length of the courses 14, 24, 34 of tubings and thus to move the ends 4', 4'' of the tubing 4 towards each other, a pull is merely exerted in the holder devices 10, 20 in a direction away from each other. In both situations the holder devices are displaced along the tubing 4, the tubing 4 sliding in the guides 11, 12.

Figure 4a shows a variant of embodiment shown in Figure 3, wherein the holder devices 10, 20 are split, the two parts 10', 10'' being preferably articulated to each other and configured for being moved from an open state shown in Figure 4b to a closed state shown in Figure 4c, and to be secured in the latter state via a lock 15, such as a snap lock. Hereby the holder devices 10, 20 can be mounted in an existing system of the kind shown in

Figure 1. In this embodiment, the holder devices 10, 20 comprise three rectilinear guides 11, 12, 13 for the tubing 4.

A further embodiment is shown in Figure 5, wherein the first holder device 10 is configured as described above with reference to Figure 3, but wherein the second holder device 20 is arranged at the first end 4' of the tubing 4 and is configured as an integral part of the cannula housing 1, said cannula housing 1 comprising an outer guide 11 for the fold 9 of the tubing 4. The guide 11 is preferably configured as a notch into which the tubing can be urged and that secures the tubing to the cannula housing 1. Like in the above-referenced embodiments, the guide 11 must be dimensioned such that the tubing 4 is able to slide in the notch when the first holder device 10 is pulled to the right in Figure 5 to increase the length of the courses 14, 24, 34 of the tubings.

Figure 6a and 6b show alternative embodiments, wherein the second holder device 20 is arranged at the first end 4' of the tubing 4 and is configured as an integral part of the coupling 3, whereby the tubing 4 is connected to the cannula housing 1. Thus, the coupling 3 secures, firstly, the end 4' of the tubing and, secondly, it also comprises two guides in the form of bores 11, 12 that secure the tubing in the region at the fold 9. The first holder device 10 can be configured like the holder device 10 shown in Figure 4c. An increase in the distance between the cannula housing 1 and the source coupling is accomplished merely by a pull in the tubing 4 at its ends 4', 4", whereby the length of the individual courses of tubing is reduced while simultaneously the first holder device 10 moves towards the second holder device 20. Conversely, an increase in the length of the courses 14, 24, 34 of the tubings, and hence movement of the ends 4', 4" of the tubing towards each other, is accomplished merely by a pull in the holder devices 10, 20 in a direction away from each other. In both situations the tubing 4 is displaced in the guides of the two holder devices 10, 20.

Finally Figure 7 shows an embodiment that, in principle, corresponds to the one shown in Figure 6a, but wherein the second holder device is configured as an integral part of the source coupling 5. The first holder device 10 can optionally be configured such that it can be locked releasably to the second holder device 20 and be separated there from, when the distance between the courses of tubing is to be increased as is shown at the bottom of Figure 7.

Claims

1. A device for subcutaneous supply of a medicament to a patient, comprising:

- a cannula housing (1) with an interior chamber;
- a cannula (2) connected to the cannula housing (1) and being in flow communication with the interior chamber;
- a flexible tubing (4) having a first end (4') and a second end (4''), wherein the tubing (4) is, at its first end (4') coupled to the cannula housing (1), such that the tubing (4) is caused to be in flow communication with the interior chamber; and wherein the tubing (4) carries a source coupling (5), at its second end (4''), by which the tubing (4) can be coupled to a source for said medicament;
- wherein the tubing (4) is, between the first and the second end (4', 4'') folded (9, 9') for forming a configuration with essentially parallel courses (14, 24, 34) of tubing;

characterised in

- that in order for the tubing (4) to be secured in said configuration, it is received in guides (11, 12, 13) in a first holder device (10) arranged between the first and the second end (4', 4'') of the tubing (4) and in guides (11, 12, 13) in a second holder device (20) arranged at the first or second end (4', 4'') of the tubing (4) or between the first and second ends (4', 4'') of the tubing; and
- that the first holder device (10) can be displaced along the tubing (4) in a direction towards the second holder device (20) by movement of the tubing (4) along said guides (11, 12, 13) in the first holder device (10).

2. A device according to the preceding claim, **characterised in** that the first holder device (10) is configured as a housing with at least two bores that form said guides (11,12, 13).

3. A device according to claim 2, **characterised in**
- that the second holder device (20) is arranged between the first and second ends (4', 4") of the tubing; and
- that the second holder device (20) can be displaced along the tubing (4) in a direction towards the first holder device (10).

4. A device according to the preceding claim, **characterised in** that the second holder device (20) is configured as a housing with at least two bores that form said guides (11, 12, 13).

5. A device according to any one of the preceding claims 1 or 2, **characterised in** that the second holder device (20) is constituted by the cannula housing (1) or by a coupling (3) by which the tubing (4) is connected to the cannula housing (1).

6. A device according to the preceding claim, **characterised in** that the tubing (4) is received in guides (11) that extend interiorly of the cannula housing (1).

7. A device according to any one of the preceding claims 1 or 2, **characterised in** that the second holder device (20) is constituted by the source coupling (5).

8. A device according to the preceding claim, **characterised in** that the tubing (4) is received in guides (11) that extend interiorly of the source coupling (5).

9. A device according to any one of the preceding claims, **characterised in** that the tubing (4) is bent for forming at least three essentially parallel courses (14, 24, 34) of tubing.

10. A device according to any one of the preceding claims, **characterised in** that the first holder device (10) and/or the second holder device (20) comprises two housing parts (10', 10") configured for being movable between a first position in which there is access to said guides (11, 12, 13) for introduction into the guides (11, 12, 13) of the tubing (4) transversally to the longitudinal expanse of the guides (11, 12, 13), and a second position, in which the tubing (4) is fixated against movement out of the guides (11, 12, 13) transversally to the longitudinal expanse of the guides.

11. A device according to any one of the preceding claims, **characterised in** that the guides (11, 12, 13) are configured for optionally being blocked, whereby removal of the tubing (4) by withdrawal of the tubing (4) transversally to the longitudinal direction of the tubing is prevented.

12. A flexible tubing for supplying a medicament from a source for said medicament to a cannula housing (1) that has an interior chamber and a cannula (2) connected to said cannula housing (1) and being in flow communication with the interior chamber, said tubing having a first end (4') with a cannula housing coupling (3), whereby the tubing (4) can be coupled to the cannula housing (1), in such a manner that the tubing (4) is in flow communication with the interior chamber, and a second end (4") having a source coupling (5), whereby the tubing (4) can be coupled to said source, wherein said tubing (4) is, between the first and the second end (4', 4"), folded (9, 9') for forming a configuration with essentially parallel courses (14, 24, 34) of tubings,

characterised in

- that in order for the tubing (4) to be secured in said configuration, it is received in guides (11, 12, 13) in a first holder device (10) arranged between the first and the second end (4', 4") of the tubing and in guides (11, 12, 13) in a second holder device (20) arranged at the first

or second end (4', 4") of the tubing (4) or between the first and second end (4', 4") of the tubing; and

- that the first holder device (10) can be displaced along the tubing (4) in a direction towards the second holder device (20) by movement of the tubing (4) along said guides (11, 12, 13) in the first holder device (10).

13. A tubing according to the preceding claim, **characterised in** that the first holder device (10) is configured as a housing with at least two bores that form said guides (11, 12, 13).

14. A tubing according to claim 13, **characterised in**
- that the second holder device (20) is arranged between the first and second ends (4', 4") of the tubing (4); and
- that the second holder device (20) can be displaced along the tubing (4) in a direction towards the first holder device (10).

15. A tubing according to the preceding claim, **characterised in** that the second holder device (20) is configured as a housing with at least two bores that form said guides (11, 12, 13).

16. A tubing according to any one of the preceding claims 12 or 13, **characterised in** the second holder device (20) is constituted by the cannula housing coupling (3).

17. A tubing according to the preceding claim, **characterised in** that the tubing (4) is received in guides (11) that extend interiorly of the cannula housing coupling (3).

18. A tubing according to any one of the preceding claims 12 or 3, **characterised in** that the second holder device (20) is constituted by the source coupling (5).

19. A tubing according to the preceding claim, **characterised in** that the tubing (4) is received in guides (11) that extend interiorly of the source coupling (5).

20. A tubing according to any one of the preceding claims 12- 19, **characterised in** that the tubing (4) is folded for forming at least three essentially parallel courses (14, 24, 34) of tubing.

21. A tubing according to any one of preceding claims 12-20, **characterised in** hat the first holder device (10) and/or the second holder device (20) comprises two housing parts (10', 10") configured for being movable between a first position in which there is access to said guides (11, 12, 13) for introduction into the guides (11, 12, 13) of the tubing (4) transversally to the longitudinal expanse of the guides (11, 12, 13); and a second position in which the tubing (4) is fixated against movement out of the guides (11, 12, 13) transversally to the longitudinal expanse of the guides.

22. A tubing according to any one of the preceding claims 12-21, **characterised in** that the guides (11, 12, 13) are configured for optionally being blocked, whereby removal of the tubing by withdrawal of the tubing (4) transversally to the longitudinal direction of the tubing is prevented.

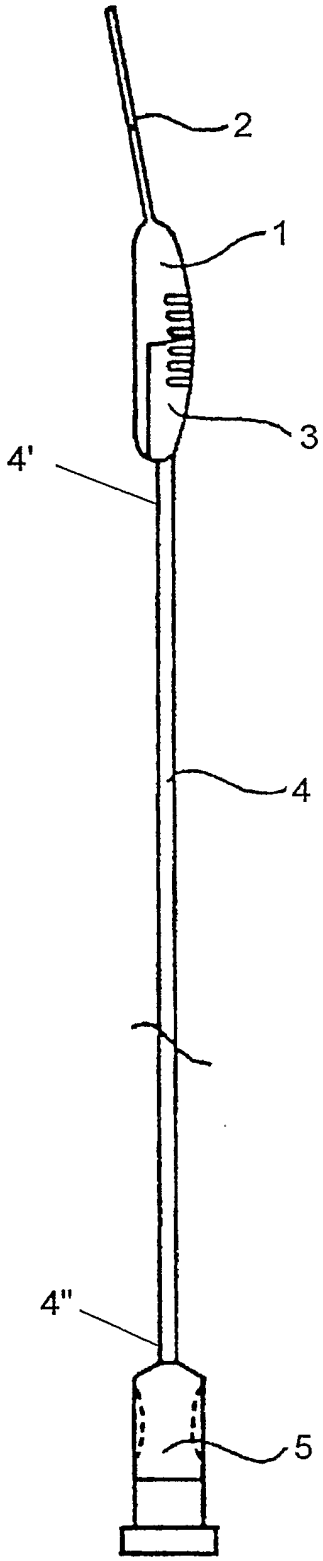


Fig. 1

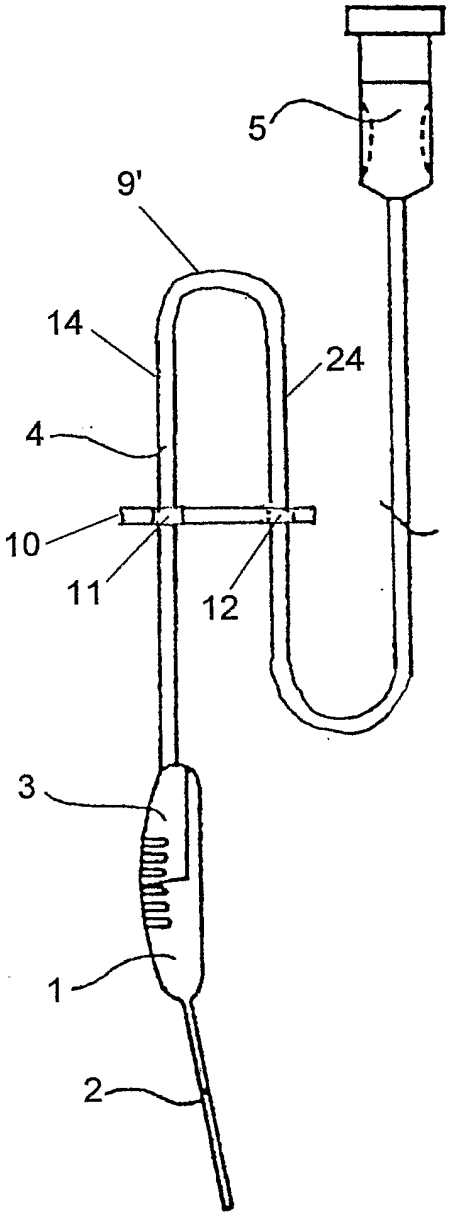


Fig. 2

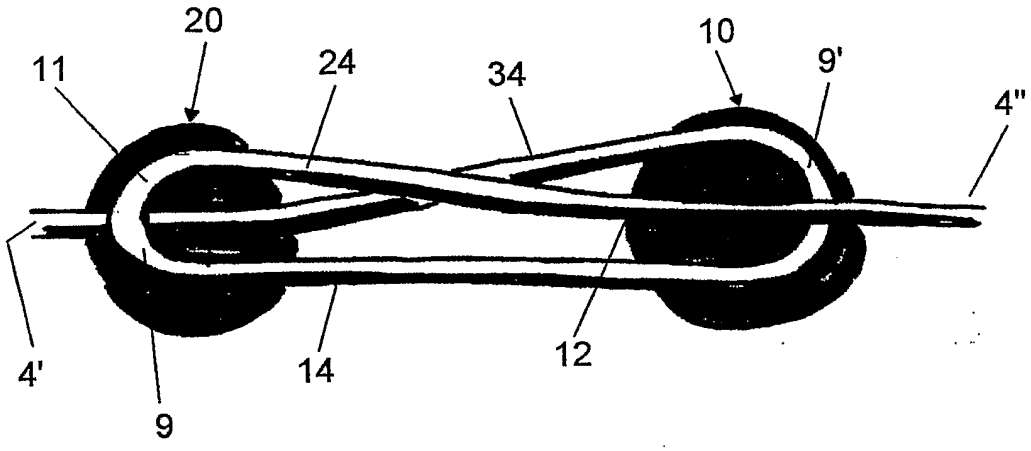


Fig. 3

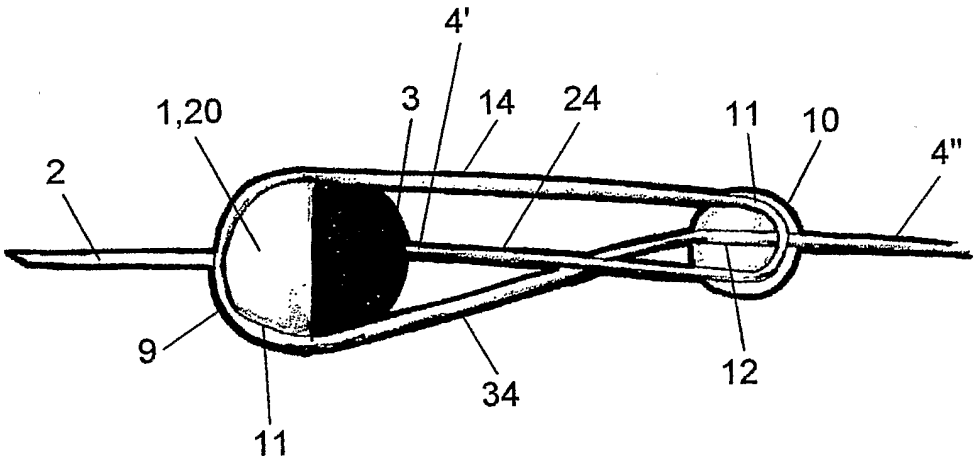
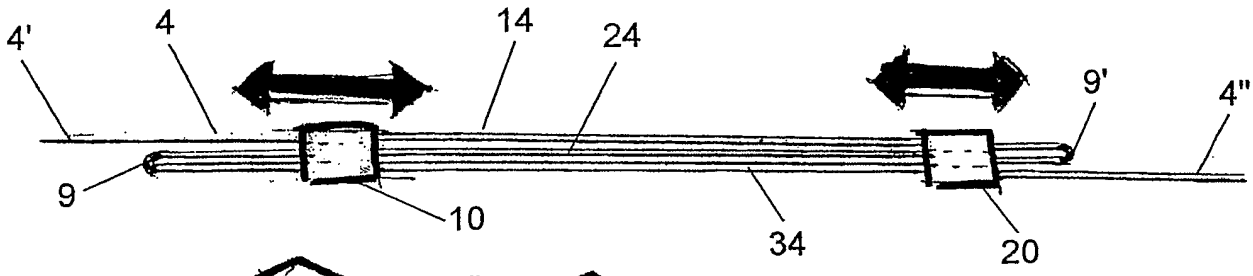


Fig. 5

Fig. 4a



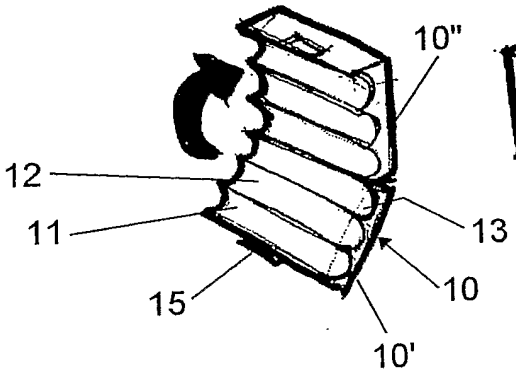


Fig. 4b

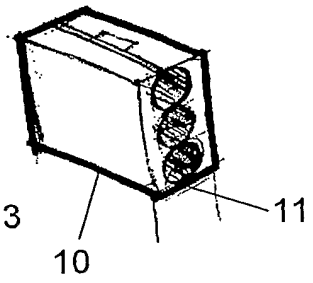


Fig. 4c

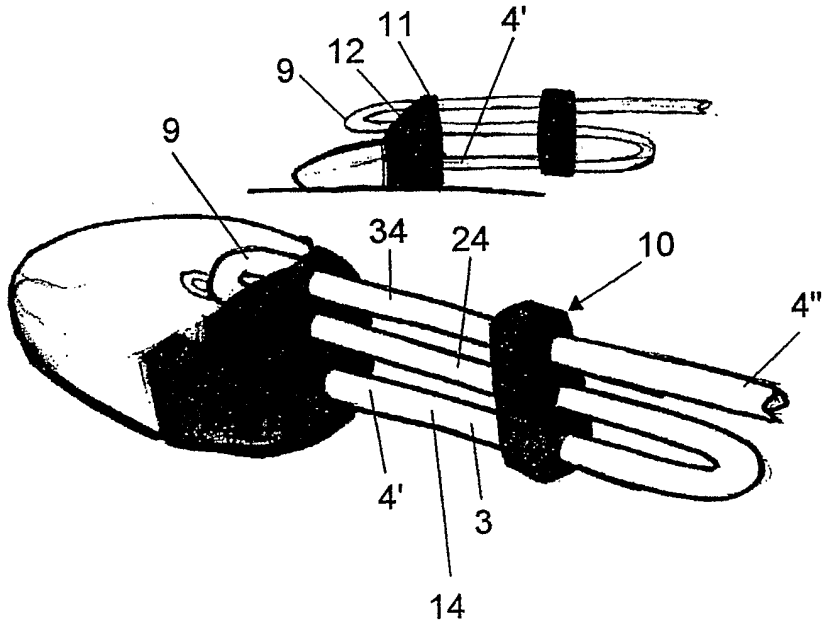


Fig. 6a

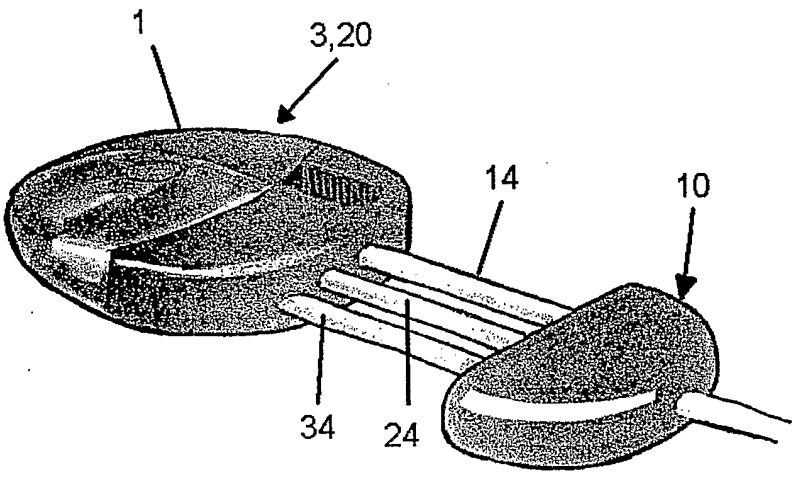


Fig. 6b

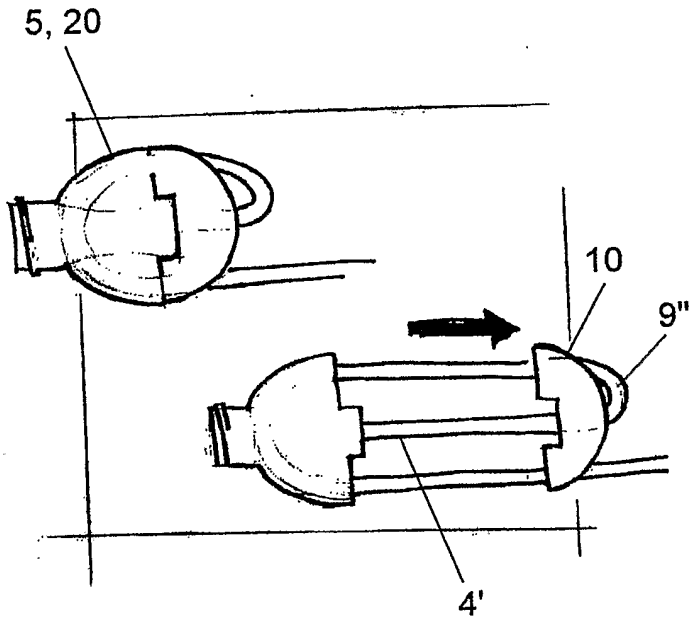


Fig. 7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/DK 03/00569

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M39/08 A61M25/02

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)
IPC 7 A61M B65H

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 406 042 A (MCPHEE CHARLES J) 27 September 1983 (1983-09-27) figures 1-6 abstract ---	1-22
A	EP 1 060 757 A (SEACREST TECHNOLOGY LTD) 20 December 2000 (2000-12-20) figures 1-9 abstract ---	1-22
A	US 4 662 873 A (LASH ROBERT ET AL) 5 May 1987 (1987-05-05) figures 1-6 abstract ---	1-22
A	US 4 606 735 A (WILDER JOSEPH R ET AL) 19 August 1986 (1986-08-19) abstract -----	1-22

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☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
24 November 2003	21 JAN. 2004

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/DK 03/00569

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4406042 A	27-09-1983	NONE	
EP 1060757 A	20-12-2000	US 6405414 B1	18-06-2002
		EP 1060757 A1	20-12-2000
		IE 20000389 A1	27-12-2000
US 4662873 A	05-05-1987	NONE	
US 4606735 A	19-08-1986	NONE	