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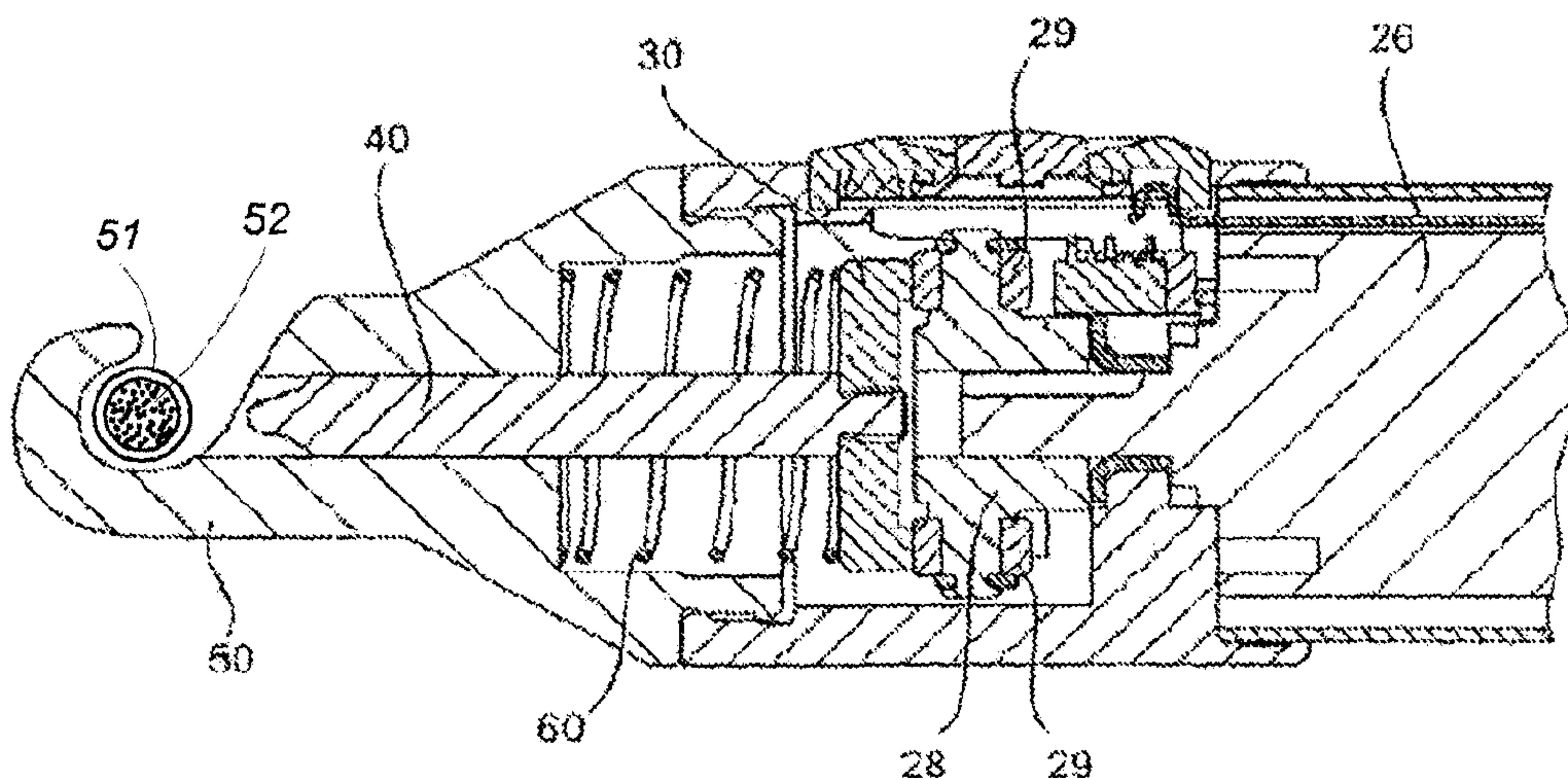
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(54) Title: DEVICE FOR OPENING A LINE



(57) Abrégé/Abstract:

The present application relates to a device for opening a line, particularly the line of a blood tube or blood bag system, wherein the line has a sealing element that blocks the line passage, wherein the device comprises at least one opening unit (10) that is configured such that the same exerts a force acting upon the line from the exterior, whereby the sealing element is pressed together and the line is opened. The opening unit is contoured such that the line can be inserted into the opening unit only such that the force acting upon the line is exerted exclusively, or at least also in the region, in which the locking element is located.

## Abstract

The present application relates to a device for opening a line, particularly the line of a blood tube or blood bag system, wherein the line has a sealing element that blocks the line passage, wherein the device comprises at least one opening unit (10) that is configured such that the same exerts a force acting upon the line from the exterior, whereby the sealing element is pressed together and the line is opened. The opening unit is contoured such that the line can be inserted into the opening unit only such that the force acting upon the line is exerted exclusively, or at least also in the region, in which the locking element is located.

WO 2010/040521

PCT/EP2009/007203

## Device for opening a line

The present invention relates to a device for opening a line, more particularly the line of a blood-tube or blood-bag system, wherein the line has a sealing element that blocks the line passage, wherein the device has at least one opening apparatus that is designed such that it applies a force that acts on the line from the outside, as a result of which the sealing element is compressed and the line is opened.

By way of example, such a device for opening a line has been disclosed in DE 10 2005 019 855 A1. The opening apparatus disclosed therein consists of two jaws that are brought together in an automated fashion or by hand. In doing so, the line section located between the jaws is compressed and the sealing element is deformed plastically, and so a free flow-cross-section is created in the line and also remains free after the action of the opening apparatus.

The clinic staff and staff in blood banks often have to process relatively large numbers of blood-bag sets in order to separate blood into its constituents in a separator and store said constituents in separate containers. This is connected with relatively high demands on the staff because the continual opening of conventional sterile seals in particular requires considerable effort and can, in the long run, lead to pain amongst members of staff. Moreover, the staff are often under significant time pressure, and so the individual method steps have to be carried out over time periods of a few seconds.

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Finally, there is the risk of operating errors and of the sterile seals inadvertently not, or only partly, being opened or having sharp edges in places. Particularly in the case of the presence of sharp edges

WO 2010/040521

- 2 -

PCT/EP2009/007203

in places, there is the risk of the blood constituents becoming damaged as a result of hemolysis.

5 It is therefore necessary to simplify and accelerate the method steps, and at the same time meet high safety and quality standards. This particularly holds true for the opening of sterile seals as have been disclosed in DE 10 2005 019 855 A1.

10 It is important that the opening apparatus for opening the sealing element operates in the shortest time possible and with the highest possible accuracy. In the process, fast and simple operation should be ensured, particularly in the case where the device is designed 15 as a manually actuated device, such that high levels of acceptance are gained amongst users.

WO 2004/058046 A2 has disclosed a blood-processing instrument with an apparatus for opening sterile seals 20 in blood tubes. This opening apparatus can be moved in the axial direction and, additionally, can be rotated. It serves for opening a sterile seal with a breaking cone. As explained above, such sterile seals are 25 disadvantageous in that sharp edges and fragments of the sterile seal can be created in certain circumstances, and these can result in damage to the blood constituents. A further disadvantage of the arrangement described in WO 2004/058046 A2 consists of 30 the fact that the described mechanism is comparatively complex because a continuous to-and-fro motion of the actuator has to be brought about. This is additionally also connected to a certain expenditure of time.

EP 1 294 061 B1 has disclosed a battery-operated 35 pressing instrument for manual operation that works on hydraulic principles and has a comparatively complex design. Such constructions are comparatively difficult to use and cannot be used quickly, as is required for

Opening sterile seals in blood-bag or blood-tube systems quickly and with high precision.

Analogous remarks hold true for the electro-hydraulic handheld tool disclosed in WO 5 03/084719 A2, which serves for pressing tubular objects and cable lugs. The disclosed construction is comparatively complex and heavy, and therefore unsuitable for opening sterile seals.

Analogous remarks hold true for the electro-hydraulic handheld tool disclosed in WO 10 03/084719 A2, which serves for pressing tubular objects and cable lugs. The disclosed construction is comparatively complex and heavy, and therefore unsuitable for opening sterile seals.

Finally, EP 0 106 182 B1 has disclosed a tool for pressing sleeves, cable lugs or the like. This tool also operates on a hydraulic basis. It is unsuitable as a handheld tool for opening sterile seals.

The object of the present invention is to develop a device of the type mentioned at the outset such that it enables quick opening of sterile seals, as known from DE 20 10 2005 019 855 A1, and has a high accuracy.

This object is achieved by a device for opening a line, more particularly the line of a blood-tube or blood-bag system, wherein the line has a sealing element that blocks the line passage, wherein the device has at least one opening apparatus that is 25 designed such that it applies a force that acts on the line from the outside, as a result of which the sealing element is compressed and the line is opened, **characterized** in that the opening apparatus is contoured such that the line can only be introduced into the opening apparatus such that the force acting on the line is applied only in the region where the sealing element is located, or that said force is at least also applied 30 therein.

Accordingly, provision is made for the opening apparatus to be contoured such that the line can only be introduced into the opening apparatus such that the force acting on the line is applied only in the region where the sealing element is located, or that said 35 force is at least also applied therein. The line or the line section with the sealing element can thus only be introduced into the opening apparatus such that the force of pressure applied on the line from the outside acts at a predefined position and the line is thereby opened. Hence there is an operational connection within the meaning of a lock-and-key principle between the opening apparatus and the line 40 section in question and this prevents a line section without the sealing element from inadvertently being introduced into the

WO 2010/040521

- 4 -

PCT/EP2009/007203

opening apparatus. This can reliably prevent the case where, although the opening apparatus is actuated, it does not lead to an opening of the line.

5 Hence, the correct introduction of the line section or line into the opening apparatus is supported by the aforementioned lock-and-key principle. In a preferred embodiment of the invention, provision is moreover made for means that prevent an only partial introduction of  
10 the line. Hence, the user of the device can be supported to the extent that actuation of the opening apparatus is prevented if the line has only been partly introduced into the opening apparatus. By way of example, these means can comprise a spring mechanism  
15 that is embodied such that the line is either pressed out of the opening apparatus or pressed into the correct position in the opening apparatus. Hence, this spring mechanism either presses incorrectly placed lines or line sections out of the opening apparatus or  
20 the receptacle thereof, or presses them into the correct position in which it is possible to open the sealing element.

25 The present invention moreover relates to a device for opening a line, more particularly the line of a blood-tube or blood-bag system, wherein the line has a sealing element that blocks the line passage, wherein the device has at least one opening apparatus that is designed such that it applies a force that acts on the  
30 line from the outside, as a result of which the sealing element is compressed and the line is opened. This device is characterized in that the device or opening apparatus has a processor unit that is designed such that, at certain times, it indicates or initiates the  
35 actuation of the opening apparatus to be undertaken and/or it only initiates this if the line is in the correct position thereof in the opening apparatus

WO 2010/040521

- 5 -

PCT/EP2009/007203

and/or it monitors the opening procedure of the sealing element.

Hence, it is for example feasible for the opening apparatus only to be activated if this is specified by the processor unit. This may become necessary at a certain time within the process (e.g. the cell separation or any other type of blood treatment). If this is the case, the processor unit transmits a signal to the opening apparatus, as a result of which the opening apparatus is actuated and the sealing element is compressed, which results in the desired opening of the line.

Alternatively, or in addition thereto, provision can be made for the processor unit to be designed such that it only initiates the opening of the sealing element by the application of force if the line is in the correct position thereof in the opening apparatus. If this is not the case, provision can be made for the processor unit to prevent an actuation of the opening apparatus.

Alternatively, or in addition thereto, provision can be made for the processor unit to be designed such that it monitors the opening procedure of the sealing element. By way of example, this can be brought about by means of force-measuring elements, torque monitoring or measuring the motor current in a drive unit that actuates the opening apparatus. In the case of a missing line or line section, or if it has been introduced incorrectly or has not been opened flawlessly, provision can be made for the processor unit to interrupt the process and/or influence it in an otherwise expedient manner, for example by alerts or generating an alarm signal.

Provision can be made for the opening apparatus to be designed such that in the case of a fault, if the line

WO 2010/040521

- 6 -

PCT/EP2009/007203

was placed incorrectly and the opening procedure was nevertheless initiated, the sealing element is not damaged to the extent where the sterility of the products is at risk. Thus, the opening procedure can 5 for example be aborted in time and/or the sealing element may only be deformed so slightly that the line remains sealed and hence the sterility of the blood products remains ensured.

10 In a further embodiment of the invention, provision is made for the device or the opening apparatus to have at least one sensor that is designed such that it registers the presence of the line in the opening apparatus and/or the position thereof in the opening 15 apparatus and/or at least one parameter characteristic for the opening procedure of the sealing element. As explained previously, this at least one characteristic parameter can be the force, the torque or the motor current or the like, which occur when the sealing 20 element is opened.

In a preferred embodiment of the invention, provision is made for the sensor to be connected to the processor unit, wherein the processor unit is designed such that 25 it only initiates the actuation of the opening apparatus when the line is in the correct position in the opening apparatus, said position being registered by the sensor.

30 Provision can furthermore be made for the sensor of the opening apparatus to be connected to the processor unit and for the processor unit to be designed such that it interrupts the opening procedure of the sealing element and/or emits an alert, which the user of the device can 35 identify, if the opening procedure deviates from an intended progression. By way of example, this can be the case if the opening procedure was initiated without

WO 2010/040521

- 7 -

PCT/EP2009/007203

the line being placed correctly into the opening apparatus.

The present invention can be embodied in the form of a handheld tool, that is to say in the form of a handheld apparatus. This handheld apparatus is preferably used in methods in which there is at least some manual handling of blood-bag systems for cell separation or for any other blood treatment. However, the invention is not restricted to these but rather also comprises e.g. blood-treatment machines that are formed by the device according to the invention or that have the device according to the invention as a constituent part. In the case of these blood-processing machines, provision can be made for using predominately automated processes for cell separation or any other blood treatment. Provision is preferably made for the sealing element to be likewise opened in an automated fashion or to be initiated at a certain time within the process.

If the tool is a handheld apparatus, provision can be made for a wired or wireless connection to provide a communication link between the handheld apparatus and the processor unit of the device. By way of example, this communication link serves for displaying information on the handheld instrument, such as a user guide that shows the user which sealing element has to be opened at what time by means of the handheld apparatus. In this case, the handheld tool can be operated particularly easily and quickly because the user is advised, for example on a display or acoustically or in any other way, that the sealing element has to be opened or which sealing element has to be opened.

By way of example, the aforementioned processor unit can be arranged in a blood-processing machine and the

sensor or sensors can be arranged in the handheld apparatus.

- 5 However, as explained above, the invention is not restricted to handheld apparatuses but likewise comprises the case where the at least one opening apparatus is a component of a larger unit, more particularly a blood-processing machine.

In a further embodiment of the invention, provision is made for the device as per one  
10 of:

- a device for opening a line, more particularly the line of a blood-tube or blood-bag system, wherein the line has a sealing element that blocks the line passage, wherein the device has at least one opening apparatus that is designed such that it applies a force that acts on the line from the outside, as a result of which the sealing element is compressed and the line is opened, characterized in that the device or the opening apparatus has a processor unit that is designed such that, at certain times, it indicates or initiates the actuation of the opening apparatus to be undertaken and/or it only initiates this if the line is in the correct position thereof in the opening apparatus and/or it monitors the opening procedure of the line;
- a device where the device or the opening apparatus has at least one sensor that is designed such that it registers the presence of the line in the opening apparatus and/or the position thereof in the opening apparatus and/or at least one parameter characteristic for the opening procedure of the sealing element;
- a device where the sensor is connected to the processor unit and in that the processor unit is designed such that it only initiates the actuation of the opening apparatus when the line is in the correct position in the opening apparatus, said position being registered by the sensor;
- a device where the sensor is connected to the processor unit and in that the processor unit is designed such that it interrupts the opening procedure of the sealing element and/or emits an alert, which the user of the device can identify, if the opening procedure deviates from an intended progression;
- a device where the opening apparatus is a component of a handheld apparatus;
- a device where a wired or wireless connection provides a communication link between the handheld apparatus and the processor unit of the device; and
- a device where the handheld apparatus comprises means that are designed such that they indicate to a user of the handheld devices that an opening procedure of a sealing element should be undertaken;

30 to be designed as per:

the opening apparatus being contoured such that the line can only be introduced into the opening apparatus such that the force acting on the line is applied only in the region where the sealing element is located, or that said force is at least also applied therein; or

40 the device moreover comprising means that prevent an only partial introduction of the line into the opening apparatus, wherein the means preferably comprise a spring mechanism that is

embodied such that the line is either pressed out of the opening apparatus or pressed into the correct position in the opening apparatus.

5

This means that in addition to the aforementioned features, the device can also have the feature that the introduction of the line section into the opening apparatus operates according to the lock- and-key principle, as a result of which the introduction of line sections without a sealing element can be prevented.

10

The invention furthermore relates to a device for opening a line, more particularly the line of a blood-tube or blood-bag system, wherein the line has a sealing element that blocks the line passage, wherein the device has at least one opening apparatus that is designed such that it applies a force that acts on the line from the outside, as

15 a result of which the sealing element is compressed and the line is opened. The device is characterized in that the opening apparatus has an opening element and a drive unit, wherein the opening element or the drive unit is connected to a guide and the drive unit or the opening element is connected to a rotational or sliding body, the latter running along the guide and being put into a rotational motion relative to the guide when the drive unit is operated, wherein the 20 guide is designed such that the relative motion between the rotational or sliding body

WO 2010/040521

- 9 -

PCT/EP2009/007203

and guide results in an extension or retraction movement of the opening element.

Hence, it is feasible, for example, for the drive unit 5 to be connected to a rotational or sliding body, which is put into a rotational motion when the drive unit is operated. This rotational or sliding body runs in or on a guide, which is designed such that the aforementioned rotational motion of the rotational or sliding body 10 leads to an extension movement of the opening element. In doing so, provision can be made for the guide to be fixedly connected to the opening element and the rotational or sliding body to be fixedly connected to the drive unit. In principle, it is likewise feasible 15 for the guide to be arranged on the drive unit and the rotational or sliding body to be arranged on the opening element. What is essential is that the relative motion between rotational and sliding body and the guide leads to an extension movement or to a retraction 20 movement of the opening element.

The opening element can be spring-loaded, wherein the spring is arranged such that it applies a force onto the opening element or a component connected thereto, 25 which force is directed counter to the extension movement. Hence the spring element ensures that the opening element is once again retracted once the latter is no longer required for opening the line.

30 The guide can be designed such that there is a constant or substantially constant torque of the drive unit during the extension movement of the opening element. Provision is preferably made for a largely constant torque to be required for providing the force, which 35 increases continuously to a maximum value, and the opening of the sealing element. As a result, use can be made of a comparatively small, light and inexpensive drive.

This embodiment is particularly advantageous if the device is used as a handheld device. By way of example, it is feasible that only one or optionally also a 5 plurality of such handheld instruments are required for a blood-processing machine. The user then only needs to open the sealing element, or successively open the various sealing elements, as per the user guide. Here, the communication with the processor unit can, as 10 explained above, be brought about over wires or radio communication.

However, the invention is not restricted to this, but likewise comprises opening apparatuses that bring about 15 the opening of the sealing elements according to a simple pliers principle with a flat or angled drive.

As explained above, the device can be a blood-treatment instrument, more particularly an instrument for cell 20 separation. However, the invention is not restricted to this.

The term "line" should be understood broadly and comprises any region through which a fluid can flow, 25 such as line sections, tubes and connector regions e.g. of blood-bag systems.

Further details and advantages of the invention are explained in more detail on the basis of an exemplary 30 embodiment illustrated in the drawing, in which:

figure 1: shows a perspective illustration of part of a blood-treatment apparatus with opening apparatus,  
35

figure 2: shows a perspective illustration of an opening apparatus in both an assembled state and an exploded view,

figures 3, 4: show a handheld device for opening sterile seals in both a perspective view and a section,

5

figures 5, 6: show detailed illustrations of the guide and the rotational body of the apparatus as per figure 1, 2,

10 figures 7-12: show detailed illustrations of the rotational body and the guide with opening element, and

15 figures 13-18: show different views and contour illustrations of the guide of the apparatus as per figures 3, 4.

Figure 1 illustrates a perspective illustration of a part 100 of a blood-treatment instrument for cell separation. On its front side, this instrument has an opening apparatus 10 that serves for opening a sealing element as described in detail in DE 10 2005 019 855 Al.

25

The opening apparatus 10 is activated at certain times by a processor unit (not illustrated in any more detail) of the instrument to bring about the compression of the sealing element and hence the 30 opening of the line.

Figure 2a shows the opening apparatus 10 in an enlarged perspective illustration; figure 2b shows the arrangement in an exploded illustration. The reference 35 sign 12 denotes the housing of the arrangement. The reference sign 14 denotes the two elements, which interact like pliers, of a mechanism that prevents the tube section from only partly being introduced into the

WO 2010/040521

- 12 -

PCT/EP2009/007203

illustrated opening apparatus 10. It emerges from figure 2b that these two jaws 14 are loaded by springs 19. The effect of these spring-loaded jaws 14 is that a tube, provided that it was only partly introduced, 5 either is completely pressed into the opening apparatus or is pressed out again. The actual jaws, which preferably interact like pliers, or pliers for opening the sealing element are, from the point of view of the observer, behind the region delimited by the jaws 14 10 and are not illustrated in the figures.

Hence, the correct introduction of the line section into the opening apparatus 10 for opening the sealing element can be supported by a mechanism like the one 15 shown in figure 2b in the form of the spring-loaded jaws 14.

The reference sign 16 denotes the front-side cover and the reference sign 18 denotes the base-side cover, 20 which additionally serves as a breaking apparatus for standard connections.

The opening apparatus 10 as per figures 1, 2 operates according to the pliers-principle. It can have a flat 25 or an angled drive. The contour of the opening apparatus 10 is formed such that the sealing elements, or the line sections containing these, can only be introduced such that they are pressed at the predetermined location and hence the lines are opened. 30 This lock-and-key principle prevents the inadvertent introduction of line sections in which no such sealing element is arranged. The result of this would be that although the opening apparatus is actuated, this would not result in an opening of the line.

35

The opening apparatuses 10 are furthermore connected to a processor unit that obtains information from a sensor of the opening apparatus 10 that a line section with a

WO 2010/040521

- 13 -

PCT/EP2009/007203

sealing element has been introduced and is in the correct position. During the opening procedure, this processor unit monitors the flawless progression of said opening procedure, which monitoring can for 5 example be brought about by means of a force-measuring element, torque monitoring or measuring the motor current. In the case of an incorrectly introduced or missing line section or sealing element, or if the sealing element has not been opened flawlessly, the 10 processor unit can, for example, interrupt or abort the opening process or trigger an alert or an alarm.

The opening apparatus according to the invention can be combined with an aid for opening standard seals 15 (reference sign 18 in figure 2b), which are opened by bending. It can be designed such that the use of conventional blood-bag systems is not a hindrance, but is supported by the aforementioned breaking aid.

20 Figures 3 to 18 relates to a handheld apparatus 20 for opening sealing elements as have been disclosed in DE 10 2005 019 855 A1.

The handheld apparatus has a rod-shaped form; this is 25 shown in figures 3 and 4. It has a rechargeable battery or a battery 22, which drives a DC motor 24. When the motor 24 is actuated, the rotational body 28 is driven, i.e. put into a rotational motion, by the transmission 26 connected to the motor 24. The rotational body 28 30 has axes in its two diametrically opposed regions, on which rotatable wheels 29 are arranged. By way of example, this emerges from the detailed illustrations in figures 5 and 6. These wheels 29 run in a guide 30, which in turn is connected in a non-rotatable fashion 35 to an opening element 40, which emerges from figure 6 in particular. Figures 7 to 12 again show the arrangement of the guide and the wheels 29 driven by

WO 2010/040521

- 14 -

PCT/EP2009/007203

the rotational body 28 in various perspective and sectional views.

If the rotational body 28 is actuated by the motor 24 5 or via the transmission 26, the wheels 29 roll on the surface of the guide 30, which leads to an axial extension or retraction movement of the opening element 40. Figures 6 to 9 show the opening element in the retracted position. If a sterile seal should be opened, 10 the corresponding line section 51 is introduced into the hook-shaped end region 50 of the apparatus 20 and thereupon the opening element 40 is extended as a result of the user actuating a push-button such that the sealing element 52 is compressed and hence the line 51 15 is opened. The return movement of the opening element is brought about by the spring 60, which emerges from figures 7 to 12 in particular. When the opening element is actuated, it partly enters this hook-shaped end section or the clear space formed by the latter and 20 thus compresses the line 51.

It is feasible for the apparatus as per figures 3, 4 to have a sensor that automatically identifies that the line was introduced correctly and automatically 25 initiates the opening procedure. It is likewise feasible for the user to be prompted by a user guide to bring about an extension movement of the opening element 40 by actuating a push-button or a switch.

30 By way of example, the apparatus as per figures 3, 4 can be connected to the blood-treatment instrument over a wired connection, or else wirelessly, and can obtain the corresponding signals therefrom. The communication between these two units can also be bi-directional and 35 for example comprise the transfer of data from which it emerges that the opening procedure has taken place.

WO 2010/040521

- 15 -

PCT/EP2009/007203

Figures 13 to 18 show different perspective illustrations of the guide 30 and the contour lines thereof. The guide 30 is substantially designed as a hollow-cylinder section and has the guide surface 32 on 5 the end side in an end region, with the wheels or sliding bodies or the like, which can be put into a rotational motion by the drive unit, running on said guide surface. Here, the contour of the surface 32 of the guide 30 is embodied such that it does not have a 10 constant incline, but that an almost constant torque is required for applying the force for opening the sealing element, which force increases continuously to a maximum value. The advantage of such an embodiment is that the drive can have a comparatively small, light 15 and inexpensive design.

**Claims**

1. A device for opening a line, wherein the line is a tube in which there is a sealing element that blocks a line passage, wherein the device has at least one opening apparatus that is

5 designed such that it applies a force that acts on the line from the outside, as a result of which the sealing element is compressed and the line is opened, wherein the opening apparatus is contoured such that the line can only be introduced into the opening apparatus such that the force acting on the line is applied at least in the region where the sealing element is located.

10

2. The device of claim 1, characterized in that the device moreover comprises means that prevent an only partial introduction of the line into the opening apparatus.

15

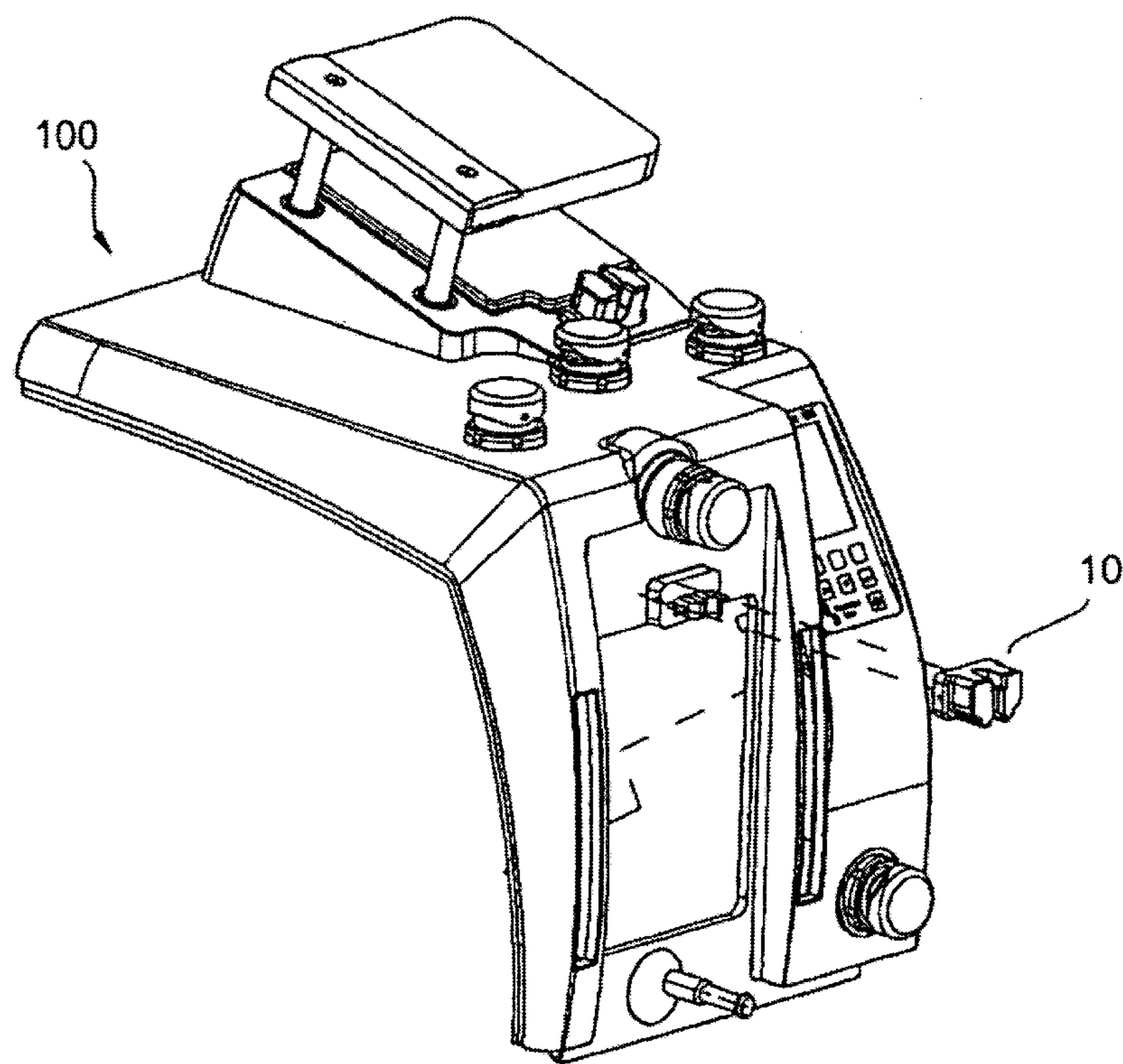
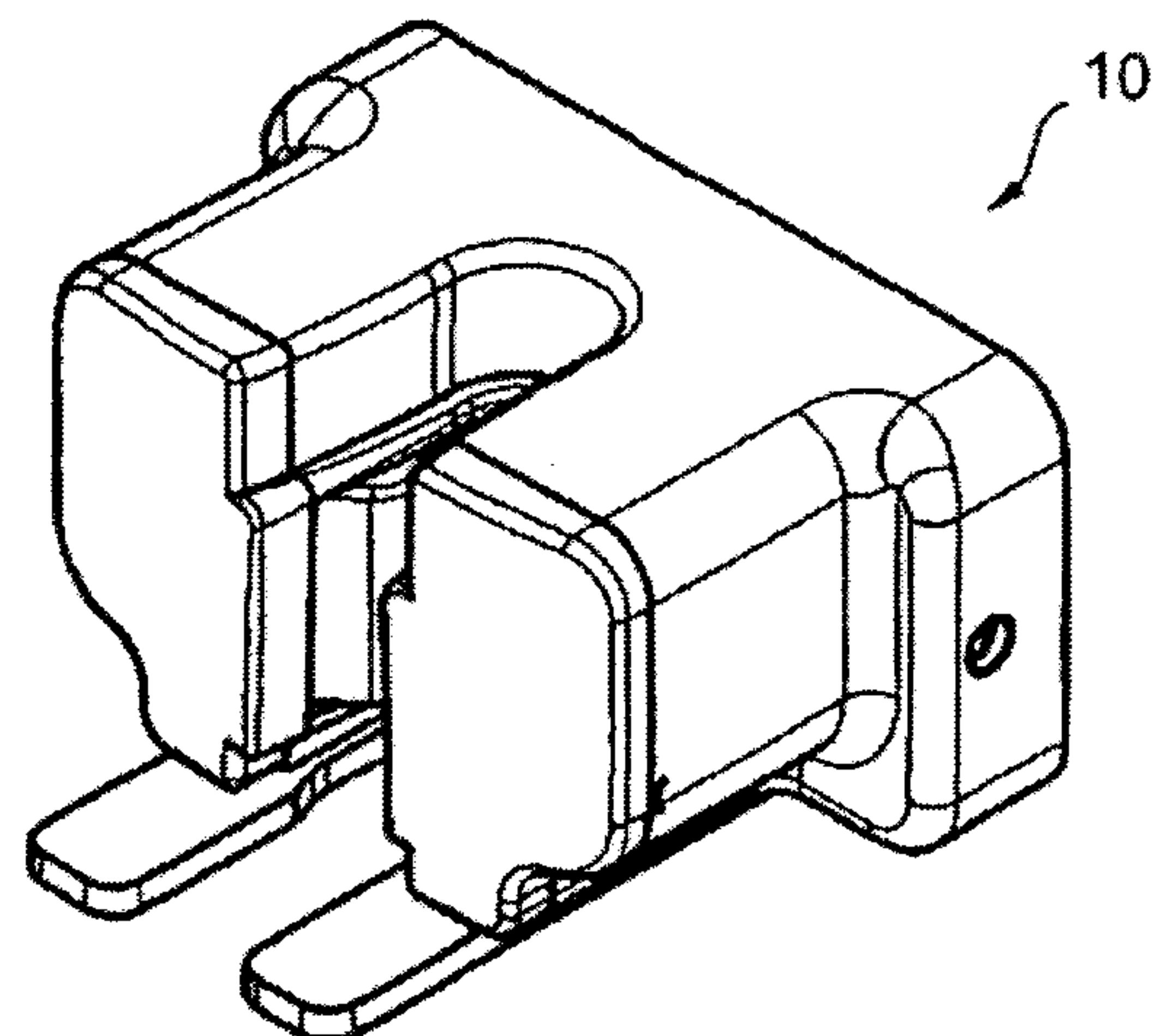
3. The device of claim 2, wherein the means comprise a spring mechanism that is embodied such that the line is either pressed out of the opening apparatus or pressed into the correct position in the opening apparatus.

4. The device of any one of claims 1 to 3, wherein the line is the line of a blood-tube or blood-bag system.

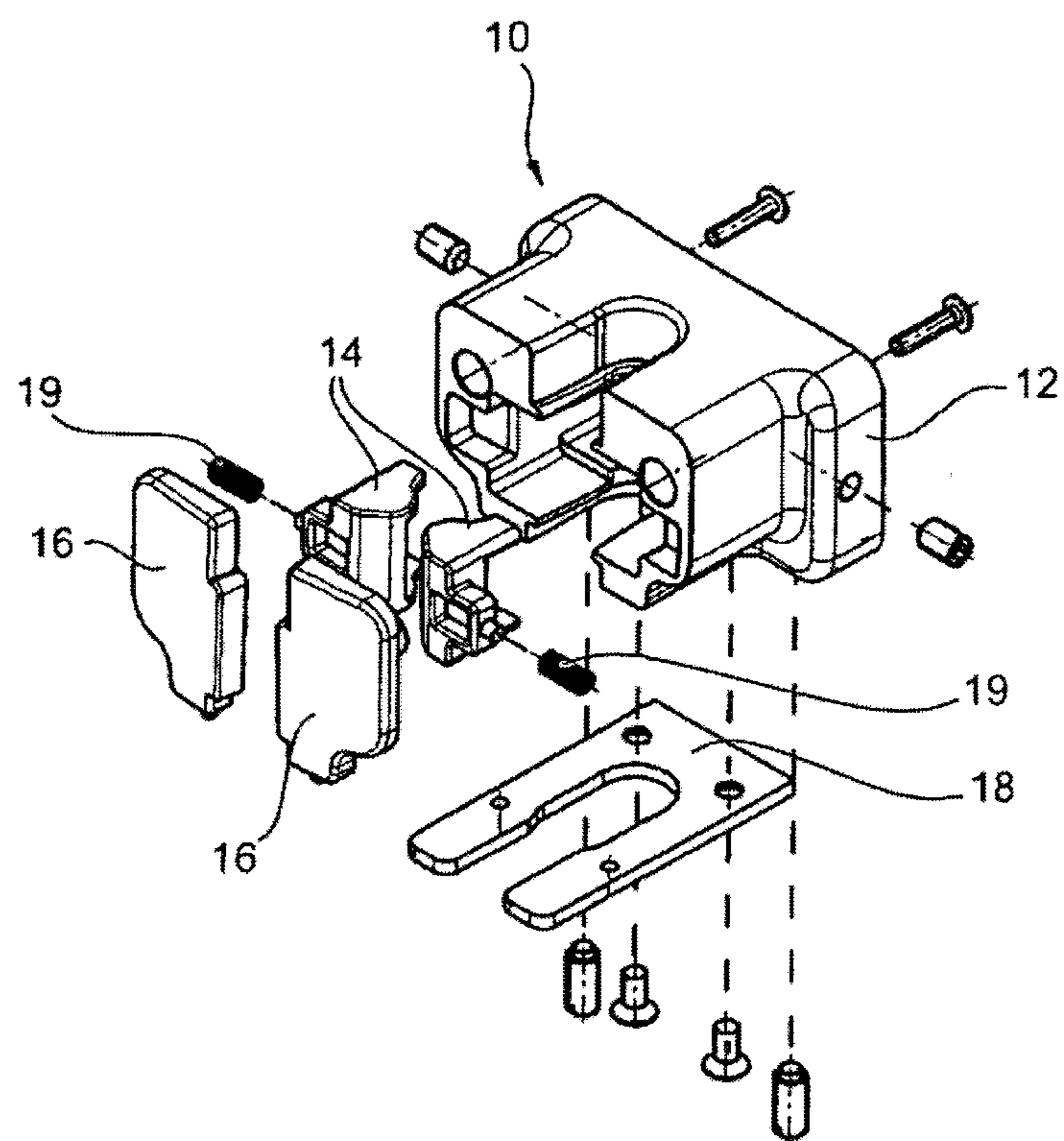
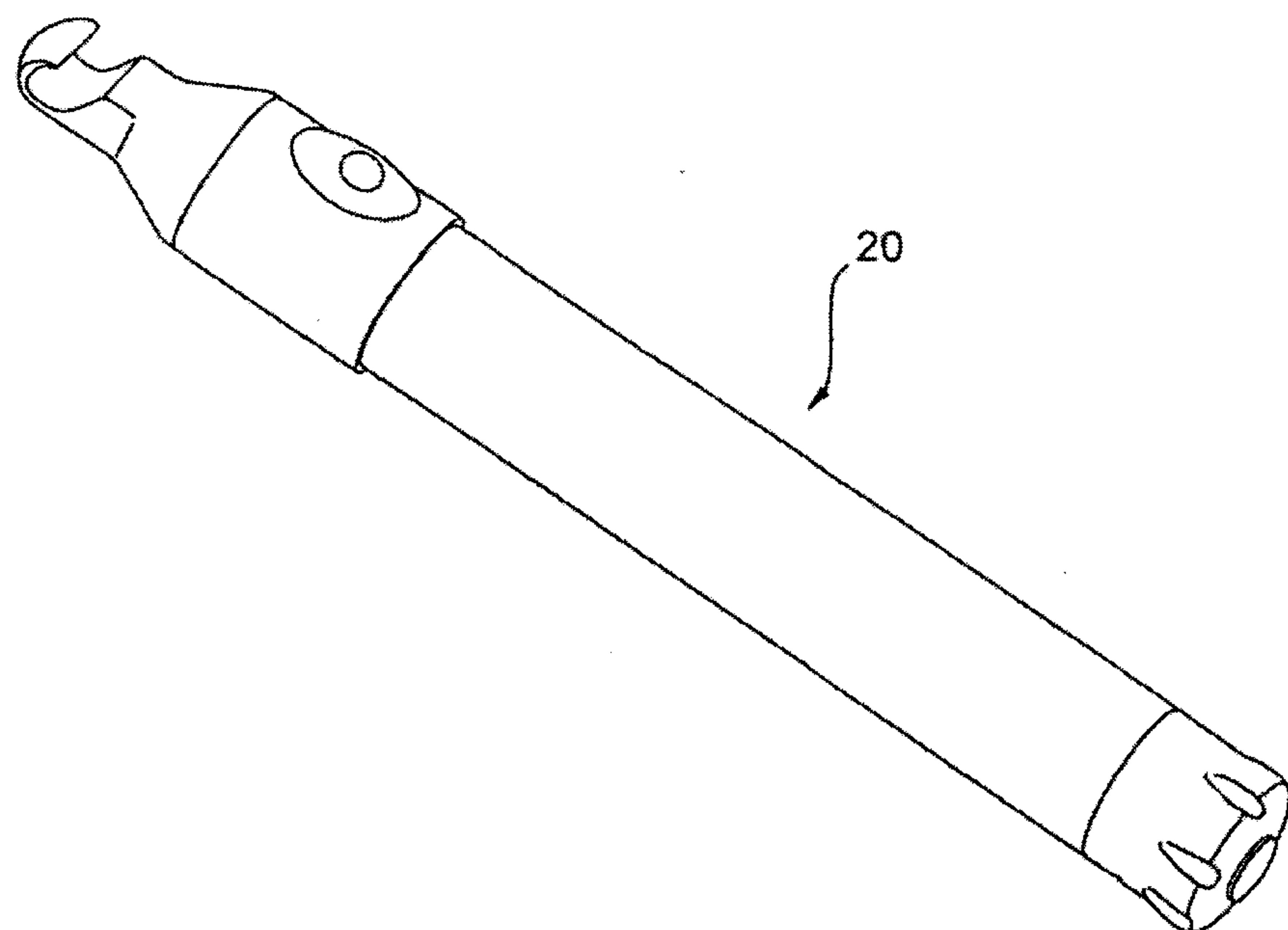
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5. The device of any one of claims 1 to 4, wherein the force is applied only in the region where the sealing element is located.

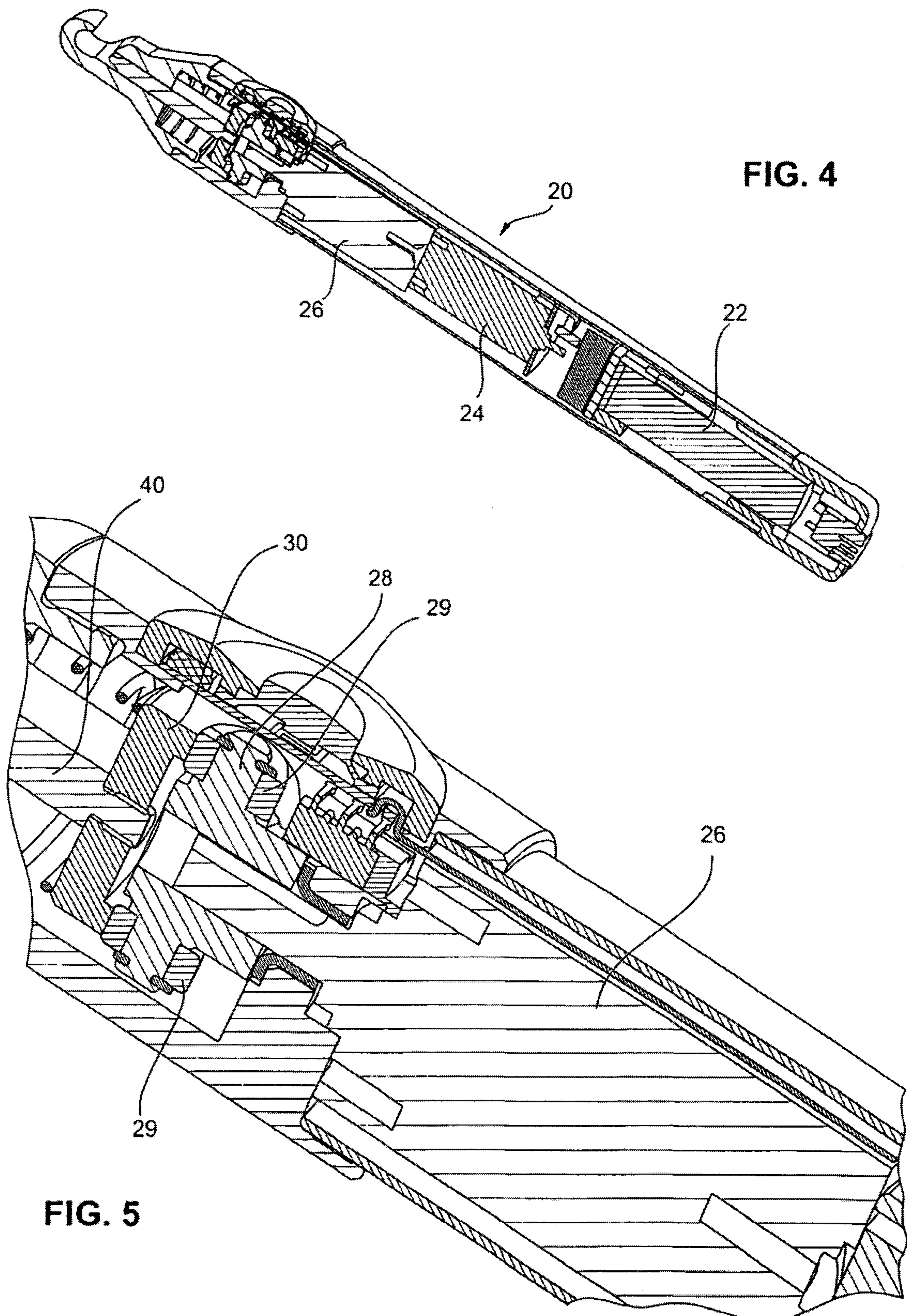
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**FIG. 1****FIG. 2a**

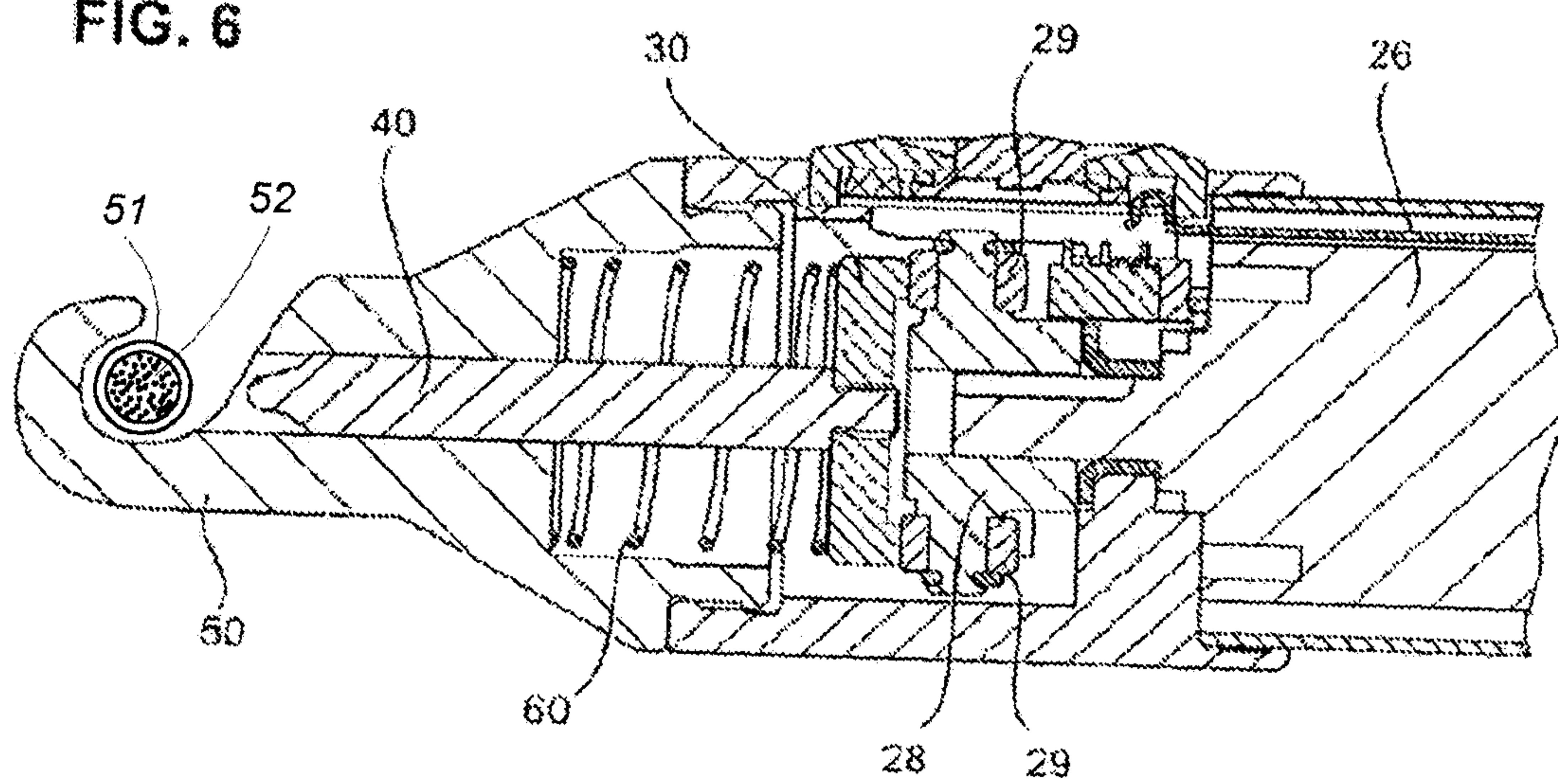
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**FIG. 2b****FIG. 3**

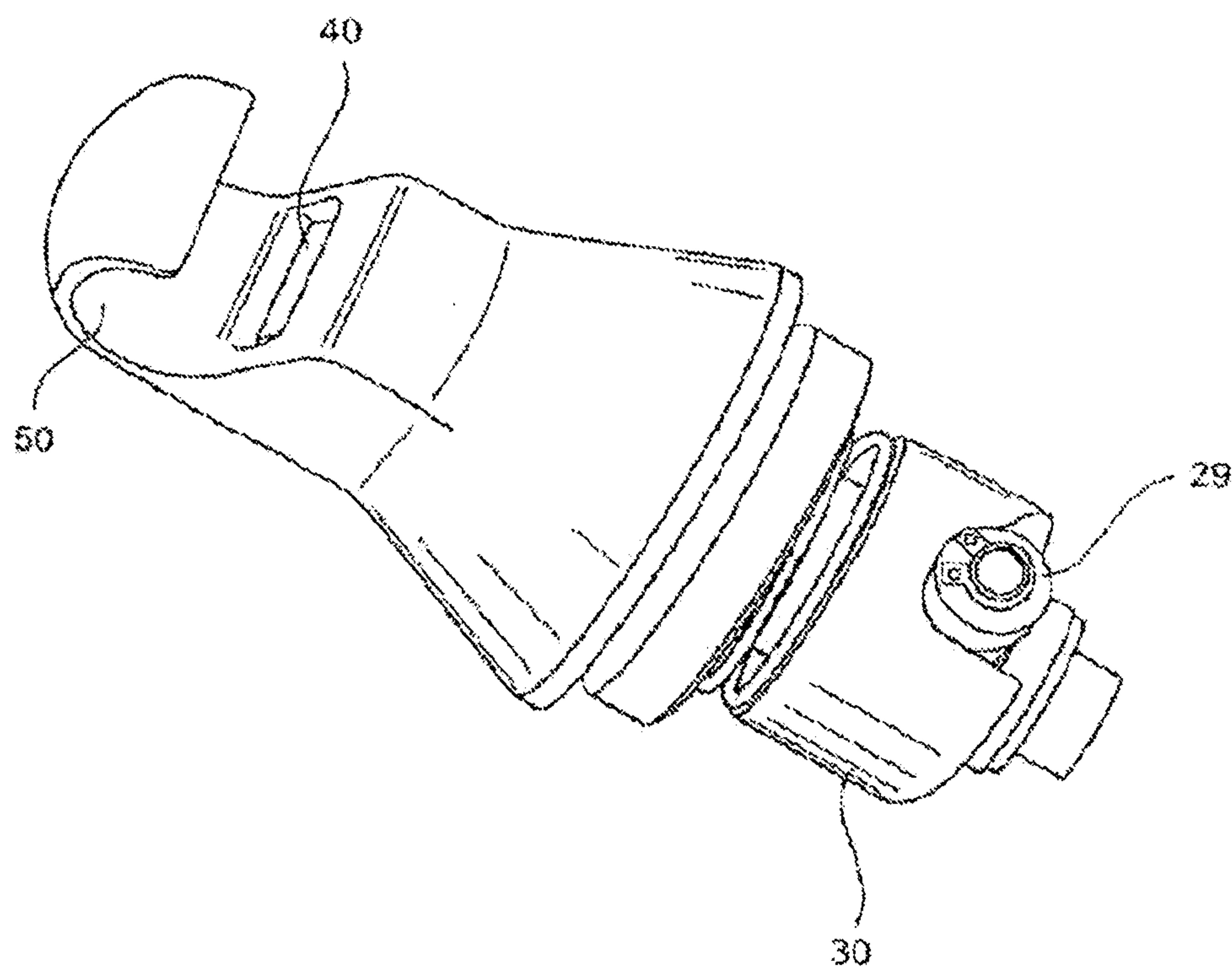
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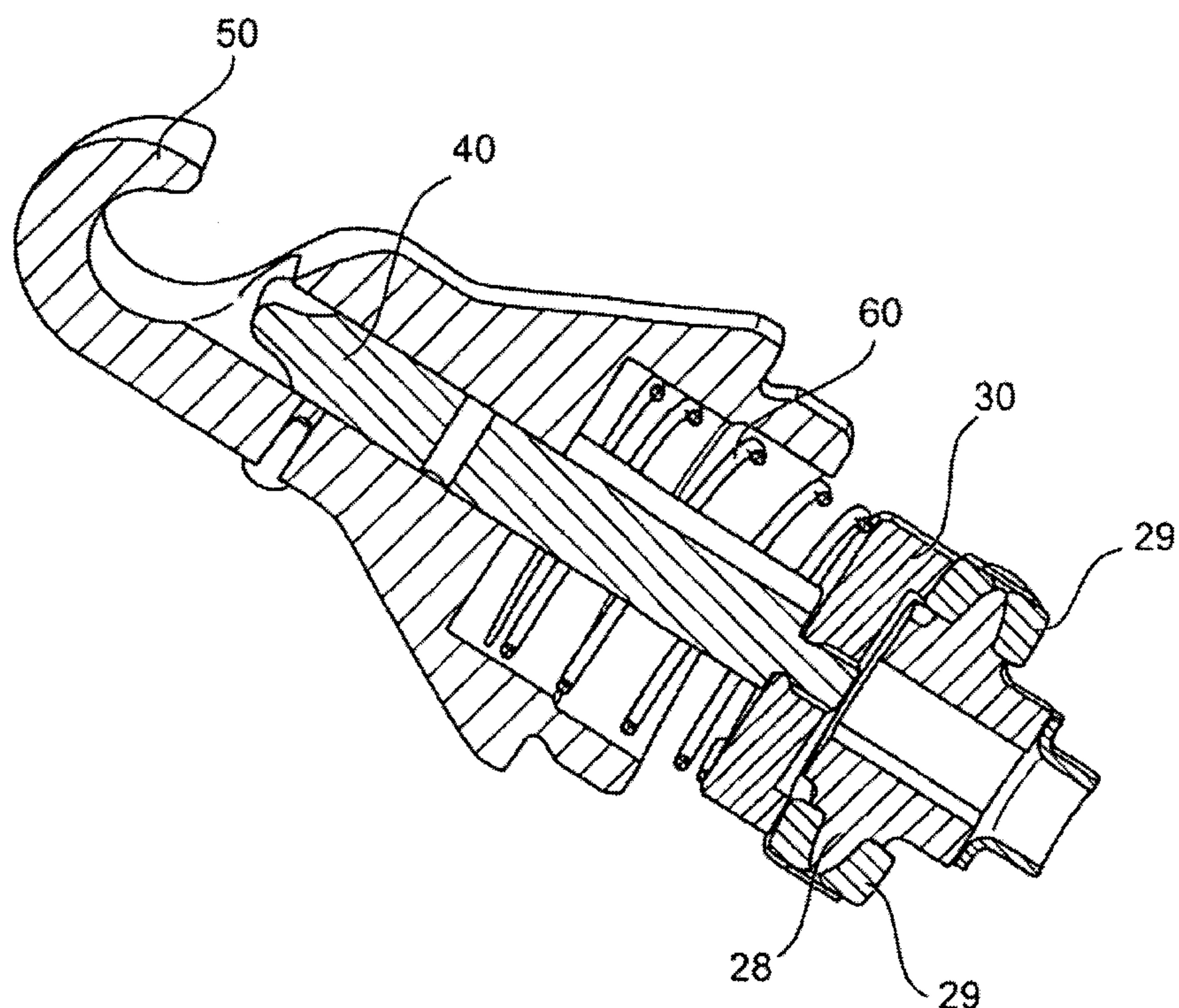
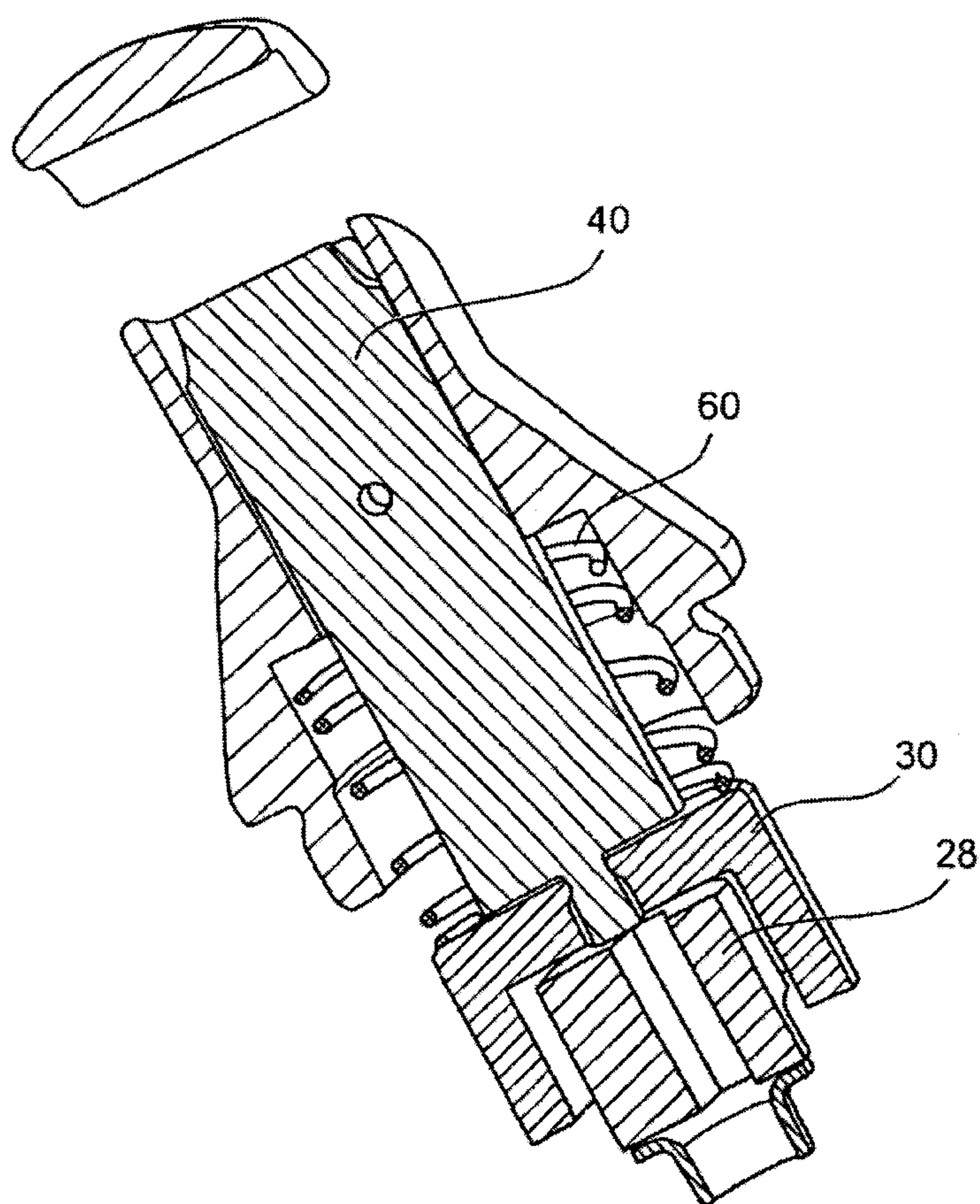
**FIG. 6**



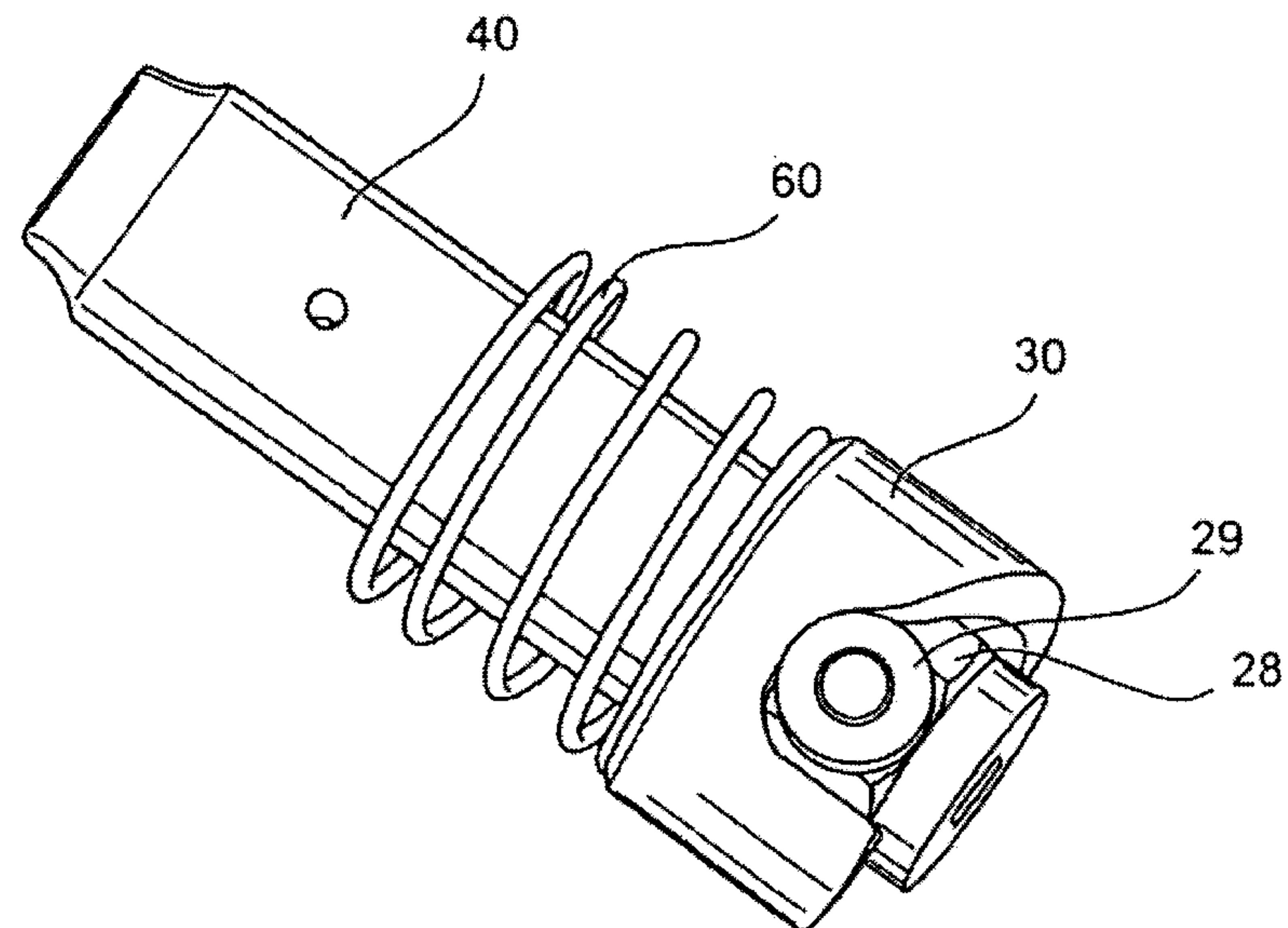
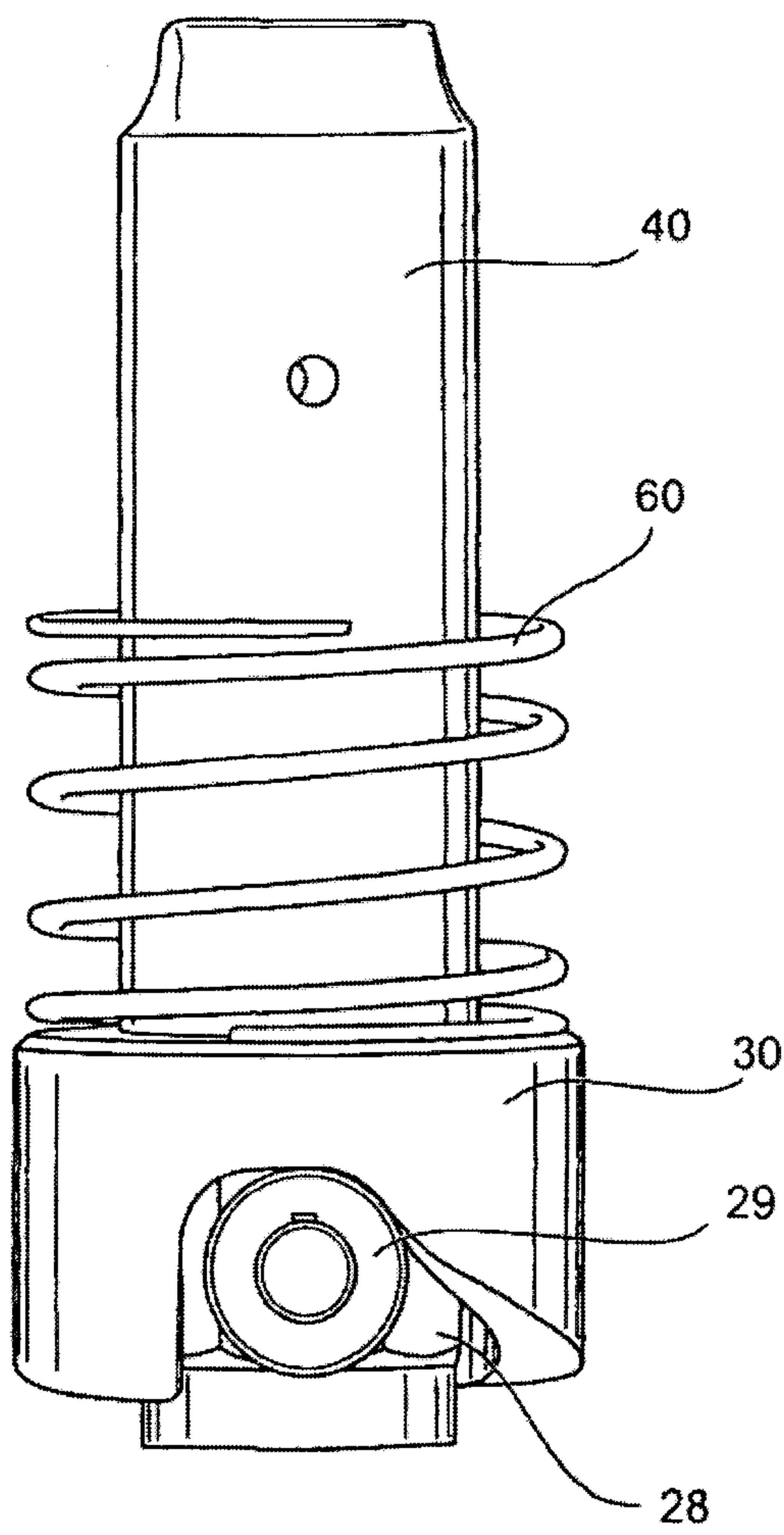
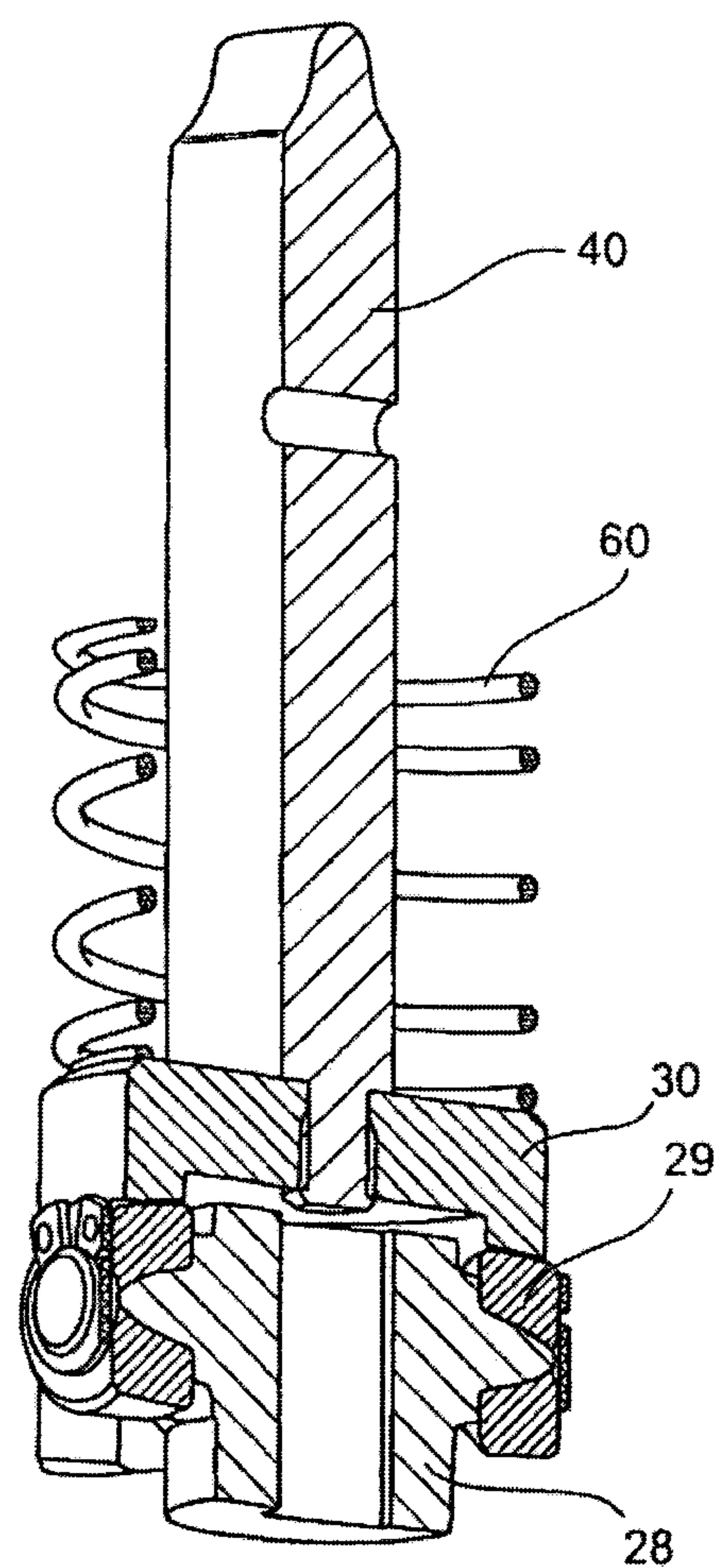
**FIG. 7**



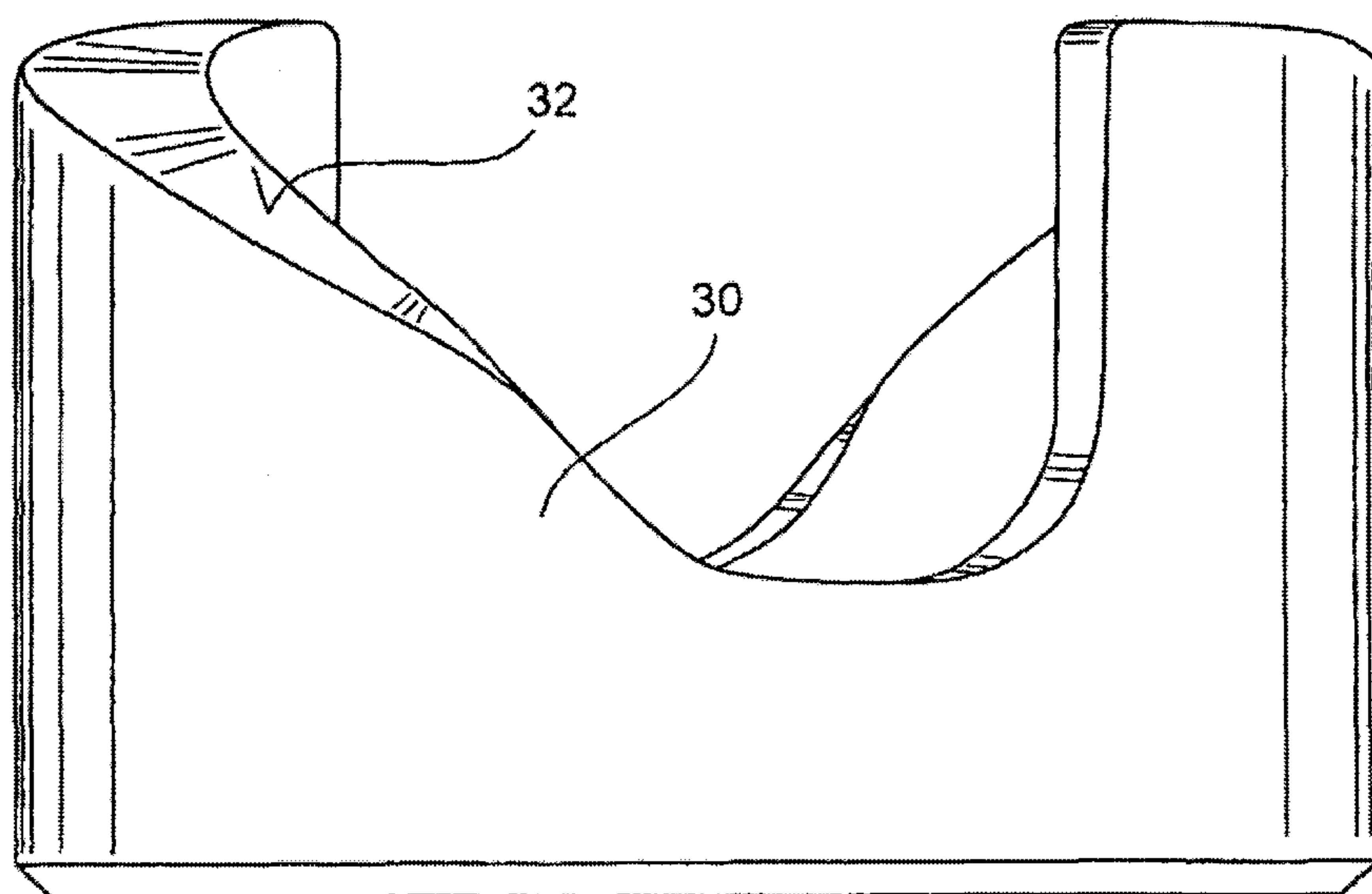
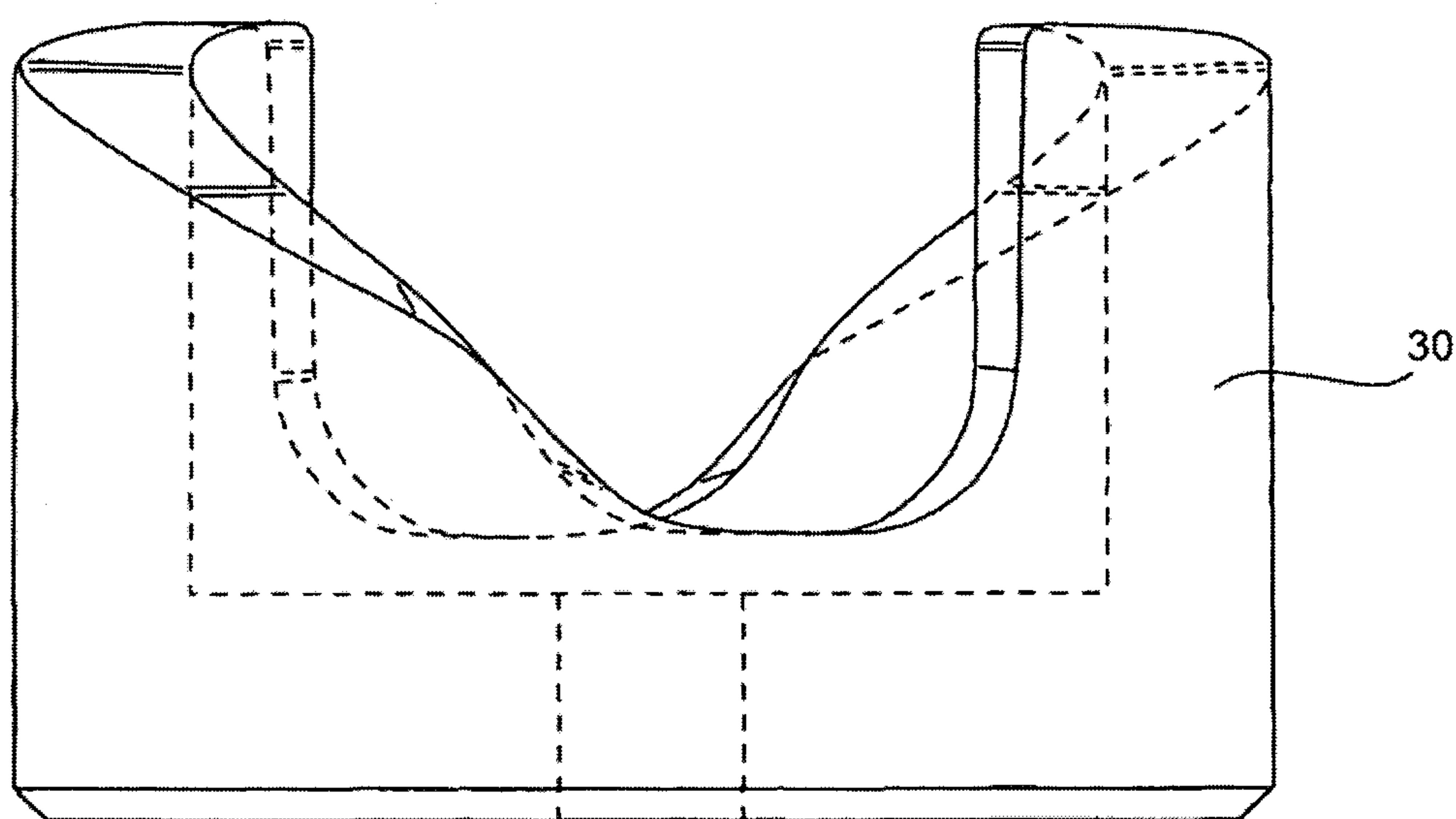
5/9

**FIG. 8****FIG. 9**

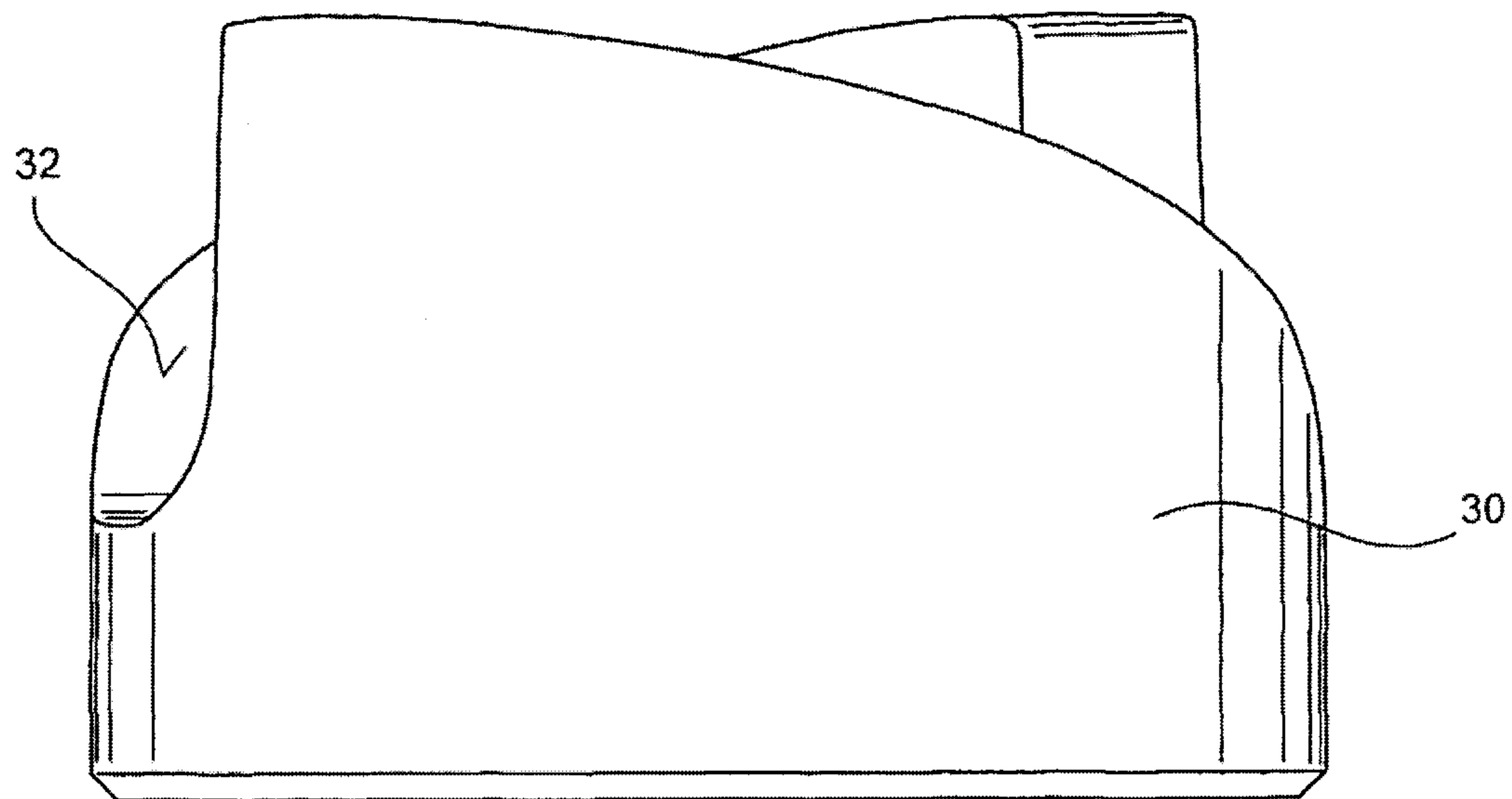
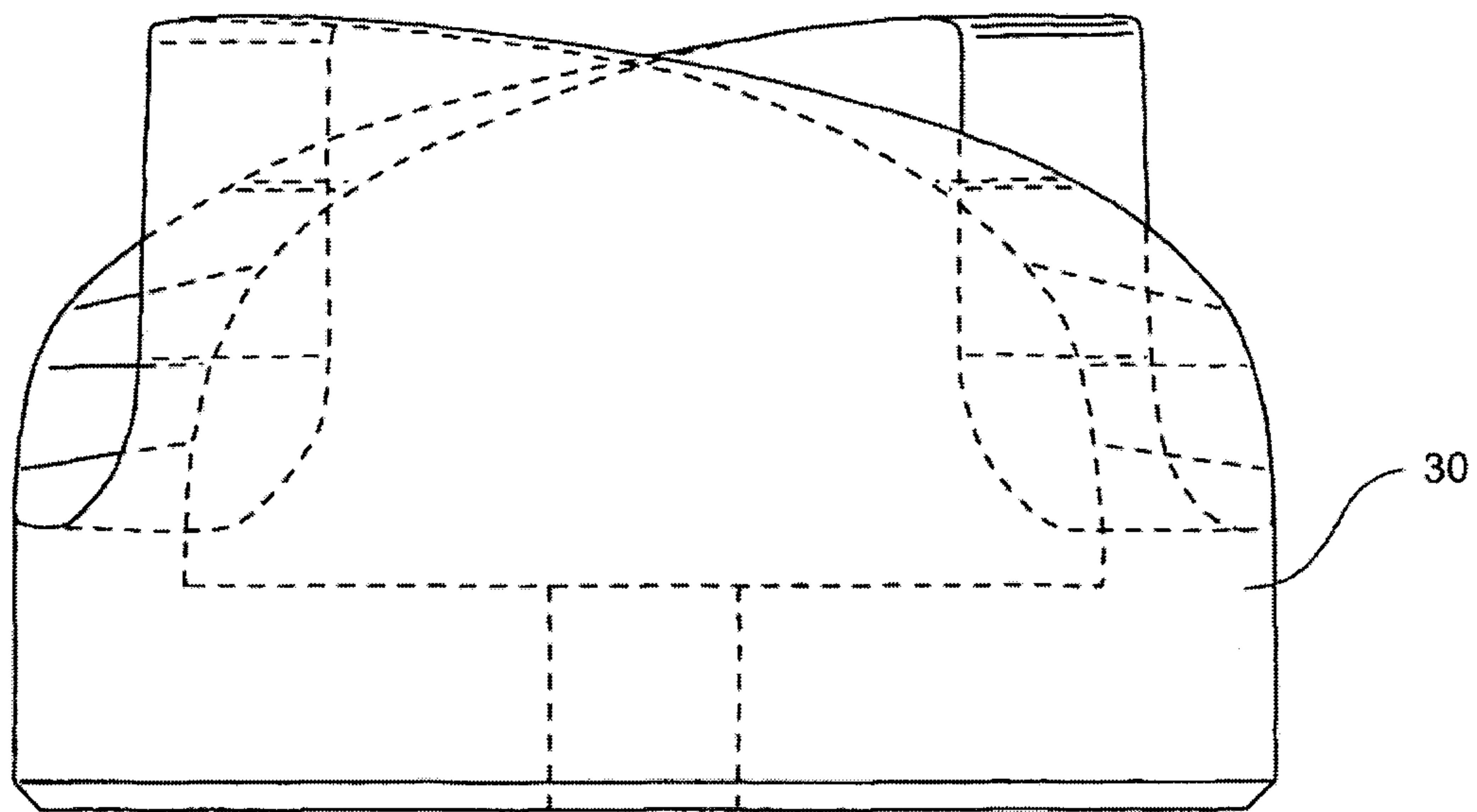
6/9

**FIG.10****FIG. 11****FIG. 12**

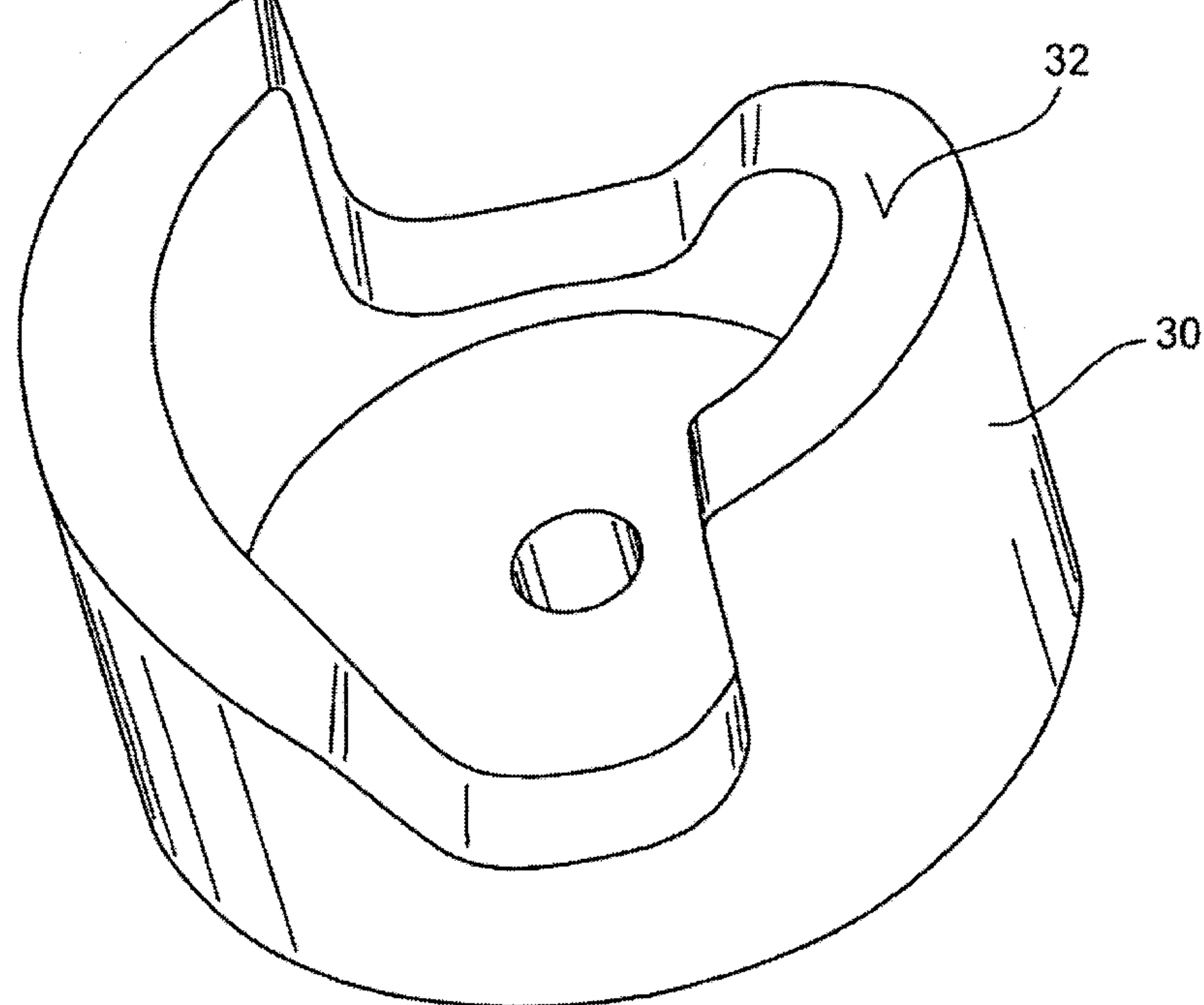
7/9

**FIG. 13****FIG. 14**

8/9

**FIG. 15****FIG. 16**

9/9

**FIG. 17****FIG. 18**