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EP 2 414 008 B1
Description

[0001] This invention relates to the use of a wave spring or wave washer in a medical device, especially a drug delivery device or injection device.

[0002] The application of mechanisms in medical devices is accompanied with an increasing demand for mechanical components or elements that require only a restricted volume. This is true especially of portable medical devices that are used by patients and have to be everywhere available. If a mechanism of restricted dimensions requires the application of a spring force, the operation of the mechanism is essentially affected by the properties of the spring element. Therefore, a number of different spring types are used in medical devices or have been suggested for an application in conjunction with medical devices, especially with injection or infusion devices.

[0003] US 7,462,169 B2 discloses a safety shield system for an injection pen needle. A mechanically operating part of the injection pen needle can be equipped with a wave spring. US 7,220,245 B2 discloses an infusion apparatus, which is furnished with a flow control means, for which, inter alia, the use of wave springs is recommended.

[0004] WO 94/22507 discloses an injection device in which the piston rod can be resetted upon disconnection of the cartridge from the injector body.

[0005] EP 1 704 883 B1 and EP 1 704 884 B1 disclose devices for administering a fluid product in doses. An embodiment comprises a cylindrical drive member having a thread inside and an output member as well as an adjustment element both having a screw thread of the same pitch. A spring is arranged between the drive member and the adjustment element in order to enhance the friction between the threads. The drive member and the adjustment element can have structures inhibiting a rotation of the adjustment element within the drive member. A further embodiment comprises a screw-like drive member and a wave spring arranged between the housing and a transfer element, which is in contact with a drive ring of the drive member. The transfer element can be rotationally fixed with respect to the housing. The transfer element and the drive ring preferably form a pair of sliding faces.

[0006] It is an object of the present invention to disclose a means of providing medical devices having mechanically operating components with sufficiently strong spring force elements of restricted dimensions.

[0007] This object is achieved with the medical device according to claim 1 and with the use of a wave spring or wave washer according to claim 10 respectively. Further aspects and variations of the invention derive from the depending claims.

[0008] The medical device according to the invention comprises a mechanism having a first element and a second element, which are engaged by a coupling device, and a spring arranged in contact with at least one of the elements and tending to disengage the first element and the second element. The spring can especially be arranged between the first element and the second element and tend to disengage the elements. If the spring disengages the first element and the second element, the elements can be moved relatively to one another. The spring is selected to be a wave spring or wave washer, preferably a multiple wave washer having a plurality of waved spring layers of an elastic material, especially a metal, mounted sequentially one above another.

[0009] The medical device is a drug delivery device or an injection device, particularly in the shape of a pen. Since such an injection pen is designed to be handy and everywhere available, the mechanism provided for the operation of the injection device has to be arranged within very restricted dimensions. It is therefore important to have the necessary spring force be provided by a spring element that occupies as little volume as possible. Using a wave spring or wave washer allows to enhance the effective spring force while restricting the occupied volume essentially. This is not easily achieved with conventional spring elements. It is a further advantage of a wave spring or wave washer to have a relatively large spring constant so that a large spring force is generated by a relatively small compression of the spring. The dimensions of the spring can therefore be kept small. The plurality of elevated contact areas formed on the waved outermost spring layers render an improved homogeneity of the distribution of the spring force over the areas where the spring force is applied, as compared to a helical spring. The application of wave springs or wave washers within medical devices is especially favorable if the spring is formed of a plurality of waved layers in the shape of an annular multiple wave washer.

[0010] Further aspects and examples of the invention are described in conjunction with the appended figures of which

FIG. 1 shows a plan view onto an annular wave washer;

FIG. 2A shows a lateral view of a wave spring;

FIG. 2B shows a lateral view of a multiple wave washer;

FIG. 3 shows a cross-section of an injection pen; and

FIG. 4 shows an enlarged cross-section of a mechanism of the injection pen according to FIG. 3.

[0011] FIGs. 1, 2A and 2B serve to explain the shape of a typical multiple wave spring or wave washer that is especially suitable for an application in a medical device. FIG. 1 shows a plan view onto a helical wave spring or wave washer, which appears in the shape of an annulus 1 in this perspective. FIG. 2A shows a lateral view of a
helical wave spring according to FIG. 1, the circumference of the wave spring having been unwound after a severance at point D, so that the lateral area of the cylindrical volume encompassed by the wave spring is projected into the plane of the drawing. Letters A to D are inserted as marks of reference between FIGs. 1 and 2A and show the relative positions of locations of the turns 2 of the wave spring. The wave spring can be formed in one piece by a curved wire or band comprising waves in the direction in which the spring force is to be exerted, for example. This amounts to a helical spring having bows in axial direction. The broken lines in FIG. 2A indicate how the wire or band of the wave spring continues at point D. The waves of the wave spring can have a sinusoidal shape, for example. When being free of tension or stress, the spring layers 2 can be narrower than shown in FIG. 2A. The outermost turns of the wire can be formed to be essentially, besides the waves, parallel to a plane that is perpendicular to the axis of the wire helix, similar to the outermost spring layers 22 of the further example shown in FIG. 2B. This is especially suitable, because the most elevated areas of the outer surfaces of the outermost spring layers thus formed can easily be brought into contact with a flat surface on which the spring force or pressure is to be exerted, and the spring force is distributed rather homogeneously over the surface.

FIG. 2B shows a lateral view according to FIG. 2A of a further example of a wave spring or wave washer, which is made up of several spring layers 2. Letters A to D are inserted as marks of reference between FIGs. 1 and 2B and show the relative positions of locations of the waved spring layers 2. The wave spring of FIG. 2B is formed of at least two waved spring layers 2 of an elastic material mounted one above the other and making several contacts with the preceding and subsequent spring layers 2, respectively. The outermost spring layers 22 can be formed to be essentially, besides the waves, parallel to a plane that is perpendicular to the axis of the wave washer, as shown in FIG. 2B.

In one general aspect, the invention discloses the use of a wave spring or wave washer comprising at least two waved turns or waved spring layers in a medical device. The wave spring or wave washer is especially suitable for a use in a medical device of restricted dimensions, if there is a plurality of waved turns 2 or spring layers as shown in FIGs. 2A and 2B, where the number of waved turns 2 or spring layers is four and six, respectively. The elastic material of which the wave spring or wave washer is manufactured can be a metal. The wave spring can be formed by a waved wire helix, or waved spring layers 2 can be mounted sequentially one above another. The waved shape of the spring layers 2 renders a good distribution of the spring force all over the annulus 1, shown in FIG. 1, which defines the area in which the spring force is exerted.

FIG. 3 shows an embodiment of a medical device comprising a mechanism that is equipped with a wave spring or wave washer. The medical device of this embodiment is a pen-type drug delivery device or injection pen. Such a device is used to inject a prescribed dose of a pharmaceutical substance or fluid from a reservoir within the device, which is emptied in correspondence with the applied doses. FIG. 3 shows a cross-section of an injection pen 3 encompassing a mechanism 20 comprising a wave spring or wave washer as spring force element. The mechanism 20 is shown as an example of the essential part of the medical device according to the invention. A further mechanism which can be provided to enable the setting of a dosage is not shown in detail and can be realized in various embodiments within the scope of the invention.

The injection pen 3 shown in FIG. 3 comprises a body 4, which is in the shape of a pen and is supplied with a needle 5 at one end, designated by distal end in the following, and an operation button 12 at the opposite end, designated by proximal end in the following. A receptacle 6 is provided for the reception of a substance or fluid that is to be delivered or injected through the needle 5. Instead of being filled directly into the receptacle 6, the substance or fluid can be introduced into the receptacle 6 by means of a cartridge 16. Refilling the injection pen is thus simplified. A piston 7 is arranged in the receptacle 6 either for reuse or for exchange together with the cartridge 16, and is moved in the longitudinal direction of the injection pen 3 by means of a piston rod 8. The piston rod 8 is moved in the longitudinal direction by means of the operation button 12 and further mechanical components which are not shown in detail.

The substance or fluid in the receptacle 6 or cartridge 16 can e.g. be a medicament. The term "medicament", as used herein, means a pharmaceutical formulation containing at least one pharmaceutically active compound, wherein in one embodiment the pharmaceutically active compound has a molecular weight up to 1500 Da and/or is a peptide, a protein, a polysaccharide, a vaccine, a DNA, a RNA, an antibody, an enzyme, an antibody, a hormone or an oligonucleotide, or a mixture of the above-mentioned pharmaceutically active compound, wherein in a further embodiment the pharmaceutically active compound is useful for the treatment and/or prophylaxis of diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as deep vein or pulmonary thromboembolism, acute coronary syndrome (ACS), angina, myocardial infarction, cancer, macular degeneration, inflammation, hay fever, atherosclerosis and/or rheumatoid arthritis, wherein in a further embodiment the pharmaceutically active compound comprises at least one peptide for the treatment and/or prophylaxis of diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, wherein in a further embodiment the pharmaceutically active compound comprises at least one human insulin or a human insulin analogue or derivative, glucagon-like...
peptide (GLP-1) or an analogue or derivative thereof, or exedin-3 or exedin-4 or an analogue or derivative of exedin-3 or exedin-4.

**[0017]** Insulin analogues are for example Gly(A21), Arg(B31), Arg(B32) human insulin; Lys(B3), Glu(B29) human insulin; Asp(B28) human insulin; human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala(B26) human insulin; Des(B28-B30) human insulin; Des(B27) human insulin and Des(B30) human insulin.

**[0018]** Insulin derivates are for example B29-N-myristoyl-des(B30) human insulin; B29-N-palmitoyl-des(B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; Lys(B28), Pro(B29) human insulin; Asp(B28) human insulin; human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala(B26) human insulin; Des(B28-B30) human insulin; Des(B27) human insulin and Des(B30) human insulin.

**[0019]** Exendin-4 for example means Exendin-4(1-39), a peptide of the sequence H-His-Gly-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Leu-Ser-Lys-Gln-Met-Glu-Glu-Glu-Ala-Val-Arg-Leu-Phe-Ile-Glu-Trp-Leu-Lys-Asn-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH2.

**[0020]** Exendin-4 derivatives are for example selected from the following list of compounds:

H-(Lys)4-des Pro36, des Pro37 Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)5-des Pro36, des Pro37 Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, des Pro37, Pro38 Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
Hormones are for example hypothysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists as listed in Rote Liste, ed. 2008, Chapter 50, such as Gonadotropin (Follitropin, Lutropin, Choriongonadotropin, Menotropin), Somatropine (Somatopin), Desmopressin, Terlipressin, Gona
dorelin, Triptorelin, Leuprolrelin, Buserelin, Nafarelin, Goserelin.

A polysaccharide is for example a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra low molecular weight heparin or a derivative thereof, or a sulphated, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium.

Pharmaceutically acceptable salts are for example acid addition salts and basic salts. Acid addition salts are e.g. HCl or HBr salts. Basic salts are e.g. salts having a cation selected from alkali or alkaline, e.g. Na+, or K+, or Ca2+, or an ammonium ion N+(R1)(R2)(R3)(R4), wherein R1 to R4 independently of each other mean: hydrogen, an optionally substituted C1-C6-alkyl group, an optionally substituted C2-C6-alkenyl group, an optionally substituted C6-C10-aryl group, or an optionally substituted C6-C10-heteroaryl group. Further examples of pharmaceutically acceptable salts are described in "Remington’s Pharmaceutical Sciences" ed. Alfonso R. Gennaro (Ed.), Mark Publishing Company, Easton, Pa., U.S.A., 1985 and in Encyclopedia of Pharmaceutical Technology.

Pharmaceutically acceptable solvates are for example hydrates.

In the embodiment shown in FIG. 3, the piston rod 8 is realized in the form of a so-called lead screw comprising a first screw thread 9 located on a section of the piston rod 8 near the piston 7 and a second screw thread 10 located on a further section of the piston rod 8 at a larger distance from the piston 7. The second screw thread 10 can be engaged with a corresponding thread 21 of the same pitch on the inner surface of an operation sleeve 11, for example. The operation sleeve 11 can be used together with further mechanical components not shown in FIG. 3 to provide a mechanism that is used for setting a dosage, which enables to move the piston rod 8 and the piston 7 by prescribed intervals along the longitu
dinal extension of the piston rod 8. In a reusable device, the mechanism can additionally serve to reset the piston rod 8 to a starting position so that the receptacle 6 can be refilled or the cartridge 16 exchanged. The mechanism 20 which is of primary interest in connection with the present invention is described in the following in more detail.

The mechanism 20 shown in FIG. 3 comprises a first element 13, which is a lock nut in this embodiment, and a spring 15 arranged between the first element 13 and the second element 14. A coupling device is provided for engaging the first element 13 and the second element 14 and can be realized, for instance, by a gear formed by surface structures of the elements. When the injection pen 3 is ready for use, the spring 15 is compressed, and the coupling device engages the first ele
ment 13 and the second element 14. The compressed spring tends to disengage the first element 13 and the second element 14. In the example shown in FIG. 3, the compression of the spring 15 is effected by the cartridge 16 inserted in the receptacle 6. Therefore, the lock nut 13 and the piston rod nut 14 are engaged when the in
jection pen 3 is used.

FIG. 4 shows the mechanism 20 in an enlarged view with more details. In the center of FIG. 4, a section of the piston rod 8 is shown. An imaginary central axis 18 is indicated by the broken line of alternating dots and dashes. The piston rod 8 goes through a hole 23 of the lock nut 13, a hole 24 of the piston rod nut 14 and a hole 26 in the bottom of the cartridge 16, which is inserted in the receptacle 6. The spring 15 is situated between the lock nut 13 and the piston rod nut 14, and its spring layers are shown as thin metal layers as viewed in the direction of the cross-section indicated with S in FIG. 1. The spring 15 surrounds the piston rod 8 in the annular shape of a washer. The raised or embossed portions of the outer surfaces of the outermost spring layers 22 are in contact with the surfaces of the lock nut 13 and the piston rod nut 14 facing the spring 15. This is shown in the cross-section of FIG. 4, which represents the spring 15 at locations in which the outer surfaces of the outermost spring layers 22 are most elevated and in contact with the nuts 13, 14. These are the locations of the wave spring in the middle between the positions marked A, B, C, D in FIG. 2B, for example.

The coupling device 17 engaging the lock nut 13 and the piston rod nut 14 can be formed by a sequence of interlocking teeth or some other kind of gear, for example. This is indicated in FIG. 4 by the lock nut 13 par

ially intruding the outer margin of the piston rod nut 14 in the area of the coupling device 17. The lock nut 13 is engaged with the body 4, by means of protruding parts or recesses 25, for example, so that the lock nut 13 cannot rotate relatively to the body 4 around the axis 18 of the piston rod 8. A translational motion of the lock nut 13 in the direction towards the piston 7 can be inhibited by the presence of the cartridge 16. The movement of the nuts 13, 14 in the opposite direction away from the piston 7 can be inhibited by barrier rims 27 or spikes, for example, which are fixed at the inner surface of the body 4 on the side of the nuts 13, 14 facing away from the piston 7.

The hole 24 of the piston rod nut 14 is supplied with a thread 19 having the same pitch as the piston rod screw thread 9. Thus, the thread 19 of the piston rod nut 14 is the female thread counterpart of the male screw thread of the piston rod 8. If the nuts are engaged by the coupling device 17 as shown in FIG. 4, a relative rotation...
of the lock nut 13 and the piston rod nut 14 is inhibited, and the piston rod nut 14 cannot rotate relatively to the body around the piston rod 8 because the lock nut 13 is rotationally fixed by the recesses 25.

[0030] If the cartridge 16 is removed and the spring 15 is released, the coupling device 17 is no longer interlocked, and the lock nut 13 and the piston rod nut 14 are disengaged. This means that the piston rod nut 14 can freely rotate around the piston rod 8, and the piston rod 8 is able to perform a translational movement along its axis 18 irrespective of a rotation around its axis 18. This is, because the piston rod nut 14 will freely rotate and compensate for a discrepancy between the actual translational movement of the piston rod 8 and a translational component of a helical movement of the piston rod 8 generated by the threads 9, 19 when the piston rod nut 14 is rotationally fixed. In particular, after the piston rod nut 14 having been released, the piston rod 8 need not rotate at all when it is shifted along its axis 18 in the direction away from the piston 7. In the latter case a relative rotation of the piston rod 8 with respect to the piston rod nut 14 caused by the threads 9, 19 is effected by only the piston rod nut 14 rotating relatively to the body 4. This feature may be of advantage for resetting the piston rod 8 back to a starting position suitable for refilling the injection pen. The reset can be performed by shifting the piston rod 8 back to a starting position without having to care about an appropriate rotational movement of the piston rod 8.

[0031] The described injection pen is only one embodiment of the medical device according to this invention, which shows by way of example the improvements and advantages that are obtained by the use of a wave spring or wave washer in medical devices, especially in view of obtaining a relatively strong and better distributed force or pressure within reduced dimensions.

Claims

1. A medical device, wherein the device is a pen-type drug delivery device or injection device (3) and comprises:
   - a mechanism (20);
   - a body (4);
   - a receptacle (6) in the body, the receptacle (6) being provided for a cartridge (16);
   - a piston (7) movable in the receptacle (6) having an axis (18), the piston rod (8) having a screw thread (9);
   - a first element (13) and a second element (14) of the mechanism (20) having a thread (19) engaging the screw thread (9) of the piston rod (8);
   - a spring (15) arranged in contact with at least one of the first element (13) and the second element (14) and tending to disengage the first element (13) and the second element (14);
   - the spring (15) being a wave spring or wave washer;
   - wherein the first element (13) and the second element (14) are engaged a relative rotation of the first element (13) and the second element (14) is inhibited and the second element (14) cannot rotate relatively to the body (4) because the first element (13) is rotationally fixed to the body (4); a spring (15) arranged in contact with at least one of the first element (13) and the second element (14) and tending to disengage the first element (13) and the second element (14);
   - the spring (15) being a wave spring or wave washer;
   - a mechanism (20);
   - a body (4);
   - a receptacle (6) in the body, the receptacle (6) being provided for a cartridge (16);
   - a piston (7) movable in the receptacle by means of a piston rod (8) having an axis (18), the piston rod (8) having a screw thread (9);

2. The medical device according to claim 1, wherein the spring (15) is formed by a helically curved wire comprising waves in the direction in which the spring force is to be exerted.

Reference numerals

1 annulus
2 spring layer
3 injection pen
4 body
5 needle
6 receptacle
7 piston
8 piston rod
9 first screw thread
10 second screw thread
11 operation sleeve
12 operation button
13 lock nut
14 piston rod nut
15 spring
16 cartridge
17 coupling device
18 axis
19 thread of the piston rod nut
20 mechanism
21 thread of the operation sleeve
22 spring layer
23 hole of the lock nut
24 hole of the piston rod nut
25 recess
26 bottom hole of the cartridge
27 barrier rim
3. The medical device according to claim 1, wherein the spring (15) is formed of at least two waved layers of an elastic material mounted one above the other.

4. The medical device according to one of claims 1 to 3, wherein the first element (13) and the second element (14) of the mechanism are nuts and the coupling device (17) is a gear formed by surface structures of the nuts.

5. The medical device according to one of claims 1 to 4, wherein

- the second element (14) is engaged with the piston rod (8) in such a manner as to generate an axial rotation of the piston rod (8) relatively to the second element (14) when the piston rod (8) is moved along its axis relatively to the second element (14).

6. The medical device according to one of claims 1 to 5, wherein the cartridge (16) contains a medicament.

7. The medical device according to claim 6, wherein the medicament is a pharmaceutical formulation containing at least one pharmaceutically active compound which comprises at least one human insulin or a human insulin analogue or derivative, glucagon-like peptide (GLP-1) or an analogue or derivative thereof, or exedin-3 or exedin-4 or an analogue or derivative of exedin-3 or exedin-4.

8. The medical device according to one of claims 1 to 7, further comprising:

- a cylindrical operation sleeve (11) surrounding the piston rod (8); and
- the operation sleeve having a thread (21) engaging the further screw thread (10) of the piston rod (8).

9. The medical device according to one of claims 1 to 8, wherein the screw thread (9) of the piston rod (8) has a smaller pitch than the further screw thread (10).

10. Use of a wave spring or wave washer within a medical device according to any of claims 1 to 9, the wave spring or wave washer having at least two waved turns (2) or waved layers formed of an elastic material in the shape of a waved wire or band.

11. The use of a wave spring or wave washer according to claim 10, wherein the spring is a helically curved wire comprising waves in the direction in which the spring force is to be exerted.

12. The use of a wave spring or wave washer according to claim 10 or 11, wherein the spring is formed of a plurality of waved layers (2) of an elastic material mounted sequentially one above another.

**Patentansprüche**

1. Medizinische Vorrichtung, wobei die Vorrichtung eine stiftartige Medikamenten-Verabreichungsvorrichtung oder Injektionsvorrichtung (3) ist und Folgendes umfasst:

- einen Mechanismus (20);
- ein Gehäuse (4);
- einen Aufnahmebehälter (6) in dem Gehäuse, wobei der Aufnahmebehälter (6) für eine Kartusche (16) vorgesehen ist;
- einen Kolben (7), der in dem Aufnahmebehälter mit Hilfe einer Kolbenstange (8) mit einer Achse (18) bewegbar ist, wobei die Kolbenstange (8) ein Schraubengewinde (9) aufweist;
- ein erstes Element (13) und ein zweites Element (14) des Mechanismus, wobei das zweite Element (14) des Mechanismus (20) ein Gewinde (19) aufweist, das in das Schraubengewinde (9) der Kolbenstange (8) eingreift;
- eine Verbindungsvorrichtung (17), die einen Eingriff des ersten Elements (13) und des zweiten Elements (14) herstellt, wenn die Kartusche (16) in den Aufnahmebehälter (6) eingeführt ist, wobei bei Eingriff des ersten Elements (13) und des zweiten Elements (14) eine Relativdrehung des ersten Elements (13) und des zweiten Elements (14) unterdrückt wird und sich das zweite Element (14) bezüglich des Gehäuses (4) nicht drehen kann, weil das erste Element (13) drehfest an dem Gehäuse (4) angebracht ist; eine Feder (15), die in Berührung mit dem ersten Element (13) und/oder dem zweiten Element (14) angeordnet ist und dazu tendiert, den Eingriff des ersten Elements (13) und des zweiten Elements (14) zu lösen;
- wobei die Feder (15) eine Wellenfeder oder Wellenscheibe ist;
- wobei die Feder (15) einen Mechanismus (20) und des zweiten Elements (14) unterdrückt wird und sich das zweite Element (14) bezüglich des Gehäuses (4) nicht drehen kann, weil das erste Element (13) drehfest an dem Gehäuse (4) angebracht ist; eine Feder (15), die in Berührung mit dem ersten Element (13) und/oder dem zweiten Element (14) angeordnet ist und dazu tendiert, den Eingriff des ersten Elements (13) und des zweiten Elements (14) zu lösen;
- wobei die Feder (15) eine Wellenfeder oder Wellenscheibe ist.

2. Medizinische Vorrichtung nach Anspruch 1, wobei die Feder (15) von einem schraubenförmig gebogenen Draht gefertigt wird, der Wellen in der Richtung umfasst, in der die Federkraft ausgeübt werden soll.
3. Medizinische Vorrichtung nach Anspruch 1, wobei die Feder (15) aus zumindest zwei wellenförmigen Schichten aus einem elastischen Material, die aufeinander angebracht sind, geformt ist.

4. Medizinische Vorrichtung nach einem der Ansprüche 1 bis 3, wobei das erste Element (13) und das zweite Element (14) des Mechanismus Muttern sind und die Verbindungsvorrichtung (17) ein Getriebe ist, das von Oberflächenstrukturen der Muttern geformt wird.

5. Medizinische Vorrichtung nach einem der Ansprüche 1 bis 4, wobei
- das zweite Element (14) mit der Kolbenstange (8) auf eine solche Weise in Eingriff steht, dass eine axiale Drehung der Kolbenstange (8) bezüglich des zweiten Elements (14) erzeugt wird, wenn die Kolbenstange (8) entlang ihrer Achse bezüglich des zweiten Elements (14) bewegt wird.

6. Medizinische Vorrichtung nach einem der Ansprüche 1 bis 5, wobei die Kartusche (16) ein Medikament enthält.

7. Medizinische Vorrichtung nach Anspruch 6, wobei das Medikament eine pharmazeutische Formulierung ist, die zumindest eine pharmazeutisch wirksame Verbindung enthält, die zumindest ein Humainsulin oder ein Humainsulin-Analogon oder -Derivat, Glucagon-like Peptid (GLP-1) oder ein Analogon oder Derivat davon, oder Exedin-3 oder Exedin-4 oder ein Analogon oder Derivat von Exedin-3 oder Exedin-4 umfasst.

8. Medizinische Vorrichtung nach einem der Ansprüche 1 bis 7, ferner umfassend:
- eine zylindrische Betätigungshülse (11), welche die Kolbenstange (8) umgibt; und
- wobei die Betätigungshülse ein Gewinde (21) aufweist, das in das weitere Schraubengewinde (10) der Kolbenstange (8) eingreift.

9. Medizinische Vorrichtung nach einem der Ansprüche 1 bis 8, wobei das Schraubengewinde (9) der Kolbenstange (8) eine kleinere Steigung aufweist als das weitere Schraubengewinde (10).

10. Verwendung einer Wellenfeder oder Wellenscheibe in einer medizinischen Vorrichtung nach einem der Ansprüche 1 bis 9, wobei die Wellenfeder oder Wellenscheibe zumindest zwei wellenförmige Windungen (2) oder wellenförmige Schichten aufweist, die aus einem elastischen Material in Form eines wellenförmigen Drahts oder Bands geformt sind.

11. Verwendung einer Wellenfeder oder Wellenscheibe nach Anspruch 10, wobei die Feder ein schraubenförmig gebogener Draht ist, der Wellen in der Richtung umfasst, in der die Federkraft ausgeübt werden soll.

12. Verwendung einer Wellenfeder oder Wellenscheibe nach Anspruch 10 oder 11, wobei die Feder aus einer Vielzahl von wellenförmigen Schichten (2) aus einem elastischen Material, die der Reihe nach übereinander angebracht sind, geformt ist.

Revendications

1. Dispositif médical, dans lequel le dispositif est un dispositif d'injection de médicament ou un dispositif d'administration du type stylo (3), et comprend:

- un mécanisme (20);
- un corps (4);
- un réceptacle (6) dans le corps, le réceptacle (6) étant prévu pour une cartouche (16);
- un piston (7) mobile dans le réceptacle au moyen d'une tige de piston (8) présentant un axe (18), la tige de piston (8) comportant un filet de vis (9);
- un premier élément (13) et un deuxième élément (14) du mécanisme, le deuxième élément (14) du mécanisme (20) comportant un filet (19) engageant le filet de vis (9) de la tige de piston (8);
- un dispositif de couplage (17) qui engage le premier élément (13) et le deuxième élément (14) lorsque la cartouche (16) est insérée dans le réceptacle (6), dans lequel, lorsque le premier élément (13) et le deuxième élément (14) sont engagés, une rotation relative du premier élément (13) et du deuxième élément (14) est empêchée, et le deuxième élément (14) ne peut pas tourner par rapport au corps (4) parce que le premier élément (13) est fixé de façon rotative au corps (4); un ressort (15) étant agencé en contact avec au moins parmi le premier élément (13) et le deuxième élément (14) en attente à désengager le premier élément (13) et le deuxième élément (14);
- le ressort (15) est un ressort ondulé ou une rondelette ondulée;
- dans lequel le premier élément (13) et le deuxième élément (14) sont désengagés au moyen du ressort (15) lorsque la cartouche (16) est enlevée, de telle sorte qu'une rotation du deuxième élément (14) et un retour ou un déplacement de la tige de piston (8) vers une position de départ soient déclenchés.

2. Dispositif médical selon la revendication 1, dans le-
quel le ressort (15) est formé par un fil incurvé de façon hélicoïdale comprenant des ondulations dans la direction dans laquelle la force du ressort doit être exercée.

3. Dispositif médical selon la revendication 1, dans lequel le ressort (15) est constitué d’au moins deux couches ondulées d’un matériau élastique montées les unes au-dessus des autres.

4. Dispositif médical selon l’une quelconque des revendications 1 à 3, dans lequel le premier élément (13) et le deuxième élément (14) du mécanisme sont des écrous, et le dispositif de couplage (17) est un engrenage formé par des structures de surface des écrous.

5. Dispositif médical selon l’une quelconque des revendications 1 à 4, dans lequel le deuxième élément (14) est engagé avec la tige de piston (8) de manière à générer une rotation axiale de la tige de piston (8) par rapport au deuxième élément (14) lorsque la tige de piston (8) est déplacée le long de son axe par rapport au deuxième élément (14).

6. Dispositif médical selon l’une quelconque des revendications 1 à 5, dans lequel la cartouche (16) contient un médicament.

7. Dispositif médical selon la revendication 6, dans lequel le médicament est une formulation pharmaceutique contenant au moins un composé pharmaceutiquement actif comprenant au moins un composé parmi l’insuline humaine ou un analogue ou un dérivé de l’insuline humaine, le glucagon-like peptide (GLP-1) ou un analogue ou un dérivé de celui-ci, ou l’exéidine-3 ou l’exéidine 4 ou un analogue ou un dérivé de l’exéidine-3 ou de l’exéidine 4.

8. Dispositif médical selon l’une quelconque des revendications 1 à 7, comprenant en outre:
   un manchon de commande cylindrique (11) qui entoure la tige de piston (8); et
   le manchon de commande comporte un filet (21) qui engage le filet de vis supplémentaire (10) de la tige de piston (8).

9. Dispositif médical selon l’une quelconque des revendications 1 à 8, dans lequel le pas du filet de vis (9) de la tige de piston (8) est plus petit que celui du filet de vis supplémentaire (10).

10. Utilisation d’un ressort ondulé ou d’une rondelle ondulée à l’intérieur d’un dispositif médical selon l’une quelconque des revendications 1 à 9, dans laquelle le ressort ondulé ou la rondelle ondulée comprend au moins deux spires ondulées (2) ou couches on-
FIG 4
REFERENCES CITED IN THE DESCRIPTION

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