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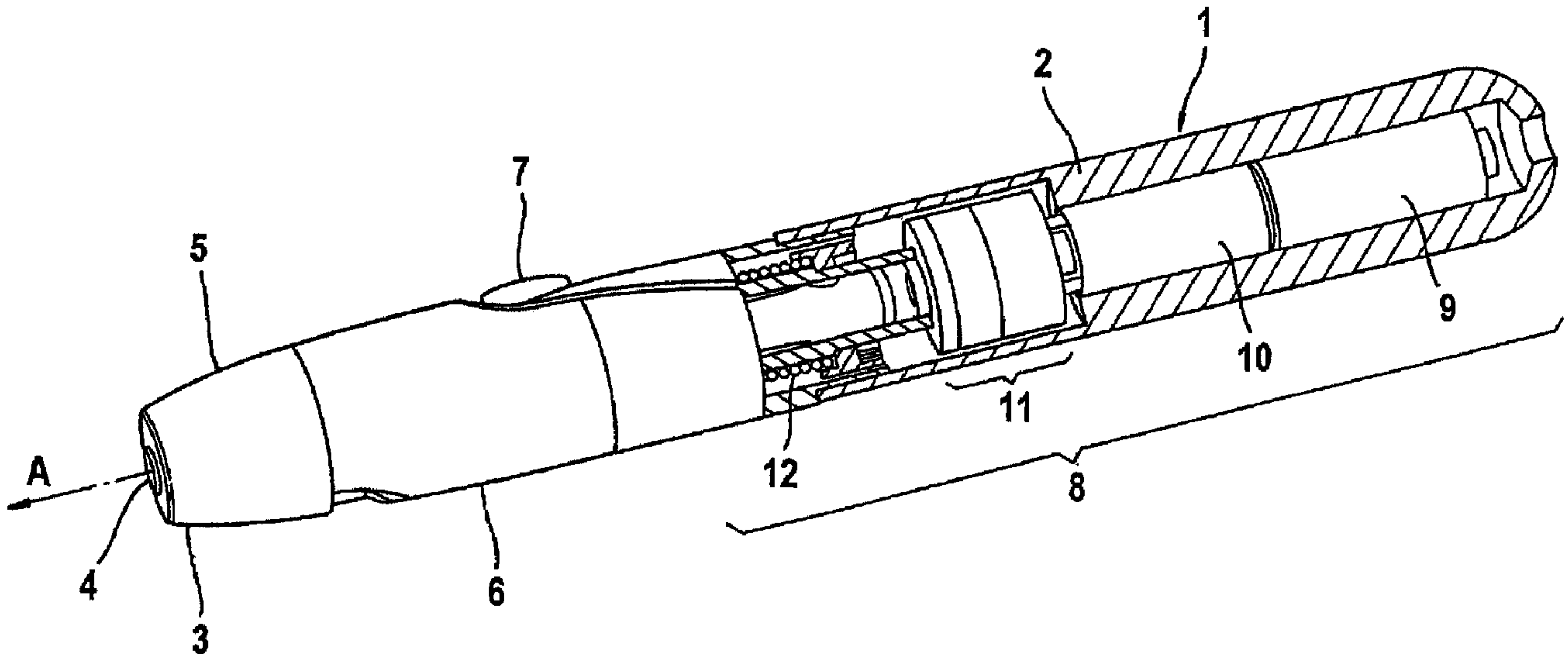

(57) Abrégé/Abstract:
The invention relates to a blood collection system (1) for collecting blood for diagnostic purposes. Said system comprises an electric motor (9), which provides energy for propelling a lancet. According to the invention, the blood collection system also comprises a mechanical energy accumulator (20), in which the electric energy that is converted by the motor is stored in the form of mechanical energy. The use of a mechanical energy accumulator permits the use of known mechanical propulsion elements. The blood collection system can be electrically activated and is thus easy to use for the operator.

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Abstract

The invention concerns a blood collection system (1) for collecting blood for diagnostic purposes. The blood collection system comprises an electric motor (9) which provides energy for propelling a lancet. According to the invention, the blood collection system comprises a mechanical energy store (20) in which the electric energy that is converted by the motor is stored in the form of mechanical energy. The use of a mechanical energy store allows the use of known mechanical drive elements. The blood collection system can also be electrically activated and is thus easy to use for the operator.

Blood collection system for collecting blood for diagnostic purposes

Lancets which are lanced into an appropriate body part to generate a wound are used to collect blood from a body part (usually from the finger or the earlobe) for analytical diagnostic purposes. Specially trained personnel is required if this is carried out manually. The puncture is nevertheless associated with considerable pain.

Blood collection systems have been used for a long time which are composed of a lancing device and associated lancets that are specially adapted to the respective device. A lancet drive which mechanically lances a lancet into the skin is located in a housing of the lancing device. A spring is usually used as the driving element for the lancing movement.

However, it is frequently necessary for a patient to be subjected several times daily to an examination in order to regularly monitor certain analytical blood values. This applies particularly to diabetics who should frequently check their blood sugar level in order to keep their blood sugar level as continuously as possible within certain required limits by adapting insulin injections to the requirements (which varies greatly depending on food intake, physical activity etc.).

Consequently a prerequisite for this intensive therapy is that the blood collection is associated with as little pain as possible. Numerous different blood collection systems which comprise mechanical drive units for a lancet or needle have been developed with the aim of achieving such an improvement. Nowadays such drive units are so highly developed that the lancing process can be carried out reproducibly in a relatively painless manner. However, before the blood collection system can be operated, a drive element which is frequently a spring of the drive unit has to be transferred into a tensioned position. When the lancing process is subsequently triggered the drive element is again transferred into a relaxed position.

The force which is released in this process is used to drive the lancet in the lancing direction.

However, a disadvantage of the prior art is that the tensioning process of a blood collection system often requires much force and/or complex handling steps by the user in the case of a mechanical drive unit. For example in the document DE 10223558.9 the tensioning of a blood collection system is described in which a spring is tensioned in the drive unit by turning a knob on the housing. This forces the patient to use both hands to operate the device.

However, it often turns out that such handling steps are perceived to be difficult by older persons or people with motoric limitations. Hence in addition to a puncture that is as pain-free as possible, an easy operation of the blood collection system is desirable especially in the intensive therapy that often has to be used for elderly people.

Blood collection systems with an automatic drive have been described in the prior art which should enable a simple and comfortable handling especially for persons with motoric disabilities. The user is thus spared as far as possible the in some cases complicated process of tensioning the lancets and the subsequent triggering of the lancing process. The patient can activate an electrical drive mechanism by pressing a button without additional handling steps or an exertion of force being required of the user. The documents WO 02/100 461, WO 02/100 460 as well as WO 02/001 01 and WO 02/100 251 each disclose blood collection systems in which an electrical drive unit moves the lancet in the drive direction and executes a lancing process. For example electromagnetic drive elements are mentioned in the document WO 02/100 251. The transfer of force from the drive units to the lancet body is controlled by control units in such a manner that a defined lancing movement can take place.

An automatic blood collection system comprising a plurality of lancets is also disclosed in the document US 6,530,892. The drive unit is realized by a magnet analogously to the above-mentioned prior art.

The described systems each utilize electrical drive units. A rapid transfer of force onto the lancet which converts the electrical energy into a movement of the lancet body has to be realized by additional components. In order to achieve a high drive speed also in the case of electrical drive units, capacitors are for example integrated into an electrical drive unit which provide the energy required for the lancing by a rapid discharge. In this manner it is attempted to transfer the energy rapidly and directly from the electrical drive unit onto the lancet. Although electrical drive units are particularly suitable for use as a long-term store in lancing aids due to their high storage density of > 100 joules per gram, it has, however, turned out that the rate at which energy can be removed from electrical drive units is usually limited to a few 10 joule/sec due to a given internal resistance. Moreover, the efficiency of the system deteriorates as the rate of removal increases. Furthermore, additional measures are necessary to control a defined motion sequence of the lancet body which ensure that the lancet pierces a body part of a patient in a vibration-free manner and the subsequent retraction of the lancet into the blood collection system.

Consequently a disadvantage of the described prior art is that complicated control mechanisms which control a defined motion sequence of the lancet body during the lancing process are required in addition to the electrical drive units. As a result of the electrical drive unit it is not possible to integrate the already well-proven mechanical drive mechanisms into the system. Hence, one is not able to utilize the advantages of the mechanical drive units which have been redeveloped again and again in recent years and enable a painless lancing due to exactly defined motion sequences.

Hence, complicated additional measures have to be implemented for electrical drives in order to control the lancing process in a comparable manner to that of mechanical drive units where these measures still often prove to be inadequate in comparison to the mechanical drive units. Furthermore, the additional components that are necessary for this such as capacitors and control units complicate the design of a lancing aid and increase its manufacturing costs. Moreover, in addition to the inadequate control of the motion sequence, there is often a delayed transfer of force from the drive unit onto the lancet body resulting in a retarded motion sequence of the lancet body. This in turn increases the lancing pain. Hence, a comparison of electrical drive units with mechanical drive units shows that although electrical drive units have a higher storage density that is available to the system, the rate of removal and thus the force transfer of the drive unit onto the lancet body is often inadequate.

Thus, blood collection systems having an electrical drive unit have difficulties in satisfying the requirements with regard to a painless puncture.

In contrast the use of a mechanical drive unit is defined by a high removal rate as is for example urgently required for a lancing movement of a lancet. Conventional springs provide a high removal rate of a few thousand joules per second at an almost ideal efficiency. However, the mechanical drive units which are often among others in the form of a spring prove to be inefficient energy stores because they would require large volumes for a high storage density. For example in comparison to electrical drive units, a spring used in a typical mechanical drive unit has a low storage density of only about 150 mJ per gram. Consequently with regard to a compact design of the blood collection system which is required in modern analytics, it is not possible to realize a high storage density with a mechanical drive. Furthermore, the use of mechanical drive units often necessitates a complicated handling by the user that requires much force which, as already described above, is regarded as disadvantageous.

Hence, it has become increasingly apparent in recent years that there is a great interest in a blood collection system which simultaneously fulfils the difficult and partly contrary requirements (minimal pain sensation, simple operation, compact, slimmest possible design and simple, economical construction) as fully as possible.

The object of the invention is to avoid the described disadvantages of the prior art and to provide a blood collection system which allows a simple handling especially for elderly or disabled persons whereby it should ensure a painless puncture for blood collection. In particular the tensioning of a blood collection system which is often complicated and involves much force should be simplified.

The object of the invention is achieved by the independent claims. Particularly preferred embodiments are derived from the dependent claims.

The invention comprises a lancing aid to generate a skin opening in a body part. The housing of the lancing aid has an opening from which a lancet can emerge. A lancet which is driven by a drive unit to execute a lancing process is positioned within the housing. The drive unit of the blood collection system comprises according to the invention a mechanical energy store that can be connected via a motor with an electrical energy store such that energy can be provided to propel the lancet. As already described an electrical energy store is characterized by a high storage density and can for example contain batteries or rechargeable batteries. In order to remove energy from the electrical energy store, a motor is coupled to the electrical as well as to the mechanical energy store such that the electrical energy provided to the motor can be converted into mechanical energy and stored. In contrast the mechanical energy store is characterized by a rapid removal rate and provides the system with the energy required to execute a lancing process within a few milliseconds. The lancet body is coupled to the mechanical energy store by means of a coupling mechanism such that the stored energy can be transferred directly and immediately to the lancet body. In a preferred embodiment the coupling mechanism between the mechanical energy store and lancet comprises a mechanical motion transducer to control the motion sequence of the lancet body such that the lancet executes a positively guided movement. In this manner the lancet movement in or opposite to the lancing direction can be controlled in such a manner that it ensures a painless puncture.

The system according to the invention enables an electric motor to be combined with a mechanical energy store and thus with other mechanical components of a drive unit of a blood collection system thus ensuring a controlled motion sequence of the lancet body during the lancing. Thus the system can utilize already known principles of mechanical components such as control guide blocks (see for example

US 6,409,740 and US 6,419,661) that are used to couple a spring to a lancet in order to couple the lancet body to the mechanical energy store. In this manner components that have already been well tested in recent years can be integrated into the system in order to guide the lancet body in a mechanical drive in a defined manner. Complicated control units such as those that are necessary for electrical drives are unnecessary. Moreover, the system has a high storage density as well as a high removal rate. Consequently the blood collection system according to the invention is characterized by a combination of an electric motor and a mechanical energy store such that electrical energy can be converted into mechanical energy.

A mechanical energy store can be realized in a variety of ways in the sense of the invention. The mechanical energy store is advantageously integrated into the drive unit as a solid body. Such an energy store is for example a spring such as those that are already used for mechanical drive units. The spring is then tensioned by an electric motor which firstly compresses the spring. A spiral spring, torsion spring or leg spring etc. such as those that are already well-known in the prior art can for example be used as a spring. The lancing process can then be accordingly triggered by releasing the spring as for mechanical drive units and appropriate coupling mechanisms between the spring and the lancet body can be used.

In order to tension the spring it may be helpful for the motor to be coupled to the mechanical energy store by means of a clutch and/or gear unit. In this manner the torque required to tension the spring can easily be provided even by relatively small motors.

If a clutch is used as a connection between the motor and mechanical energy store, torques of 30 mNm can thus be transferred to the mechanical energy store in a simple manner. Torque-controlled or angle of rotation-controlled clutches which at the same time allow a simple control of the motor are for example advantageous as a clutch between the motor and mechanical energy store. Bevel gearing can for example be used as a gear unit. Other types of gearing or coupling that are already known in the prior art which enable a coupling of the motor to the mechanical energy store are also conceivable.

If a clutch is used to transfer the force of the motor to the mechanical energy store, it is, as described above, conceivable that the motor is controlled on the basis of the applied torque. In this case in an advantageous embodiment the motor current is measured during the tensioning process and compared with preset values. If for example a spring is used as the mechanical energy store, the torque required to tension the spring increases with an increasing compression of the spring. Consequently the motor current increases as a function of the compression of the spring where each measured value of the motor current represents a defined compressed state of the spring. Hence, a preset value for the motor current can be a signal to the system that the tensioning process has been completely executed. If the motor current exceeds such a threshold value, the motor is stopped to end the tensioning process of the spring. Hence, the motor is automatically controlled in a simple manner. The described advantageous embodiment allows a propulsion of the blood collection system without needing additional positioning sensors to control the operating sequence. The lancing process can subsequently be triggered in the same manner by a control based on the applied torque. In this case the motor is firstly activated again so that the tensioning process of the spring is initially continued until a second preset torque, a second threshold, is reached. Once the preset torque of the second threshold is reached, the connection between the motor and the spring is automatically released so that the mechanical energy stored by the spring can be released. The spring relaxes as a result of which the lancet body is propelled by the energy released by the spring. In this connection the energy can act in a defined manner on the lancet body by means of appropriate coupling mechanisms such as those that are used in the prior art to transfer force between a spring and lancet body.

An analogous control of the motor by other embodiments is also conceivable in which for example the coupling is controlled by means of the angle of rotation.

Furthermore, a mechanical energy store in the form of a solid body can also be realized by a mass which is for example rotated by a motor. The kinetic energy generated in this manner is transferred to the lancet body such that the lancet executes a puncturing movement. Hence, this shows that the electrical energy of the motor can be converted in the form of potential as well as kinetic energy and can be stored by a mechanical energy store. If the electrical energy is stored by the mechanical energy store as kinetic energy, the lancet body must also in this case be subsequently coupled to the mechanical energy store such that the stored energy can be released directly and without loss and converted into a targeted movement of the lancet body. When a rotating mass is used as the energy store, a clutch is advantageously provided as a coupling mechanism between the mechanical energy store and lancet body which allows the kinetic energy of the mass to in turn act on the lancet body or, in a preferred embodiment, on a mechanical motion converter. Such a coupling can for example comprise a frictional directional lock and a shaft as are well-known in the prior art. Embodiments comprising a coil spring or an automatic clutch as described in detail in the following are also conceivable. The integration of the clutch between the moved mass and the lancet body enables the energy to be removed at a high rate and thus achieves a coupling time preferably in the range of 1 ms.

Hence, in addition to the embodiments for coupling the spring to the lancet body that are already known in the prior art, it is also possible to use clutches as a coupling mechanism between a mechanical energy store and lancet body which allow a direct transfer of energy from a moved mass to the lancet body. The mechanical energy store and lancet body can thus be coupled by simple mechanisms that are for example described for mechanical drive units in US 5,318,584. On the other hand, it is also advantageous to use clutches and/or gear units. In this case the component that is responsible for the coupling between the mechanical energy store and lancet body can also at the same time act as a mechanical motion converter or in turn be connected to the lancet body by means of a mechanical motion converter such that the lancet executes a positively guided movement. Examples of this are a cross-sliding gear unit which enables the components to be coupled and also acts as a mechanical motion converter.

Said embodiments are only cited as examples. Other embodiments such as those that are known in the prior art for transferring energy are also conceivable as is a combination of these embodiments with the mechanical energy stores known in the prior art.

Mechanisms such as those used in the prior art for mechanical drive units can also be used as mechanical motion converters to guide the propelled lancet body in a defined manner. The principle of a controlled link (DE 10223558.9) is mentioned in this connection. In this case a control guide block enables a defined motion sequence of the lancet body in and opposite to the direction of lancing. However, it is also possible to use gear units e.g. cross-sliding gear units as described above.

The system according to the invention allows an electric motor to be integrated into conventional mechanical drive units of blood collection systems. In this manner it is possible to fulfil the high demands with regard to painless puncturing and at the same time to ensure a comfortable handling especially for patients with motoric limitations.

The system according to the invention allows a simple and economic design. According to the invention a motor is coupled to mechanical drive elements as is already well-known in the prior art. This is achieved in particular by converting electrical energy into mechanical energy by means of a motor. Use of a mechanical energy store allows the coupling to further mechanical components such as a mechanical motion converter such as are used in the prior art for a defined guidance of the lancing movement in mechanical drive units. This results in a high removal rate as well as a defined motion sequence.

Electric motors (DC motors, external rotor motors or brushless motors) or a so-called “memory shaped alloy actuator” can for example be used as the motor. In the case of the so-called “memory shaped alloy actuator” which is also referred to in the prior art as “nanomuscle”, individual elements consisting of preferably extremely pure alloys are heated by a current which results in a change in their shape (expansion of the respective elements).

The system according to the invention also proves to be particularly advantageous for use in integrated systems which advantageously combine several functions in one analytical system. Such systems save the user complex handling steps by integrating several system functions in one device. Thus, the use of integrated systems enables the user to, among others, firstly carry out a lancing process and subsequently to apply the blood to a test element provided by the system using a single device. The test element is then analysed directly in the instrument without the patient having to switch between different elements of the device (lancing aids, test elements, measuring instrument). For example an integration of a lancing aid in a measuring instrument is described in the document WO 98/24366. This enables the patient to carry out all handling steps necessary for the analysis by one device. However, systems are also known in the prior art which have different types of integration.

Examples of less complex instruments in which the lancing aid is handled separately from the measuring instrument have a store of test elements as well as an automatic dispensing of test elements. Examples of this are the AccuCheck Compact® instrument from Roche Diagnostics GmbH. Such integrated systems can in addition also advantageously have a lancet magazine in addition to a test element magazine. If a system according to the invention is combined as described with an integrated system, this would fulfil the high requirements for comfortable handling.

When integrating the system according to the invention the electric motor can then be used as a combined drive in an advantageous embodiment. With a combined drive in the sense of the invention the electrically driven motor, on the one hand, provides energy for the mechanical energy store and, on the other hand, the electrically driven motor can at the same time or at a time that is independent thereof provide energy for another system function. This system function can for example be magazine transport, test element transport etc.

If the motor is used successively for different functions, it proves to be advantageous to use an additional gear unit and/or clutch which couples or uncouples the motor to the corresponding system function. In this manner the motor can be used for the respective system functions in a spatially as well as chronologically independent manner. A compact design of highly integrated systems is thus possible.

Examples of preferred embodiments are described in more detail in the following on the basis of the figures.

Figure 1a) Electric lancing aid with a spring as a mechanical energy store.
Figure 1b) Electric lancing aid with bevel gearing and spring.
Figure 1c) Electric lancing aid with a movably guided guide block.
Figure 2 Rotating mass as a mechanical energy store with an automatic clutch.
Figure 3a) Integrated system with a combined drive.
Figure 3b) Integrated system with a combined drive for a drum magazine.
Figure 4 System with a clutch controlled by the angle of rotation.
Figure 5 System with a torque-controlled clutch.
Figure 6 System with a rotating mass as a mechanical energy store.

Figure 1a) shows transverse section through a blood collection device (1). The device comprises an outer housing (2) the front end of which (3) has an exit opening (4) for a lancet tip. The exit opening (4) is integrated into a cap (5) of the lancing aid which is rotatably connected to the housing (1). The extent to which a needle tip emerges from the opening (4) can be changed by rotating the cap (5) about the axis (A) and thus the puncture depth of the blood collection device can be selected by the user. In addition a lancet and preferably a lancet magazine (not shown) from which lancets are removed for the lancing process is preferably arranged in the front area (6) of the blood collection device. In order to perform the lancing process, the lancet is propelled by a drive unit (8) in the direction of lancing along the axis (A) and is retracted again into the housing after the lancing process. In the example shown the drive unit comprises a motor (9) which is connected to a store of electric energy in the form of a battery (not shown). The electric motor is coupled by a gear unit (10) to a clutch (11). If the motor is activated by the user to execute a lancing process, a rotational movement is transferred via the gear unit and clutch to the spring (12) which is thus compressed. In this process the clutch generates the torque required to compress the spring such that the spring can be adequately compressed even when the motor has a low power. The motor is advantageously controlled by measuring the applied motor current and thus the prevailing torque. If this exceeds a predetermined limit, it is a signal to the system that the spring is now adequately pretensioned and the motor is automatically stopped. The user can now trigger the lancing process by a trigger button (7). In this process the user again activates the motor by actuating the trigger button as a result of which the spring is again compressed until a second predetermined torque is reached. When the second limit is reached, the spring which was previously locked in a tensioned state is automatically released such that the potential energy stored by the spring can be released. The released energy of the spring is now diverted by a motion converter (not shown) e.g. a control guide block onto the lancet body such that the lancet executes a positively guided movement and a painless insertion into a part of the body can be performed.

Figure 1b) shows a rough functional model of an automated lancing aid which illustrates the coupling of the motor to a mechanical energy store and to a mechanical motion converter which guides the lancing movement of the lancet body. In the example shown the motor (9) is only shown schematically and is coupled by a gear unit (10) and a clutch (11) to a spring (20) as a mechanical energy store. The second end of the spring is connected to a guide block (15) which is movably supported by the bearings (13) in a system according to the invention. The guide block has a guide slot (16) which serves as a control guide block for the lancet holder (14). If the motor is activated to tension the spring, the spring is compressed and the guide block is moved towards the motor. Hence, the guide block can be moved laterally relative to the motor. In contrast the lancet holder (14) has a fixed position in the system along the direction (B) and remains fixed in its lateral position relative to the motor while the guide block is moved laterally. Meanwhile the lancet holder is guided along the guide slot (16) which, as a control curve causes the lancet holder to be deflected perpendicularly to the movement of the guide block. Consequently the lancet holder makes a movement stroke along the lancing direction (A) and is subsequently returned again to its original position by the design of the guide slot. After the tensioning, the position of the guide block is locked in the system. When the lancing process is triggered, the arrestment is firstly released so that the spring can again return to its tensioned state. Due to the resulting movement of the guide block perpendicular to the lancing direction (A), the lancet holder (14) again passes through the guide slot (16) which executes the lancing process.

Figure 1c) shows a system according to the invention with a cross slip gear unit as a mechanical motion converter. The system has an electrically driven motor (9) which is fixed in position in the system by a bearing (19). The motor is connected to a bevel gear (10) which is in turn connected to a clutch (11) (only indicated schematically). The conical gear enables a flexible design of the spatial structure of the system such that the motor, as shown in the figure as an example, does not have to be located linearly behind the lancet holder (14). Thus, the energy provided by the motor can be readily deflected by 90°. This enables a compact design of the system. It is also possible to integrate other system functions (not shown here) in which case the spatial structure of the system according to the invention can be adapted according to the other system functions. If the bevel gear and the clutch are driven by the motor, a spiral spring (12) is tensioned. In the described example the motor is controlled according to the angle of rotation and the motor is stopped as soon as the clutch has rotated by 360°. The spring is locked in its tensioned state. The blood collection system is now ready for operation. The spring is released by actuating a trigger switch (7) and the stored potential energy is transferred to the lancet body by a cross slip gear unit (18). In the example shown a cross slip gear unit is used as mechanical motion converter which causes a positively guided movement of the lancet holder. The described embodiment shows an example of a combination of various possible constructional elements of a system according to the invention. It is also conceivable that instead of a cross slip gear unit, a control guide block as described in figure 1b is integrated into the system. In this connection a versatile combination of the individual constructional elements allows a flexible design of the system according to the invention which can be adapted according to the requirements especially for integrated systems.

Figure 2) shows a detailed view of a drive in which a rotating mass is used as the mechanical energy store. Such a system is essentially designed like the blood collection device already shown in figure 1. However, instead of the mechanical energy store which is shown by a spring in figure 1, a rotating mass is used in this case. This results in some adaptations in the system to enable a rapid and efficient energy transfer of the rotating mass onto the lancet body. In the following only the detailed view will be shown for the system complexes which enable a direct transfer of energy from a rotating mass onto a lancet body. In this connection figure 2 illustrates the function of an automatic clutch which transfers the kinetic energy directly onto a lancet body or, on the other hand, is firstly coupled to a spring such that a clutch is indirectly coupled to the lancet body by means of a spring. If the clutch is connected to a spring, the kinetic energy is firstly converted into potential energy which is firstly stored temporarily in the spring. An abrupt coupling of the automatic clutch transfers sufficient energy from the rotating mass to the spring in order to tension the spring. Of course the automatic clutch can also be directly connected to the lancet body. The advantages and disadvantages of these system variants are as described below in figure 6. Furthermore, similarly to the system shown in figure 1, the constructional elements are coupled to a motor, lancet body etc. which are not shown here in order to simplify the illustration.

Figure 2a) shows an exploded view of a drive with a rotating mass as well as an automatic clutch. A brushless external rotor motor is used as the drive. It essentially consists of a bank of stator plates (21) on which coils are applied (not shown), a soft iron rotor (23) with incorporated magnets and a common spindle (22). An automatic clutch consisting of the constructional elements 24-27 is permanently connected to the rotor (23). A clutch housing (24) is, as described above, either directly connected to a lancing gear unit to be driven or is axially connected to it by means of a spring (not shown). The bank of stator plates (21) and the spindle (22) are fixed in position (non rotating) in the system. When it is switched on, the rotor (23) rotates and the clutch elements (25-27) that are permanently connected to the rotor follow the sequence of movements and rotate about the stator (21). The clutch housing (24) is pivoted on the common spindle (22) and is not connected to the constructional elements (23, 25, 26, 27) such that the clutch housing firstly remains stationary in the system. Above a threshold revolution speed the rotating constructional elements of the automatic clutch are abruptly coupled to the clutch housing (24). The stored energy of rotation of the rotor as well as of the rotating constructional elements is thus transferred into the clutch housing and the lancing gear unit that is connected thereto or a spring. The motor is blocked after the coupling process and is switched off by control electronics. The automatic clutch subsequently automatically separates the connection between the rotor (23) and the clutch housing (24). The system is ready for a new operation.

The detailed mode of operation of the automatic clutch is shown in figures 2b-2d. Fig. 2b) shows the clutch in an uncoupled state below the threshold rotation speed. The two symmetrically disposed coupling jaws (25) are held in a resting position by the springs (26). The surfaces of the coupling jaws (25) have no contact with the surrounding clutch housing (not shown). When the rotation speed threshold is exceeded, the coupling jaws (25) rotate about the bearing pins (27) and touch the clutch housing. The clutch is coupled into the clutch housing (24) by frictional coupling of the jaws (25) with the inner wall of the housing such that the clutch housing follows the rotational movement. In order to avoid frictional losses during the coupling process, this must occur as suddenly as possible. For this purpose a special spring arrangement (26) is selected as a sprung mechanism as elucidated in the following. The position of the spring during the coupling process is shown schematically in figure 2d by the lines A-C. Line A symbolizes the initial position (not coupled) of the clutch whereas line C shows the final position of the spring above the rotation speed threshold. The spring is attached in the system between points (28) and (29) and acts as a pressure spring. Due to the position of the centre of mass of the coupling jaws outside of the pivot bearing, a centrifugal force F_2 is generated during rotation which is proportional to the rotation speed. As a result of the chosen arrangement the spring is compressed with an increasing centrifugal force F_2. The maximum of compression is achieved at the rotation speed threshold and is symbolized by the line B. However, this state is unstable and leads directly and suddenly to a further rotation of the jaws into the position corresponding to line C. As soon as the rotor is stopped, the clutch housing is decoupled. Stopping the motor reduces the centrifugal force F_2 to zero and due to the spring force F_{spring}

the coupling jaws are rotated back into the uncoupled initial position. The described embodiment of an automatic clutch ensures that by means of the coupling of the clutch housing the energy can be directly transferred suddenly onto the lancet holder in a direct or indirect manner. This enables the energy to be removed at a sufficiently rapid rate so that a lancing process of the lancing body can be carried out in a painless manner or so that a spring can be tensioned as a temporary store.

Figure 3a) shows schematically a possible design of a combined drive (combidrive). A combidrive according to the invention enables a further miniaturization and a reduction of the weight of the device for integrated systems. The user is thus ensured a comfortable handling with a compact portable device. Furthermore, operating errors of the system are reduced. In this connection the motor (9) is connected via a gear unit (10) to a gear wheel (32) which is pivoted in the system. The gear wheel can execute a rotation in different directions of rotation by setting the motor in motion. In the example shown the gear wheel is coupled to a spring (20) to store mechanical energy and is also directly coupled to one side of the housing of a drum magazine (34). Hence, the motor is coupled by a gear unit (10) to two system functions. Rotation of the gear wheel results in compression of the spring (20). On the other hand, the gear wheel engages in an appropriately designed base of the drum magazine such that the magazine is rotated about its longitudinal axis. The magazine can for example be provided to store test strips or lancets and thus the magazine is rotated in such a manner that a disposable in the magazine is positioned opposite to a removal unit in the device. Thus, for example it is conceivable that during the tensioning of the spring to propel a lancet, the drum is at the same time advanced by one step such that a test strip can be removed from the magazine for sample application by means of a withdrawal unit provided for this purpose such as a plunger.

Figure 3b) shows a detailed view of the combidrive shown in figure 3a) which serves as a magazine transporter and is also used to tension a spring to propel a lancet. The combidrive consists of a DC motor (9) which at the same time advances a drum magazine (not shown) in steps and tensions a lancing aid (35). The motor is connected with a gear unit (36) to drive the drum. The gear unit diverts the electric energy provided by the motor onto a spindle (37) which is made to rotate. The upper head of the spindle has a tooth-like structure which engages in a correspondingly shaped housing base of a drum magazine (not shown). Thus, when the drum magazine is inserted into the measuring device it is placed on the spindle (37) and is arrested there. If the motor is activated and the spindle is rotated, the drum follows the movement. In order to also tap off energy to tension the lancing aid, a spur gear (40) is also connected to the gear unit (36). Hence, in the example shown the magazine is advanced by one step while at the same time the spring of the blood collection system is tensioned. The user can now trigger a lancing process as desired and request the output of one new test element from the magazine. It is of course possible to chronologically separate the system functions (tensioning of the spring and advancing the magazine) from one another. Under these circumstances the system advantageously comprises a clutch which uncouples and couples a system function from the motor provided an activation of the respective system function is desired. The lancing aid can, to start with, be designed at will whereby a spiral spring is used in the example shown as a mechanical energy store. With regard to the further design of the lancing aid, reference is made here to the systems that are already known in the prior art for example DE 10336933.3 in their entirety.

In principle a combidrive according to the invention could be used for any system functions and is not limited to particular applications. A test element transport etc. is mentioned here as an example.

Figure 4) shows a detailed view of a coupling controlled by the angle of rotation as it is for example used to couple the electric motor to a spring. A first spindle region (45) of a spindle (47) of the clutch is contacted with a spring (not shown) of a lancing aid while a second spindle region (46) of the spindle is connected to an electric motor (not shown) and is driven by this motor. For this purpose the spindle region (46) is inserted into an interface of the motor (not shown) and is turned by this motor. The end of the spindle region (46) that is not connected to the motor has a toothed structure (42) which engages in the toothed structure of the opposite end (41) of the spindle region (45). The rotation-secure intermeshing of the two spindle ends ensures that a rotary movement of the spindle region (46) caused by the motor is transferred onto the spindle region (45). Hence, a rotation of the spindle region (46) results in a rotary movement of the entire spindle (47). Thus, a spring (not shown) that is permanently connected to the spindle region (45) is compressed and thus tensioned as a result of the rotation of the spindle. The coupling additionally has a guide block (44) in which the first spindle region (46) is guided by a bolt (43) which is permanently connected to the spindle region (46). If the spindle region (46) is rotated, the bolt (43) is guided correspondingly along the guide block (44). As a result the bolt (43) and the spindle region (46) that is permanently connected thereto are axially deflected according to the contour of the guide block. As a result of the axial displacement of the spindle region (46) the toothed structures (41) and (42) are uncoupled such that the spindle regions (45) and (46) are detached from one another. The torque caused by the compression of the spring now results in a rotation of the spindle region (45) in the opposite direction so that the spring drive can run back in an almost frictionless manner. The energy released in this process is transferred onto the lancet body such that the lancet body is moved in the direction of lancing. Thus, figure 4 shows a clutch which allows a control of the motor and thus of the drive unit as a function of a specified angle of rotation which is predetermined by the contour of the guide block. By turning the spindle (47), the bolt (43) of the spindle region (46) firstly reaches a position (48) of the guide block. In this position the spindle region (46) is subjected to a first axial deflection which stops the motor. In order to trigger the lancing, the motor is again activated by the user. As the angle of twist increases, the bolt (43) continues to follow the forced guidance by the guide block until it reaches the position (49). As a result the spindle region (46) is deflected to such an extent that the spindle ends are uncoupled as described above.

Figure 5) shows a torque-controlled clutch which is also used as the coupling mechanism between the motor and a spring. The torque-controlled clutch consists of a first drive element (52) which has a leaf spring (53). Another drive element (51) with pins (54) is rotatably connected to the drive element (52). As shown in figures 5a) to d) the spring is tensioned by firstly rotating the drive element (51) by means of a motor (not shown) while the drive element (52) remains stationary in the system. As a result the leaf spring (53) is pressed against the pins (54) and is thus bent. As the angle of rotation increases, the torque increases and thus the motor current necessary to tension the spring increases as illustrated in the graph 5f). The motor current is measured by a drive electronics (not shown) and is compared with a set limit value. When a first specified limit is reached, the motor is stopped. The spring is now completely tensioned (see figure 5d)). The motor is again switched on to trigger the lancing process. The torque increases again. When the trigger point of a second given limit value of the clutch is reached which is larger than the first set limit value, the form-locking connection between the leaf spring (53) and the pins (54) is released and the spring can run back in an almost frictionless manner. The released energy is converted in order to execute a lancing movement (see figure 5e)). The applied torque decreases back to almost zero as shown in graph (5 f).

Figure 6) shows several embodiments of a coupling in which a rotating mass is used as a mechanical energy store. In this manner the energy required for a lancing process is stored in the form of kinetic energy and is subsequently provided for a lancing process. When a mass is used as a mechanical energy store it is possible to among others omit gearing and/or clutch to couple the motor to the mechanical energy store. This simplifies the design of the system compared to a design which has a spring as a mechanical energy store. The structure of the drive unit can also be reduced in size. If a moving mass is used as a mechanical energy store, it is thus possible for example to directly connect an electric motor to the mass to be accelerated and to rotate the mass. In this way kinetic energy is firstly stored by a simple type of construction. However, the stored energy must be rapidly transferred from the energy store to the lancet body with little loss. Such an energy transfer can take place by means of a suitable clutch between the mechanical energy store, in this case the moving mass, and the lancet. This coupling should operate with as little loss as possible and have short response times to minimize energy losses due to friction. In principle two advantageous embodiments are possible which allow a transfer of energy to the lancet body in a rapid and low-loss manner. On the one hand, the kinetic energy can be directly transferred onto the lancet body or onto a mechanical motion converter and thus into a lancing process. It is, however, also possible that firstly the energy of rotation is transferred onto a further intermediate store which is for example in the form of a spring. This has the advantage that when a lancing process is triggered, the mass does not at first have to be rotated to provide the necessary energy for the lancing process. The consequence of such a mechanism would be that after triggering the lancing process, the user would have to firstly wait a few seconds until the mass has been suitably accelerated by the electric motor and subsequently energy transfer can take place. If, however, an intermediate store is used in conjunction with the rotating mass, it is possible to firstly temporarily store the energy obtained by rotation in a spring. The lancing process can then be triggered at any time and directly by for example relaxing a compressed spring as an intermediate store and is implemented similarly to the systems already described above in which a spring is used as a mechanical energy store. Consequently if a rotating mass is used in combination with an intermediate store, the user is provided with the same methods of handling the system according to the invention as already described. Thus, in this example the rotating mass is an alternative solution for tensioning a spring without requiring appropriate gearing and/or clutches to connect the motor and energy store. Thus, tensioning a spring which would otherwise require high torques, is possible by a direct transfer of the kinetic energy onto the spring. In general a coupling between the mass and an intermediate store or a lancet body enables the kinetic energy to be transferred suddenly in about 1 ms. This thus allows either a direct conversion of rotational energy into a lancing movement or an efficient storage of energy in an intermediate store despite a simple design of the system.

Figure 6a) shows an electric motor (9) which is connected to a mass (62) in order to accelerate the mass and to rotate it. The windings of a wrap spring (63) are pressed onto the pin of the rotation mass (62) by pressing the switch button (65). If the mass is driven by the motor, the spring (63) is thereby abruptly wound onto the pin which accelerates the spindle (64). Depending on the drive principle that is used, the rotary movement of the spindle (64) is used to tension the drive spring (66) which is used as an intermediate store, or is directly converted into the lancing movement. Thus, the lancing process can be directly triggered by pressing the switch button (65). If, however, an intermediate store (66) is used, the kinetic energy is firstly temporarily stored by automatically actuating the switch button and the spring (66) is thereby compressed. The spring is subsequently relaxed by a separate triggering process for the intermediate store, by which means a lancet body can be propelled. In order to simplify the release of a wrap spring (63) that may have got jammed, the motor can be briefly turned in the opposite direction after carrying out the tensioning or lancing process. In principle the process steps necessary for the lancing process can be automated so that for example the switch (65) is automatically actuated when a preset rotational frequency is reached. Furthermore, the release of the wrap spring and thus the actuation of the motor in the opposite direction can be initiated automatically after completion of the lancing process. However, it is often desirable that the lancing process is triggered consciously by the user.

Figure 6b) shows another principle with a frictional directional lock which enables the kinetic energy of a rotating mass to be transferred onto a lancet body. Like in figure 6a), the mechanical energy store in figure 6b) firstly has an electric motor (9) which accelerates a mass (62). The frictional directional lock (67) is axially displaced by sliding a switch (65). As a result the clamping arms of the frictional directional lock (67) are pressed against the outer wall of the cone of the rotating mass (62). Once the clamping arms are locked with the mass (62), the frictional directional lock is abruptly accelerated and follows the course of movement of the rotation mass (62). Similarly to the embodiments already described above, the drive mechanism can be directly coupled to the lancet body or to an intermediate store. The frictional directional lock (67) is pulled out of the cone of the rotation mass (62) by sliding the switch (65) in order to release the coupling connection and thus the locking connection between the frictional directional lock (67) and the rotation mass (62).

Figure 6c) shows a further embodiment for coupling a rotating mass to a lancet body or to an intermediate store as already presented in figures 6a) and 6b). Similarly to the embodiments described above, the system has an electric motor (9) which accelerates the rotation of a mass (62). The freewheeling spindle (68) is abruptly coupled to the rotation mass (62) by sliding a switch (65) such that the kinetic energy of the mass (62) can be transferred to the lancet body or to an intermediate store as free from loss and as directly as possible. For this purpose the system has a number of locking balls (69) which, similarly to the principle presented in figure 6b), are locked with the cone of the rotation mass by sliding the switch. In this case holding disks (70) prevent the balls (69) from falling out where the said balls couple the spindle (63) to the rotation mass (62). In this manner the freewheeling spindle (68) is forced to follow the movement of the rotation mass (62) whereby the energy is transferred within a millisecond from the rotation mass onto the spindle (69). Also in this case the spindle (64) is pulled out of the cone of the mass to detach the coupling connection by sliding the switch (65) which disconnects the spindle (64) and rotation mass (62).

Amended claims

[filed in the international office on 23 December 2005 (23.12.2005);
original claims 1-19 replaced by amended claims 1-17 (3 pages)]

1. Lancing aid for generating a skin opening in a body part comprising
   - a housing with an opening from which a lancet can emerge,
   - a lancet with a lancet body and
   - a drive unit to propel the lancet body and the lancet such that the tip of the lancet can at least partially protrude from the housing to perform a lancing process, wherein
   - the drive unit comprises
   - a motor that can be contacted with an electric energy store such that energy can be provided to propel the lancet,
   - a mechanical energy store which is coupled to the motor in such a manner that the electric energy stored by an electric energy store is converted into mechanical energy and is at least partially stored by the mechanical energy store and
   - a coupling mechanism which couples the lancet body to the mechanical energy store such that the stored energy of the energy store can be at least partially transferred to the lancet body, wherein
   - the coupling mechanism comprises a mechanical motion converter which diverts the energy of the energy store onto the lancet body in such a manner that control of the lancet movement is converted into a positively guided movement, characterized in that
   - the lancing aid is integrated into a measuring device to determine an analyte from a blood sample and
   - the motor is coupled to a further system function in the measuring device which is independent of the mechanical energy store.

2. Lancing aid according to claim 1, in which the mechanical energy store is integrated as a solid body in the lancing aid.

3. Lancing aid according to claim 1, in which the mechanical motion converter has a control guide block.

4. Lancing aid according to claim 1, in which the mechanical motion converter has a cross-slip gear unit.

5. Lancing aid according to one of the claims 1 – 4, in which the motor has a gear unit which couples the motor to the energy store.

6. Lancing aid according to one of the claims 1 – 5, in which the motor has a clutch by which means the motor is coupled to the energy store.

7. Lancing aid according to claim 2, in which the mechanical energy store is a spring.

8. Lancing aid according to claim 6, in which the motor current in the drive unit is measured and compared with predefined values and the motor is controlled on the basis of this comparison.

9. Lancing aid according to claim 6, in which the clutch transfers at least a torque of 10 mNm onto the energy store.

10. Lancing aid according to claim 5, in which the gear unit is a bevel gearing.

11. Lancing aid according to claim 2, in which the mechanical energy store is a mass.

12. Lancing aid according to claim 1, in which the coupling mechanism comprises a clutch.

13. Lancing aid according to claim 6, in which the clutch is controlled by torque or angle of rotation.

14. Lancing aid according to claim 1, in which the electric motor is a Piezo motor or an external rotor motor.

15. Lancing aid according to claim 1, in which the energy for the mechanical energy store and the energy for the system function that is independent of the energy store are provided simultaneously or independently of one another.

16. Lancing aid according to claim 1, in which the system function that is independent of the energy store is a test element transport or a magazine transport.

17. Lancing aid according to claim 1, in which several test elements are stored in a magazine in the measuring device.

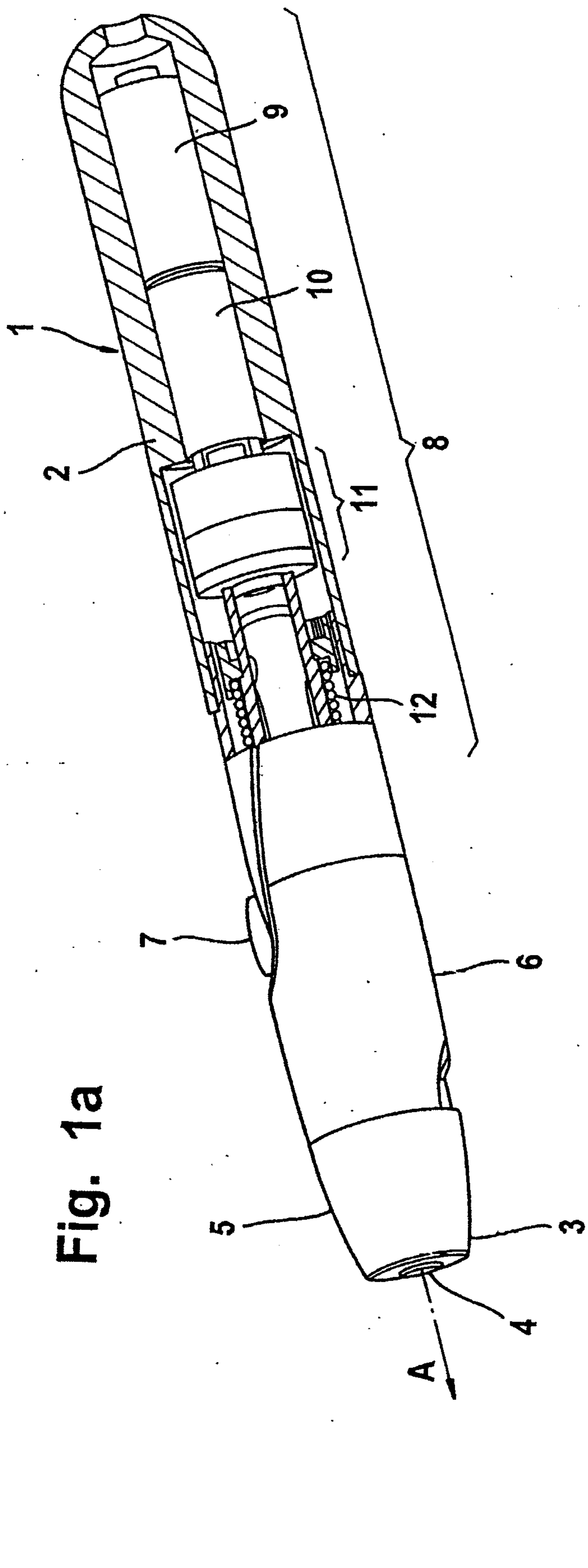


Fig. 1a

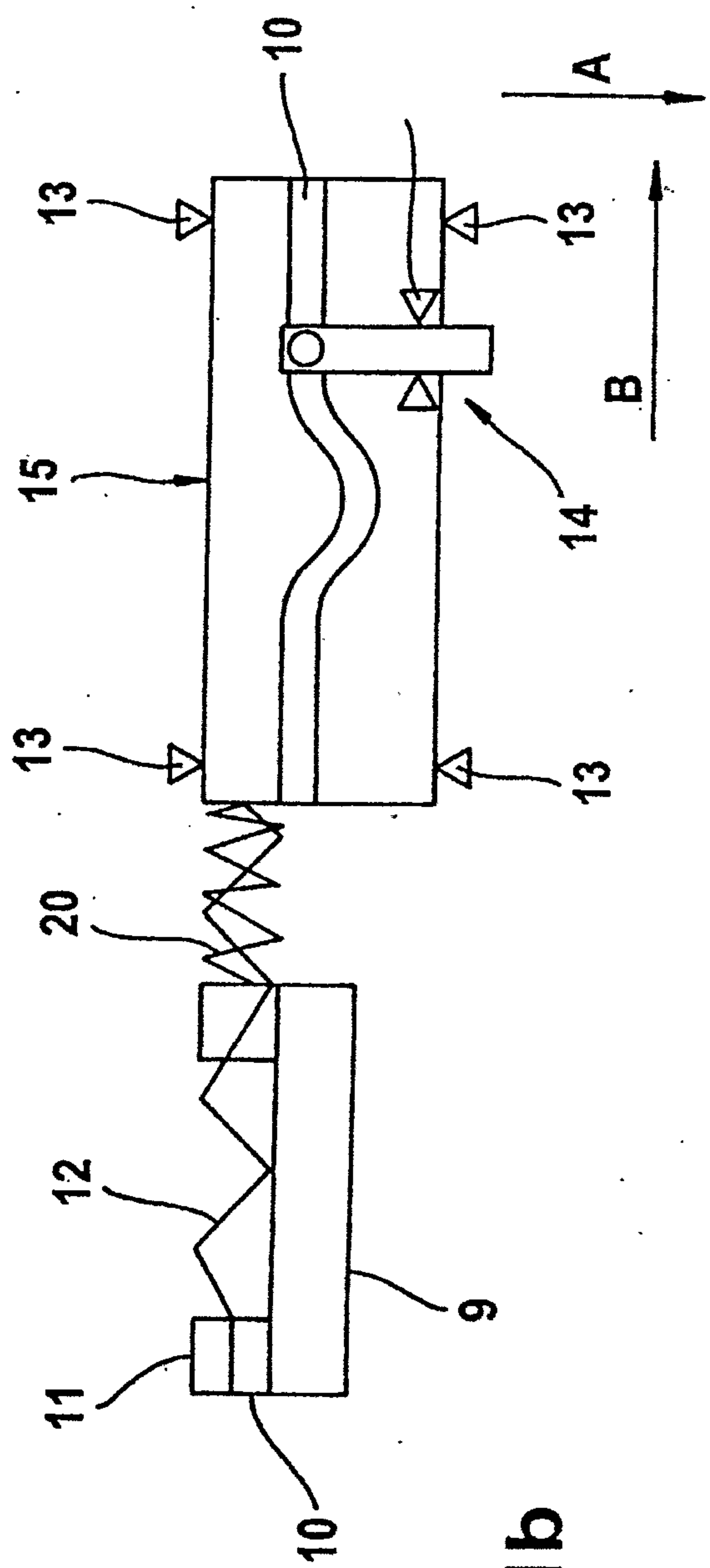


Fig. 1b

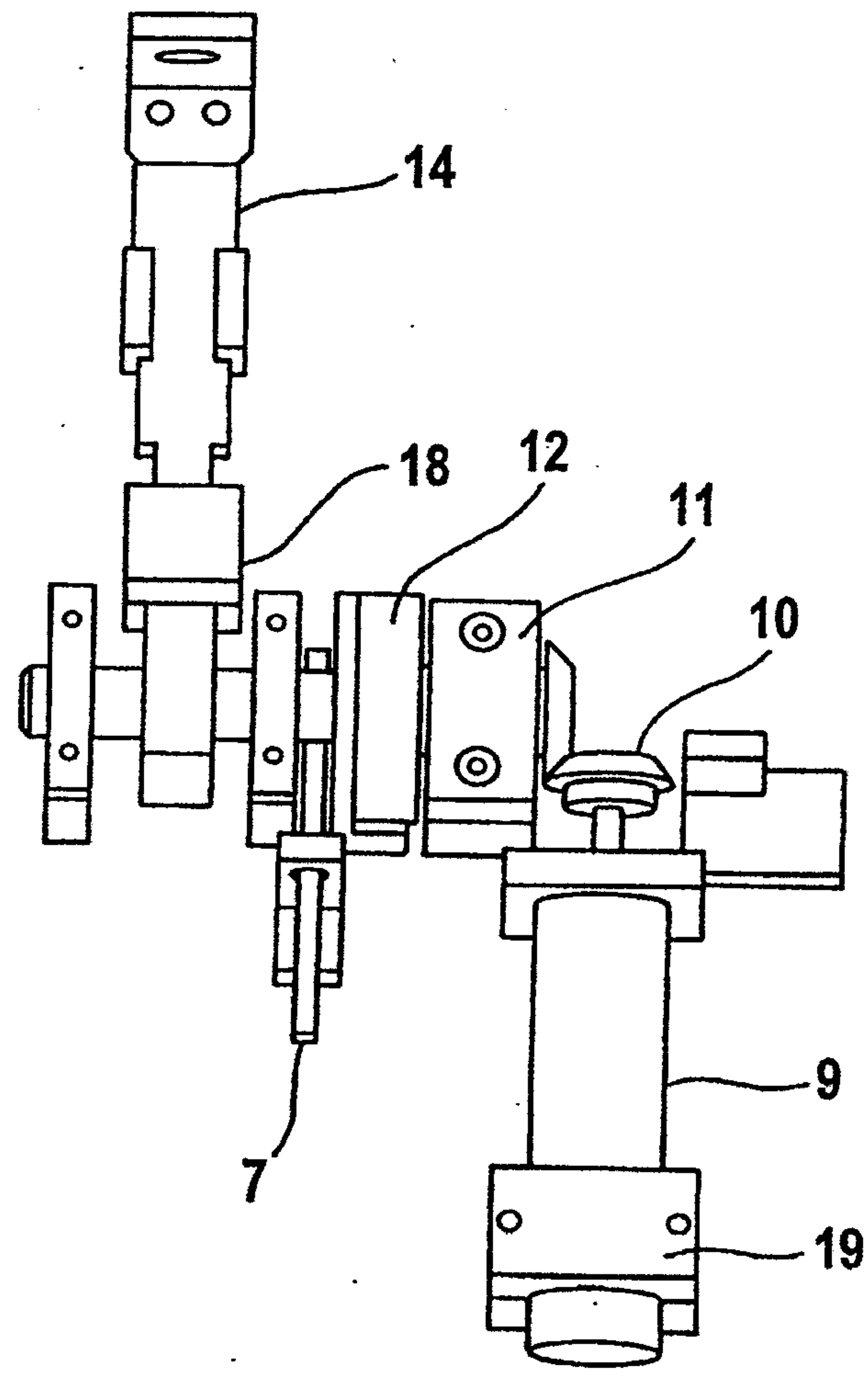


Fig. 1c

Fig. 2a

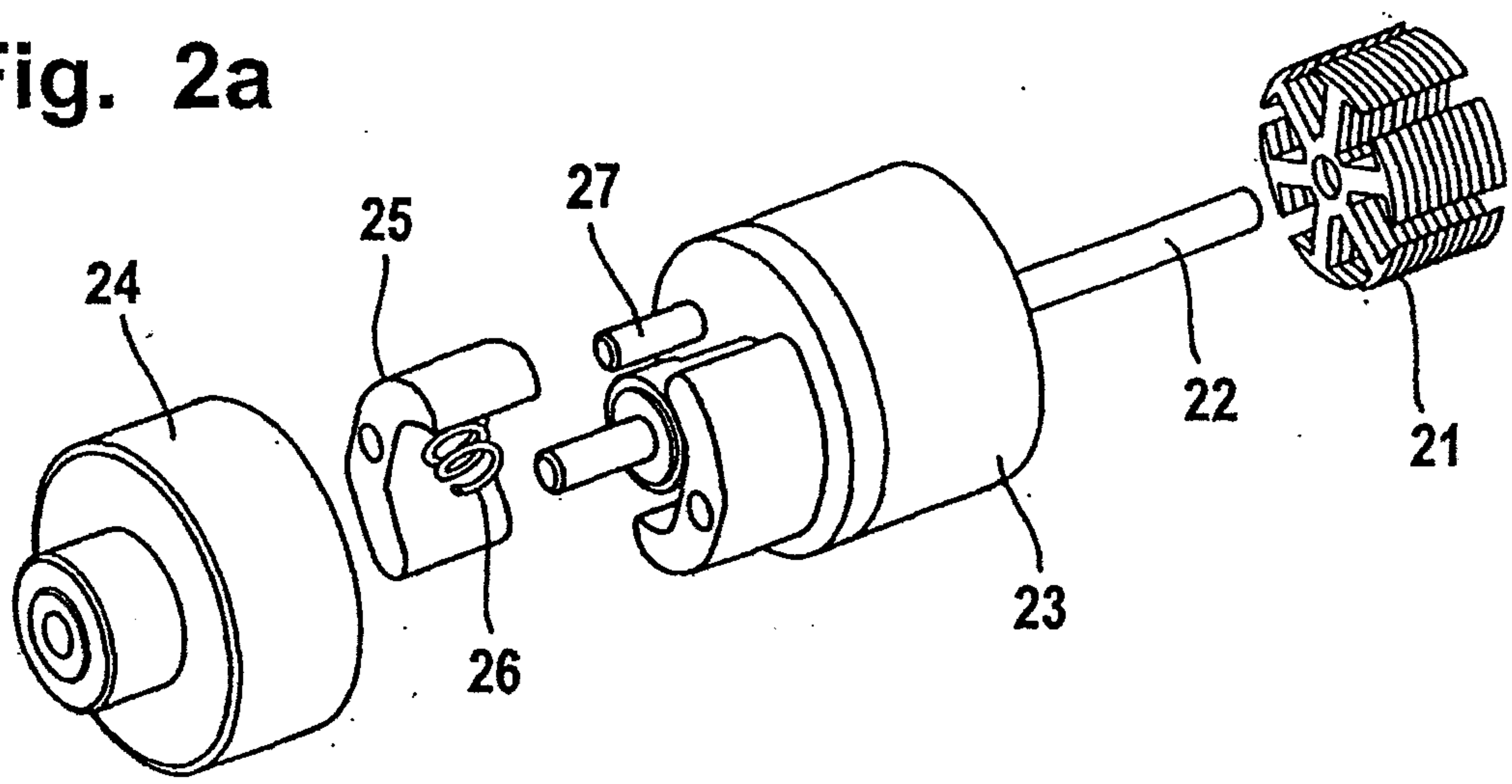


Fig. 2b

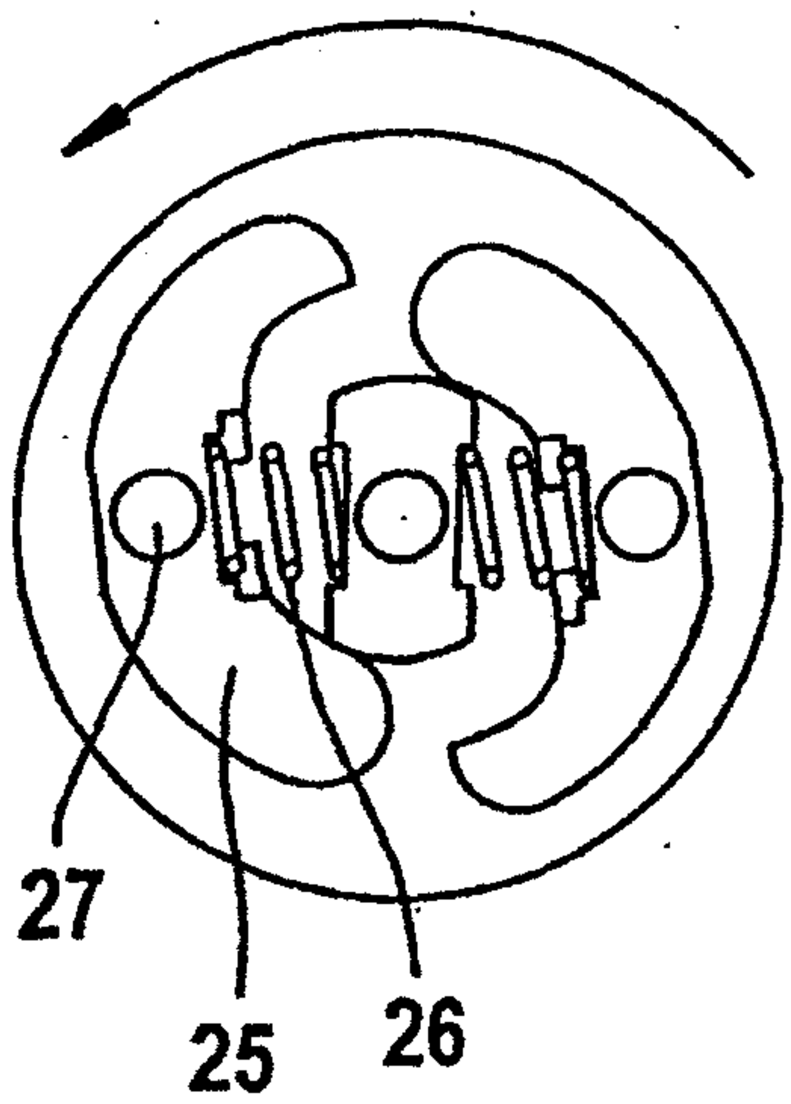
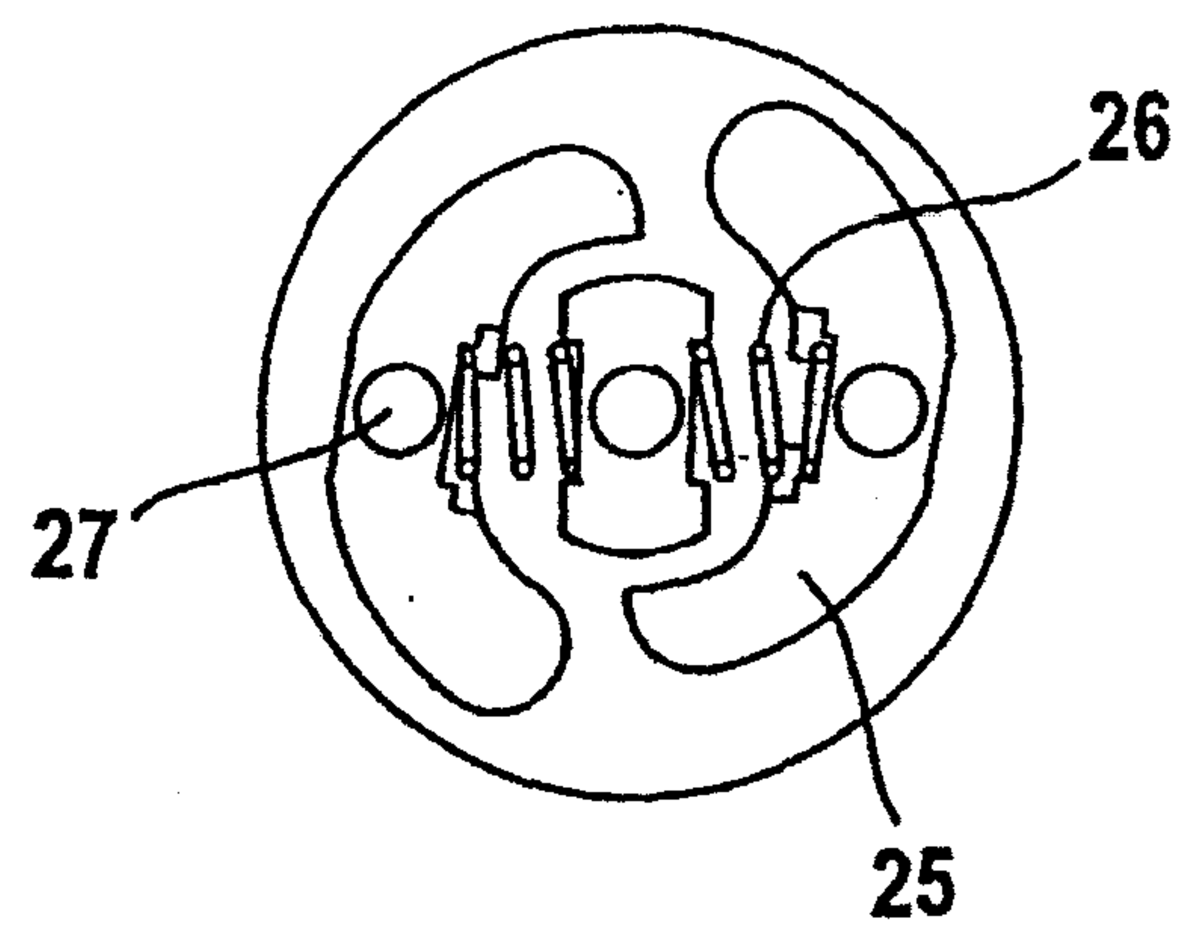


Fig. 2c



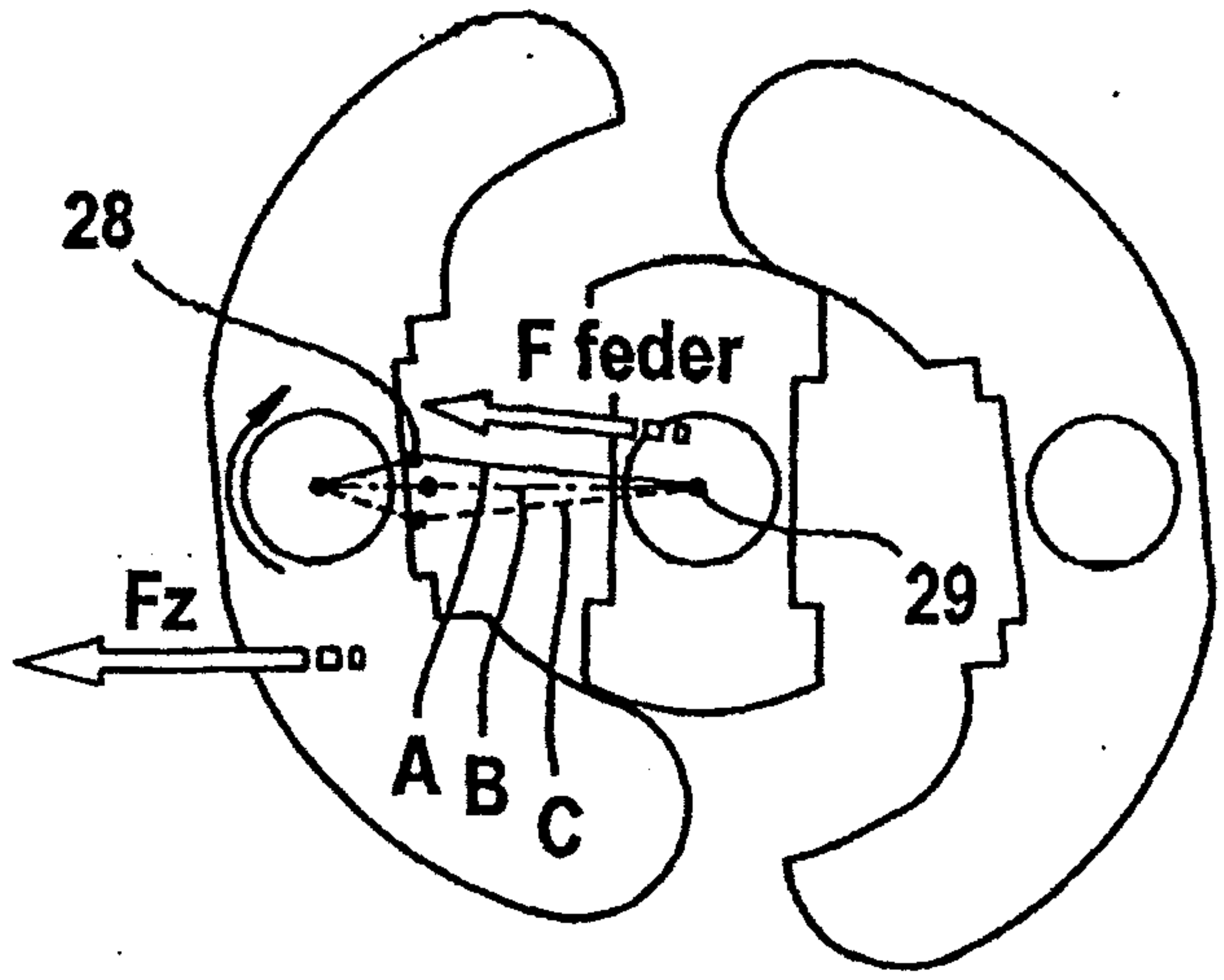


Fig. 2d

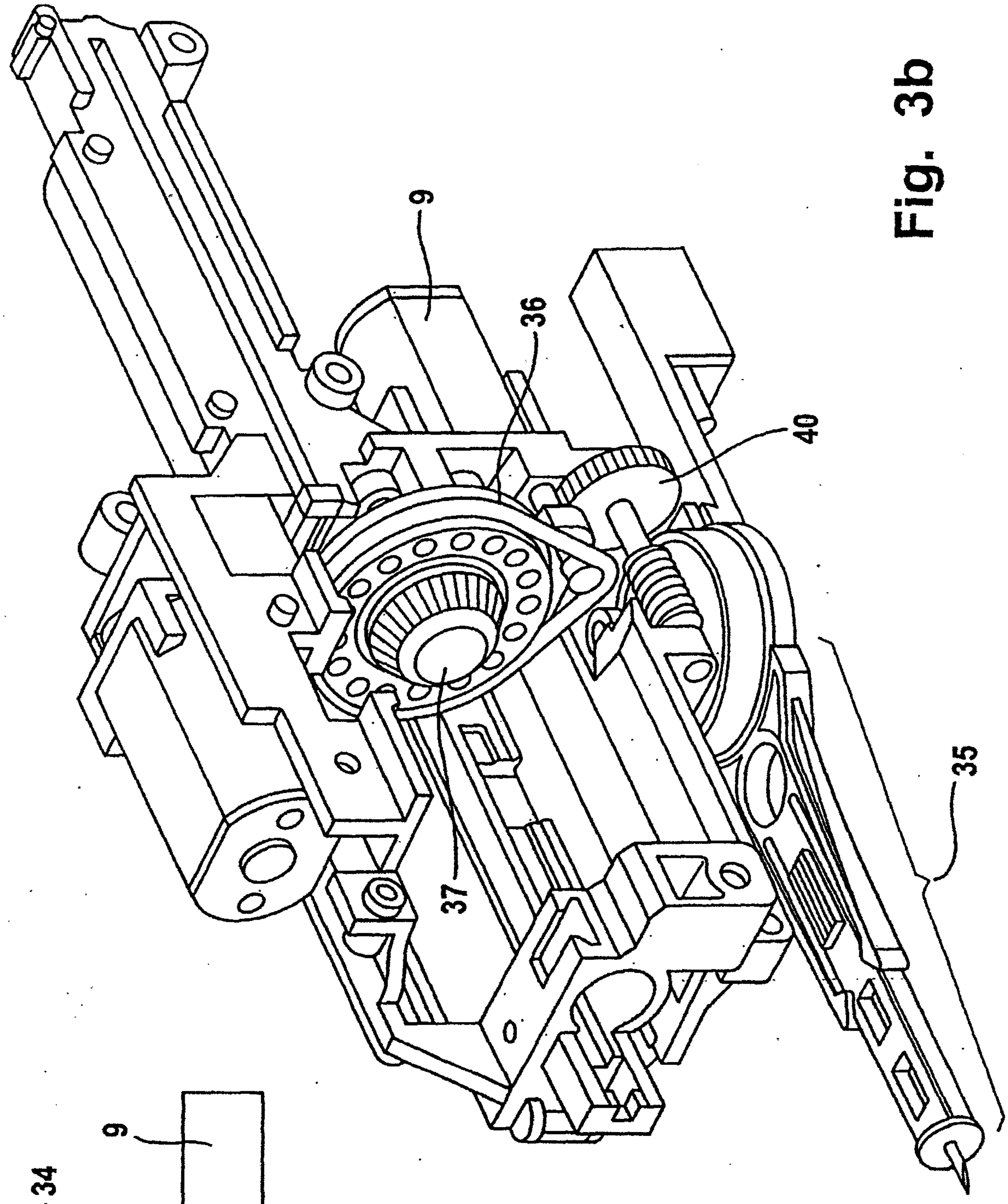


Fig. 3b

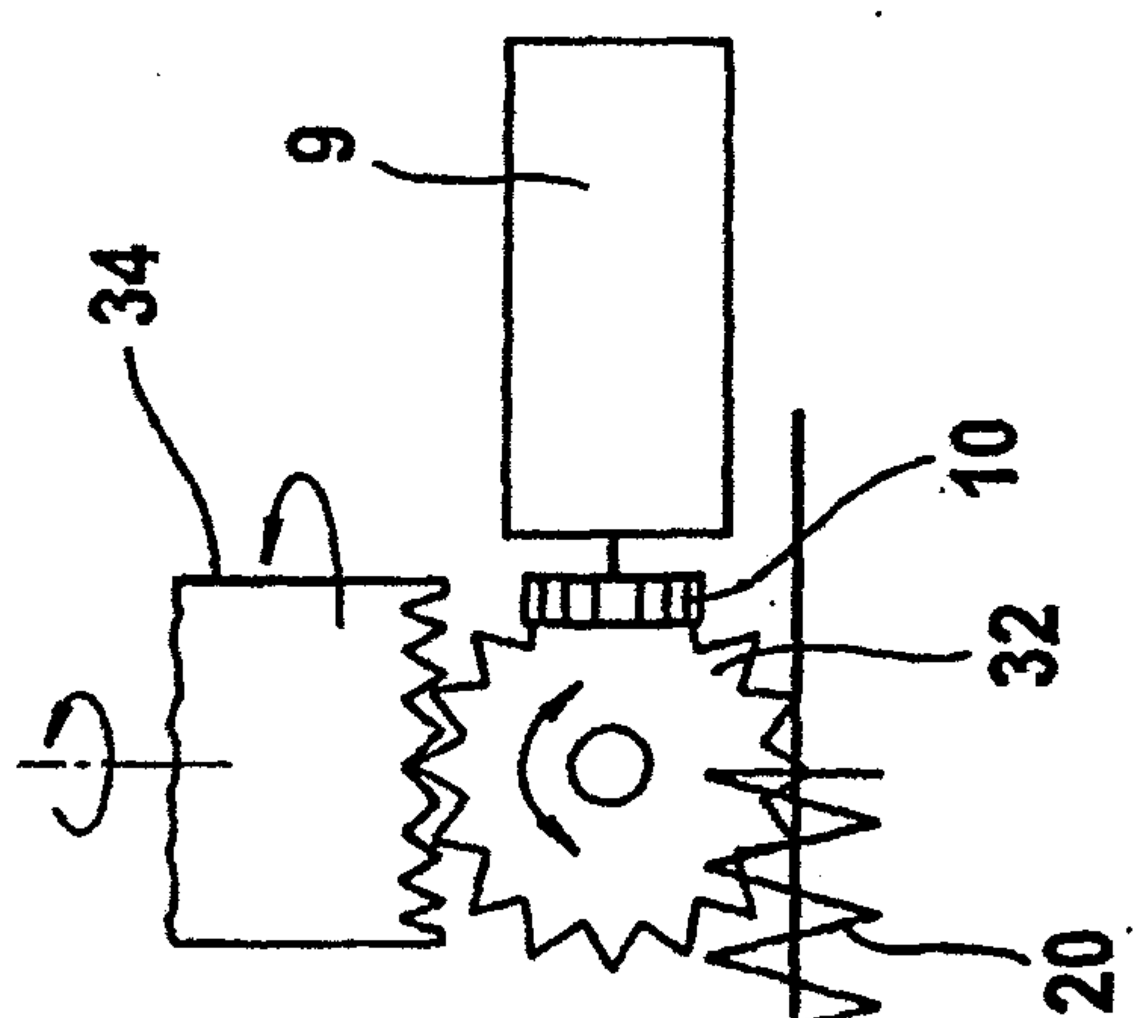
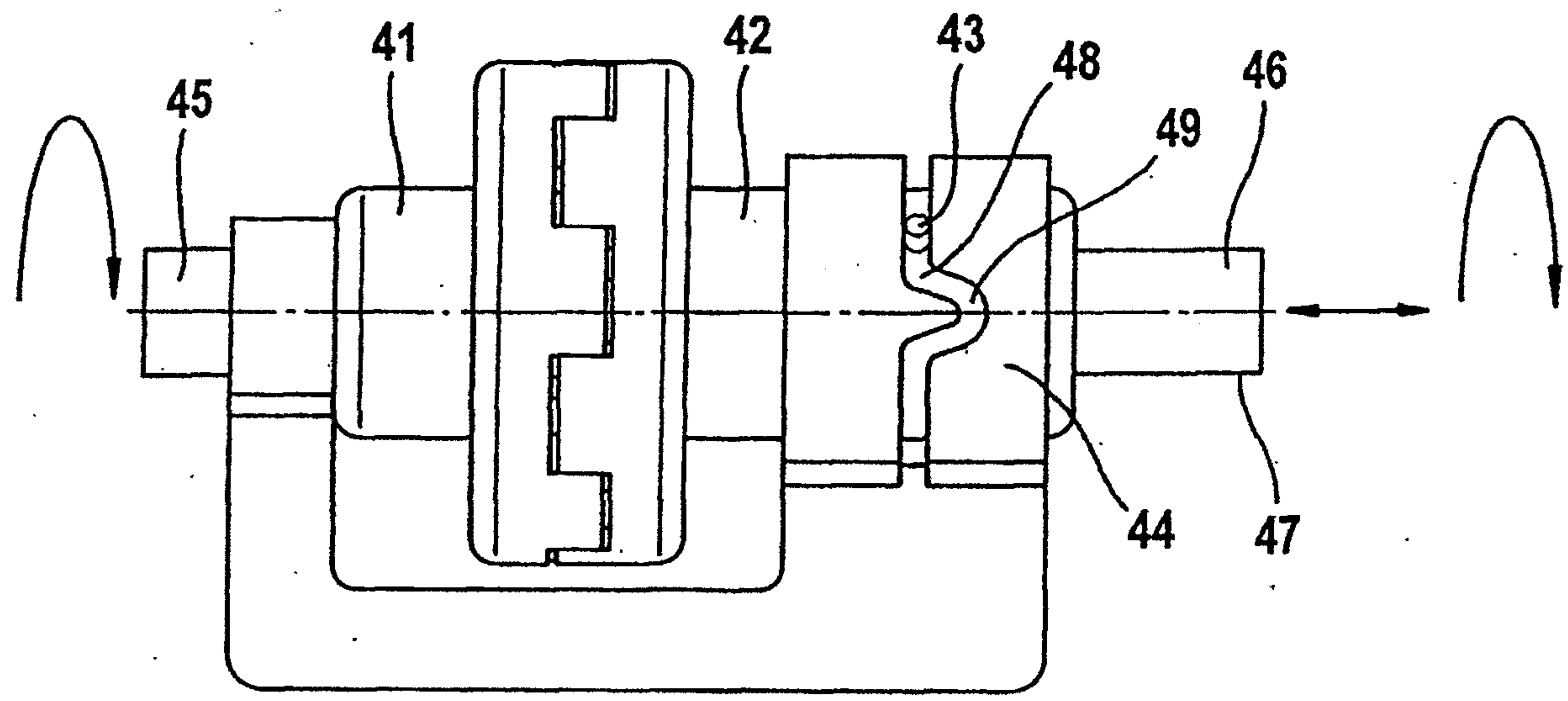
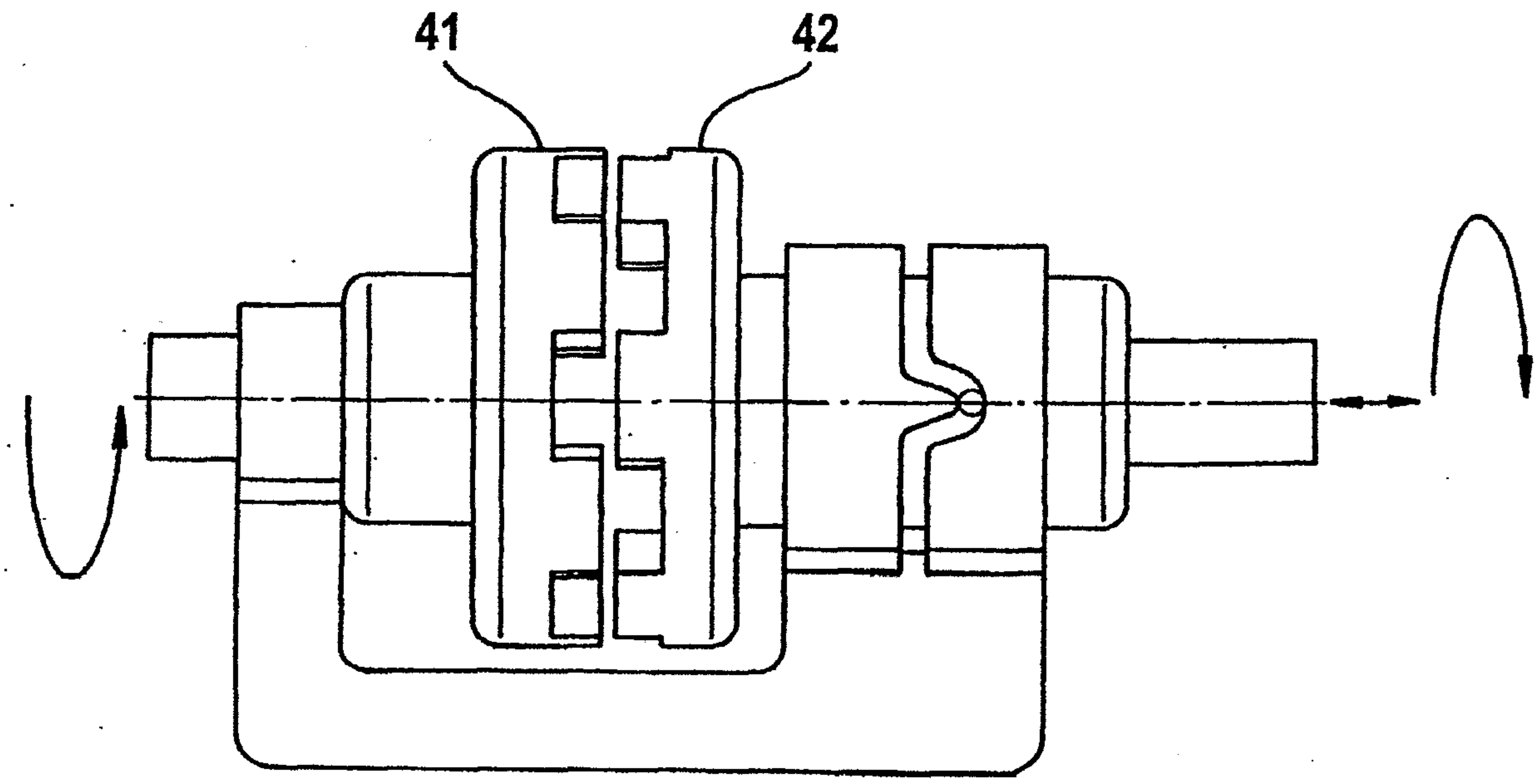


Fig. 3a

Fig. 4





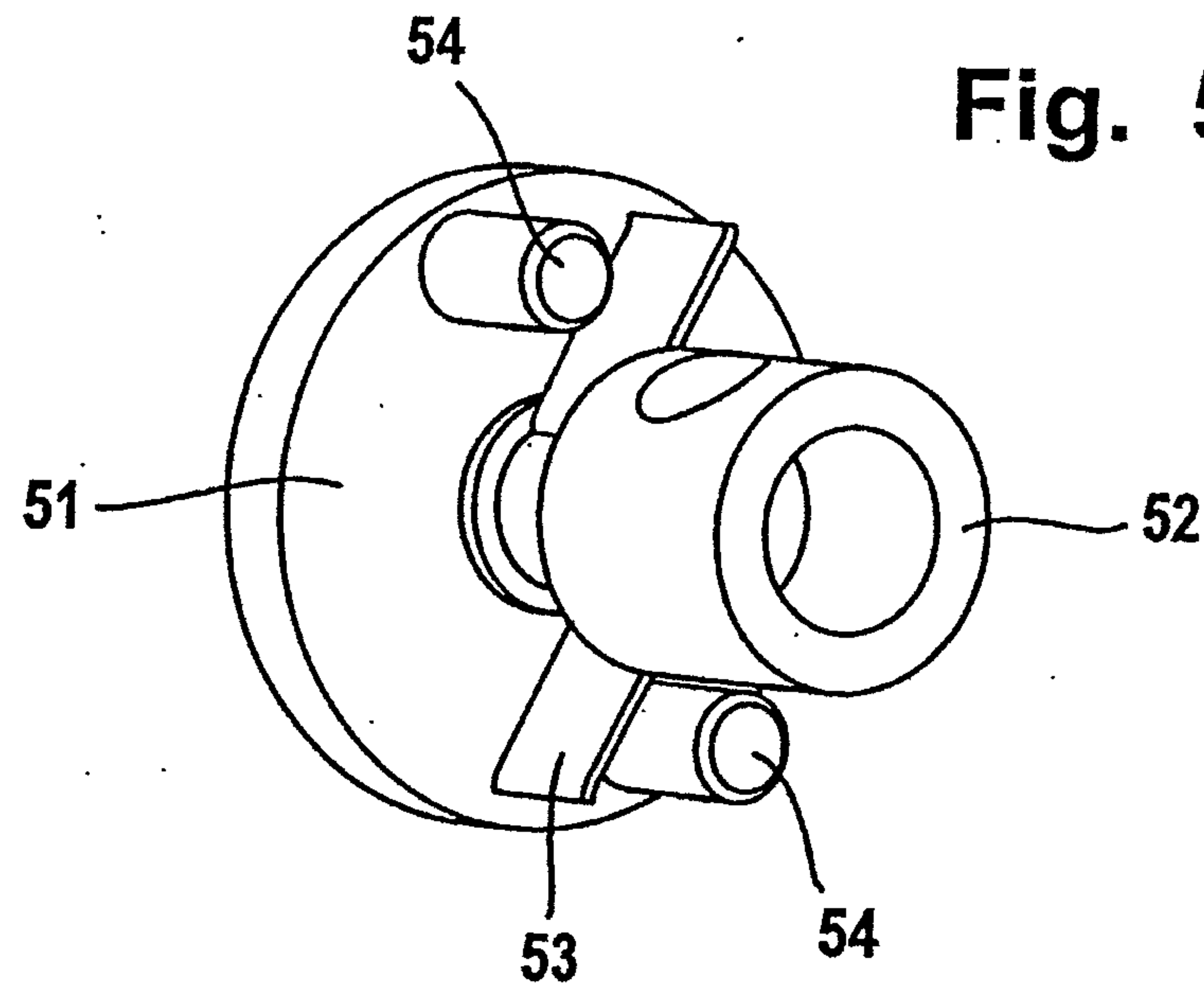


Fig. 5a

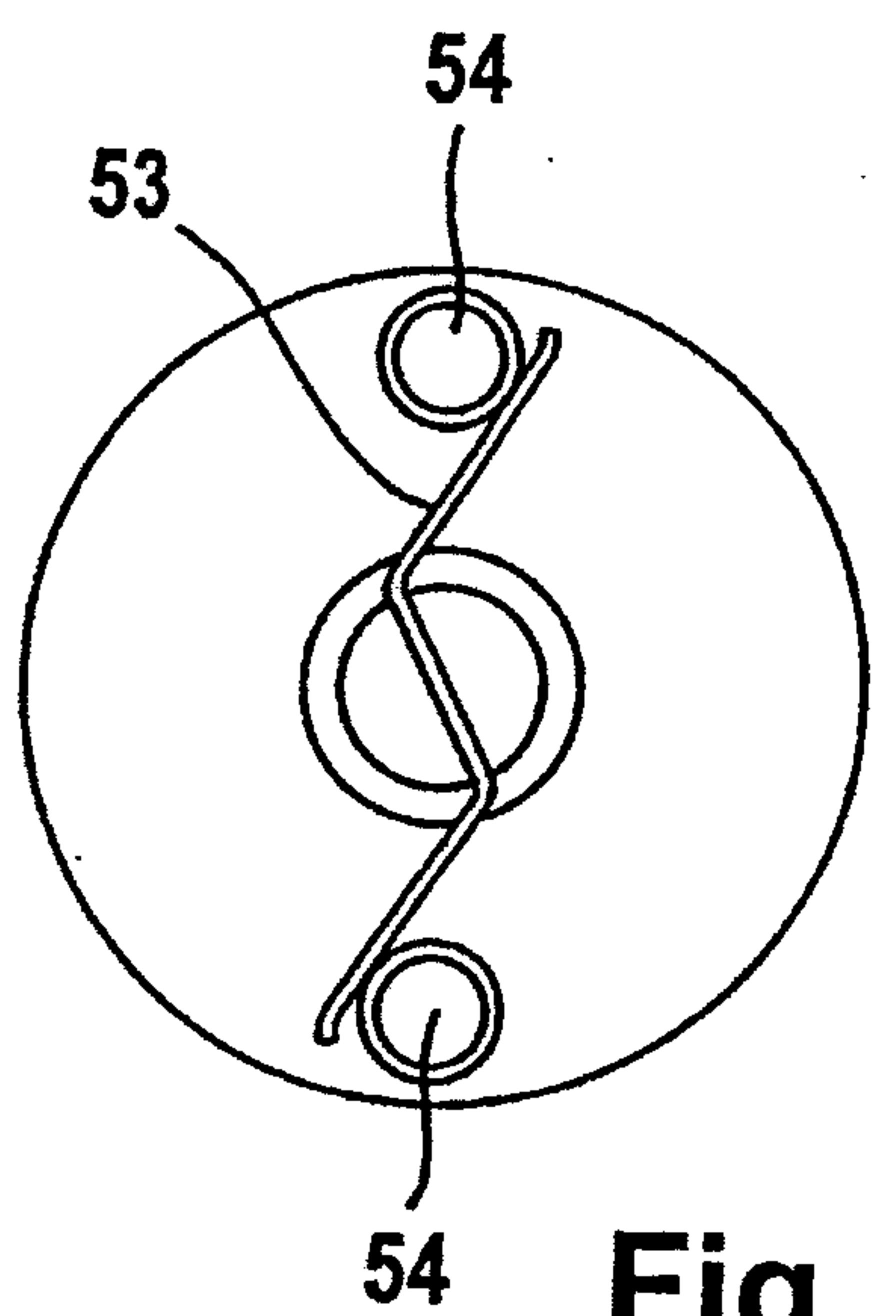


Fig. 5b

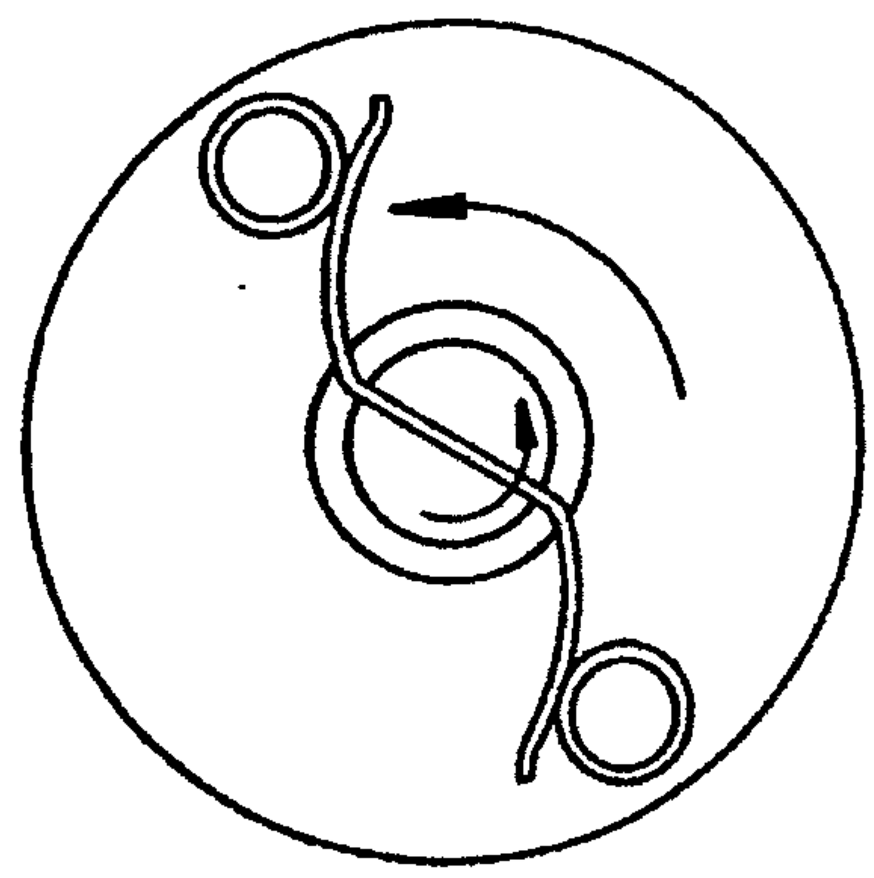


Fig. 5c

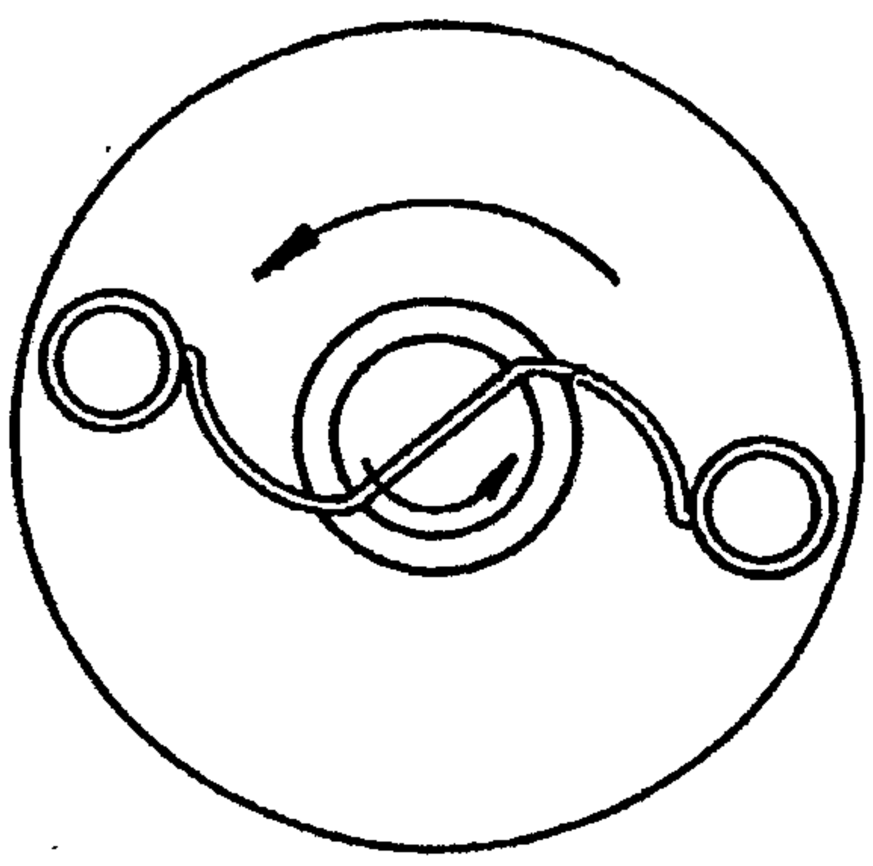


Fig. 5d

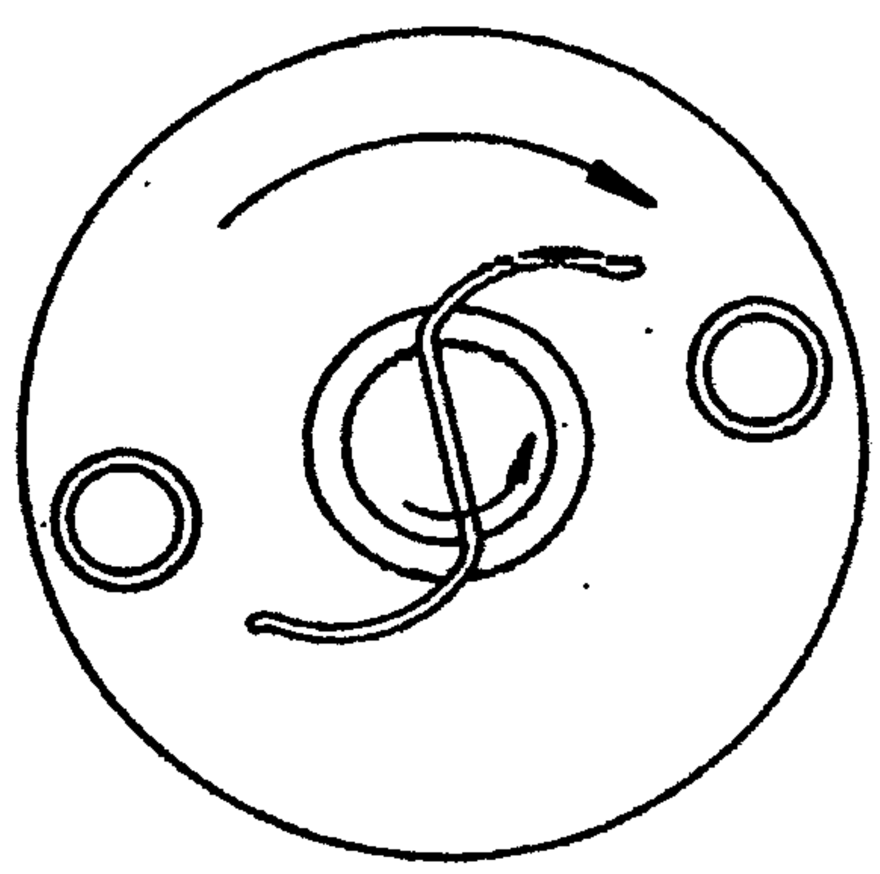


Fig. 5e

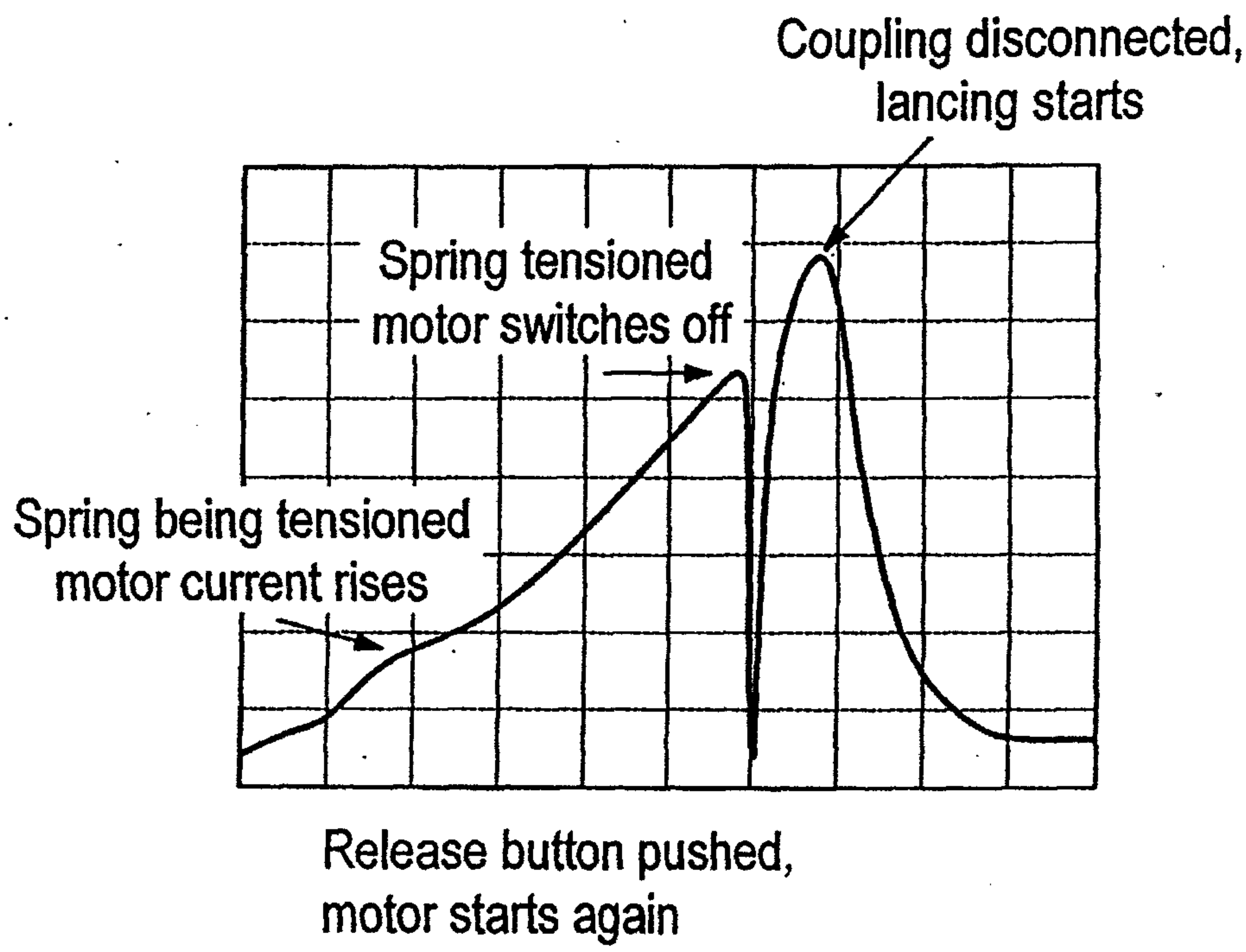

Coupling disconnected,
lancing starts
Spring tensioned
motor switches off
Spring being tensioned
motor current rises
Release button pushed,
motor starts again

Fig. 5f

Fig. 6a

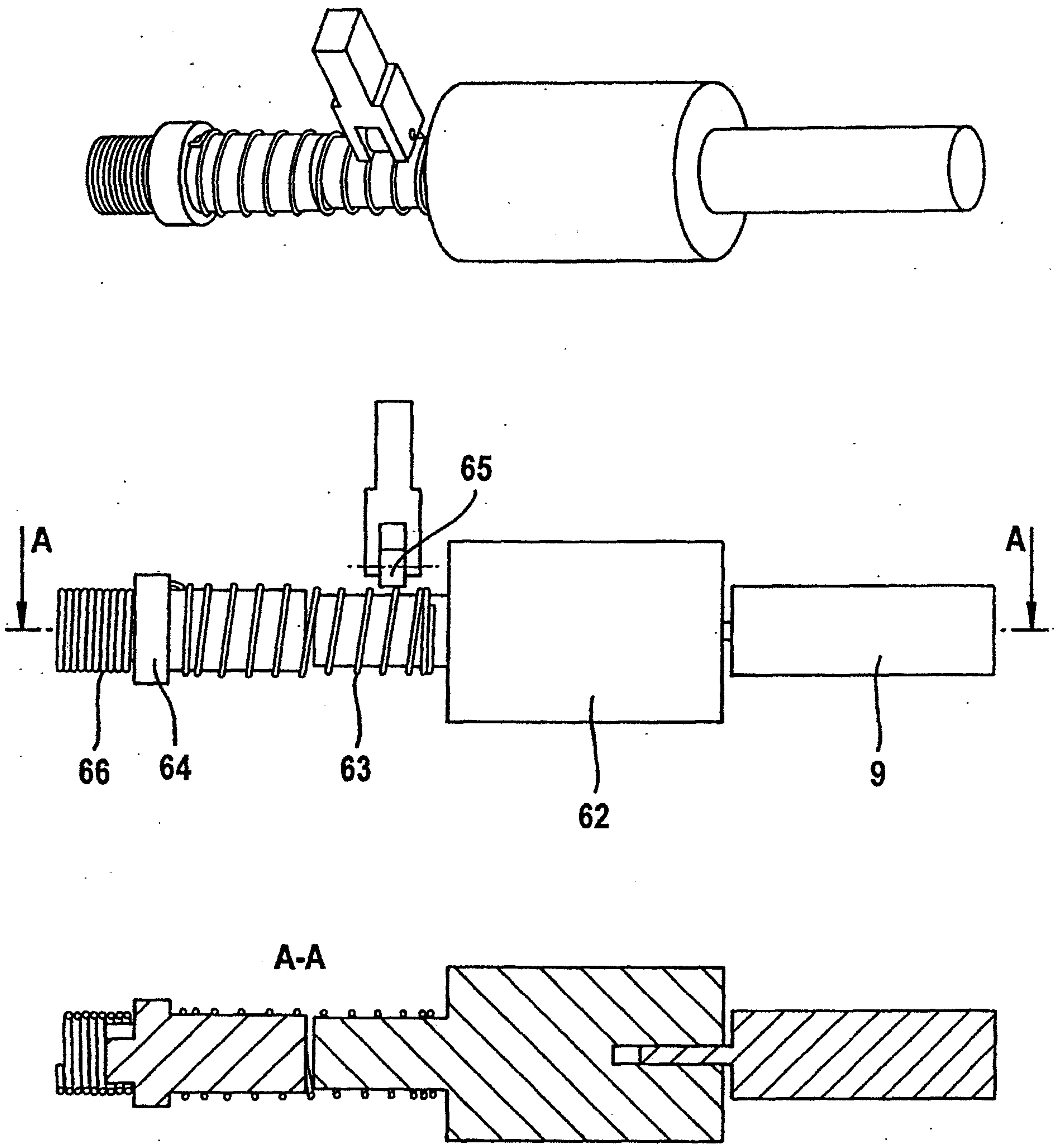


Fig. 6b

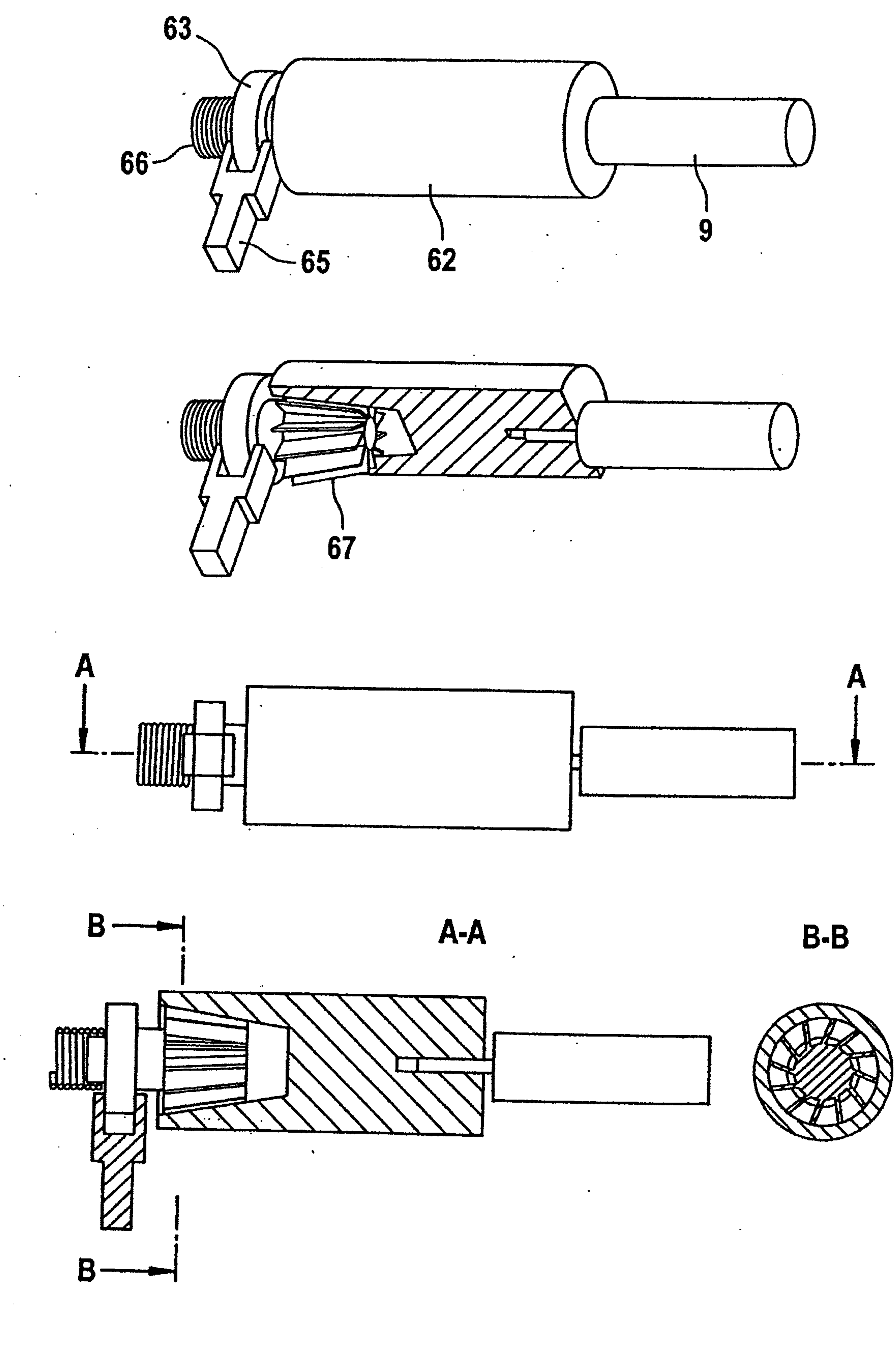
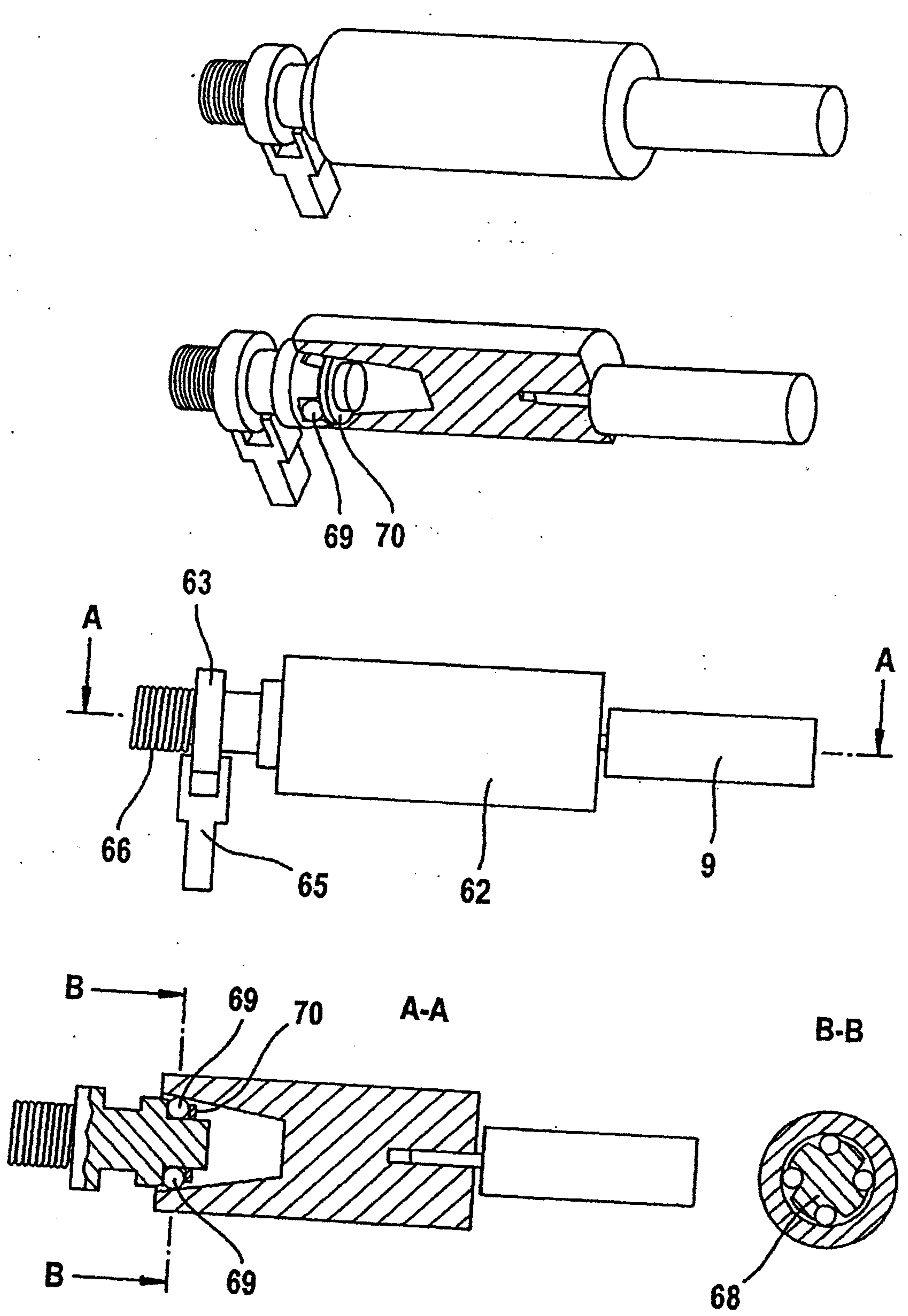


Fig. 6c



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