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INJECTION DEVICE COMPRISING AN IMPROVED DELIVERY ELEMENT

Technical Field

5 The present invention relates to a device for administering a fluid product. The device can be developed as an injection device for the injection of an adjustable dose of the product and in particular can take the form of an injection pen, i.e. a compact injection device in pen form.

10

Prior Art

A large number of injection devices are known from the prior art for the dosed administering of medicaments such as
15 insulin, growth hormones or osteoporosis drugs, which must be administered regularly. Such devices are on the one hand intended to distribute reliably and precisely a dose which is able to be pre-set. On the other hand, they are intended to be reliable in operation and user-friendly to a high
20 degree. This applies all the more because they are generally operated by the patient himself.

The medicament can be housed in an exchangeable carpule, which is able to be inserted into a carpule holder. The
25 latter can then be fastened to a housing of the injection device, e.g. by a screw connection or a bayonet connection. For distribution, a product stopper in the carpule is pushed forward by a delivery arrangement with a delivery element in the form of a piston rod.

30

In particular, compact, pen-shaped administering devices are known, in which the distribution takes place automatically after a first triggering ("power-assisted pens"). The dose in such devices is generally pre-set by a rotation on a
35 dosing button. A drive is present in the device, e.g. a spring drive, which is tensioned on setting of the dose. The device is triggered by pressing in a triggering arrangement,

which can be identical to the dosing button. In so doing, the drive generates a drive movement, e.g. in the form of a rotary movement, which is converted into an advancing movement of the piston rod in a distal direction. In the
5 case of a drive by a rotary movement, the piston rod is mostly constructed as a threaded rod on which a drive nut runs.

10 In DE-A 10 2004 063 644, DE-A 10 2004 063 647, WO-A 2004/002556 and DE-A 102 29 122 such injection pens are disclosed, which constitute the general prior art for the present invention.

15 In EP-A 1 681 070 in Figures 7A and 7B a manually driven injection pen is disclosed, the piston rod 30 of which is constructed so as to be hollow and has an internal thread instead of an external thread. This internal thread is in engagement with the external thread of a rotatable drive shaft 31, which in the region of its proximal end is mounted
20 opposite an inner housing part 13. The piston rod has on its outer side continuous longitudinal grooves into which projections of a fixing bush 32 engage. This fixing bush is secured relative to the housing when a receptacle holder 1 is connected with the housing, and can freely rotate when
25 the receptacle holder is detached from the housing. On administering of a dose, the drive shaft rotates and thereby advances the piston rod linearly, which is guided so as to be locked against relative rotation via the fixing bush. In the case of a change of reservoir, the receptacle holder is
30 detached from the housing. Thereby, the fixing bush, and with it also the piston rod, is freely rotatable with respect to the housing. When the piston rod is now pushed into the housing again, the drive shaft remains stationary and the piston rod performs a screw motion.

35

This device is capable of improvement in several respects. Thus, the screw motion of the piston rod compulsorily

requires, on insertion, that at its distal end a cap is rotatably mounted, which, on insertion, does not co-rotate with the piston rod, because otherwise on insertion no suitable counter-surface would be available which is locked
5 against relative rotation, on which the axial force, required for insertion, could engage. Furthermore, the presence of the fixing bush requires that longitudinal grooves are formed on the outer side of the piston rod. Dirt can accumulate in these. Moreover, a bearing of the drive shaft relative to
10 the housing in its proximal end region is disadvantageous, because a large amount of space is required for this in a region in which otherwise, for example, drive components could be housed. Finally, in this device it is not ensured that the piston rod also actually touches the stopper of the
15 medicament reservoir.

Representation of the Invention

It is therefore an object of the present invention to
20 indicate an administering device which at least partially overcomes these disadvantages.

These problems are solved by a device with the features of Claim 1. Advantageous further developments are indicated in
25 the dependent claims.

According to the present invention, a pen-shaped injection device is indicated for the administering of a fluid product, which has a housing and a delivery element for the delivery
30 of the product from a reservoir. The delivery element is movable relative to the housing along a thrust axis. Instead of an external thread, the delivery element has an internal thread, the thread axis of which runs along the thrust axis. Thereby, the thread which is used for the drive is all but
35 invisible to the user, and a configuration of the outer side of the delivery element is made possible which is largely as desired, adapted to the needs of the user and other technical

requirements. In addition, a particularly compact arrangement becomes possible. The device has, in addition, a drive arrangement and a thread element with an external thread, which is in engagement with the internal thread and
5 is able to be fixed relative the housing along the thrust axis and is able to be set in a rotary movement about the thrust axis by the drive arrangement, in order to advance the delivery element along the thrust axis.

10 Unlike the prior art, the delivery element is guided so as to be locked against relative rotation with respect to the housing at any time, and therefore performs a purely linear thrust movement both on the thrust movement for the ejection of the product and also on pushing back on the change of a
15 receptacle.

The thread element is constructed as an external threaded rod, and the delivery element has a short internal thread, compared with the external thread of the thread element,
20 only in the region of its proximal end, in order to minimize friction losses.

The delivery element can be spring-loaded in particular in a distal direction, i.e. the direction in which the thrust
25 takes place. The spring serving for this is preferably so weak that it does not bring about an ejection of the product out of the reservoir. Rather, it serves, in the case of a reservoir change, to bring the delivery element automatically into its distal final position, i.e. to move
30 it out completely, when the reservoir is removed from the housing. In this way, it is ensured that the delivery element touches the reservoir stopper at all times. The corresponding spring is preferably housed in the interior of the thread element, which for this is developed as a hollow spindle. It
35 is preferably constructed as a helical spring and is guided on a guide needle.

In a preferred development, the device has, in addition, a receptacle holder which is detachable from the housing, to hold the reservoir with the product. In a state in which the receptacle holder is detached from the housing, the thread element is then preferably rotatable with respect to the housing such that the delivery element in this state is able to be inserted into the housing by a purely axial displacement in proximal direction. Here, the thread element co-rotates owing to the thread engagement with the delivery element.

In a preferred embodiment, the delivery element is surrounded radially at least partially by a guide sleeve with a proximal and a distal end. The length of this guide sleeve preferably corresponds at least to the maximum thrust range of the delivery element, i.e. the distance between the distal and the proximal final position of the delivery element. Close to its distal end, the guide sleeve is connected, at least during the administering, so as to be locked against relative rotation with the housing or with an element fixed to the housing. The delivery element is guided along the thrust direction so as to be locked against relative rotation in the guide sleeve. For this, preferably the delivery element, at least in the region of its proximal end, is in an engagement, locked against relative rotation, with the interior of the guide sleeve, which engagement, however, permits an axial displacement. For this, in the region of the proximal end, an engagement structure, e.g. in the form of several longitudinal ribs, can be constructed projecting radially outwards from the outer peripheral surface of the delivery element, cooperating with a complementary structure, e.g. in the form of several longitudinal grooves on the inner peripheral surface of the guide sleeve. The device then preferably comprises in addition an outer sleeve with a proximal and a distal end, which in turn radially surrounds the guide sleeve at least partially. Close to its proximal end, this outer sleeve is connected with the

rotatable element. Close to its distal end, the outer sleeve is rotatable and is guided so as to be secured with regard to displacement relative to the guide sleeve.

- 5 The considerations forming the basis of this embodiment can be summarized as follows: The delivery element is to be secured against rotation relative to the stationary housing and guided longitudinally. Here, the delivery element has a substantially smooth outer surface. This means that the
- 10 delivery element is only guided longitudinally in the region of its proximal end in an element which is locked against relative rotation with respect to the housing. However, this in turn requires that this element, which is locked against relative rotation, is at least so long that the guiding is
- 15 also ensured over the entire range of the thrust of the delivery element. In order to ensure this, a sleeve-like structure of the element which is locked against relative rotation is selected, which is therefore designated as a guide sleeve, with a length of this guide sleeve which
- 20 corresponds at least to the thrust range of the delivery element. To drive the delivery element, furthermore, the rotatable element must be arranged inside the delivery element. So that a thread engagement is ensured over the entire thrust range, the rotatable element must extend at
- 25 least over a length of proximal to distal into the delivery element which corresponds to the thrust range. The sole available access to the rotatable element exists here from the proximal end. A driving of the rotatable element must therefore take place over its proximal end. At the same time,
- 30 the rotatable element must be mounted in any manner relative to an element which is fixed to the housing. This mounting must be able to absorb axial forces, because axial forces are transmitted from the delivery element via the thread engagement to the rotatable element. In fact, a mounting
- 35 could be provided directly at the proximal end of the rotatable element. However, this would take up a large amount of space in a region which is to be available as far as

possible for other functions. It is therefore desirable to reposition the site of the bearing to another location, as close as possible to one of the ends of the housing. This takes place here by means of the outer sleeve which is

5 securely connected with the rotatable element and continues this, as it were, along the outer side of the guide sleeve towards the distal direction. The mounting then takes place between the outer sleeve and the guide sleeve, and namely in the region of the distal end of the outer sleeve. Thereby,

10 a very compact unit is created, the mounting of which, taking up a relatively large amount of space radially, comes to lie in a proximal region, where it is only slightly intrusive, and which makes it possible to accommodate further elements of the injection device in the radial intermediate space

15 between the outer sleeve and the housing. Furthermore, the fact that the outer sleeve (and hence finally the rotatable element) is mounted on the guide sleeve and not, for instance, on the housing itself, makes it possible that the entire unit of guide sleeve, outer sleeve, mounting,

20 rotatable element and delivery element can be formed so as to be movable systematically with respect to the housing, e.g. in the changeover of a receptacle.

According to the present invention, the pen-shaped injection

25 device for the administering of a fluid product comprises a housing and a delivery element for the delivery of the product from a reservoir. The delivery element is movable relative to the housing along a thrust axis between a proximal initial position and a distal final position and is

30 guided so as to be locked against relative rotation. It projects here through a passage opening in a boundary wall of the housing. Furthermore, a drive arrangement is present for producing a rotary movement of a rotatable element relative to the housing, wherein the rotatable element is

35 coupled with the delivery element so that the rotary movement brings about a thrust movement of the delivery element along the thrust axis. The delivery element has a substantially

smooth outer wall region, the length of which corresponds at least to the distance between the distal final position and the proximal initial position. In this way, it becomes possible to arrange the delivery element so that during the thrust only the smooth outer wall region is advanced through the opening in the housing wall. Thus, it can be avoided that the user comes to see an external thread which could have a deterrent effect on him or could be difficult to clean.

10

A "substantially smooth" outer wall region means in particular a region of the outer peripheral surface of the delivery element, which does not have any technically necessary structures which could lead to an insufficient acceptance by the user or could make cleaning difficult. On the other hand, however, the outer wall region can well have fine structures, e.g. a micro- or nanostructuring. Distally from the smooth outer wall region, for example a structure can adjoin which is constructed to advance a stopper in the product container, e.g. a thrust flange projecting radially over the outer wall region. The region arranged proximally from the outer wall region, on the other hand, is normally situated permanently inside the housing and is therefore invisible to the user. This proximal region can therefore be developed as desired within the framework of the technical requirements.

25

If the thrust of the delivery element is to take place via an external thread on which a drive nut runs in a conventional manner, then this external thread will typically adjoin the smooth outer wall region proximally.

30

In an advantageous embodiment, the delivery element is sealed so as to be fluid-tight, at least protected against splash water, with respect to the housing or to an element fixed to the housing. Thereby, a penetration of fluids is effectively prevented.

35

A corresponding seal can be constructed directly between the delivery element and the housing. However, it is also conceivable that a first seal is constructed between the delivery element and an element which is movable relative to the housing, and a second seal is constructed between the movable element and the housing. The movable element can be arranged for example so that it is only movable when the reservoir is being changed, and is immovable with respect to the housing during the actual administering. It can, in particular, be sleeve-shaped.

Preferably a substantially smooth, cylindrical, preferably circular cylindrical outer wall region is surrounded by at least one ring-shaped sealing element. In this way, a simple and efficient sealing can be achieved, as is not possible in the case of the piston rods with external thread of the prior art. The length of the substantially smooth outer wall region corresponds here at least to the distance between the distal final position and the proximal initial position, between which the delivery element is movable in the course of the administering, in order to ensure a sealing over this entire region. The outer wall region can have fine structures, in particular in the range below 100 micrometres, preferably below 10 micrometres, which are suited to at least not impairing the sealing effect, or even to improving it, e.g. a micro- or nanostructuring. These structures can have a preferred direction, in order to inhibit a flow of fluids.

The at least one ring-shaped sealing element preferably comprises at least one circumferential, flexible sealing lip, which rests on the cylindrical outer wall region and acts in the manner of a windscreen wiper as a stripper. The contact angle between the sealing lip and the outer wall region preferably amounts here to less than 90 degrees. However, it can also be constructed for example as a ring with a round or polygonal cross-section.

Preferably, the interior of the housing is sealed in a fluid-tight manner completely with respect to the exterior of the housing, i.e. not only in the region in which the delivery
5 element is guided outwards, but also in other regions, e.g. in the region of movable dosing- or actuating elements.

The delivery element or an element cooperating therewith in a sealing manner can consist in particular of a hydrophobic
10 material or be coated hydrophobically, in order to achieve or improve a sealing effect, by a creep by capillary effect being avoided.

The reservoir is preferably held in a receptacle holder which
15 is able to be fastened to the housing in a detachable manner. On fastening, this receptacle holder is preferably guided with respect to the housing such that relative to the housing it carries out a combined rotary movement about a rotation axis and a translation movement along the rotation axis. The
20 device then preferably further comprises a spring element and a detent element. These elements are arranged such that the spring element produces a spring force onto the detent element acting substantially along the rotation axis. The detent element thereby brings about in a predetermined
25 holding position of the receptacle holder a detachable detent connection, by which the receptacle holder is fixed relative to the housing. For this, for example, a projection of the detent element can project into a depression of the receptacle holder or of an element which is locked against
30 relative rotation with respect thereto. A reverse arrangement is also conceivable. The detent connection is preferably configured so that it is able to be detached again through a movement of the receptacle holder relative to the housing which is opposed to the movement on fastening, i.e.
35 the detent connection does not need to be unlocked manually.

Therefore, preferably a connection in the manner of a screw- or preferably bayonet connection is provided between the receptacle holder and the housing or between elements connected with these. In conventional bayonet connections
5 between two elements, generally an element with a bayonet pin is guided in a suitably formed slit or in a corresponding groove in the manner of a connecting link guide of the other element, until the bayonet pin reaches a final position (corresponding to the holding position). In such
10 connections, the problem exists of avoiding an unintentional sliding back of the pin out of the final position. A similar problem also occurs in screw connections which are fixed by a clamping force and which can likewise become detached unintentionally. The present development solves this problem
15 by providing an axially spring-loaded (and axially movable) detent element. Such a detent element ensures a defined fixing of the receptacle holder in the holding position, without there being the risk of an unintentional detachment. The connection is only detachable again by overcoming a
20 sufficiently great force. Here, an abrasion which could lead to a wearing out of the connection, is avoided. By the detent element being spring-loaded into the axial direction, a simple and space-saving development of the detent element and of the spring element is made possible.

25

Generally, the receptacle will be a container with a cylindrical wall region and with a stopper which is displaceable therein, a so-called carpule, which defines a longitudinal direction and is housed in a receptacle holder
30 with a correspondingly elongated form. When fastening on the housing, the receptacle holder is preferably rotated about this longitudinal direction, i.e. the rotation axis coincides with the longitudinal axis. For the administering of the product, the stopper is advanced by the delivery
35 element along the longitudinal direction. Expressed more generally, the thrust direction of the delivery element therefore preferably corresponds to a direction along the

rotation axis about which the receptacle holder is rotated during its fastening.

Various possibilities exist for the arrangement of the
5 spring- and detent element. According to a preferred development, the detent element is locked against relative rotation with respect to the housing and in the detent position it is detachably engaged with an element which is locked against relative rotation with respect to the
10 receptacle holder. In other words, the detent element does not follow the rotation of the receptacle holder, but remains locked against relative rotation with respect to the housing on fastening of the receptacle holder. However, the reverse arrangement is also conceivable, in which the detent element
15 is locked against relative rotation with respect to the receptacle holder.

In a preferred embodiment, the device comprises a carrier element which is rotatably arranged relative to the housing.
20 The carrier element is guided with respect to the housing such that on fastening of the receptacle holder on the housing and on detaching the receptacle holder from the housing it is entrained by the receptacle holder and is set into a movement which comprises a rotary movement about the
25 rotation axis. In the holding position of the receptacle holder, the detent element then brings about a detachable detent connection, by which the carrier element is fixed relative to the housing. This, in turn, then holds the receptacle holder. The receptacle holder is therefore fixed
30 indirectly, via the carrier element, relative to the housing. Thereby, a greater freedom is made possible in the design of the receptacle holder and of the detent element and spring element.

35 In an advantageous development, the device comprises a guide element which is arranged so as to be locked against relative rotation with respect to the housing, which guide element

can be constructed in particular as a guide sleeve. This guide element can be rigidly connected with the housing, in particular can be produced integrally therewith, or it can be displaceable axially with respect to the housing. The carrier element, which can likewise be formed as a sleeve and can then be designated as a bayonet sleeve, is connected at least rotatably with the guide element. The spring element and the detent element are preferably arranged so as to be locked against relative rotation with respect to the guide element, and in the holding position of the receptacle holder the detent element is engaged detachably with the carrier element. In particular, the guide element can be connected so as to be axially displaceable with respect to the housing and the carrier element can be in fact connected rotatably, but axially secure as regards displacement, with the guide element. Through this configuration, it is made possible that further parts of the device, arranged in the housing, which are connected with the guide element, are displaced axially, when the receptacle holder is mounted on the housing. Thereby, the administering device can be automatically reset for example on detaching of the receptacle holder and on fastening of the receptacle holder it can be brought into a state ready for operation again. In particular it is possible in this way, on detaching of the receptacle holder, to move the interior of the device (in particular the drive arrangement and if applicable a triggering arrangement connected therewith) in a distal direction, so that the triggering arrangement, which can be formed as a push button, is drawn into the housing and thus indicates that the device is not ready for operation.

Preferably, the carrier element is guided here with respect to the housing such that on fastening of the receptacle holder to the housing it is entrained by the receptacle holder and is set into a combined rotational movement relative the housing about the rotation axis and translation movement along the rotation axis in a proximal direction.

Preferably the carrier element is moveable between two defined final positions, and the detent element brings about in *both* positions a detachable detent connection, by which

5 the carrier element is fixed relative to the housing. The carrier element assumes its first final position here, when the receptacle holder assumes its holding position, and it assumes its second final position when the receptacle holder is removed from the housing. Preferably, the detent element

10 is detachably engaged both in the first final position and also in the second final position directly with the carrier element.

The carrier element is preferably guided in at least one

15 guide slit relative to the housing, i.e. on the actual housing itself or on an element which is fixed to the housing, in particular by one or more corresponding pins. Likewise, on fastening to the housing, the receptacle holder is guided in at least one guide slit, in the manner of a

20 bayonet connection, relative to the housing.

The detent element is preferably constructed in the form of a ring which extends around the rotation axis and in particular around the thrust element. Suitable detent noses

25 can be constructed on the ring. This detent element can be axially spring-loaded by a separate spring element. This may be, for example, a helical spring which is subjected to pressure, or another type of elastic element. However, the spring element preferably has the form of a ring which

30 extends around the rotation axis and is curved about an axis perpendicularly to the rotation axis, so that the spring force is produced by a compressing of the spring element along the rotation axis.

35 The detent element is preferably constructed integrally with the spring element. This leads to a particularly simple development. In particular, the detent element can be

constructed as a projection, protruding in the direction of the rotation axis, on the spring element. This is particularly advantageous when the spring element, as described above, has the form of a curved ring.

5

The device can further comprise at least one ball bearing which absorbs forces which are transmitted between the delivery element and the housing. By a ball bearing being provided, frictional losses which are caused during the
10 administering owing to the transmission of forces between the delivery element and the housing, are largely minimized.

A ball bearing is advantageous in particular when the device comprises at least one rotatable element cooperating with
15 the delivery element, and a drive arrangement for generating a rotary movement of the rotatable element relative to the housing, with the rotary movement of the rotatable element bringing about a (linear) thrust movement of the delivery element along the thrust axis in a distal direction,
20 preferably by a thread engagement, which is preferably not locking. In this case, the ball bearing is advantageously arranged such that it absorbs (axial) forces acting along the thrust axis, which are transmitted from the delivery element (locked with respect to rotation relative to the
25 housing) via the rotatable element to the housing, i.e. which act between the rotatable element and the housing. Expressed in general terms, axial forces, in particular acting in proximal direction, are therefore transmitted between the delivery element and the housing via a rotatable connection
30 which is secure with respect to displacement in axial direction. For this, in the prior art, generally a sliding connection is provided between the rotatable element and the housing or an element which is fixed to the housing. In the present invention, on the other hand, at least one ball
35 bearing is provided, which is preferably arranged between the rotatable element or an element connected therewith on the one hand, and the housing or an element which is fixed

to the housing at least during the administering, on the other hand. Thereby, frictional losses during the rotation of the rotatable element can be avoided.

5 Preferably, two ball bearings are present, which are preferably arranged so that they can absorb forces along the thrust axis both in a proximal direction and also in the distal direction opposite thereto, i.e. the direction in which the thrust takes place. Axial forces in the proximal
10 direction occur generally during the administering, whereas axial forces in the distal direction can occur in particular when the delivery element is spring-loaded in the distal direction, as is the case in a preferred embodiment. The spring serving for this is preferably so weak that it does
15 not cause any ejection of the product out of the reservoir. Rather, it serves, in a change of reservoir, to automatically bring the delivery element into its distal final position, i.e. to move it out completely, when the reservoir is removed from the housing. When the delivery element is in a suitable
20 connection with the rotatable element, this leads to the rotatable element being set into a rotation when the delivery element moves out due to the spring force. In order to keep the spring force, which is necessary for this, small, a ball bearing is particularly advantageous, because with the
25 moving out of the delivery element, it minimizes the frictional forces acting then.

Brief Description of the Drawings

30 Preferred embodiments of the invention are described below with the aid of the drawings, in which are shown:

Fig. 1 a perspective exploded view of an injection device according to a first embodiment;

35 Fig. 2 a longitudinal section through the injection device of Fig. 1;

Fig. 3 an enlarged cut-out of Fig. 2;

- Fig. 4 a longitudinal section through an arrangement of a guide sleeve and of a coupling sleeve in the injection device of Fig. 1;
- Fig. 5A a top view onto a ball bearing ring;
- 5 Fig. 5B a sectional view of the ball bearing ring in the plane A-A;
- Fig. 6 a perspective view of a coupling sleeve;
- Fig. 7 a longitudinal section through selected parts of the injection device of Fig. 1;
- 10 Fig. 8 a perspective illustration of a bayonet sleeve;
- Fig. 9A a top view onto a bayonet spring;
- Fig. 9B a side view of the bayonet spring of Fig. 9A;
- Fig. 9C a perspective view of the bayonet spring of Fig. 9A;
- 15 Fig. 10 a longitudinal section through selected parts of the injection device of Fig. 1;
- Fig. 11A a longitudinal section through selected parts of the injection device of Fig. 1 with a dose limiting ring in its final position;
- 20 Fig. 11B a longitudinal section through selected parts of the injection device of Fig. 1 with the dose limiting ring in its initial position;
- Fig. 12A a perspective view of a coupling shaft with a dose limiting ring of the injection device of Fig. 1;
- 25 Fig. 12B the parts of Fig. 12A in an exploded view;
- Fig. 12C the coupling shaft of Fig. 12A in a perspective view from another direction of view;
- Fig. 13 an exploded view of an arresting sleeve, a coupling spring and a support ring;
- 30 Fig. 14 a perspective view of selected parts of the injection device of Fig. 1;
- Fig. 15 a perspective exploded view of the proximal end of the injection device of Fig. 1;
- Fig. 16 a longitudinal section through the injection device of Fig. 1 in the initial position;
- 35 Fig. 17 the longitudinal section of Fig. 16 with depressed push button;

- Fig. 18 the longitudinal section of Fig. 16 after a first increase of dose up to half the maximum dose;
Fig. 19 the longitudinal section of Fig. 16 after a first increase of dose up to the full maximum dose;
5 Fig. 20 the longitudinal section of Fig. 16 after a first triggering and a second increase of dose;
Fig. 21 a longitudinal section through the injection device of Fig. 1 after a complete emptying of the carpule;
10 Fig. 22 a perspective view of the injection device of Fig. 1 after removal of the carpule sleeve; and
Fig. 23 a longitudinal section through an injection device according to a second embodiment.

15 Detailed Description of Preferred Embodiments

By means of Figures 1 and 2, firstly the basic structure and the basic operation of an injection device according to the invention are explained, before for a first embodiment the
20 structure of the device and the mode of operation of the dosing mechanism are explained in detail with the aid of Figures 3 to 20. A second embodiment is then discussed with the aid of Fig. 21.

25 *Basic structure and operation*

Fig. 1 shows an injection device in the form of an injection pen in a perspective exploded view. Fig. 2 shows the device in longitudinal section. The following description relates
30 to the device in the assembled state, as is illustrated in Fig. 2.

The injection device has a housing sleeve 20 in which a mechanism is housed for setting and distributing a dose. The
35 housing sleeve 20 has substantially the form of a circular cylinder and hereby defines a longitudinal axis. A receptacle holder in the form of a carpule housing 30 is detachably

fastened to a distal end of the housing sleeve 20 by means of a bayonet connection which is described in further detail below. This receives a receptacle in the form of a carpule 40 with a fluid medicament, in which a stopper 41 is

5 displaceably guided. A medicament reservoir R of changeable volume is thereby delimited inside the carpule. Instead of a carpule, a different receptacle can also be present, the volume of which is changeable, e.g. a receptacle with walls folded in a concertina-like manner in the manner of a

10 bellows. The content of the carpule 40 can be monitored through an elongated viewing window 34 in the carpule sleeve 30. A needle holder 31 is screwed on the distal end of the carpule sleeve 30, which needle holder 31 carries a hollow needle (cannula) 32, serving as injection needle, the

15 proximal end of which projects through a sealing septum into the medicament reservoir R. A removable needle protection sleeve 33 surrounds the forwardly projecting region of the needle 32 and protects a user from being pricked accidentally. A protective sleeve 10, the distal end of which

20 is permanently closed by a protective cap 50, is pushed over the carpule sleeve 30. A holding ring 11 with detent arms 12 extending in proximal direction is mounted inside the protective sleeve 10. The ends of the detent arms 12 are detachably engaged with the carpule sleeve 30. Whilst the

25 invention is described here by means of an injection device which has a needle 32, it is also conceivable that the injection device has several needles or no needle, as in a jet injector.

30 At the proximal end of the housing sleeve 20, a dosing sleeve 60 is rotatably arranged with a push button 80 held therein. The dosing sleeve serves for the setting of a dose which is to be distributed from the medicament reservoir R and for the tensioning of a drive arrangement with a drive element

35 in the form of a spiral spring 310, acting as a torsion spring, which is only indicated in the drawings. The dose which is set is displayed on a display drum 70 and can be

read through a window 21 in the housing sleeve 20 which is covered by a transparent covering 22. A correcting (reduction) of the set dose is possible in a simple manner by turning back the dosing sleeve 60. It will be explained
5 in further detail below, with reference to the further figures, how this setting is made possible.

With reference to these parts, the following directions can be defined, which will be referred to consistently below:

10 The distal direction is the direction in which the administering takes place, i.e. it points along the longitudinal axis from the push button 80 in the direction of the hollow needle 32. The proximal direction is accordingly defined as the opposite direction. If reference
15 is made to a direction of rotation (clockwise, anticlockwise), this means the direction of rotation which one observes when one views along the longitudinal axis in distal direction.

20 After the setting of the dose, the hollow needle 32 is pierced through the skin of the patient and a distribution of the dose is triggered by the user pushing the push button 80 into the dosing sleeve 60. A rotary movement is produced by the drive arrangement via a mechanism which is described
25 in detail below, this rotary movement being converted into an advancing of a delivery element in the form of a thrust sleeve 90 in distal direction. The thrust sleeve 90 pushes the stopper 41 of the medicament carpule 40 by the set amount in distal direction via a thrust flange 100 arranged at its
30 distal end, whereby the distribution of the medicament is brought about out of the reservoir R. The thrust sleeve 90 therefore acts as a piston rod for the piston which is formed by the thrust flange 100 and the stopper 41. After the end of the administering, the user releases the push button 80
35 again. During the advance of the thrust sleeve 90, the display drum is entrained by the drive arrangement such that it returns to its zero position in the course of the

distribution. The injection pen is thereby immediately ready for the next dose setting.

When the medicament in the medicament reservoir R is running
5 low, i.e. the thrust sleeve 90 is almost completely extended, this is detected by a dose limiting arrangement in the injection pen, which is described in further detail below. The dose limiting arrangement allows the user to only set as
10 a maximum the remaining available residual dose. In a subsequent carpule change, the dose limiting arrangement and also the display drum 70 automatically return into the initial state. No manual resetting is therefore necessary.

The structure and mode of operation of the mechanism are
15 described in detail below.

Structure of the Mechanism

Fig. 3 shows an enlarged illustration of the rear (proximal)
20 region of the injection device of Fig. 1. The structure of this region will now be described in detail substantially from the interior outwards.

The thrust sleeve 90 is mounted in a guide sleeve 110,
25 arranged locked against relative rotation with respect to the housing and displaceably, again locked against relative rotation and displaceably in longitudinal direction. For this, the thrust sleeve 90 has at its proximal end several radially outwardly projecting guide cams 91 which are guided
30 in longitudinal grooves, complementary thereto, on the inner side of the guide sleeve 110.

The guide sleeve 110 can be seen particularly well in Fig. 4, which illustrates the cooperation of the guide sleeve
35 with further parts. The guide sleeve 110 has at its distal end a radially outwardly projecting, circumferential ring flange 111 with radial bores 112. A ring-shaped bearing

holder 130 is pushed from the proximal side via the guide sleeve 110, surrounds the ring flange 111 radially and is connected rigidly therewith via radial cylinder pins which are not illustrated in the drawings.

5

A coupling sleeve 120 is rotatably mounted between the ring flange 111 of the guide sleeve 110 and an inwardly projecting shoulder 132 of the bearing holder 130. As is described in further detail below, the coupling sleeve 120 is connected
10 via a threaded rod 180 with the thrust sleeve 90 and therefore forms a part of a delivery arrangement, which is driven by a rotary movement and brings about a thrust of the delivery element in the form of the thrust sleeve. The coupling sleeve 120 therefore absorbs considerable axial
15 forces in operation, which are transmitted via its bearing onto the guide sleeve 110, the bearing holder 130, the mechanism holder 150 and therefore finally to the housing.

In order to construct the bearing so as to be as low-loss as possible, the bearing takes place by means of ball bearings.
20 For this, a first ball bearing ring 140 is provided between the flange 111 of the guide sleeve and a radially encircling flange 124 of the coupling sleeve 120. A further such ball bearing ring 140 is arranged between the flange 124 and an
25 end face of the bearing holder 130.

The ball bearing ring 140 is illustrated in detail in Figures 5A and 5B. It carries a plurality of bearing balls 141 (twelve, here). These run, as can be seen in Fig. 3, in flat,
30 circular grooves which are formed in both end faces of the radial flange 124 of the coupling sleeve 120, in the corresponding end face of the flange 111 of the guide sleeve 110 and in the end face of the bearing holder 130.

35 The coupling sleeve 120 is illustrated in Fig. 6 together with the ball bearing rings 140 (but without balls 141). As can be seen particularly well here, on the cylindrical sleeve

body 121 a plurality of longitudinal ribs 122 are formed, which extend over a considerable part of the length of the sleeve body in longitudinal direction up to its proximal end. Corresponding grooves are present therebetween. From a
5 thickening 123 the flange 124 follows towards the front, which adjoins the ball bearing rings 140 on both sides.

There is illustrated in Fig. 7 how the unit of guide sleeve 110 and bearing holder 130 is held in a sleeve-shaped
10 mechanism holder 150 so as to be locked against relative rotation, but displaceably in longitudinal direction.

The mechanism holder 150 has a distal section 151 with increased internal and external diameter and a proximal
15 section 152 with a somewhat smaller internal and external diameter. These two sections are connected by a step 153. The outer side of the distal section 151 is held rigidly in the housing sleeve 20. Thereby, the entire mechanism holder 150 is therefore also immovable with respect to the housing,
20 therefore forming functionally a part of the housing.

Adjoining the step 153, at least two longitudinal slits 154 are formed in the mechanism holder 150. Pins, which are not illustrated in Fig. 7, are inserted in the bearing holder
25 130. These project radially beyond the bearing holder 130 and into the longitudinal slits 154 of the mechanism holder. Hereby, the bearing holder 130 and the guide sleeve 110, which is securely connected therewith, are guided displaceably between a distal and a proximal final position
30 and so as to be secured with regard to rotation in the mechanism holder 150. Towards the proximal end, on the outer covering surface of the mechanism holder 150, an external thread 157 is formed. Several longitudinal grooves 158 are formed in this region on the inner surface.

35

In distal direction, a bayonet sleeve 160 adjoins the guide sleeve 110 and the bearing holder 130, which is also

illustrated in Fig. 8. It is held on the bearing holder 130 in axial direction and is rotatable with respect thereto. With an inwardly projecting ring flange 161 it supports the unit of guide sleeve 110 and bearing holder 130, with coupling sleeve 120 held therein, in the distal direction. The bayonet sleeve 160 has two arms 162 projecting axially in the distal direction and lying diametrically opposite each other, which arms 162 have radial openings 163. Radially outwardly projecting pins are inserted into these openings, which pins run in two guide slits 155 of the mechanism holder 150 acting as connecting link guides (positive guides). These guide slits 155 are developed so that the bayonet sleeve 160, with an anticlockwise rotation (in the sense of the definition indicated above, i.e. on observation along the longitudinal axis in distal direction) is compulsorily also moved axially in the proximal direction. In this way, the unit of guide sleeve 110, bearing holder 130 and coupling sleeve 120 is moved in proximal direction. Vice versa, with a rotation of the bayonet sleeve 160 clockwise, this unit moves in the distal direction. Parallel to the guide slits 155, a further pair of guide slits 156 runs, in order to receive radial pins 36 of a locking region 35 of the carpule sleeve 30 (cf. Figures 1 and 3). On introduction of the carpule sleeve 30 into the housing, the carpule sleeve is therefore also subject to a positive guidance, so that the carpule sleeve 30 performs a combined rotary movement and displacement. The carpule sleeve 30 is developed here so that on its movement it is coupled with the arms 162 of the bayonet sleeve 160 and entrains the bayonet sleeve 160.

The guide slits 155 are of finite length and delimit the movement of the bayonet sleeve between a distal and a proximal final position. In Fig. 7 the proximal final position is illustrated. In particular, the guide slits 155 allow a rotation of the bayonet sleeve through 90 degrees between these positions.

In order to fix the bayonet sleeve detachably in its two final positions so as to be locked against relative rotation with respect to the guide sleeve 110 and hence with respect to the housing sleeve 20, a bayonet spring 170 is arranged
5 between the bayonet sleeve 160 and the guide sleeve 110. This is illustrated in detail in Figures 9A to 9C. The bayonet spring 170 has a substantially flat and ring-shaped base body 171 acting as a spring element. Two diametrically opposite, axially flatly projecting bulges or projections
10 172 protrude out from this base body as detent elements or detent cams axially in the distal direction. Two diametrically opposite flat tongues 173 protrude inwards and come to lie in corresponding flat recesses of the guide sleeve 110. Thereby, the bayonet spring 170 is held, so as
15 to be secured with regard to torsion, on the guide sleeve 110. As can be seen from Fig. 9B, the base body 171 is bent slightly about an axis perpendicularly to the longitudinal axis, and namely such that the curvature mid-point lies on the same side of the bayonet spring as the projections 172
20 (i.e. distal). Hereby, the bayonet spring 170 is pre-stressed between the guide sleeve 110 and the bayonet sleeve 160 permanently such that the projections 172 are pressed in distal direction against the corresponding counter-surface on the ring flange 161. In this counter-surface, four
25 depressions are present which are arranged at intervals of 90 degrees about the longitudinal axis. In the proximal final position, the projections 172 come to lie in a first pair of these depressions, whereas in the distal final position, in which the bayonet sleeve is turned through 90 degrees, they
30 are held in the second pair of the depressions. Thereby, two defined detent positions are produced, in which the bayonet sleeve 160 engages via the bayonet spring 170 with the projections 172 detachably with the guide sleeve 110. In both positions, firstly a certain force must be overcome, in
35 order to move the bayonet sleeve in the direction of the respective other final position again. The depressions can be distinctive differently, e.g. of different depth, so that

a different releasing force is necessary in the two detent positions.

In one detent position, the carpule sleeve 30 is held via
5 its coupling with the bayonet sleeve 160 so as to be secure with regard to rotation and displacement on the guide sleeve 110 and hence finally on the housing. In the other detent position, the carpule sleeve 30 is detached from the housing. In this position, the bayonet sleeve 160 is again engaged
10 with the guide sleeve 110 and is thereby fixed on the housing 20 so as to be secure with regard to rotation and displacement. In this way, it is ensured that the carpule sleeve, on insertion into the guide slits 156, "finds" the arms 162 of the bayonet sleeve again in the correct position
15 around the longitudinal axis and can then entrain these after the releasing of the detent connection.

In the present example, the detent elements are constructed as projections 172 integrally with the spring element in the
20 form of the base body 171. Instead of this, however, a separate detent element can be provided, e.g. in the form of a rigid ring with detent cams, which is pressed in the axial direction by the spring element. Instead of projections, the detent element can also have depressions which then cooperate
25 with corresponding projections of the counter surface. In the present example, the detent element is locked against relative rotation with respect to the housing. Instead of this, it can also be locked against relative rotation with respect to the bayonet sleeve. The spring element can also
30 be developed differently to produce an axial force. Various modifications of the locking illustrated here between the carpule sleeve 30 and the housing are therefore possible.

In Fig. 10, the parts of the injection device illustrated in
35 Fig. 7 are illustrated together with further components. In particular, the thrust sleeve 90 is now pushed into the guide sleeve 110. At its proximal end, the thrust sleeve 90 has a

short internal thread 92 in which a hollow external threaded rod 180 is guided. The latter is connected at its proximal end rigidly with the coupling sleeve 120 via a transverse pin 181. A thrust of the thrust sleeve 90 in distal direction

5 therefore takes place, by the coupling sleeve 120, which is in fact rotatably mounted, carrying out a rotary movement. Owing to the rigid connection between coupling sleeve 120 and external threaded rod 180, this rotary movement also brings about a rotation of the external threaded rod 180.
10 The thrust sleeve 90 runs with its internal thread 92 on the external threaded rod 180, similar to a nut. The thrust sleeve 90 is locked against relative rotation with respect to the guide sleeve 110, because it runs via the guide cams 91 in longitudinal grooves on the inner side of the guide
15 sleeve 110. In this way, the thrust sleeve 90 is advanced axially on a rotation of the external threaded rod 180. As a whole, therefore, a rotary movement of the coupling sleeve 120 is converted into an axial displacement of the thrust sleeve 90.

20

As can be seen from Fig. 3, the thrust sleeve 90 is assisted in this thrust movement by a long helical spring 190 which is subjected to pressure, which is arranged in the interior of the threaded rod 180 and is guided on a guide needle 200.

25 The helical spring 190 presses a ring-shaped thickening 201 close to the distal end of the guide needle 200 in the distal direction against the thrust flange 100. An axial pin 202 projects into a corresponding blind-end bore of the thrust flange 100 and is rotatable in this blind-end bore.

30

Furthermore, in Fig. 10 a substantially cylindrical transmission sleeve 210 is inserted into the mechanism holder 150 from the proximal side, which transmission sleeve partially surrounds the coupling sleeve 120. The

35 transmission sleeve 210 has on the outer side a plurality of longitudinal ribs 212. The external diameter of the transmission sleeve 210 is selected here so that, despite

its external longitudinal ribs, it is freely rotatable inside the mechanism holder 150. On the inner side, the transmission sleeve 210 has an internal thread 211, in which a dose limiting ring 220 runs with a corresponding external thread 221. In the interior of the dose limiting ring 220, longitudinal grooves 222 are present which can be seen particularly well in Figures 12A and 12B, into which the longitudinal ribs 122 of the coupling sleeve 120 (cf. Fig. 6) engage. Thereby, the dose limiting ring 220 is movable on the one hand so as to be secure with regard to rotation in axial direction on the coupling sleeve, and on the other hand is guided in the internal thread of the transmission sleeve 210. A rotation of the coupling sleeve 120 with respect to the transmission sleeve 210 therefore leads to a rotation and axial displacement of the dose limiting ring 220.

The axial displacement range of the dose limiting ring is limited in distal and in proximal direction. This is to be described by means of Figures 11A, 11B, 12A and 12B.

In Figures 11A and 11B a coupling shaft 230 is connected with the transmission sleeve 210. The coupling shaft has an axis 231 with a transverse bore 232 close to the proximal end 233. A circumferential flange 234 extends radially outwards from the distal end of the axis. A ring flange 235 extends in turn therefrom axially in distal direction. The external diameter of the flange 234 is greater than that of the ring flange 235, whereby the flange 234 protrudes radially over the ring flange 235 and forms a stop for the transmission sleeve 210. The ring flange 235 is pushed into the transmission sleeve 210, so that the latter lies with its proximal end against the flange 234. The ring flange is secured by radial pins in the transmission sleeve 210, which are pushed into bores 237. Thereby, the coupling shaft 230 and the transmission sleeve 210 are connected with each other so as to be locked against relative rotation and secured

against displacement. Several longitudinal grooves 238 are formed in the inner surface of the ring flange 235.

Figures 12A and 12B show the coupling shaft 230 and the dose limiting ring 220 alone. A radial stop 223, which cooperates with a corresponding radial stop 236 on the ring flange 235 of the coupling shaft, is formed on the dose limiting ring 220. A radial stop is understood to mean a stop surface, the surface normal of which points substantially in the tangential direction, and which is formed to cooperate with a corresponding counter surface. The radial stop is therefore primarily stressed in tangential direction (i.e. in rotational direction) instead of in axial direction. Thereby, a radial stop avoids the risk of jamming, which exists when two parts collide axially via a screw connection, and which is especially marked in particular in the case of a small pitch of the helical thread. The radial stop 236 delimits here the screw motion of the dose limiting ring 220 in proximal direction. In Fig. 11A the dose limiting ring 220 is shown in the resulting proximal final position, and in Fig. 11B on the other hand in a distal initial position.

The proximal end of an arresting sleeve 280 is rotatably clicked into an inwardly directed ring flange 213, chamfered in the distal direction, at the distal end of the transmission sleeve 210. For better clarity, the arresting sleeve 280 is not illustrated in Fig. 10. However, it is shown in Fig. 13. The arresting sleeve comprises a ring-shaped main body 281, from which four arms 282, extending in distal direction, extend in the distal direction. On its inner surface, the main body has longitudinal grooves 284 which are meshed with the longitudinal ribs 122 of the coupling sleeve 120. Thereby, the arresting sleeve 280 is displaceable in longitudinal direction relative to the coupling sleeve 120, but is secured as regards torsion with respect thereto. At the end of the arms 282, inwardly extending flange regions 283 are present. The possible

displacement range is limited in proximal direction by these flange regions. These abut in the proximal final position of the arresting sleeve 280, as illustrated in Fig. 3, onto the distal end of the longitudinal ribs 122 of the coupling sleeve 120. Longitudinal ribs are formed on the outer peripheral surface of the main body 281. These longitudinal ribs engage, in the position of Fig. 3, into the inner longitudinal grooves 158 of the mechanism holder 150. Thereby, the arresting sleeve 280 is displaceable in this position axially with respect to the mechanism holder 150, but secured with regard to torsion. Finally, the arresting sleeve 280 in this position therefore secures the coupling sleeve 120 against a rotation in the mechanism holder 150. As described further below, the arresting sleeve 280 is, however, displaceable so far in the distal direction that it can come out of engagement with the mechanism holder 150 and is then rotatable with respect thereto together with the coupling sleeve 120.

The arresting sleeve 280 is pre-stressed in the proximal direction by means of a coupling spring 290. The coupling spring has the form of a helical spring which is subjected to pressure, which surrounds the arms 282 of the arresting sleeve 280 and lies with its proximal end against the distal end face of the main body 281. At the distal end of the coupling spring 290, the latter is held on a support ring 300 which abuts against the bearing holder 130 in the distal direction and on the inner side of which longitudinal grooves are formed.

In Fig. 14 the unit of Fig. 10 is now illustrated with further components again. The display drum 70, which has already been previously mentioned, is now held on the mechanism holder 150. In addition, a stop sleeve 240 can be seen. As can be seen in Fig. 2, the stop sleeve 240 is connected immovably with the housing sleeve 20 by pins which project into the radial holes 242 which can be seen in Fig.

14. At its distal end, radial stops 243 are formed. Its proximal end is formed so as to be serrated, i.e. teeth 244 are formed on the end face for a ratchet connection which is yet to be described.

5

The display drum 70 has an internal thread which can be seen in Fig. 3. This runs on the external thread 157 of the mechanism holder, which can be seen particularly well in Figures 7 and 10. At its proximal end, the display drum 70
10 narrows to a ring-shaped region 72. Longitudinal grooves are formed on the inner side of the ring-shaped region 72. By these longitudinal grooves, the display drum 70 is secured with regard to torsion, but is guided displaceably in longitudinal direction on the longitudinal ribs 212 of the
15 transmission sleeve 210. Through the combination of this longitudinal guide on the transmission sleeve and the thread guide on the mechanism holder, a rotation of the transmission sleeve 210 leads to a combined rotation and longitudinal displacement of the display drum 70. This movement is
20 delimited by radial stops in both directions. At the proximal end, a radial stop cooperates with the radial stop 243 of the stop sleeve 240. At the distal end, a corresponding radial stop 73 cooperates with a radial stop 159 of the mechanism holder 150. Thereby, the screw motion of the
25 display drum 70 is limited in both directions by radial stops.

The mechanism for setting a dose and for triggering the administering of this dose is now described in the following
30 with the aid of Figures 3 and 15. The dosing sleeve 60, which has already been mentioned, is arranged at the proximal end of the housing sleeve 20. It is secured with regard to displacement axially with a spring ring 61 and is fixed rotatably on the stop sleeve 240. The dosing sleeve 60 is
35 rotatable via a slip coupling in the form of a ratchet connection both clockwise and also anticlockwise about the longitudinal axis towards the housing sleeve 20, being able

to assume several predefined detent positions. This mechanism is to be described in the following.

5 An inner ring 250 is arranged inside the dosing sleeve 60 and is rigidly connected with the dosing sleeve 60. The inner ring 250 has in its radial inner surface a plurality of longitudinal grooves. In distal direction from the inner ring 250, a ratchet ring 260 is held so as to be axially displaceable but secured with regard to rotation in the
10 dosing sleeve 60. The ratchet ring 260 is formed so as to be serrated on its distal end face, and namely in a complementary manner to the teeth 244 of the serrated proximal end face of the stop sleeve 240, so that teeth of the ratchet ring 260 can engage in depressions on the end
15 face of the stop sleeve 240 and vice versa. The ratchet ring 260 is axially displaceable by a certain amount between the distal end face of the inner ring 250 and the serrated proximal end face of the stop sleeve 240. The amount by which an axial displacement is possible is at least so great here
20 that the serrated end faces of the ratchet ring 260 and of the stop sleeve 240 can come out of engagement. The ratchet ring 260 is pressed elastically by an elastic force against the stop sleeve 240. For this, several axial bores 251 are present in the form of blind-end bores in the inner ring
25 250. Helical springs 252 which are subjected to pressure are inserted in at least one of these bores, preferably in at least two bores at a uniform spacing along the circumference of the ring. The helical springs 252 press the ratchet ring elastically against the stop sleeve.

30

In the position of rest, the ratchet ring 260 with its serrated end face is in engagement with the serrated end face of the stop sleeve 240. Thereby, the ratchet ring and the dosing sleeve 60 connected therewith assume one of
35 several defined angle positions about the longitudinal axis. With a rotation of the dosing sleeve 60 relative to the housing sleeve 20, the teeth of the ratchet ring 260 and of

the stop sleeve 240 slide on each other against the axial spring force of the helical springs 252, until they come out of engagement and arrive in engagement again in the next defined angle position. In this way, an elastically detachable detent connection is produced by rotation with a sufficient torque in several predefined angle positions of the dosing sleeve 60 relative to the housing sleeve 20. This mechanism can also be designated as a double slip coupling.

By rotation of the dosing sleeve 60 clockwise, the spiral spring 310 can be tensioned, which is indicated in Fig. 3. The spiral spring 310 has a plurality of spring coils which run around the longitudinal axis and are arranged over one another radially to the longitudinal axis. The inner end of the spiral spring 310 is fastened to a spring holding region 311 of the coupling shaft 230 which region can be seen particularly well in Fig. 12C. The outer end of the spiral spring 310 is mounted on a spring sleeve 320, which is held so as to be locked against relative rotation in the stop sleeve 240.

A coupling disc 270 is mounted on the coupling shaft 230 and is secured against rotation and displacement by means of a pin 271 in the transverse bore 232 of the coupling shaft 230. The coupling disc 270 has a plurality of longitudinal ribs on its outer peripheral surface. In the position of Fig. 3, these longitudinal ribs engage into the longitudinal grooves, which are complementary thereto, on the inner side of the inner ring 250, but can be brought out of engagement by an axial displacement.

The dosing sleeve 60 has an axial passage opening, in which the push button 80 is arranged so as to be axially displaceable. The push button 80 is rotatable with a plurality of radially elastic arms 81 and is clicked on the proximal end 233 of the coupling shaft 230 so as to be secured against displacement. It abuts with its distal end

against a proximal end face of the coupling disc 270. In the interior of the push button 80 there is a helical spring 82 which lies with its proximal end against the inner end face of the push button and presses with its distal end against a bearing ring 83. The bearing ring 83 has on its outer peripheral face longitudinal ribs which are guided in corresponding longitudinal grooves in the inner covering surface of the push button 80. Thereby, the support ring 83 is arranged in the push button 80 so as to be locked against relative rotation and so as to be axially displaceable. The bearing ring 83 is formed so as to be serrated in a flat manner on its distal end face. The proximal end face of the coupling disc 270 is formed so as to be serrated in a complementary manner hereto, so that the bearing ring 83 is axially meshed with the coupling disc 270. On distribution of the medicament, the coupling disc 270 rotates with respect to the bearing ring 83. Thereby, the serrated surfaces slide on one another, so that the tothing comes alternately into and out of engagement. Thereby, a characteristic clicking sound is produced, which indicates to the user that an administering is just taking place. The tothing of bearing ring 83 and coupling disc 270 is preferably developed here so that each clicking corresponds to precisely one unit (or of a predetermined multiple of one unit) of the administered medicament.

Sealing

The entire mechanism for setting the dose and the distribution is housed in the housing sleeve 20 so as to be protected against splashing. For this, in total four seals D1, D2, D3 and D4 are present. The seal D1 comprises a sealing ring which lies in a sealing manner between the mechanism holder 150 and the bayonet sleeve 160. The mechanism holder 150 is mounted immovably and tightly in the housing 2, whilst the bayonet sleeve 160 is both displaceable and also rotatable with respect to the mechanism holder 160

and is sealed here with respect to the housing by means of the seal D1. The seal D2 comprises a further sealing ring, constructed so as to be flat here, which lies in a sealing manner between the bayonet sleeve 160 and the smooth outer
5 side of the thrust sleeve 90. Furthermore, the thrust flange 100 is arranged tightly on the thrust sleeve 90. The region of the injection device, including the interior of the thrust sleeve 90, lying proximally from the bayonet sleeve 160, is thereby sealed completely against the region lying distally
10 herefrom. In case fluids were to arrive into this distal region, e.g. due to a breakage of the medicament carpule 40, these cannot penetrate into the difficult mechanics and contaminate or jam it.

15 The other two seals are situated at the proximal end of the injection device. The seal D3 comprises a sealing ring which lies in a sealing manner between the dosing sleeve 60 and the stop sleeve 240. The stop sleeve 240 is mounted immovably and tightly in the housing sleeve 20, whereas the dosing
20 sleeve 60 is rotatable with respect to the stop sleeve 240. The seal D4 comprises a further sealing ring which lies in a sealing manner between the dosing sleeve 60 and the push button 80. In addition, a transparent window covering 22 is placed in a fluid-tight manner on the window 21. Hereby, the
25 entire mechanics, which are delimited toward the exterior by the housing sleeve 20, the dosing sleeve 60 and the push button 80, is also completely sealed toward the exterior and is thus fully protected against the penetration of fluids. Rainfall or a glass of water accidentally spilt by the user
30 can therefore also not harm the injection device.

In particular the seal towards the thrust sleeve is preferably constructed such that it acts as a stripper, similar to a windscreen wiper in a car. For this, at least
35 towards the distal side, there is as small a contact angle as possible between the surfaces of the sealing element and the thrust sleeve. This can lie below 90 degrees.

- Instead of conventional seals or in addition hereto, the parts which are to be sealed with respect to each other can have a hydrophobic surface, in particular can be formed from a hydrophobic material or be coated therewith. A hydrophobic surface prevents the parts from being wetted. Drops of water thereby roll off and a leaking of fluids through gaps is efficiently prevented between the parts which are to be sealed due to capillary effects. The parts provided with a hydrophobic surface which are to be sealed with respect to each other can therefore be arranged at a certain distance (gap) from each other, without the sealing effect being lost ("virtual seal").
- A hydrophobic surface is understood here to mean a surface for which the contact angle of a water drop is at least 90 degrees, preferably at least 110 degrees. The contact angle is the angle between the surface normal of the water drop and the respective surface at the contact site. Examples of materials with hydrophobic characteristics are PTFE (polytetrafluoroethylene) or PVDF (polyvinylidene fluoride). Several further materials, in particular also for thin coatings in the range of a few micrometres, are known.
- In experiments, various pens and a sleeve were provided nanotechnologically with a hydrophobic coating. 20 pens with external diameters of 10.0 to 11.9 mm in graduations of 0.1 mm were examined. The pens were arranged centrally in a sleeve with 12 mm internal diameter, which corresponds to gap thicknesses of 0.05 mm to 1.0 mm in graduations of 0.05 mm. The interior of the sleeve was then acted upon with water. A sealing effect up to a gap thickness of approximately 0.5 mm was observed. With reciprocal rotation between pen and sleeve, a sealing effect up to a gap thickness of approximately 0.25 mm was observed.

In order to improve the sealing effect, the surfaces can be micro- or nanostructured, i.e. provided with structures, the dimensions of which lie in the nanometre to micrometre range. These structures can have a preferred direction, in order to inhibit the flow of fluids on the surface in one direction. Thus, for example, scales can be provided.

Couplings

10 The mode of operation of the injection device is now to be described below. For this, firstly reference is made to Fig. 16, in which the injection device is illustrated in its initial position before the first use. The mechanism described above for setting and distributing a dose has three
15 couplings K1, K2 and K3 for the transmission of torques. Each of these couplings can be brought into and out of engagement by an axial movement of two components with respect to each other.

20 The coupling K1 is formed by the longitudinal grooves on the inner surface of the axial flange 235 of the coupling shaft 230 as a coupling input member in cooperation with the longitudinal ribs 122 on the outer side of the coupling sleeve 120 (cf. Fig. 5) as coupling output member. In the
25 position of Fig. 16, this coupling is uncoupled, i.e. the tothing formed by the longitudinal grooves and longitudinal ribs is out of engagement. The coupling K1 can be coupled by an axial displacement of the coupling shaft 230 in distal direction.

30

The coupling K2 is formed by the longitudinal grooves in the radial inner surface of the inner ring 250 as a coupling input member in cooperation with the longitudinal ribs on the radial outer surface of the coupling disc 270 as coupling
35 output member. In the position of Fig. 16, this coupling is coupled, i.e. the tothing formed by the longitudinal grooves and longitudinal ribs is in engagement. The coupling K2 can

be uncoupled by an axial displacement of the coupling disc 270 in distal direction.

5 The coupling K3 is formed by the longitudinal ribs on the outer side of the outer ring flange 282 of the arresting sleeve 280 as coupling input member in cooperation with the longitudinal grooves 158 on the inner surface of the mechanism holder 150 as coupling output member. In the position of Fig. 13, this coupling is coupled. It can be
10 uncoupled by an axial displacement of the arresting sleeve 280 in distal direction.

All three couplings K1, K2 and K3 can be coupled and respectively uncoupled by the push button 80 being displaced
15 sufficiently far axially. Here, a particular sequence is adhered to. On pressing in of the push button 80, the coupling disc 270 and the coupling shaft 230, which is securely connected therewith, are displaced in distal direction. Here, firstly the coupling K1 comes into
20 engagement, i.e. the coupling shaft is coupled for torque transmission with the coupling sleeve 120. At the same time, the coupling shaft 230 advances the transmission sleeve 210 in the distal direction. This entrains the arresting sleeve 280 in distal direction, whereby the coupling spring 290 is
25 compressed. When the coupling K1 arrives in engagement for the first time, the arresting sleeve 280 is not yet advanced sufficiently far in order to arrive with its outer ring flange 282 out of engagement with the mechanism holder 250. The coupling K3 is therefore initially still coupled. The
30 same applies to the coupling K2: The coupling disc 270 is firstly still in engagement with the inner ring 250. Firstly, therefore, all three couplings are coupled. When the push button 80 is pushed in further, next the coupling K2 comes out of engagement. With a still further pushing in, finally
35 also the coupling K3 comes out of engagement. Therefore, the following sequence is adhered to:

- Initial state: K1 uncoupled, K2 and K3 coupled.
- Pushing in of the push button 80: K1 couples, thereafter K2 uncouples, thereafter K3 uncouples.

- 5 Fig. 19, which is to be described later in further detail, shows the injection device with the push button 80 pushed in completely. The coupling K1 is now coupled, whereas the couplings K2 and K3 are uncoupled.
- 10 On releasing of the push button 80, the engaging of the couplings into each other runs in the reverse sequence. Here, the coupling spring 290 presses the arresting sleeve 280, the transmission sleeve 210, the coupling shaft 230, the coupling disc 270 and the push button 80 back into the distal
- 15 initial position.

The couplings K1, K2 and K3 and the ratchet connection make possible the systematic transmission of torques between five functionally independent units. A first unit is formed by

20 the housing sleeve 20, the mechanism holder 150, the stop sleeve 240 and the spring ring 320. This unit can be regarded functionally as a holding arrangement or as a housing in an extended sense. It constitutes the stationary reference system for all movements.

25 A second unit is formed by the dosing sleeve 60, the inner ring 250 and the ratchet ring 260. It can be regarded functionally as a rotatable dosing arrangement. This dosing arrangement is held detachably on the housing by means of

30 the ratchet connection, but so as to be secure with regard to torque up to a certain value.

A third unit is formed by the coupling disc 270, the coupling shaft 230 and the transmission sleeve 210, which are in fact

35 all rigidly connected with each other, and by the spiral spring 310, connected therewith, which acts as the actual drive element. This unit can be regarded as a drive

arrangement. The rotary movement of the drive arrangement is limited by two limiting elements which are both guided on the transmission arrangement. The first limiting element is formed by the display drum 70, which limits the range of movement of the drive arrangement in both directions, a dosing direction and a correction- and distribution direction. The second limiting element is formed by the dose limiting ring 220, which limits the range of movement of the drive arrangement at least in one direction, the dosing direction, independently of the first limiting element. The drive arrangement is able to be coupled detachably by the coupling K2 so as to be locked against relative rotation with respect to the dosing arrangement, which makes it possible to tension the drive element in the form of the spiral spring 310.

A fourth unit comprises the coupling sleeve 120 and the threaded rod 180 which form a rigid unit, the elements on which these parts are mounted, namely the guide sleeve 110, the bearing holder 130 and the ball bearing rings 140, and also the thrust sleeve 90. This unit constitutes a delivery arrangement which converts a rotary movement of an input member in the form of the coupling sleeve 120 into a thrust of the delivery element in the form of the thrust sleeve 90. Its input member is able to be detachably coupled by the coupling K1 so as to be locked against relative rotation with the drive arrangement. In addition, it is able to be detachably coupled via the coupling K3 so as to be locked against relative rotation with the holding arrangement (i.e. the housing).

Furthermore, a triggering arrangement is present, which primarily comprises the push button 80 and serves for the operation of the couplings K1 to K3.

Mode of operation

The injection device is operated as follows. Starting from the initial position of Fig. 16, firstly a dose is set which is to be administered. For this, the dosing sleeve 60 is turned clockwise. In so doing, the dosing sleeve entrains the coupling disc 270 and the coupling shaft 230 via the coupling K2. Hereby, the spiral spring 310 is wound up. The torque being generated hereby is held by the ratchet connection between the co-rotating ratchet ring 260 and the stationary stop sleeve 240. Through the rotation of the coupling shaft 230, the transmission sleeve 210 and the display drum 70, which is guided thereon, are also co-rotated. The display drum 70, owing to its thread guidance on the mechanism holder 150, is additionally displaced axially in proximal direction, and therefore performs as a whole a screw motion in proximal direction. Hereby, markings on the surface of the display drum 70 pass through under the window 21 and indicate the currently set dose. Furthermore, the dose limiting ring 220, owing to its thread engagement with the interior of the transmission sleeve 210 and owing to its arrangement, secured with regard to rotation, on the coupling sleeve 120, is displaced in proximal direction.

Fig. 17 shows the injection device after half the maximum individual dose has been set. The display drum has travelled rearwards half-way between its distal and its proximal final position. In addition, the dose limiting ring 220 has travelled in the proximal direction by an amount which is proportional to the individual dose which has been set.

The rotation of the dosing sleeve 60 clockwise is limited on the one hand by the maximum movement range of the display drum 70 and on the other hand by the maximum movement range of the dose limiting ring 220. After a predetermined number of revolutions of the dosing sleeve 60, the display drum 70 abuts with its proximal radial stop against the stop sleeve 240, in so far as the rotation of the dosing sleeve 60 has not already been previously limited by the dose limiting

ring 220, as is described in further detail below. Thereby, no further rotation of the dosing sleeve 60 is possible. This position corresponds to the maximum individual dose which can be set. This situation is illustrated in Fig. 18.

5

If the dose which has been set is to be corrected, i.e. reduced, then the dosing sleeve 60 can be turned back anticlockwise against the force of the ratchet connection. As the ratchet connection in this direction additionally
10 also has to absorb the torque of the spiral spring 310, the ratchet connection is developed asymmetrically: The toothing on the end face has a larger angle of inclination on the side which is stressed by a torque which acts anticlockwise onto the dosing sleeve than on the side which is stressed
15 with a torque clockwise (cf. the development of the teeth 244 in Fig. 14). The angle of inclination is understood here to mean the absolute amount of the angle between the respective flank of a tooth on the end face of the ratchet ring 260 or on the end face of the stop sleeve 240 and a
20 cross-sectional area through the injector.

The distribution of the dose which has thus been set takes place by the push button 80 being pushed in. Hereby, firstly the coupling K1 is coupled. Thereby, a connection is produced
25 which is locked against relative rotation between the coupling shaft 230 on the one hand and the coupling sleeve 120 and also the threaded rod 180 rigidly connected therewith on the other hand. All three couplings K1, K2 and K3 are now coupled. On further pushing in of the push button 80, the
30 coupling K2 uncouples. Thereby, the connection which is locked against relative rotation between the dosing sleeve 60 on the one hand and the coupling shaft 230 with the now coupled coupling sleeve 120 and threaded rod 180 on the other hand is cancelled. This leads to the ratchet connection no
35 longer absorbing the torque of the spiral spring 310. However, the system is still held so as to be locked against relative rotation via the coupling K2 in the mechanism holder

150 and hence in the housing sleeve 20. When the push button 80 is now pressed in still further, the coupling K3 also uncouples. At this moment, the torque of the spiral spring 310 becomes free and acts via the coupling shaft 230 and the
5 coupling sleeve 120 on the threaded rod 190. Hereby, these parts are set in an anticlockwise rotation. Through its thread engagement with the threaded rod 190, the thrust sleeve 90 undergoes an axial displacement in distal direction. Via the thrust flange 100, the thrust sleeve
10 advances the stopper 41 in the carpule 40. In this way, the medicament is distributed.

During the distribution, considerable axial forces act on the thrust sleeve 90: The torque of the spiral spring 310 is
15 converted into a force in the thrust direction, which advances the stopper 41 in the carpule 40. These forces are absorbed by the ball bearings between the coupling sleeve 120 on the one hand and the guide sleeve 110 and the bearing holder 130 on the other hand in a low-friction manner, so
20 that counter forces, due to friction, which could reduce the driving torque, are minimized.

In the distribution, the display drum 70 is entrained again by the rotation of the transmission sleeve 210 anticlockwise
25 and is thereby moved again in distal direction owing to its thread engagement with the stationary mechanism holder 150, until it assumes its distal initial position again. In this position, it is prevented from rotating further by a radial stop, whereby the distribution is terminated. After the end
30 of the distribution, the display drum therefore indicates the dose "zero" again.

The distribution can be interrupted at any time, by the push button 80 being released. Thereby, the couplings K3 and K2
35 couple again, and the coupling K1 uncouples again. The display drum 70 indicates the remaining residual dose which

is further distributed when the push button is pressed again and thereby the distribution is continued.

5 The dose limiting ring 220 maintains its axial position during the distribution, because the transmission sleeve 210 and the coupling sleeve 120, between which the dose limiting ring 220 is situated, rotate synchronically.

10 After the end of the distribution, the injection device is ready for the next injection process. Compared with Fig. 16, however, two components have changed their position: On the one hand, the thrust sleeve 90 has travelled in accordance with the distributed dose in the distal direction. On the other hand, the dose limiting ring 220 has likewise travelled
15 by an amount proportional thereto in proximal direction. Apart from this, the state after the end of the injection corresponds to the initial state of Fig. 16. With each further injection, the thrust sleeve 90 therefore travels further in the distal direction, whereas the dose limiting
20 ring 220 travels in the proximal direction. This is illustrated in Fig. 19, which illustrates the injection device after firstly a first dose was administered, which corresponds to half the maximum individual dose, and then with the dosing sleeve a dose was again set, which in turn
25 corresponds to half the maximum individual dose. The display drum now indicates again, as in Fig. 15, half the maximum individual dose, whereas the dose limiting ring 220 now assumes a position in the transmission sleeve 210 which corresponds to the sum of the doses which have been set
30 hitherto, here therefore twice half the maximum individual dose.

The maximum axial path by which the dose limiting ring 220 can travel in proximal direction in the transmission sleeve
35 corresponds precisely to the content of a completely filled carpule. As soon as the sum of the doses set on the dosing sleeve corresponds to the carpule content, the dose limiting

ring 220 reaches its proximal final position and abuts with its radial stop against the axial ring flange 235 of the coupling shaft 230, as is illustrated in Fig. 12A. Thereby, the dosing sleeve 60 is prevented from a further clockwise rotation. Therefore, no larger dose can be set than the dose which corresponds to the remaining residual amount of the medicament in the carpule. Fig. 20 shows this situation, in which no further increasing of the dose is possible, although the display drum is situated in the distal initial position, i.e. the zero position. Correspondingly, the thrust sleeve 90 has reached its distal final position, and has therefore moved out at a maximum.

Carpule change

In order to exchange the carpule, the carpule sleeve 30 is detached from the mechanism holder 150 against the elastic resistance of the bayonet spring 170 and is unscrewed, guided through the corresponding guide slit 156 in the mechanism holder. Hereby, compulsorily, the bayonet sleeve 160 is likewise twisted along its own, parallel guide slit 155 and at the same time is displaced in distal direction. Hereby, the guide sleeve 110 is drawn in the distal direction. Hereby, all the movable parts which are connected axially therewith also travel in the distal direction, in particular the coupling sleeve 120, the threaded rod 190, the arresting sleeve 280, the transmission sleeve 210, the coupling shaft 230, the coupling disc 270 and the push button 80. In particular, the push button 80 is therefore drawn into the dosing sleeve 60 and thus indicates that the injection device is not ready for operation.

Through this axial displacement of the various parts of the mechanism, the couplings K2 and K3 come out of engagement, whilst K1 was in any case already out of engagement. If a dose had still been set before the carpule change, but had not been administered, then the accordingly wound spiral

spring 310 now sets the coupling shaft 230 and the transmission sleeve 210 connected therewith into an anticlockwise rotation, until the display drum 70 has reached its distal final position and prevents a further turning

5 back by means of its radial stop on the mechanism holder 150. In this way, the display drum 70 is brought back into its distal initial position, the zero position. An automatic resetting of the dose display to zero therefore takes place.

10 If, before the carpule change, a residual amount of the medicament was still situated in the carpule 40, then the thrust sleeve 90 had not yet moved out to a maximum before the carpule change, and had therefore not yet reached its distal final position. On removal of the carpule sleeve 30,

15 the helical spring 190 now presses the guide needle 200, the thrust flange 100 and the thrust sleeve 90 in the distal direction. Hereby, the threaded rod 180 is set in rotation via its screw connection with the interior of the thrust sleeve 90. Here, the threaded rod 180 entrains in particular

20 the coupling sleeve 120 and the dose limiting ring 220. With this rotation, the dose limiting ring 220 is displaced into its proximal final position through its thread engagement with the transmission sleeve 210. As soon as the dose limiting ring 220 has reached this initial position, it

25 prevents a further rotation of the coupling sleeve 120 and of the threaded rod 180, so that no further moving out of the thrust sleeve 90 is possible. The thrust sleeve 90 has thereby now reached its distal final position. This situation is illustrated in Fig. 1. As a whole, therefore, the display

30 drum 70 is now situated in the zero position, the dose limiting ring 220 in the proximal final position and the thrust sleeve 90 in its distal final position.

A new carpule 40 is now pushed into the carpule sleeve 30,

35 and the carpule sleeve 30 with the carpule 40 held therein is guided axially in the proximal direction against the housing sleeve 20. Here, firstly the stopper 41 of the

carpule presses the thrust flange 100 and the thrust sleeve 90 against the force of the helical spring 190 in the proximal direction. Hereby, in turn, the threaded rod 180 is set in rotation. The threaded rod again entrains the coupling sleeve 120 and the dose limiting ring 220. Thereby, the dose limiting ring, owing to its thread engagement with the transmission sleeve 210, is displaced in the distal direction, i.e. in the direction of its initial position. The amount by which it is displaced in this direction corresponds exactly to the dose which is present in the carpule 40. With a completely filled carpule, the dose limiting ring 220 travels into its distal initial position. The carpule sleeve 30 is then pushed into the mechanism holder 150, with the radial pins 36 of the carpule sleeve 30 engaging again into the guide slits 156 in the mechanism holder 150 (cf. Figures 1 and 3). Through the positive guidance of the carpule sleeve 30 on insertion into the mechanism holder 150, in turn the bayonet sleeve 160 is forced to follow the movement of the carpule sleeve 30 in the corresponding guide slits. The bayonet sleeve 160 is thereby brought back into its proximal final position, in which it is detachably locked by the bayonet disc 170 (cf. Figures 8 to 10). The injection device is now situated again in the initial position of Fig. 16 and, after the screwing of a new needle holder 31, is available for a new sequence of administerings.

Second embodiment

In Fig. 21, a second embodiment of the injection device according to the invention is illustrated as a variant. The mode of operation is substantially the same as in the first embodiment. Parts which act identically are therefore designated by the same reference numbers as in the first embodiment. Only the essential differences are to be described in detail below.

In the second embodiment, the stop sleeve 240 is omitted. Its function is taken over by the correspondingly extended housing sleeve 20.

- 5 The drive arrangement which, in the first embodiment, apart from the spiral spring 310, is formed from the coupling disc 270, coupling shaft 230 and transmission sleeve 210, is formed here by different parts, namely by a connecting shaft 400 (with coupling disc 410 formed integrally thereon), a
- 10 first transmission sleeve 410 closed at the proximal end, and a second transmission sleeve 420 adjoining distally thereto. These three parts are, in turn, connected rigidly with each other.
- 15 Whereas in the first embodiment the display drum not only served to indicate the set dose but also served to delimit the maximum individual dose which was able to be set in the dosing direction and to delimit the movement in the distribution direction, the latter function in the second
- 20 embodiment is taken over by a second dose limiting ring 430. The latter is guided so as to be locked against relative rotation, but axially displaceable, in the housing sleeve 20. With an internal thread it runs on a corresponding external thread of the first transmission sleeve 410. Its
- 25 axial movement is limited by two radial stops between a distal initial position, which corresponds to the zero position, and a proximal final position, which corresponds to the maximum dose which is able to be set. In this way, it takes over the stop functions of the display drum according
- 30 to the first embodiment.

- The display drum 70 in the second embodiment is guided axially displaceably via a carrier sleeve 440, rigidly connected therewith, and so as to be locked against relative
- 35 rotation on the second transmission sleeve 420. Its mode of operation is otherwise identical to the first embodiment.

Apart from these differences, the structure and mode of operation of the injection device are substantially the same as in the first embodiment.

5 *Further variants*

The differences between the first and the second embodiment show that the functions of the injection device according to the invention can be reached in a variety of ways and the
10 invention is in no way restricted to the example embodiments represented above, but by the appended claims. Various further modifications are possible within the limits of the claims. These can be due, in particular, to manufacturing requirements.

15

List of reference numbers

	R	medicament reservoir
	D1	seal
5	D2	seal
	D3	seal
	D4	seal
	K1	first coupling
	K2	second coupling
10	K3	third coupling
	10	protective sleeve
	11	holding ring
	12	detent arm
	20	housing sleeve
15	21	window
	22	window covering
	30	carpule sleeve
	31	needle holder
	32	hollow needle
20	33	needle protection sleeve
	34	viewing window
	35	locking region
	36	pin
	40	carpule
25	41	stopper
	50	protective cap
	60	dosing sleeve
	61	spring ring
	70	display drum
30	72	ring-shaped region
	73	radial stop
	80	push button
	81	arm
	82	helical spring
35	83	bearing ring
	90	thrust sleeve
	91	guide cam

	92	internal thread
	100	thrust flange
	110	guide sleeve
	111	flange
5	112	bore
	120	coupling sleeve
	121	sleeve body
	122	longitudinal rib
	123	thickening
10	124	flange
	130	bearing holder
	132	shoulder
	140	ball bearing ring
	141	bearing ball
15	150	mechanism holder
	151	distal section
	152	proximal section
	153	step
	154	longitudinal slit
20	155	guide slit
	156	guide slit
	157	external thread
	158	longitudinal groove
	159	radial stop
25	160	bayonet sleeve
	161	ring flange
	162	arm
	163	opening
	170	bayonet spring
30	171	base body
	172	projection
	173	tongue
	180	external threaded rod
	181	transverse pin
35	190	helical spring
	200	guide needle
	201	thickening

	202	pin
	210	transmission sleeve
	211	internal thread
	212	longitudinal rib
5	213	ring flange
	220	dose limiting ring
	221	external thread
	222	longitudinal groove
	223	radial stop
10	230	coupling shaft
	231	axis
	232	transverse bore
	233	proximal end
	234	flange
15	235	ring flange
	236	radial stop
	237	bore
	238	longitudinal groove
	240	stop sleeve
20	242	hole
	243	radial stop
	244	tooth
	250	inner ring
	251	bore
25	252	helical spring
	260	ratchet ring
	270	coupling disc
	271	pin
	280	arresting sleeve
30	281	main body
	282	arm
	283	flange region
	284	longitudinal groove
	290	coupling spring
35	300	support ring
	310	spiral spring
	311	spring holding region

- 320 spring sleeve
- 400 connecting shaft
- 401 coupling disc
- 410 first transmission sleeve
- 5 420 second transmission sleeve
- 430 second dose limiting ring
- 440 carrier sleeve

PATENTKRAV

1. Penformet injektionsindretning til administration af et flydende produkt der omfatter:

5 et hus (20),

et transportelement (90) til transport af produktet fra et reservoir (40), hvilket transportelement (90) er bevægeligt i forhold til huset (20) langs en fremadgående bevægelsesakse over et fremføringsbevægelsesområde mellem en proximal og distal endeposition, og hvilket transportelement (90) har et indre
10 gevind, hvis gevindakse strækker sig langs den fremadgående bevægelsesakse, og

et gevindelement (180) der har et ydre gevind, som går i indgreb med transportelementets (90) indre gevind, hvilket gevindelement (180) kan fastgøres i forhold til huset (20) langs den fremadgående bevægelsesakse og kan indstilles
15 i en roterende bevægelse omkring den fremadgående bevægelsesakse for at fremføre transportelementet (90) langs den fremadgående bevægelsesakse, hvilket transportelementet (90) er roterbart fastgjort til og styret i længderetningen i forhold til huset,

kendetegnet ved, at transportelementet (90) i det væsentlige er glat på ydersiden og styres kun i længderetningen i området af sin proximale ende i et element, som er ikke-roterbart i forhold til huset (20).
20

2. Injektionsindretningen ifølge krav 1, hvor det ikke-roterbare element er mindst så langt, at styring er sikret over hele bevægelsesområdet.
25

3. Injektionsindretningen ifølge krav 2, hvor det ikke-roterbare element er en rørignende struktur.

4. Injektionsindretningen ifølge krav 3, hvor den rørignende struktur betegnes som et styrerør (110) med en længde, der mindst svarer til fremføringsbevægelsesområdet for transportelementet (90).
30

- 5.** Injektionsindretningen ifølge krav 4, hvor gevindelementet (180) er anbragt i det indre af transportelementet (90) og strækker sig mindst over en længde fra proximalt til distalt ind i transportelementet (90), hvilket svarer til fremføringsbevægelsesområdet.
- 5
- 6.** Injektionsindretningen ifølge krav 5, hvor drevet af gevindelementet (180) er implementeret ved dets proximale ende.
- 7.** Injektionsindretningen ifølge krav 6, hvor styrerøret (110) mindst delvist om-
- 10 giver transportelementet (90).
- 8.** Injektionsindretningen ifølge krav 7, hvor styrerøret (110) mindst under administrationen er forbundet med huset (20) nær sin distale ende, og transportelementet (90) styres ikke-roterbart i styrerøret (110) langs den fremadgående be-
- 15 vægelsesretning.
- 9.** Injektionsindretningen ifølge krav 8, hvor et ydre rør (120) med en proksimal og en distal ende mindst delvist radialt omslutter styrerøret (110).
- 20 **10.** Injektionsindretningen ifølge krav 9, hvor det ydre rør (120) nær sin proximale ende er forbundet med gevindelementet (180).
- 11.** Injektionsindretning ifølge et af de foregående krav, hvor den ydre side af transportelementet (90) er designet cirkulært-cylindrisk.
- 25
- 12.** Injektionsindretning ifølge et af de foregående krav, hvor den i det væsentlige glatte ydre side repræsenterer en perifer overflade af transportelementet (90), som ikke har nogen teknisk krævede strukturer.
- 30 **13.** Injektionsindretning ifølge et af de foregående krav, hvor huset (20) har et cirkulært-cylindrisk husrør, i hvilket en mekanisme til indstilling af en dosis er anbragt.

- 14.** Injektionsindretningen ifølge krav 13, hvor en doseringsrør (60) med en trykknop (80), der er fastholdt deri, er roterbart anbragt ved den proksimale ende af husrøret (20).
- 5 **15.** Injektionsindretningen ifølge krav 14, hvor den indstillede dosis vises på en displaytromle (70) og aflæses gennem et vindue (21) i husrøret (20).

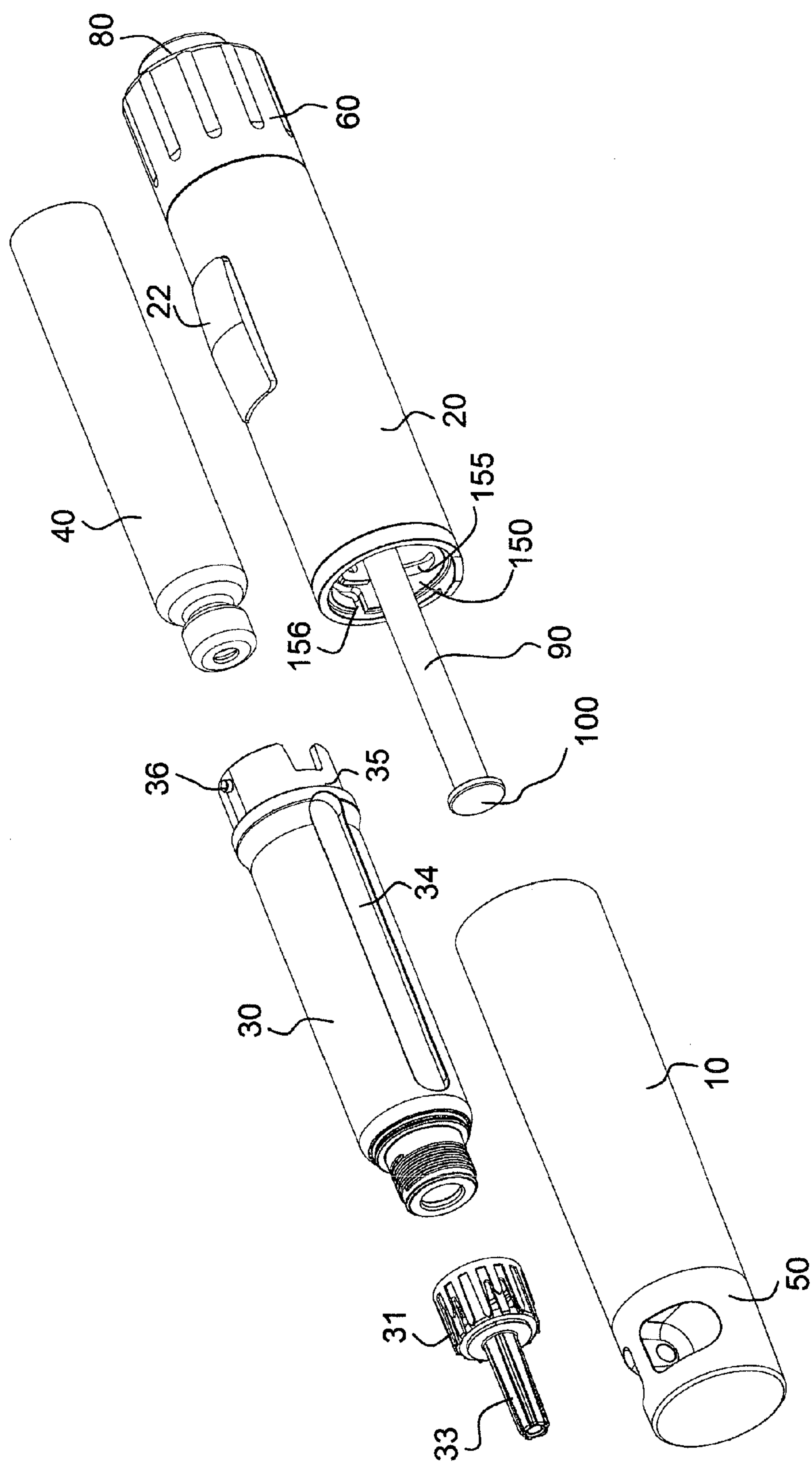


FIG. 1

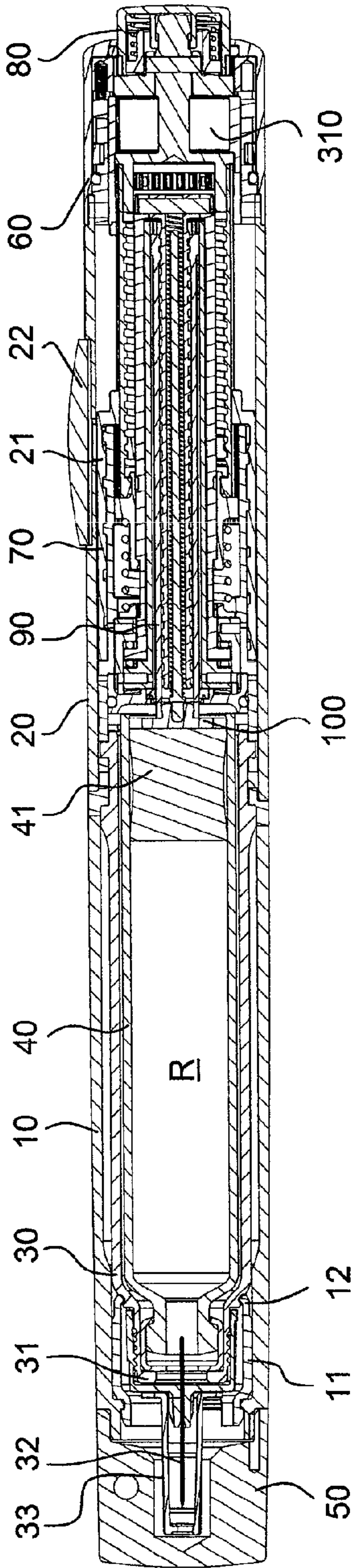


FIG. 2

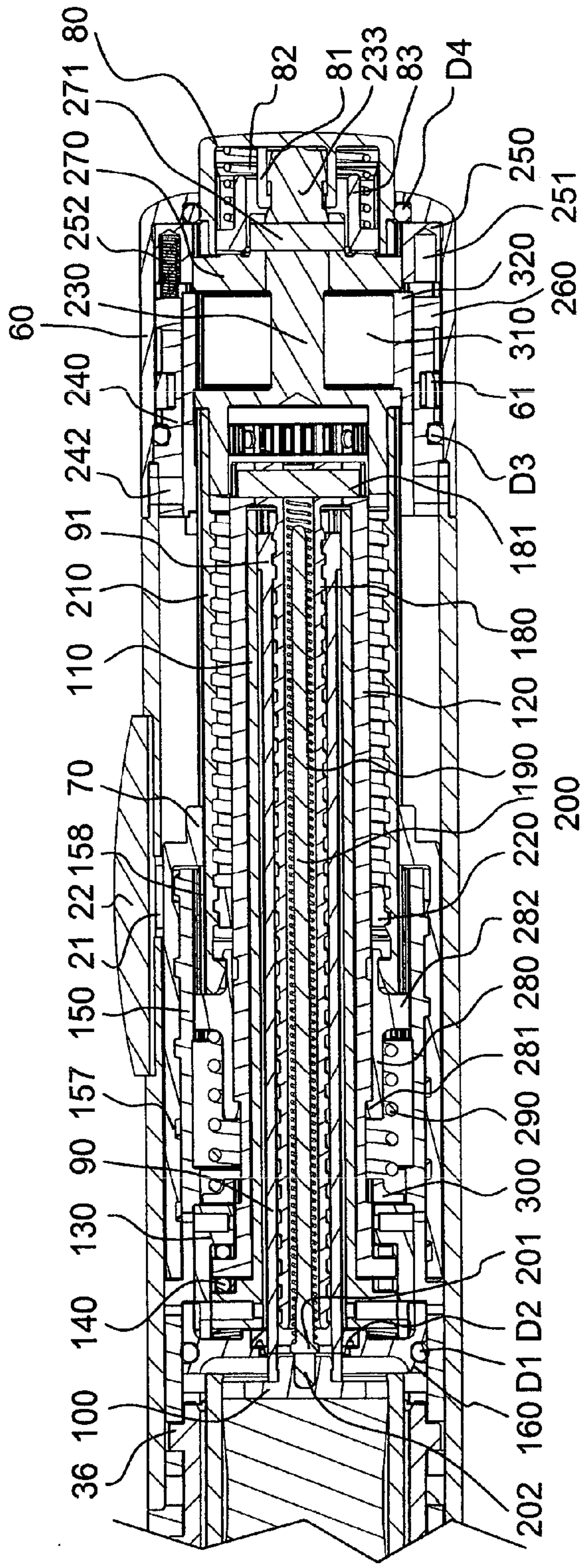
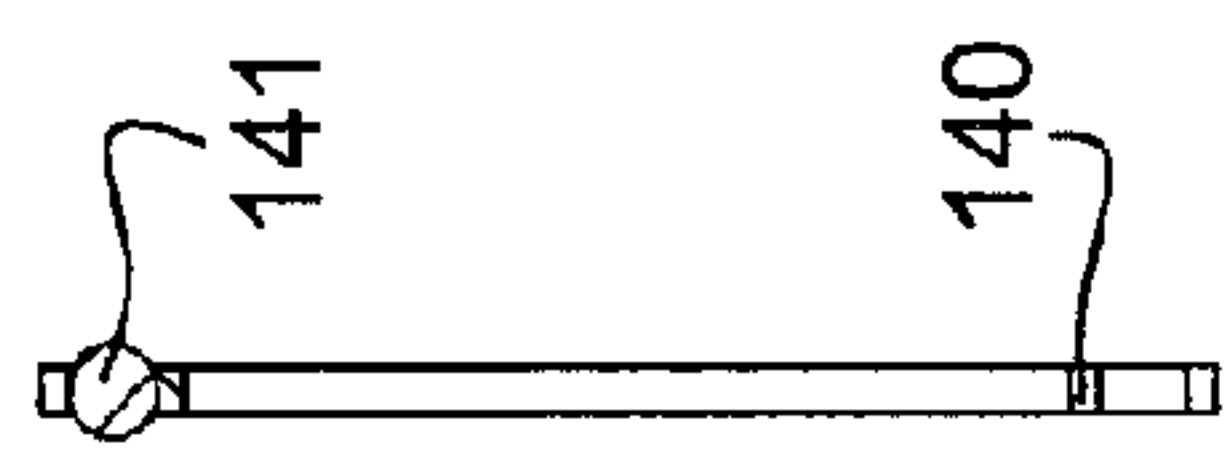
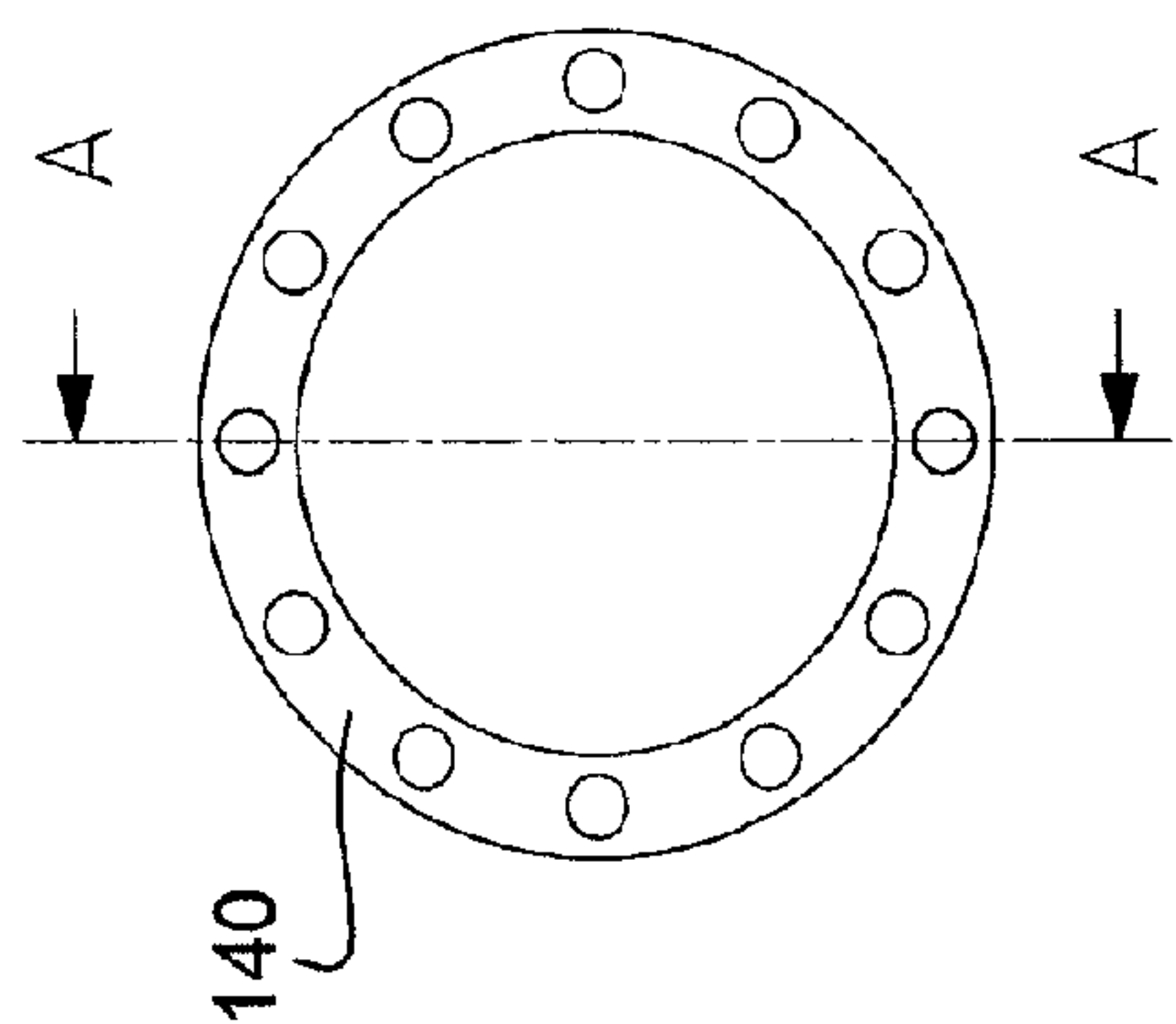
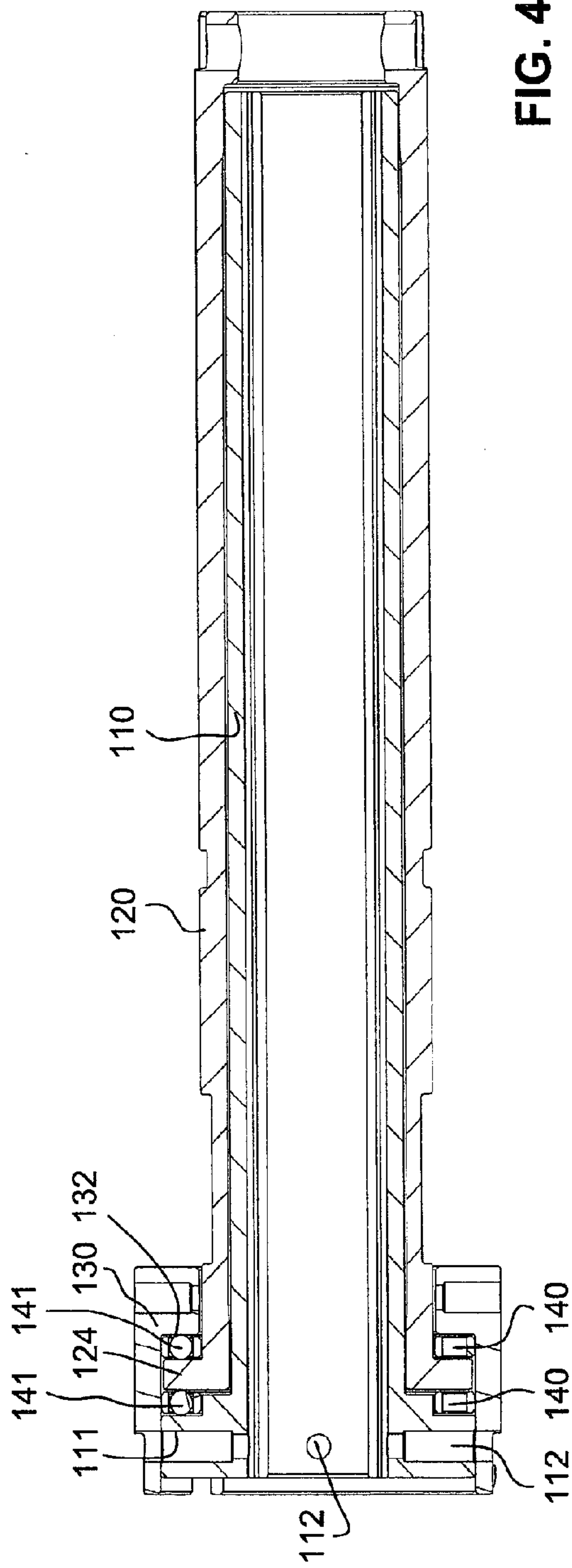


FIG. 3



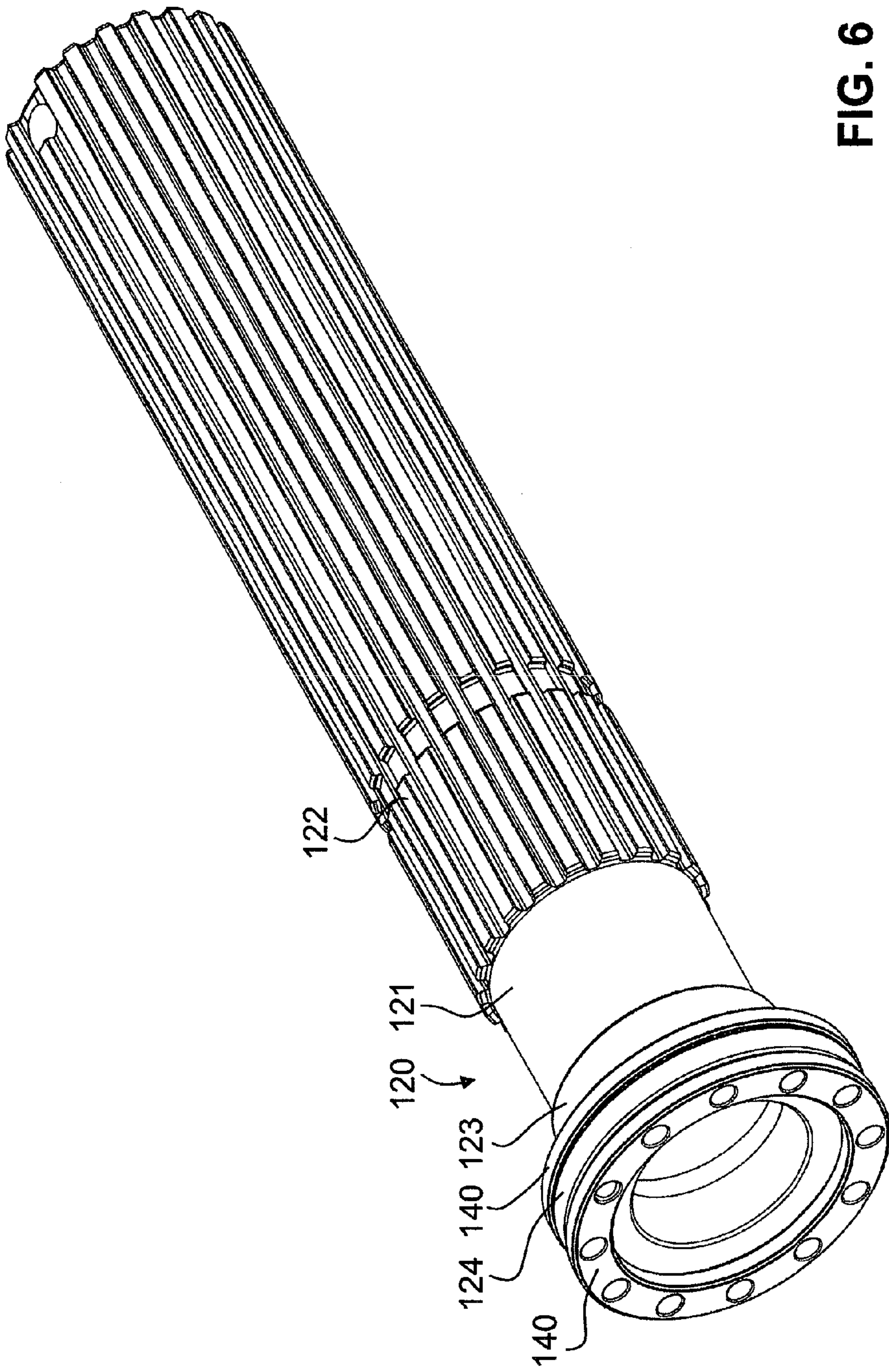


FIG. 6

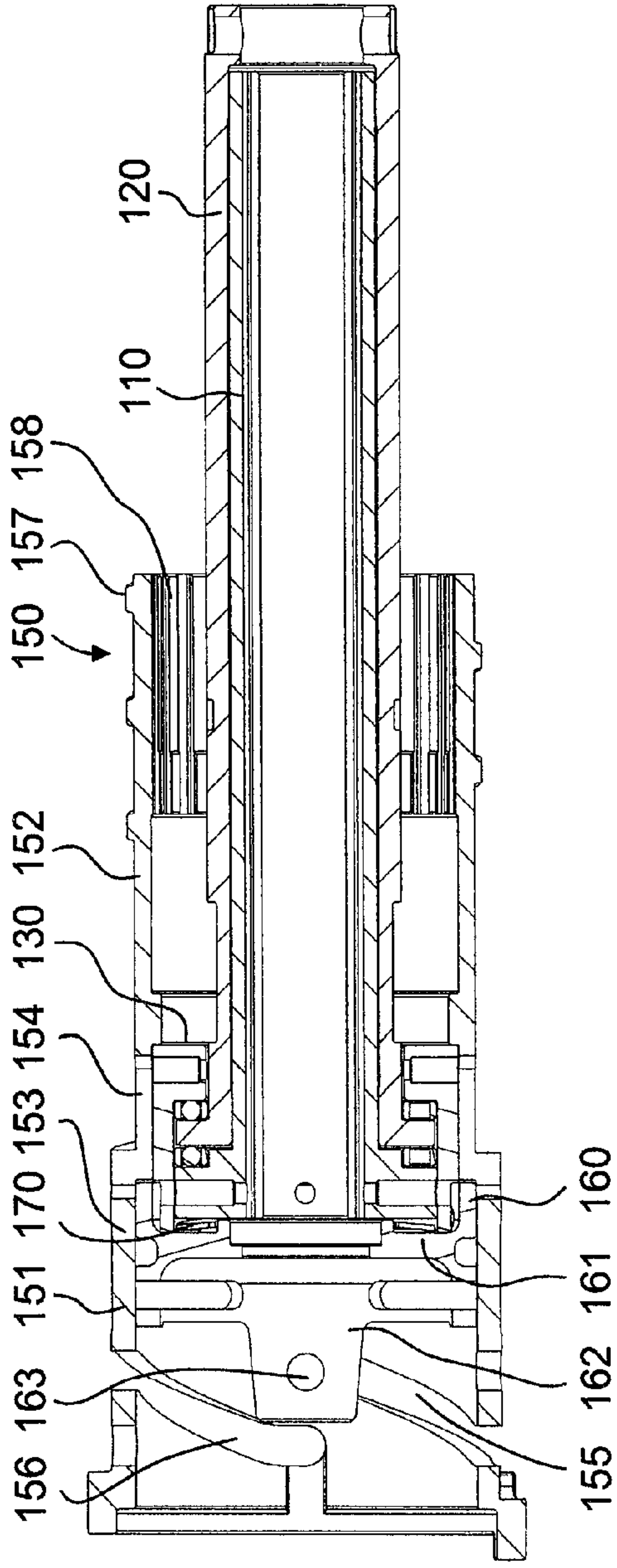


FIG. 7

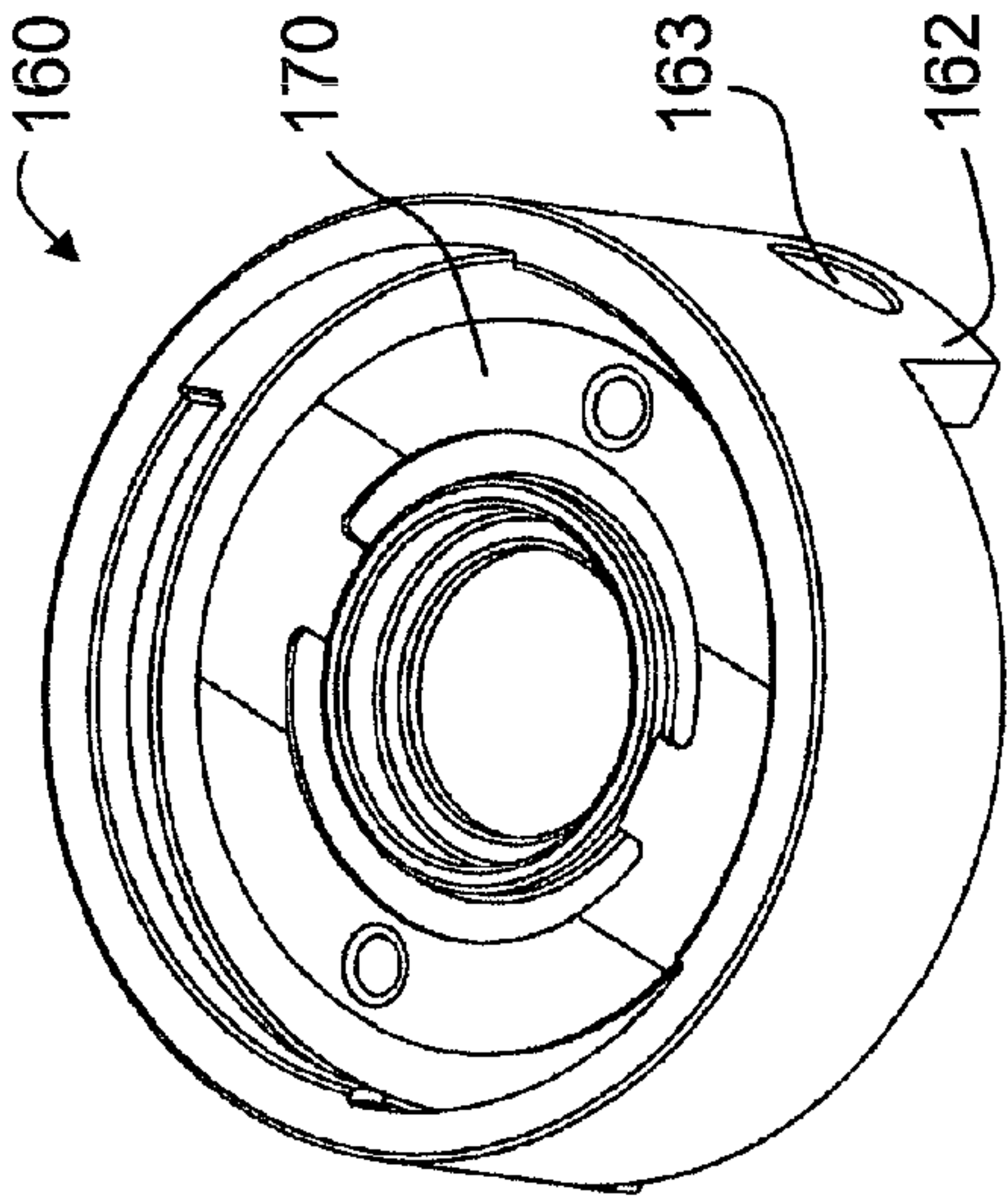


FIG. 8

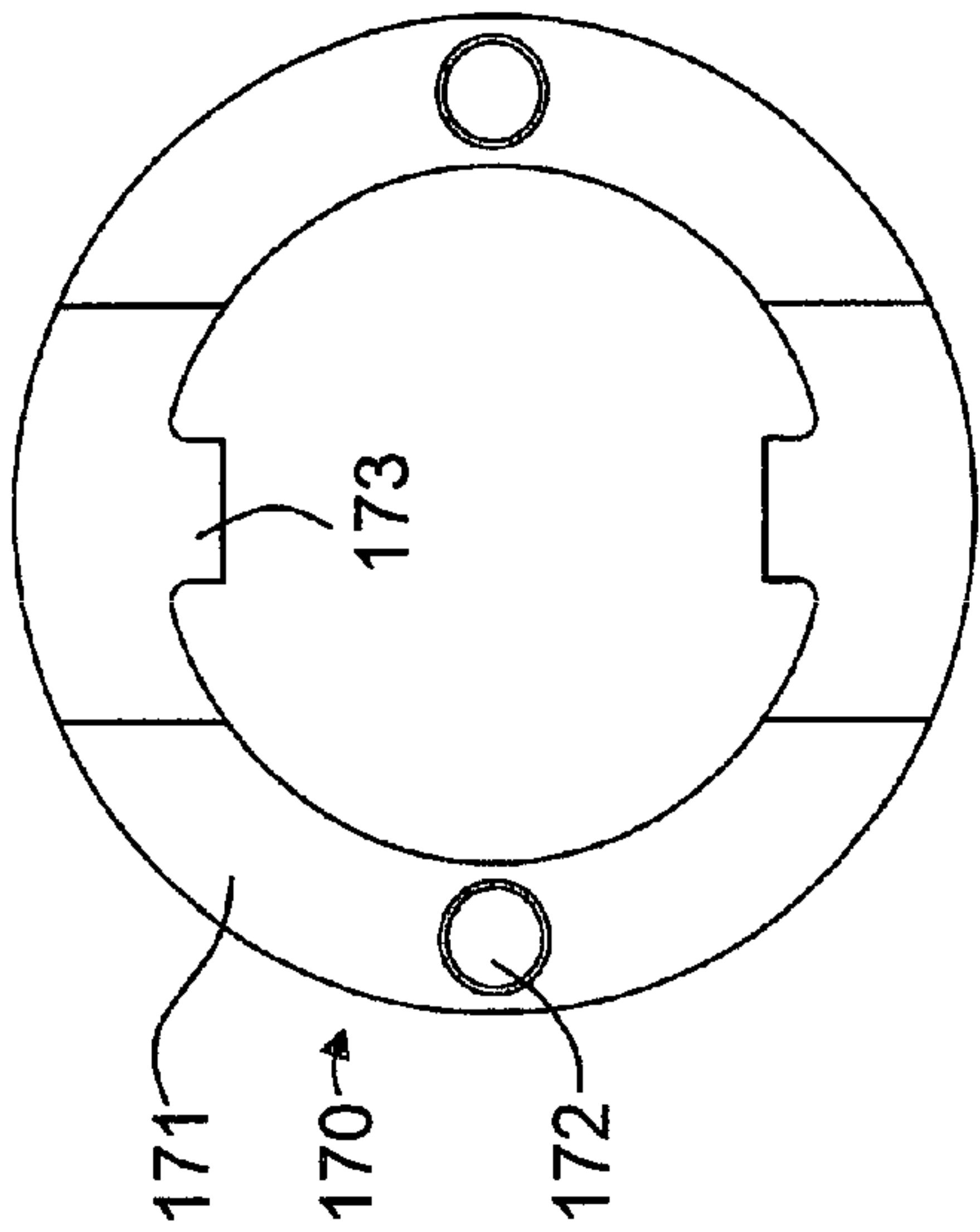


FIG. 9A

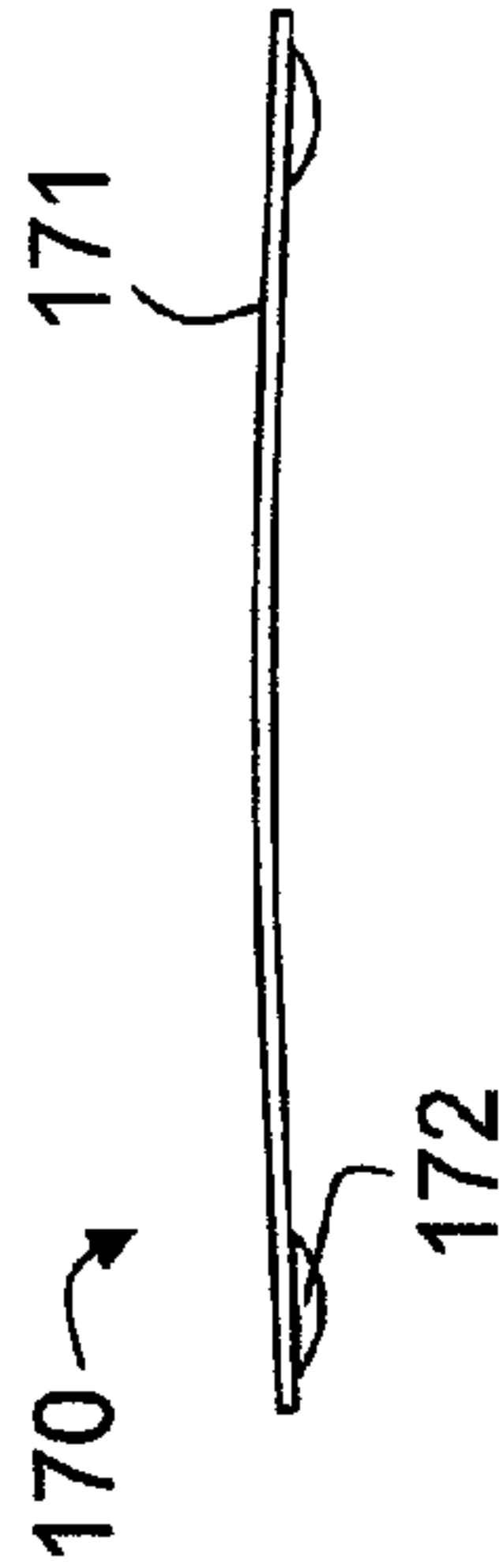


FIG. 9B

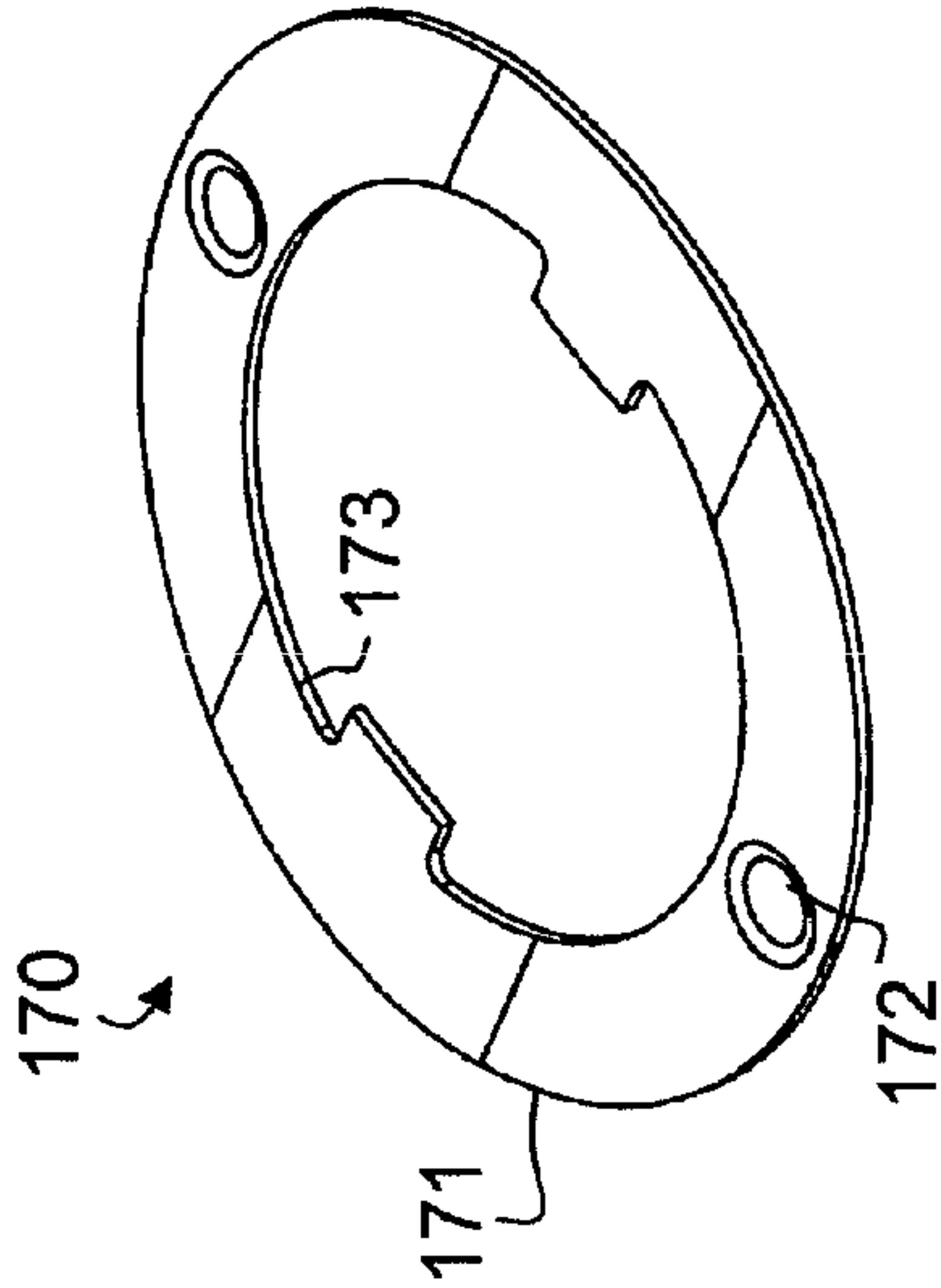


FIG. 9C

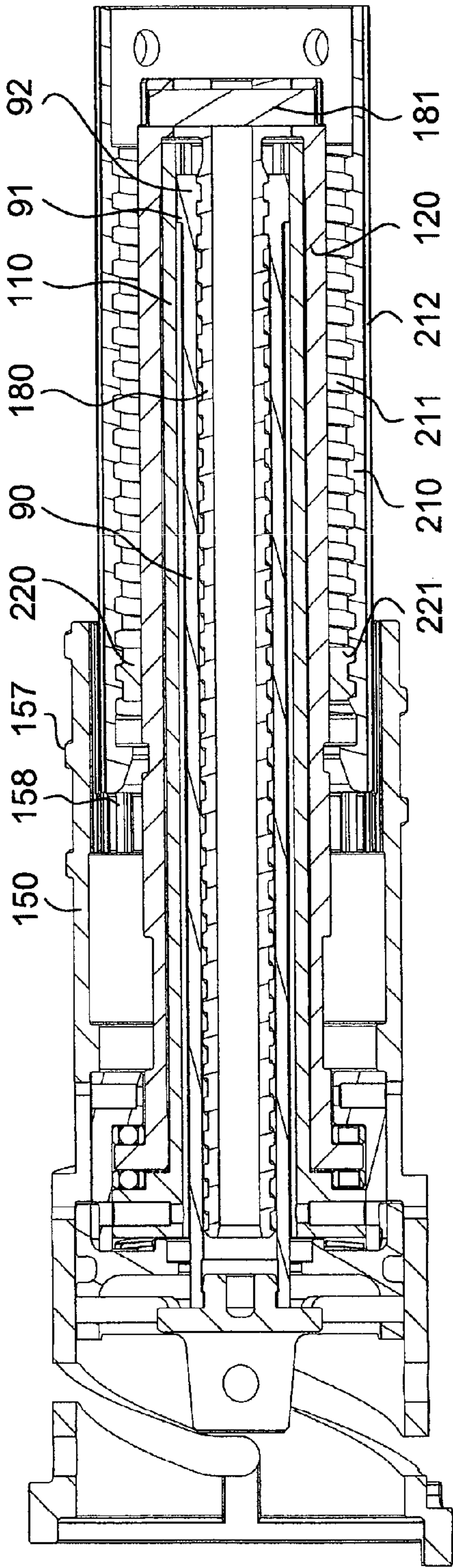
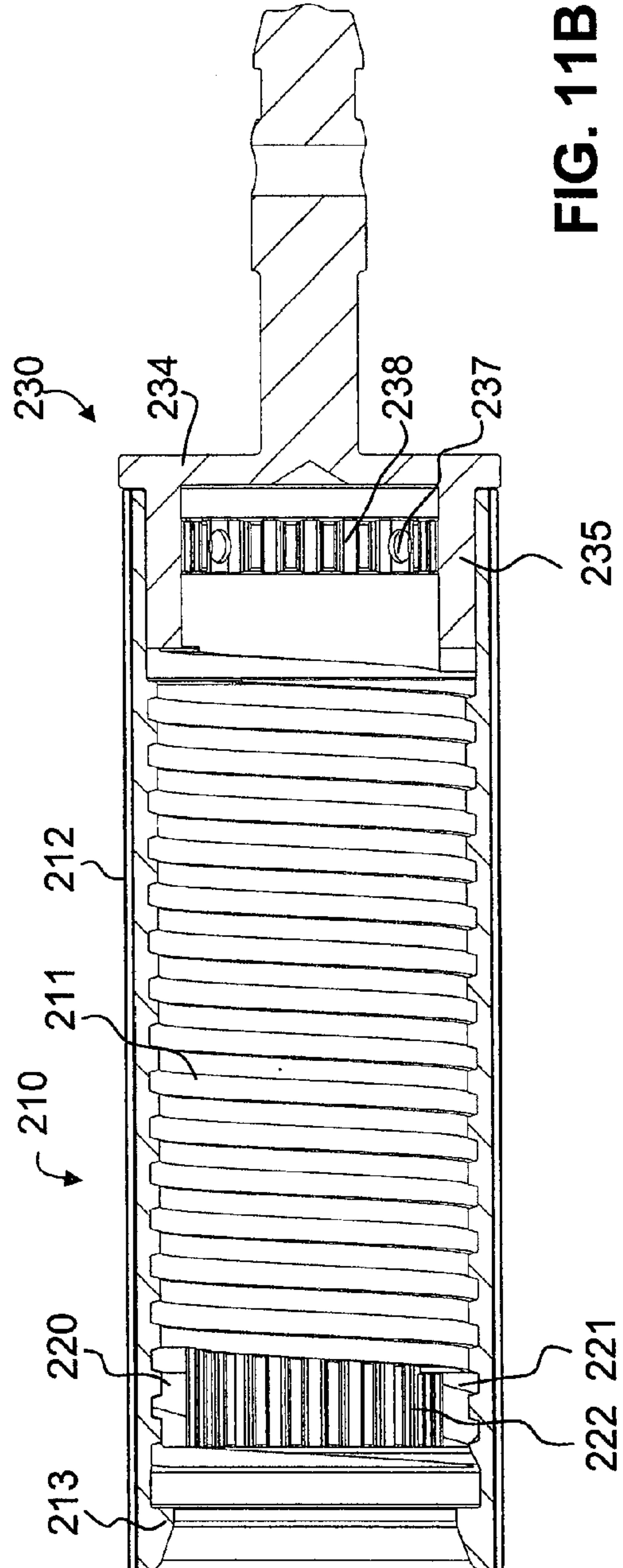
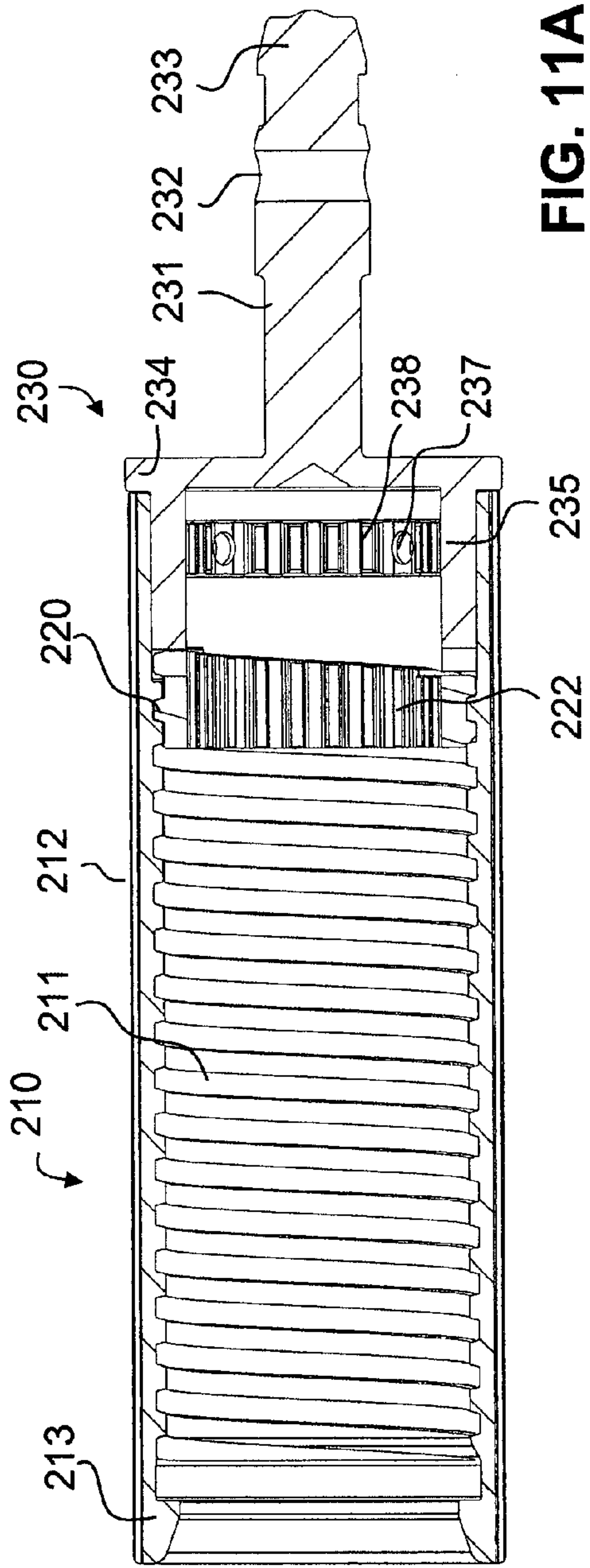


FIG. 10



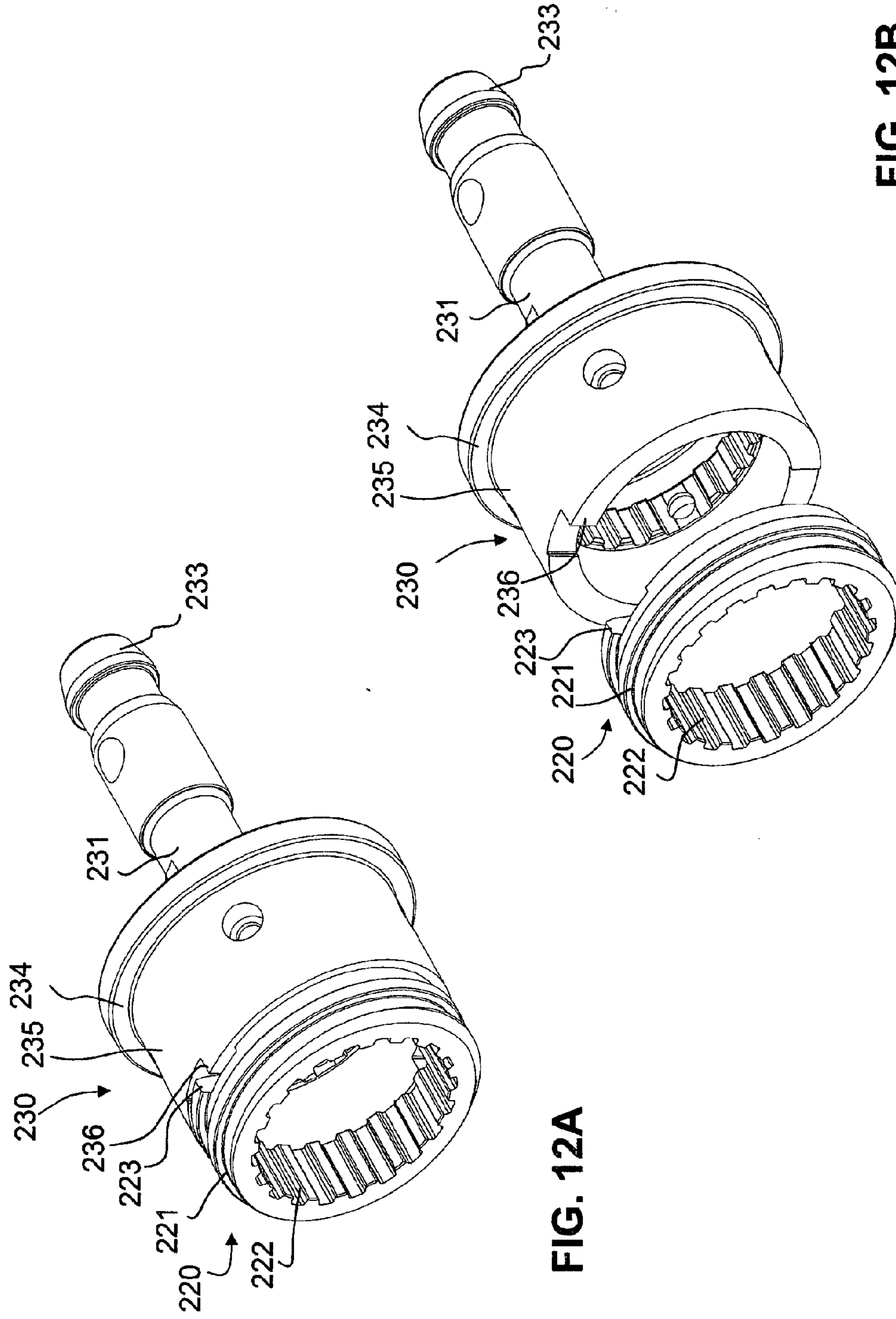
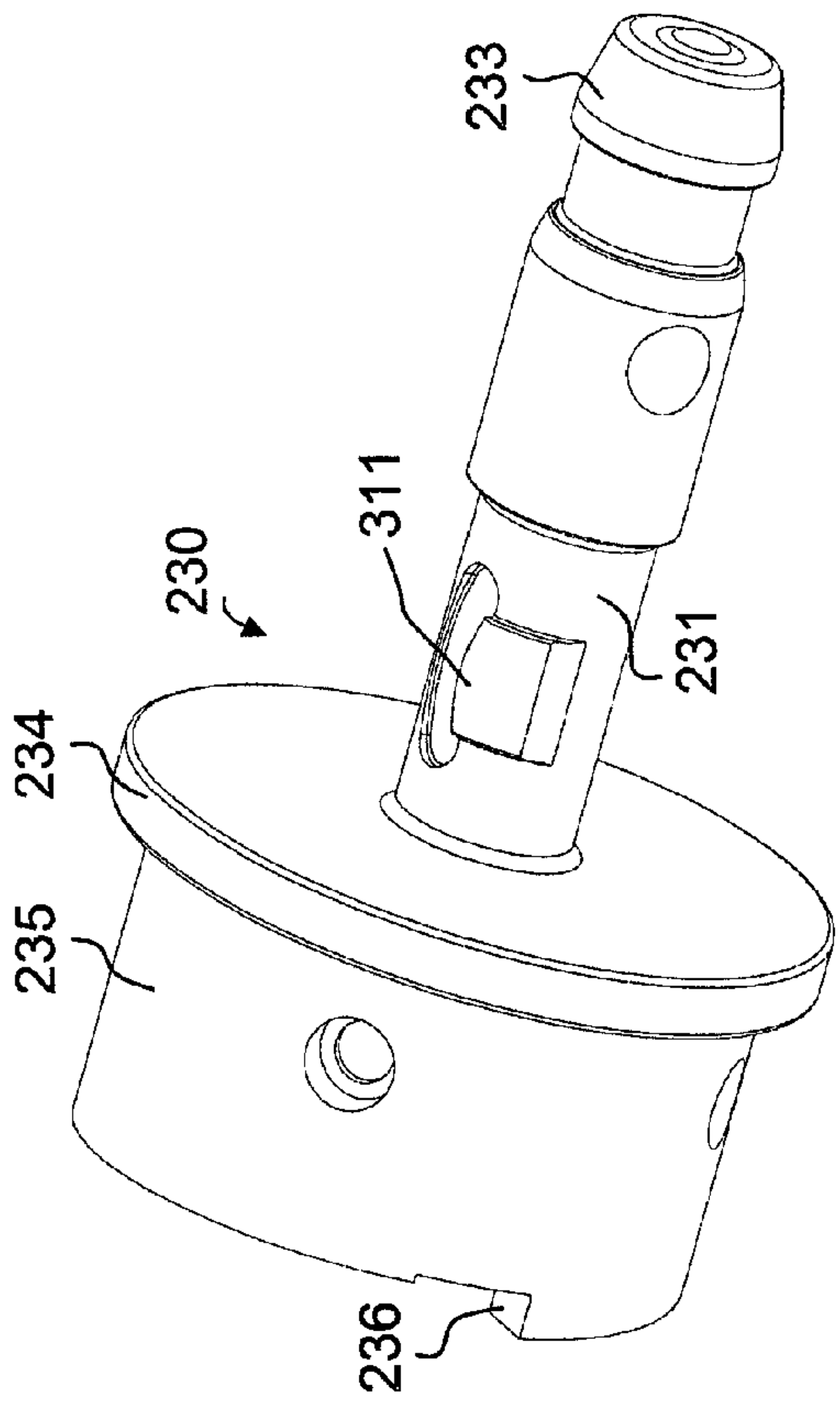


FIG. 12B

FIG. 12A

**FIG. 12C**

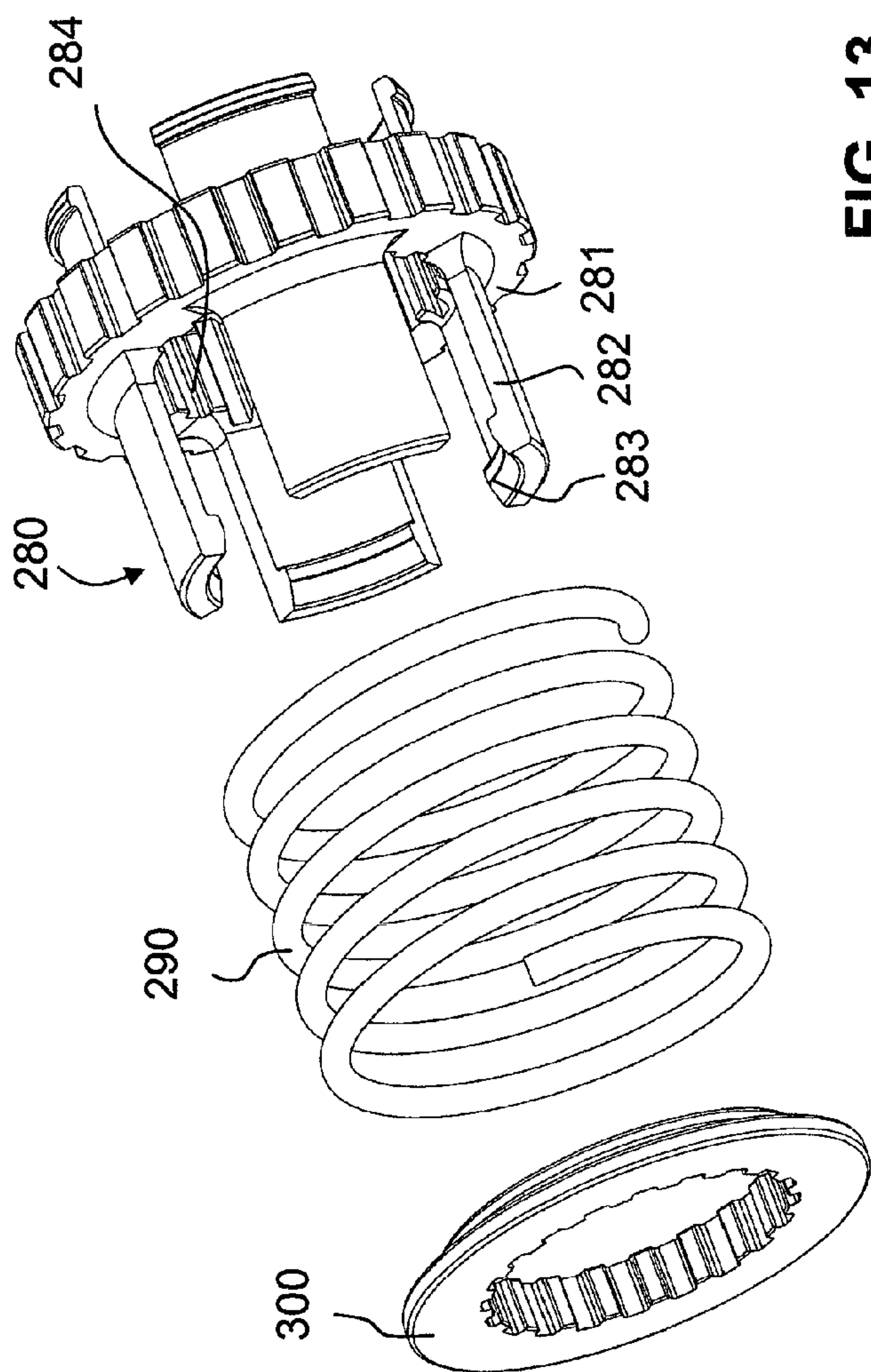
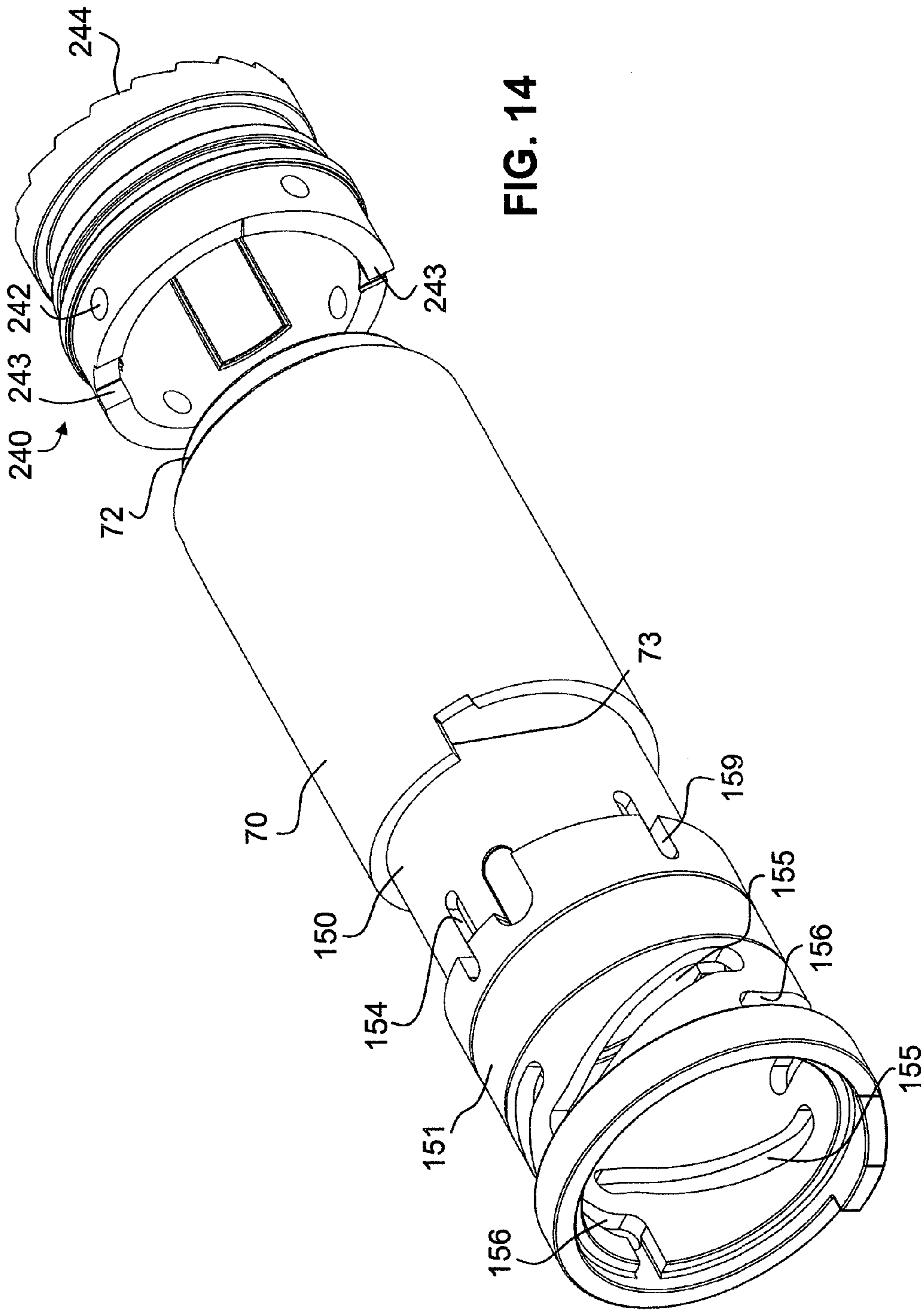


FIG. 13



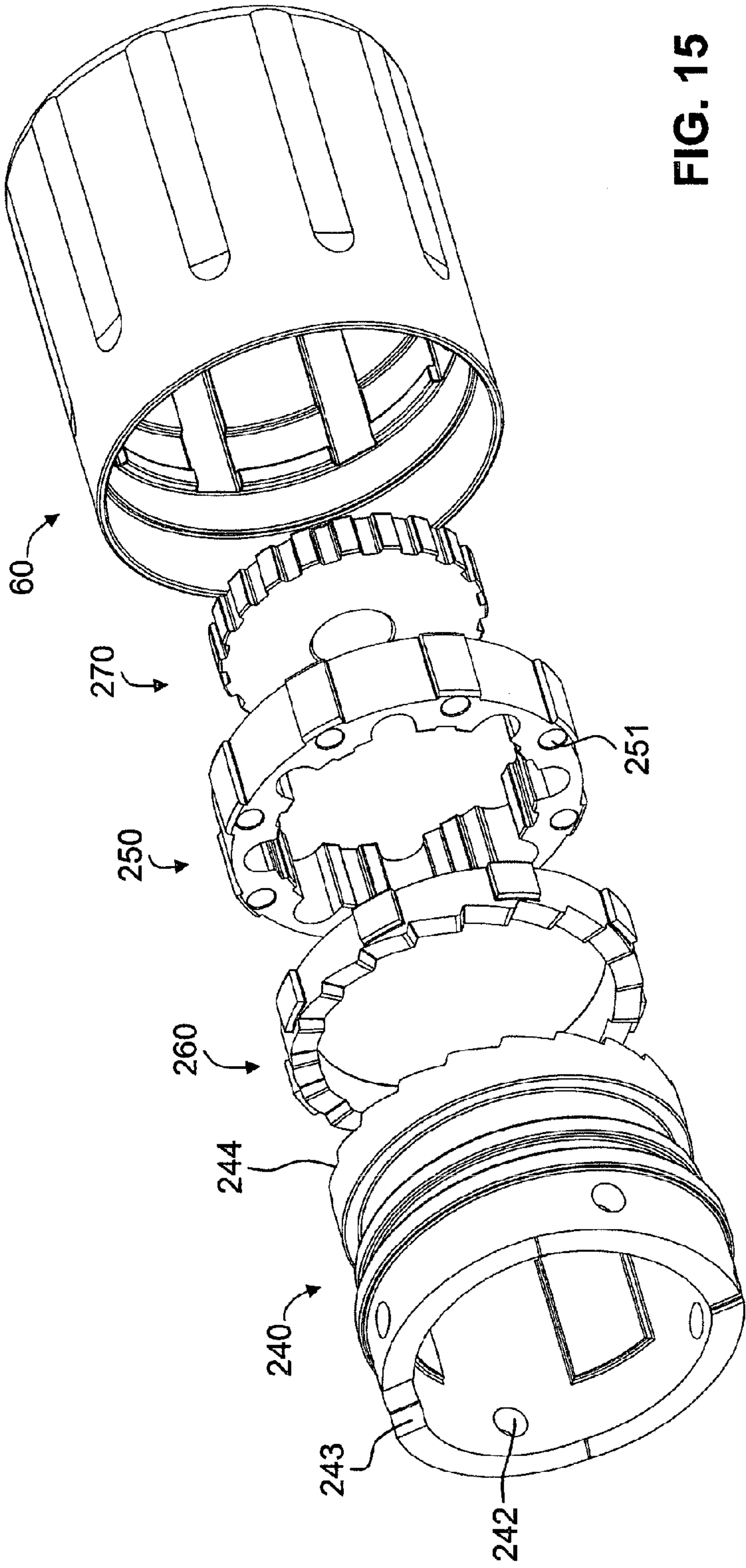


FIG. 15

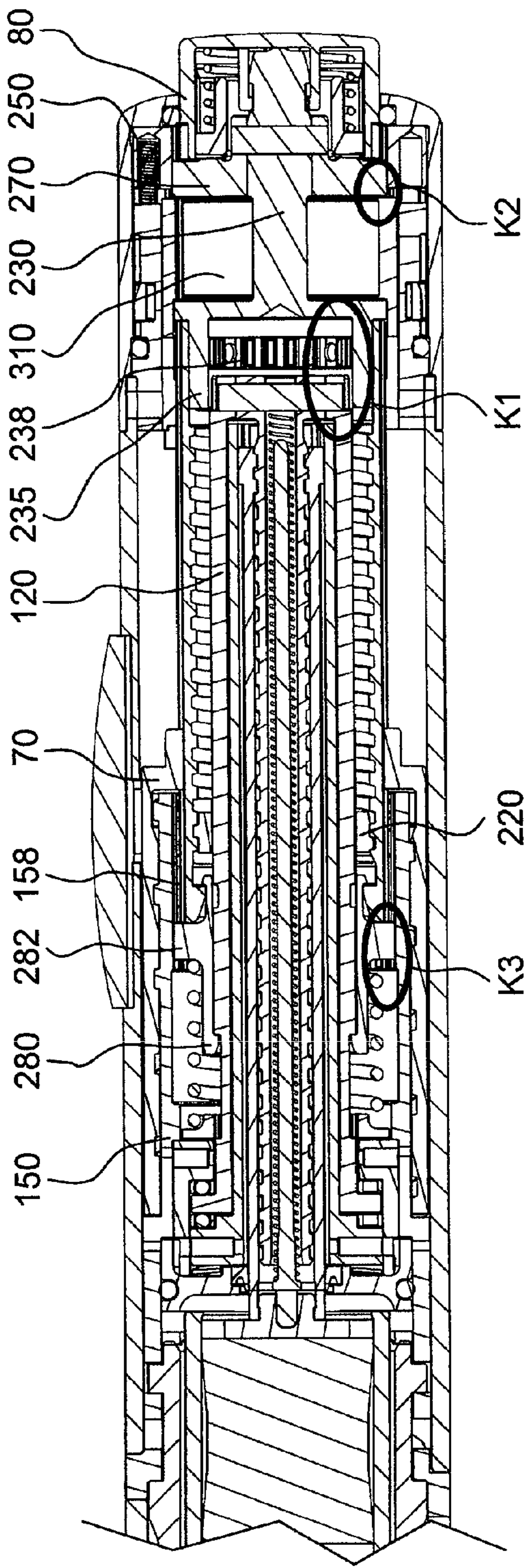


FIG. 16

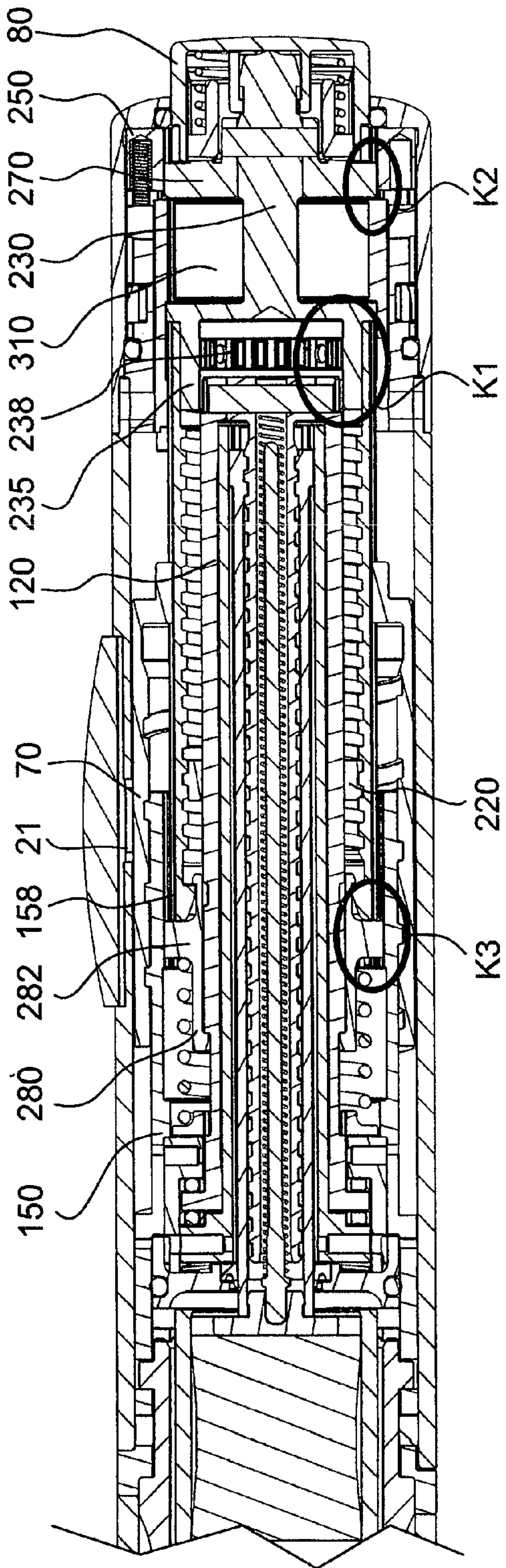


FIG. 17

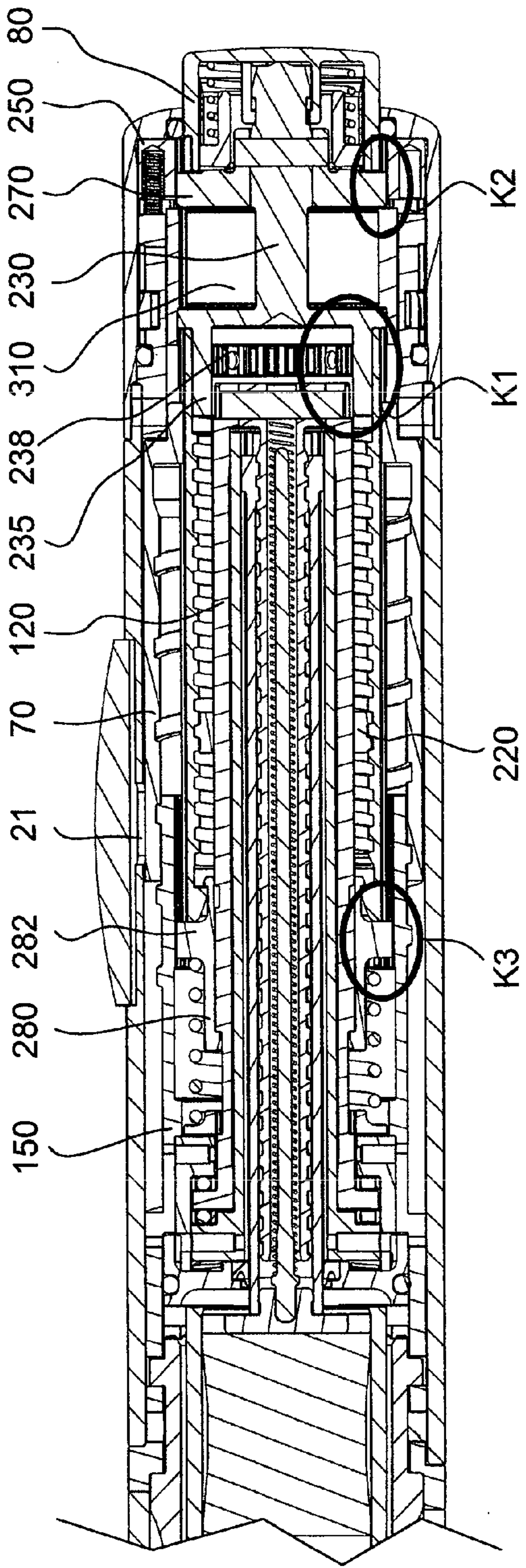


FIG. 18

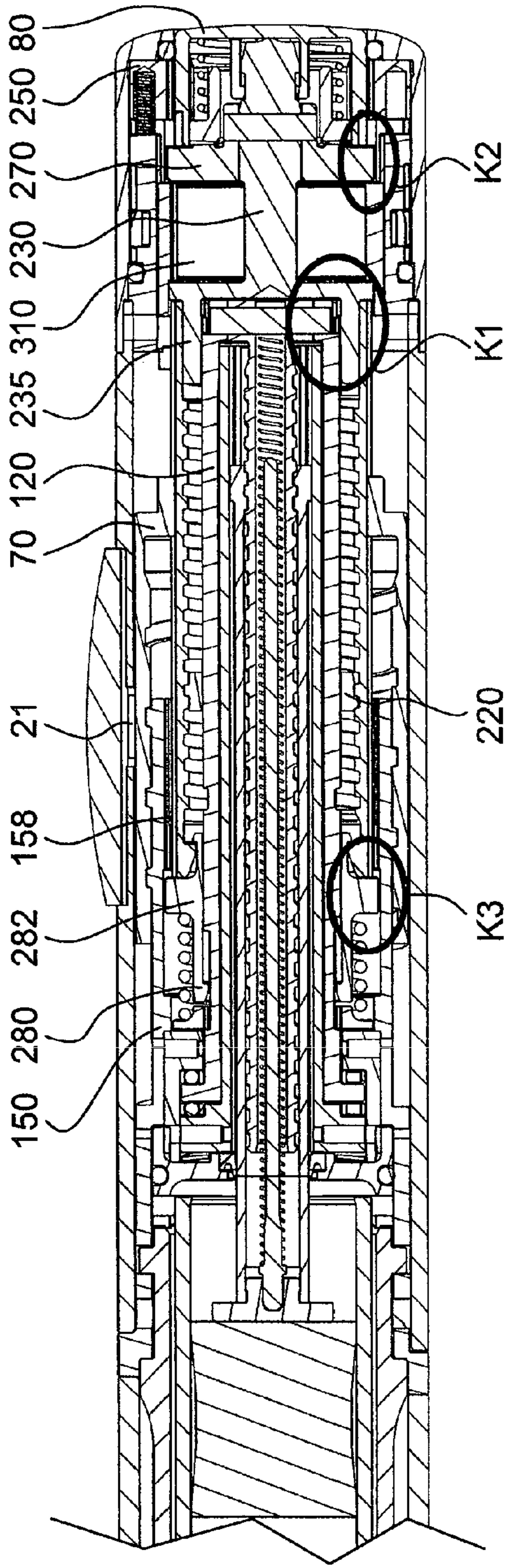


FIG. 19

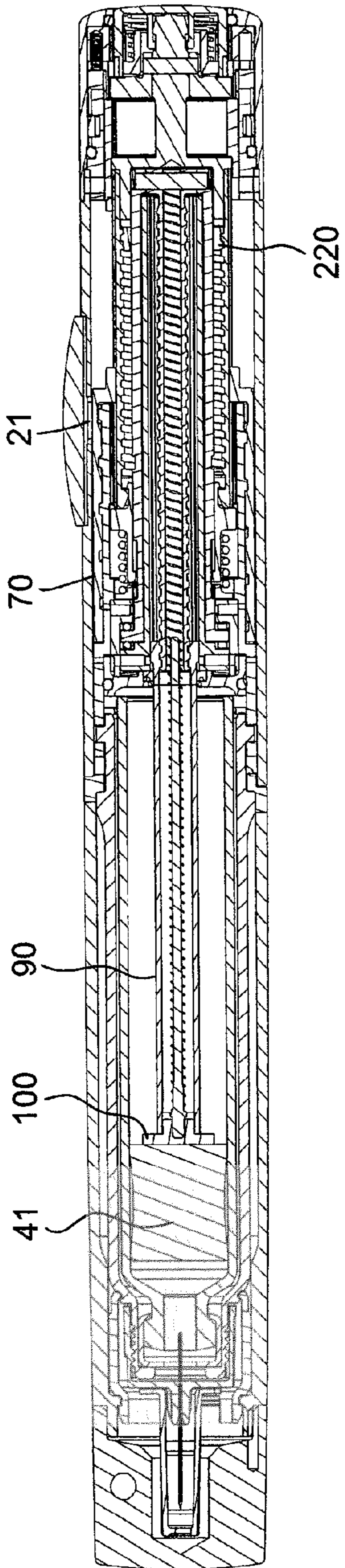


FIG. 20

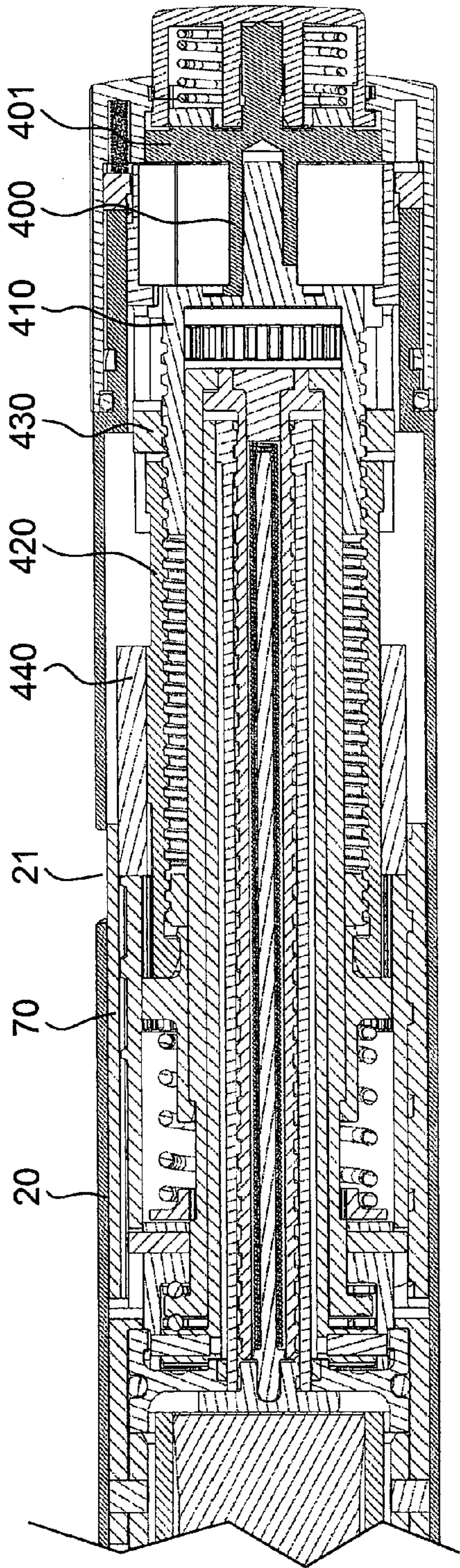


FIG. 21