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(71) Applicant: **NOVO NORDISK A/S** [DK/DK]; Novo Allé, DK-2880 Bagsværd (DK).

(72) Inventors: **HØHOLT, Jesper**; Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd (DK). **ANDERSEN, Carsten, Schau**; Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd (DK). **LARSEN, Bjørn, Gullak**; Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd (DK). **SØRENSEN, Thomas**; Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd (DK). **BROCKMEIER, Peter**; Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd (DK). **MEWS, Steffen**; Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd (DK).

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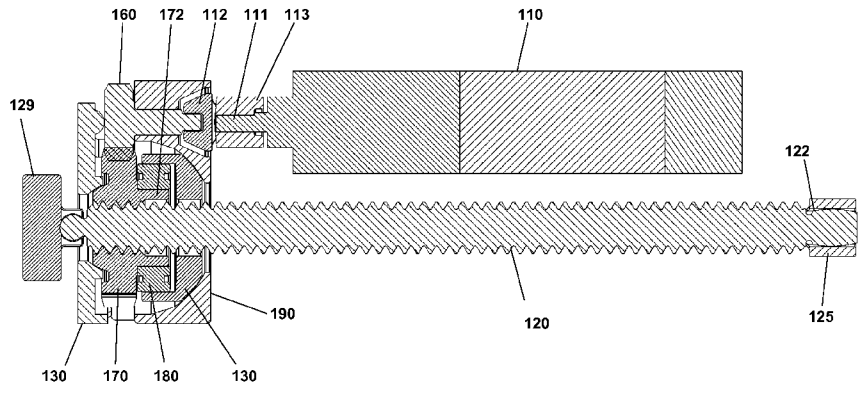
(54) Title: TRANSMISSION ARRANGEMENT FOR MOTORIZED DRUG DELIVERY DEVICE

Fig. 3



(57) Abstract: A transmission comprises a first gear wheel and a second gear wheel with a threaded bore, and a threaded non-rotationally arranged rod in threaded engagement with the threaded bore, rotation of the second gear wheel thereby providing axial movement of the rod. The first and second gear wheel are arranged in a common plane and in rotational engagement with each other, wherein the combined second gear wheel and rod are arranged to pivot corresponding to a centre point defined by the intersection of the rod axis and the common plane, whereby the rod, with the gear wheels in engagement, can be arranged out of alignment with the first gear wheel axis.

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TRANSMISSION ARRANGEMENT FOR MOTORIZED DRUG DELIVERY DEVICE

The present invention generally relates to a transmission arrangement. In a specific aspect, the invention relates to a motorized drug delivery device adapted to receive a drug filled cartridge and subsequently expel a dose therefrom.

BACKGROUND OF THE INVENTION

In the disclosure of the present invention reference is mostly made to the treatment of diabetes by subcutaneous drug delivery, either discrete or continuous, however, this is only an exemplary use of the present invention.

The most common type of durable drug delivery devices adapted to receive a drug filled cartridge and expel a discrete dose of a desired size therefrom are driven by manual means or by a spring energized during dose setting, the cartridge being of the type comprising an axially displaceable piston having an initial proximal position and which is moved distally by a piston rod. Subcutaneous drug delivery takes place via an injection needle arranged in fluid communication with the cartridge. The device may be pen-formed or in the form of a more box-shaped so-called doser. In order to improve convenience, user-friendliness and provide additional features, e.g. detection and storing of expelling data, drug delivery devices have been provided with electrically driven means, typically in the form of an electronically controlled motor driving a piston rod through a gear arrangement, e.g. as shown in US 6,514,230 and US 2011/306927.

Whereas motorized drug delivery devices for treatment of diabetes by discrete injections of e.g. insulin are used relatively rarely, in the field of continuous drug delivery motorized drug delivery devises have been used widely for decades. The latter type of devices are generally known as infusion pumps and are normally engineered to very high standards and are correspondingly very expensive. Although a motorized drug delivery device for discrete injections of drug also has to meet very high safety standards, the cost issue is more important as the relatively inexpensive mechanical drug delivery devices, e.g. of the pen-type, to most users are an acceptable alternative.

Motorized drug delivery devices, either of the pen or pump type, often have a two-axis design in which rotation is transferred form a motor arranged corresponding to a first to an axially displaceable drive member, e.g. a piston rod, arranged corresponding to a second axis. In most cases transfer between the two axes takes place using a transmission with gear wheels. To secure reliable and durable transmission in a compact design high precision on

the components is required to avoid misalignment in the transmission. Examples of two-axis designs are known from e.g. US 2012/0191043 and US 6,854,620 disclosing infusion pumps and US 2012/179112 disclosing a doser-type injection device, all including a drive mechanism comprising a motor and a transmission gear arrangement capable of linearly displacing a piston rod.

Having regard to the above, it is an object of the present invention to provide a motorized drug delivery device as well as components therefor which provide a high degree of reliability in a cost-effective way.

DISCLOSURE OF THE INVENTION

In the disclosure of the present invention, embodiments and aspects will be described which will address one or more of the above objects or which will address objects apparent from the below disclosure as well as from the description of exemplary embodiments.

Thus, in accordance with a first aspect of the invention a transmission is provided comprising a first axis and a second axis which in a reference position are arranged in parallel with each other, the transmission comprising first and second gear wheels and a rod. The first gear wheel has a first centre plane, and an axis of rotation corresponding to the first axis. The second gear wheel has a second centre plane, a reference axis of rotation corresponding to the second axis, and a threaded bore corresponding to the second axis. The rod is arranged non-rotationally relative to the second gear wheel and has an outer thread along at least a part of its length, the rod in a reference position being arranged corresponding to the second axis and in threaded engagement with the threaded bore, rotation of the second gear wheel thereby providing axial movement of the rod. The first and second gear wheel, when in the reference position, are arranged with the first and second centre plane in a common plane and in rotational engagement with each other, wherein the combined second gear wheel and rod are arranged to pivot corresponding to a centre point defined by the intersection of the second axis and the second centre plane, whereby the rod, with the gear wheels in rotational engagement, can be arranged out of alignment with the first axis.

By such an arrangement a transmission is provided which provides a high degree of reliability in a cost-effective way. More specifically, the above-described pivoting between the different components can be used to compensate for “imperfections” of the transmission: (i) static misalignment during assembly due to “loose” tolerances of the different components are accommodated, (ii) dynamic misalignment during operation can be accommodated, e.g. the

piston rod may wobble if not perfectly straight, and the gear wheels may twist relative to the rod during load.

In the context of the present disclosure the term “pivot” is generally used to describe “smaller” rotational movements, e.g. less than 10 degrees, bringing the components out of a reference position and having an axis different from the reference axis of rotation.

In an exemplary embodiment the transmission comprises a ball joint assembly having a ball portion comprising the second gear wheel, and a ball housing, whereby the ball joint allows the combined second gear wheel and rod to pivot corresponding to the centre point.

The ball portion may comprise a gear wheel member comprising the threaded bore and a first circumferential ball bearing surface arranged perpendicularly relative to the second axis, a ball housing comprising a second circumferential ball bearing surface arranged perpendicularly relative to the second axis, and a rotational bearing member arranged between the gear wheel member and the ball housing and perpendicularly relative to the second axis. In such an arrangement the first and second circumferential ball bearing surfaces in combination with corresponding bearing surfaces on the ball housing form first and second circumferential bearings which in combination provides the ball joint. The friction of the rotational bearing is lower than the rotational friction of the second circumferential bearing. The radius of the first circumferential bearing may be smaller than the radius of the second circumferential bearing.

The above-described transmission may be incorporated in a drug delivery device which further comprises a compartment adapted to receive a drug-filled cartridge, the cartridge comprising a body portion, an axially displaceable piston, and a distal outlet portion adapted to be arranged in fluid communication with a flow conduit, wherein the rod is adapted to directly or indirectly engage and axially move the piston of a loaded cartridge to thereby expel drug from the cartridge, the drug delivery device further comprising an electronically controlled drive arrangement adapted to rotate the first gear wheel. The drive arrangement may comprise a motor and a controller for controlling a motor. The controller may be associated with or comprise a receiver and/or transmitter allowing the device to communicate with an external source, e.g. by wireless means with a smartphone. In this way a log of expelled doses could be transferred to a smartphone or the smartphone could be used to conveniently enter pre-set dose sizes.

The drug delivery device may be provided with setting means allowing a user to set a dose of drug to be expelled. The setting means may be in the form of a setting device, e.g. one or more user input keys, or the above-mentioned wired or wireless receiver adapted to receive setting input from an external source such as a PC or a smartphone.

As used herein, the term "drug" is meant to encompass any flowable medicine formulation capable of being passed through a delivery means such as a cannula or hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension, and containing one or more drug agents. Representative drugs include pharmaceuticals such as peptides (e.g. insulins, insulin containing drugs, GLP-1 containing drugs as well as derivates thereof), proteins, and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. In the description of the exemplary embodiments reference will be made to the use of insulin containing drugs, this including analogues thereof as well as combinations with one or more other drugs.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following exemplary embodiments of the invention will be further described with reference to the drawings, wherein

fig. 1 shows in a cross-sectional view a drug delivery device with a transmission assembly,
fig. 2 shows an exploded view of the transmission assembly of fig. 1, and
fig. 3 shows a cross-sectional view of the transmission assembly of fig. 1.

In the figures like structures are mainly identified by like reference numerals.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

When in the following terms such as “upper” and “lower”, “right” and “left”, “horizontal” and “vertical” or similar relative expressions are used, these only refer to the appended figures and not necessarily to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as their relative dimensions are intended to serve illustrative purposes only. When the term member or element is used for a given component it generally indicates that in the described embodiment the component is a unitary component, however, the same member or element may alternatively comprise a number of sub-components just as two or more of the described components could be provided as unitary components, e.g. manufactured as a single injection

moulded part. The term “assembly” does not imply that the described components necessarily can be assembled to provide a unitary or functional assembly during a given assembly procedure but is merely used to describe components grouped together as being functionally more closely related.

Referring to fig. 1 a generally pen-formed drug delivery device 1 will be described. More specifically, the pen device comprises a cap part (not shown) and a main part 10 having a proximal body or drive assembly portion with a housing 11 in which a motorized drug expelling assembly 100 (described in greater detail below) and an electronic controller 30 with an electric power source are arranged, and a distal cartridge holder portion 12 with a compartment 19 in which a drug-filled cartridge 20 is arranged and retained in place. The power source may be rechargeable with the device further comprising an electrical connector allowing an external connector of a power source to be connected for recharging the power source. The controller may be associated with or comprise a receiver and/or transmitter allowing the device to communicate with an external source, e.g. by wireless means with a smartphone. In this way a log of expelled doses could be transferred to a smartphone or the smartphone could be used to conveniently enter pre-set dose sizes.

The cartridge comprises a generally cylindrical main portion with an axially displaceable piston 21 and a distal outlet portion comprising a needle-penetrable septum 22. The cartridge is further provided with distal coupling means in the form of a needle hub mount 25 having, in the shown example, an external thread adapted to engage an inner thread of a corresponding hub of a needle assembly. The cartridge may for example contain an insulin, a GLP-1 or a growth hormone formulation. The device further comprises dose setting means allowing a user to set a dose of drug to be expelled as well as a display showing the set dose (not shown). The display may be adapted to show text or the display may be a simple 7-segment display which could be adapted to display one or more additional symbols.

In the shown embodiment the device is designed to be loaded by the user with a new cartridge through a distal receiving opening 13 in the cartridge holder assembly, the cartridge holder comprising closure means (not shown) operatable by a user between an open position in which a cartridge can be inserted respectively removed, and a closed position in which an inserted cartridge is held in place. In order to axially position the cartridge, the device comprises a seat member 15 adapted to receive the proximal end of the cartridge, the seat member being biased in the proximal direction by springs 17 thereby forcing the cartridge into contact with the closure means.

Turning to fig. 2 the motorized drug expelling assembly 100 will be described. The assembly comprises a motor assembly adapted to be mounted within the housing, a gear box assembly adapted to be mounted within the housing, and a piston rod assembly adapted to be mounted axially displaceable in the housing. The rotational axes for the different rotating components are arranged generally co-axially in the Z-direction as defined e.g. by the longitudinal axis of the piston rod. Referring to figs. 1 and 3, the Z- and X-axes are arranged in the plane of the drawing and the Y-axis perpendicularly thereto. The motor assembly comprises a motor unit 110 with a rotating output shaft 111 (see fig. 1) and a coupling for interfacing with an input shaft of the gear box. In the shown embodiment the coupling is in the form of an Oldham coupling comprising a first member 112 adapted to be mounted on the output shaft 111 (as shown in fig. 3) and a second member 113 adapted to engage a gear box input shaft, the two members being connected by a hinge when assembled. Alternatively a cardan joint or another type of flexible connection could be used. In the shown embodiment the motor unit comprises schematically shown a motor, a gear box and a motor controller.

The piston rod assembly comprises a threaded piston rod 120, a guide member 125 and a piston washer 129. The piston rod comprises an external thread 121, a proximal coupling portion 122 (see fig. 3) adapted to engage the guide member, and a distal ball-formed coupling head 123 adapted to engage the piston washer. The guide member comprises a through-going opening adapted to engage the piston rod proximal end non-rotationally in respect of the Z-axis yet provide a ball-like joint allowing a small degree of pivoting in respect of the X- and Y-axes. The guide member further comprises a pair of opposed outwardly oriented protrusions 126 adapted to slidingly engage corresponding guide grooves 16 (see fig. 1) associated with the housing, the guide member thereby preventing rotation of the piston rod relative to the housing. As can be seen the outer protrusions have slightly curved faces allowing a small degree of pivoting of the guide member relative to the housing in respect of the X-axis. In the shown embodiment the piston rod comprises a longitudinal groove 124 which is intended to accommodate a wire connection between sensor means (not shown) arranged in the piston washer and the device electronic controller.

The gear box assembly comprises a gear box housing 130, a gear box cover 140, a nut assembly 150, and an input spur gear wheel 160 having a first gear wheel centre plane. The nut assembly comprises an output spur gear wheel 170 having a second gear wheel centre plane, a ball bearing 180 and a bearing housing 190. The gear box housing and the gear box cover are adapted to be snap-fitted to each other to thereby form a ball housing holding the

nut assembly and input gear wheel in position. The output spur wheel comprises a central bore with an internal thread 171 adapted to engage the piston rod external thread (the output gear wheel thereby providing what is traditionally termed a “nut member” for the piston rod), as well as a proximally extending portion 172 with an external cylindrical surface adapted to be mounted non-rotationally in the ball bearing inner housing, the ball bearing outer housing being mounted non-rotationally in the bearing housing, the ball bearing thereby providing a low-friction bearing between the output gear wheel and the bearing housing. The distally facing surface of the “nut gear wheel” comprises a circumferential first inner ball joint surface 175 adapted to engage a corresponding circumferential first outer ball joint surface 145 of the gear box cover, and the proximally facing surface of the bearing housing comprises a circumferential second inner ball joint surface 195 adapted to engage a corresponding circumferential second outer ball joint surface 135 of the gear box housing. In the shown embodiment the first ball joint surfaces have a small radius and a narrow width whereas the second ball joint surfaces have a larger radius and a broader with, however, as they have a common centre of rotation arranged in the second gear wheel centre plane corresponding to the nut gear wheel axis, a combined ball joint is formed. As appears, the rotating nut gear wheel is provided with a proximal low-friction bearing in the form of the ball bearing 180 and a distal bearing formed directly between the nut gear wheel and the gear box cover which can be expected to have a somewhat higher friction. In principle the nut assembly could be formed as a single member with the ball joint providing a rotational bearing between both sides of the nut assembly and the gear box housing, however, for polymeric components this would result in rather high friction from the proximal large-diameter bearing. This said, for the intended small pivoting movements between the nut assembly and the gear box housing (see below) the relatively high friction is not essential. The input spur wheel 160 comprises an input shaft 161 rotationally received in gear wheel bore 132 of the gear box housing, the input shaft having a pair of opposed coupling surfaces adapted to non-rotationally engage the coupling member 112. As described above, in the shown embodiment the coupling is in the form of an Oldham coupling providing a non-rotational coupling between the motor output shaft and the gear box input shaft, yet allows relative axial and pivoting movements in other directions. In the mounted state the first and second gear wheel centre planes are arranged in the same plane, with the teeth in rotational force-transmitting engagement.

Turning to fig. 3 the expelling assembly 100 is shown in an assembled state with the gear wheels being arranged in a common plane and engaging each other. Shown in dark hatching the nut assembly “ball” can be identified in the gear box housing. As the two gear wheels are arranged with a slight amount of play, the ball in the ball joint is allowed to pivot a small

amount in respect of both the X- and Y-axes without any substantial influence on transmission efficiency. Especially, as the centre of rotation for the nut assembly is the same as the centre for the output gear wheel, the axis distance and thus gear ratio is kept essentially constant. Further, the Oldham coupling between the motor and gear box allows both translation and rotation to take place between the two assemblies, just as the above-described piston rod guide member allows the piston rod proximal end to pivot slightly.13

The above-described allowed movements between the different components can be used to compensate for different “imperfections” of the entire expelling assembly: (i) static misalignment during assembly due to “loose” tolerances of the different components are accommodated, (ii) dynamic misalignment during operation can be accommodated, e.g. the piston rod may wobble if not perfectly straight, and the motor and gear box may twist relative to each other during load.

In the above description of exemplary embodiments, the different structures and means providing the described functionality for the different components have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

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CLAIMS

1. A transmission (100) comprising:

- a first axis and a second axis which in a reference position are arranged in parallel with each other,

- a first gear wheel (160) having:
  - a first centre plane, and
  - an axis of rotation corresponding to the first axis,

- a second gear wheel (170) having:
  - a second centre plane,
  - a reference axis of rotation corresponding to the second axis, and
  - a threaded bore (171) corresponding to the second axis,

- a non-rotationally arranged rod (120) having an outer thread (121) along at least a part of its length, the rod in a reference position being arranged corresponding to the second axis and in threaded engagement with the threaded bore, rotation of the second gear wheel thereby providing axial movement of the rod,

wherein:

- the first gear wheel and the second gear wheel in a reference position are arranged with the first centre plane and the second centre plane in a common plane and in rotational engagement with each other,
- the combined second gear wheel and rod are arranged to pivot corresponding to a centre point defined by the intersection of the second axis and the second centre plane,

whereby the rod, with the gear wheels in rotational engagement, can be arranged out of alignment with the first axis.

2. A transmission as in claim 1, comprising a ball joint assembly having:

- a ball portion (170, 180, 190) comprising the second gear wheel, and
- a ball housing (130, 140),

whereby the ball joint allows the combined second gear wheel and rod to pivot corresponding to the centre point.

3. A transmission as in claim 2, wherein the ball portion comprises:

- a gear wheel member (170) comprising the threaded bore (171) and a first circumferential ball bearing surface (175) arranged perpendicularly relative to the second axis,
- a bearing housing (190) comprising a second circumferential ball bearing surface (195) arranged perpendicularly relative to the second axis, and
- a rotational bearing member (180) arranged between the gear wheel member and the ball housing and perpendicularly relative to the second axis,

wherein the first and second circumferential ball bearing surfaces in combination with corresponding bearing surfaces (145, 135) on the ball housing form first and second circumferential bearings which in combination provides the ball joint, and

wherein the friction of the rotational bearing is lower than the rotational friction of the second circumferential bearing.

4. A transmission as in claim 2, wherein the radius of the first circumferential bearing is smaller than the radius of the second circumferential bearing.

5. A drug delivery device comprising a transmission as in any of claims 1-4, further comprising:

- a compartment (19) adapted to receive a drug-filled cartridge (20), the drug-filled cartridge comprising a body portion, an axially displaceable piston (11), and a distal outlet portion adapted to be arranged in fluid communication with a flow conduit, and
- an electronically controlled drive arrangement (110) adapted to rotate the first gear wheel,
- wherein the rod is adapted to directly or indirectly engage and axially move the piston of a loaded drug-filled cartridge to thereby expel drug from the cartridge,

6. Drug delivery device as in claim 5, further comprising setting means allowing a user to set a dose of drug to be expelled.

7. Drug delivery device as in claim 5 or 6, wherein the compartment comprises a distal opening allowing a drug-filled cartridge to be received in a proximal direction.

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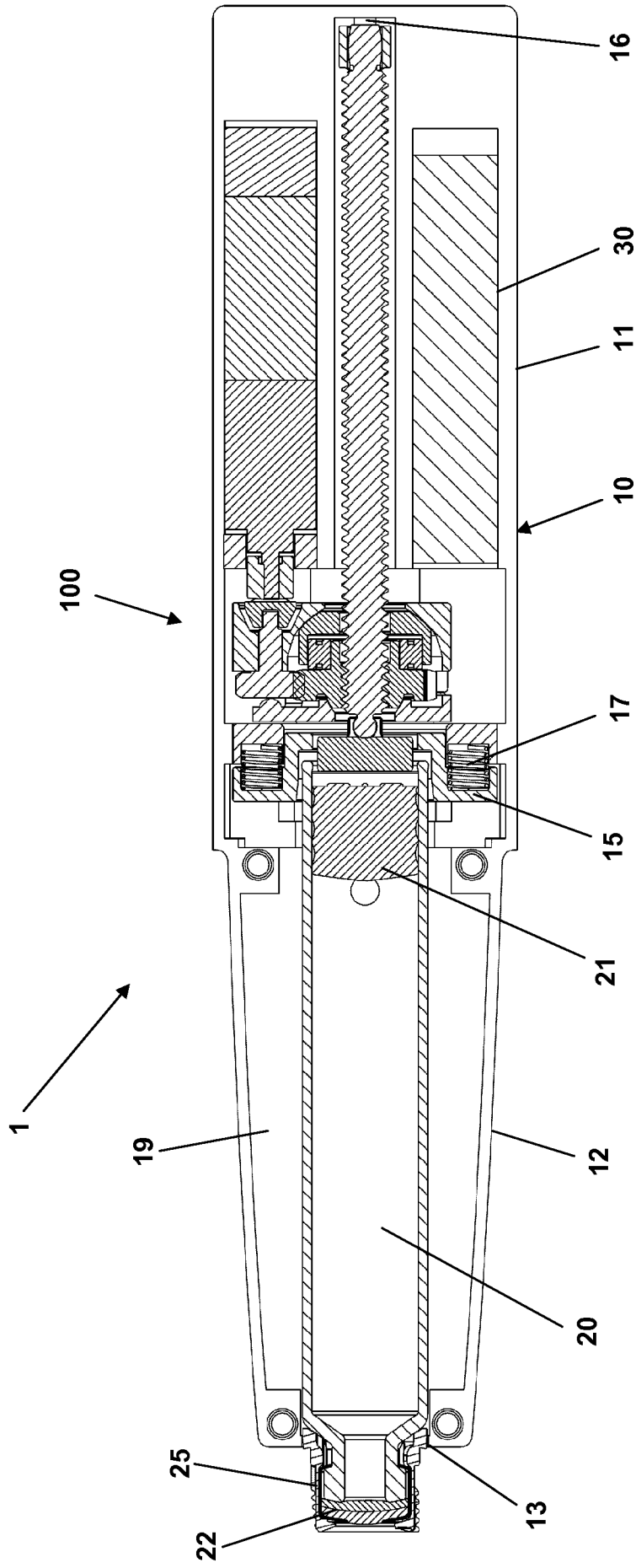

Fig. 1

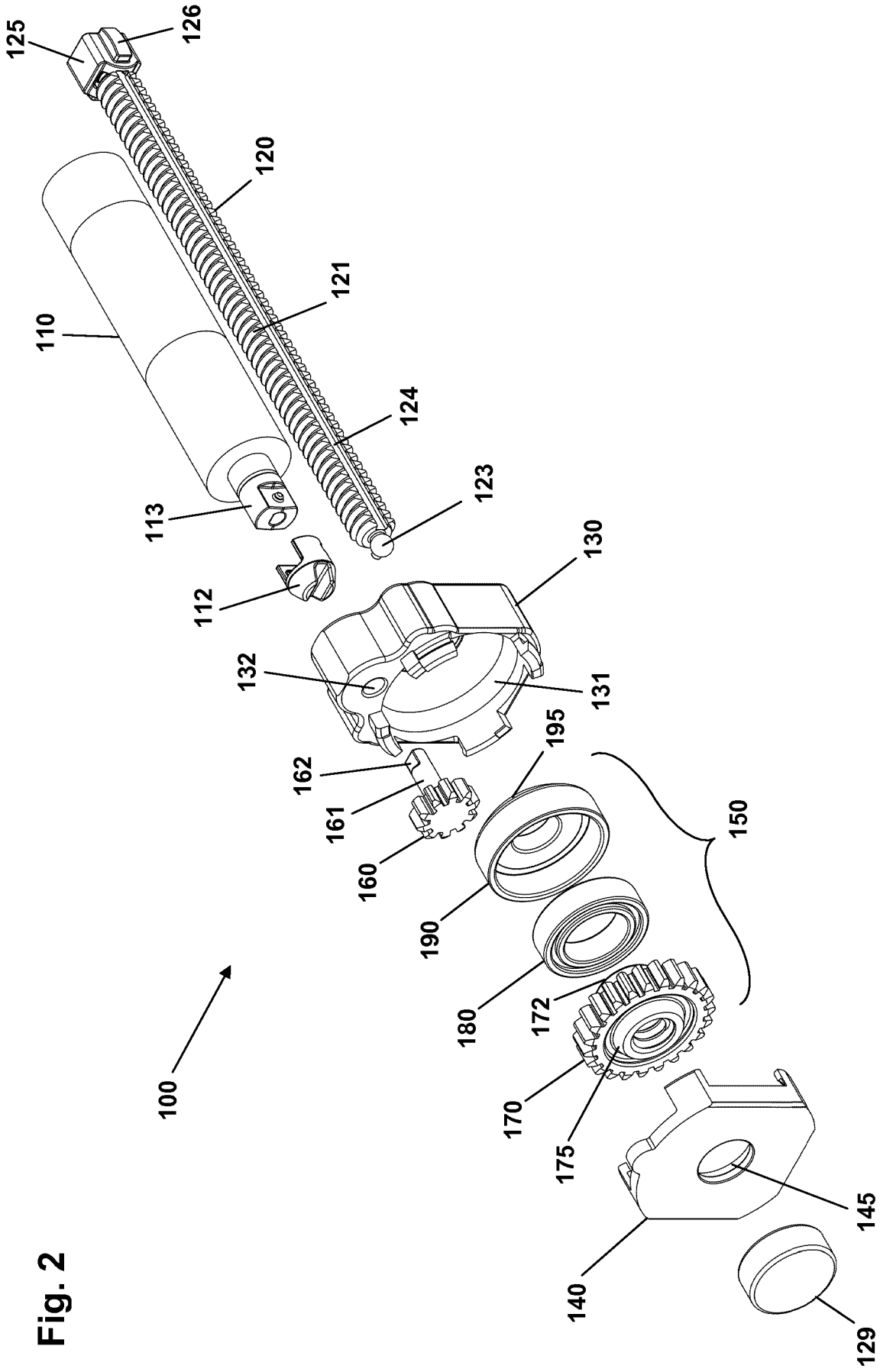
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Fig. 2

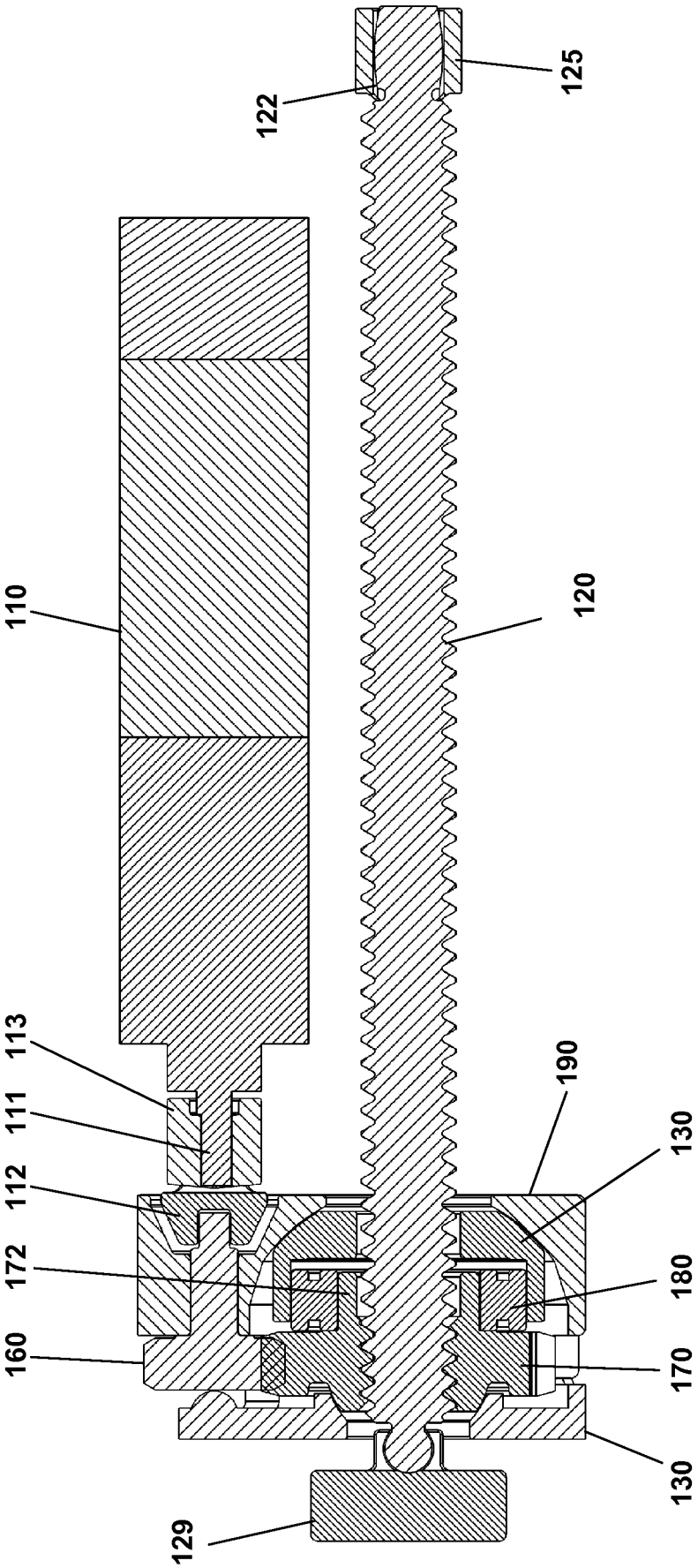

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/050417

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/145
ADD.

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)
A61M

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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2012/191043 A1 (YODFAT OFER [IL] ET AL) 26 July 2012 (2012-07-26) cited in the application the whole document -----	1-7
A	GB 2 094 904 A (TORRINGTON CO) 22 September 1982 (1982-09-22) the whole document -----	1-7

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 March 2015	07/04/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Mausser, Thomas

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2015/050417

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