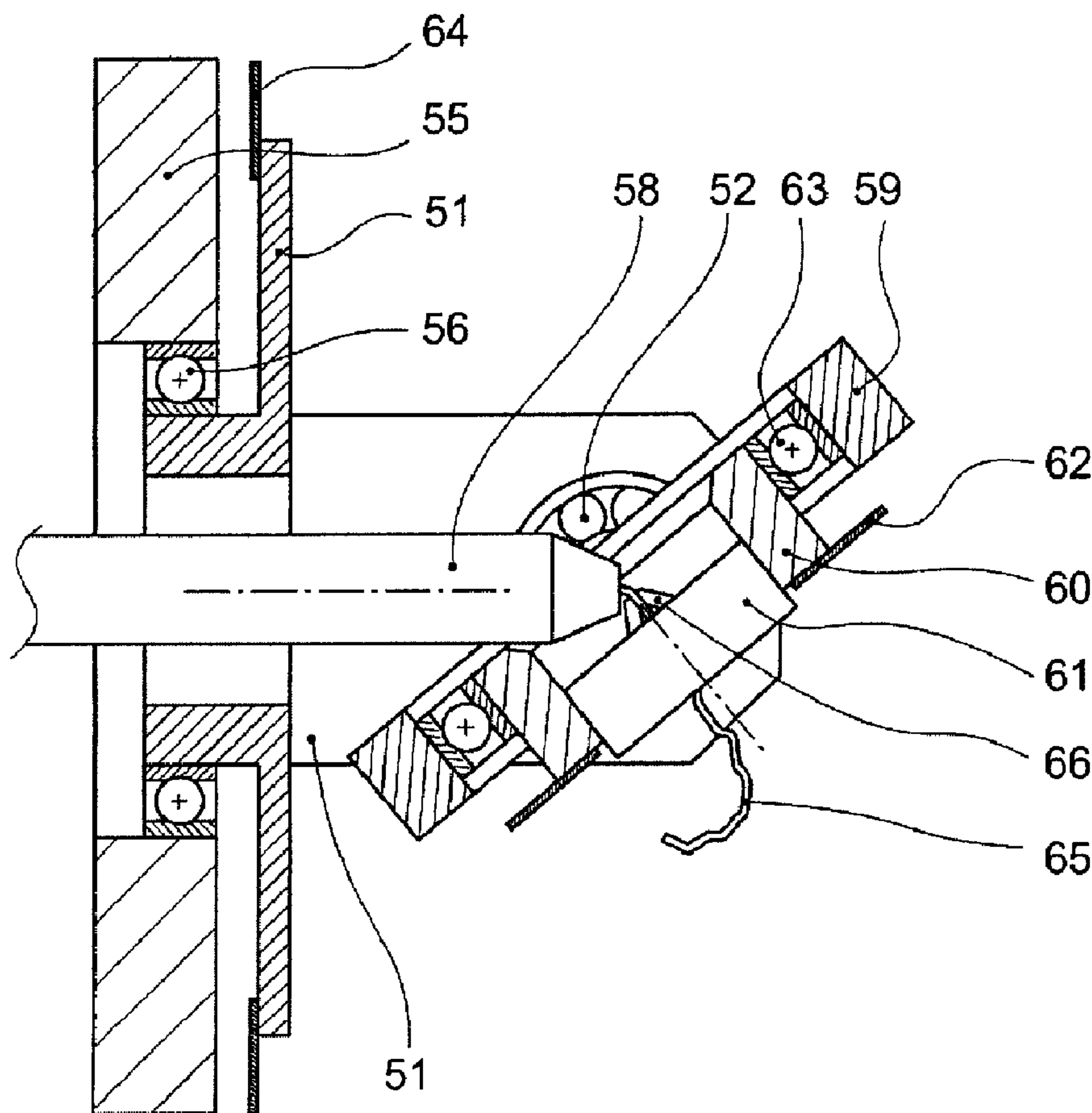




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(54) Titre : METHODE ET DISPOSITIF DE MISE EN FORME D'UN FIL METALLIQUE POUR ARC ORTHODONTIQUE
 (54) Title: METHOD AND DEVICE FOR SHAPING AN ORTHODONTIC ARCHWIRE



(57) Abrégé/Abstract:

An apparatus for bending orthodontic wires has means for guiding and holding a wire. In order to prevent forces resulting from compressive or stretching strain during the bending process, one of these means does not apply any longitudinal forces onto the



(57) **Abrégé(suite)/Abstract(continued):**

wire by design. In another implementation, the apparatus for bending orthodontic wires has a gimbal-mounted gripper for bending the wire. Furthermore, a method is disclosed for applying two bends at the same longitudinal wire location in two different directions.

ABSTRACT OF THE DISCLOSURE

An apparatus for bending orthodontic wires has means *for* guiding and holding a wire. In order to prevent forces resulting from compressive or stretching strain during the bending process, one of these means does not apply any longitudinal forces onto the
5 wire by design. In another implementation, the apparatus for bending orthodontic wires has a gimbal-mounted gripper for bending the wire. Furthermore, a method is disclosed for applying two bends at the same longitudinal wire location in two different directions.

METHOD AND DEVICE FOR SHAPING AN ORTHODONTIC ARCHWIRE

This application is a divisional application of Canadian Patent File No. 2,527,056 filed November 15, 2005.

BACKGROUND OF THE INVENTION

(01) The present invention relates to methods for applying a desired shape to archwires to be used in orthodontic appliances for the straightening of teeth, and more particularly, to the automated manufacture of customized archwires using robotic devices.

(02) The common approach for orthodontic appliances is to bond small metallic parts ("brackets") onto the outer ("labial") side of the teeth, and to insert a wire into the slots of the brackets. The wires are typically preformed off-the-shelf wires, and the brackets are bonded basing on visual judgment by the orthodontist. However, the use of computerized processes in orthodontics increases. Especially when the brackets are bonded to the back side of the teeth ("lingual orthodontics"), the use of computer assisted processes for designing the brackets and manufacturing the wires has achieved a significant market share. Using computerized proccsses typically results in providing a numeric description of an orthodontic archwire.

(03) Devices for bending orthodontic archwires have been proposed in the prior art. In U.S. Patent No. 5,431,562, Andreiko et al. describes an apparatus that takes a straight archwire and imparts a simple planar arcuate curvature to the wire. However, the Andreiko et al. wire bending apparatus cannot produce any complex and twists bends in the wire, e.g., bends requiring a combination of translation and rotational motion.

(04) In U.S. Patent No. 6,612,143 ("Robot and method for bending orthodontic archwires and other medical devices"), Butscher et al. discloses a robot capable of bending fully three-dimensional orthodontic archwires. The device comprises two grippers, one of the grippers being mounted to a six-axis-robot arm and thus moveable. The gripping tools preferably incorporate force sensors which are used to determine overbends needed to get the desired final shape of the archwire. The manufacturing process uses straight pieces of wire and step by step applies bends and/or twists to the wire, thus forming an archwire. The process as described in the '143 patent requires the calculation of the consumed wire length for a bend. Even a slight miscalculation of the consumed wire length for a bend generates significant

forces along the longitudinal axis of the wire. Those high forces arising by estimating an improper consumed wire length for a bend will superimpose the bending forces and significantly disturb the desired measurements of those forces.

(05) The patent to Orthuber et al., U.S. Patent No. 4,656,860 also describes a bending robot for bending archwires. A robot as described in the '860 patent was manufactured and sold as part of a complete orthodontic solution by Geyer Medizintechnik GmbH in Berlin, Germany, but never widely commercialized. The robot consisted of two characteristic design features: a bending cone that could move forwards and backwards to bend the wire, and a rotating cone that could twist the wire. As such, it could only apply torque or bends over the two main axes of a cross section of a rectangular shaped wire. Basing on the embodiment distributed by Geyer Medizintechnik GmbH, a series of three twists and two bends were required to shape an archwire so that it would fit in the slots of two adjacent brackets. This series of twists and bends required as much as 5 mm of wire length between adjacent brackets. This length of wire is greater than that available for closely spaced teeth, especially in lingual orthodontics.

(06) The present invention presents substantial improvements over prior art as disclosed in the cited applications.

BRIEF SUMMARY OF THE INVENTION

(07) A primary aspect of the present invention seeks to provide a reliable and efficient method for applying a permanent customized shape to an orthodontic archwire using robotic devices.

(08) If a device similar to the description in U.S. Patent No. 6,612,143 is used, it is preferable over the disclosed apparatus to replace one of the grippers with a bushing for supporting and guiding the wire. Such a guide bushing would preferably be adapted to the cross section of the wire in order to allow for precise twists. The design of the bushing would be optimized for low friction. In a preferred embodiment, the bushing is mounted to the base plate of the robot. The moveable arm carries the gripper as described in the '143 patent. The wire would be fed through the bushing. The moveable gripper would grip the wire extending through the bushing and pull a predefined length of the wire out of the bushing, said length basing for instance on

best estimates as disclosed in the '143 patent. During the bending process, the discrepancy between the calculated and the actual consumed wire length for the bend would generate longitudinal forces. These forces would cause the wire to slip through the bushing and therefore automatically correct the discrepancy. Only the amount of friction forces between the wire and the bushing would remain, and these forces can be minimized by a variety of means.

(09) In another embodiment, a device as disclosed in U.S. Patent No. 4,656,860 is used. As implemented by Geyer Medizintechnik GmbH, Berlin, Germany, specific straight portions of the wire are assigned to specific bracket slots. The original implementation of the robot used a sequence of three twists and two bends in order to define a geometry leading from a straight wire portion assigned to a first slot to a straight wire portion assigned to a second slot. While this implementation has specific advantages, it has the big disadvantage of consuming significant wire length. Due to the design of the robot, after each twist action a relevant wire feed is required before the next bend may be applied. Therefore the required total wire length from the end of one bracket slot to the beginning of a second bracket slot quickly adds up to approx. 5mm, depending on the specific amounts of bends and twists and the specific mechanical layout of the robot. For lingual archwires, this is far too much. Especially the lower front teeth often have a width not exceeding 5mm, and the arch length of a lingual wire is even shorter than the length of the dental arch. Additionally, a bracket width of 2mm minimum can be assumed, so that the available length between two brackets is below 3mm.

(10) In order to overcome this limitation, an alternative command sequence is generated. Instead of applying a twist followed by a bend, two bends at the same location along the wire axis, but in different directions are applied. This has the same effect like the original sequence, but consumes much less wire length. Only one twist between the couple of bends has to be applied in order to adapt the rotational orientation of the wire.

(11) In yet another embodiment of the invention, a modified device is used. Both devices disclosed in the '143 and in the '860 patent have weaknesses in ensuring the desired precision of the applied bends and twists. The device according to the '860 patent clamps the wire only below the point where it is bent. The portion of the wire

extending beyond the cone is free and unconstrained; the robot had no control as to the effective deformation of the wire. Therefore, the material properties of the wires to be used have to be calibrated in a tedious process, and very tight material tolerances have to be maintained. The device according to the '143 patent does clamp the *wire* on both ends of the applied deformation. However, in order to control the precise shape of the bent wire, the residual spring-back forces are measured. This is a process prone to errors, especially since side effects as discussed before will introduce additional disturbances.

(12) The device according to this invention clamps the wire on both ends of the portion to be deformed. Unlike the device disclosed in the '143 patent, it has restricted capabilities with respect to the shapes that may be applied to the wire, but it can be build using a mechanically extraordinarily stiff design. This stiff design is the foundation for the principle of measuring the precision of the applied deformations. After applying the force for the deformation, one of the grippers is decoupled from any driving force, but remains clamped to the wire. Now, the exact location and orientation of the gripper is measured, directly reflecting the new shape of the wire. Depending on the predefined tolerances, the deformation may be refined by subsequent application of corrective forces, or the deformation is accepted. Due to the stiff design, a combination of bends and twists can be applied at one location. Unlike the device disclosed in the '860 patent, the device disclosed in this application it is not limited to bends along a main axis of the cross section.

(13) The device comprises mainly a guide bushing for guiding the *wire* on one side of the deformation to be applied and a gripper for clamping the wire on the opposite side of the deformation to be applied. While the guide bushing is fixed, the gripper is mounted on three bearings. The first bearing allows rotating the gripper around the longitudinal axis of the wire in order to apply the twisting component of the deformation. The second bearing is mounted around the gripper and the first bearing and allows to apply the bending component to the deformation. The third bearing is mounted around the second bearing and allows to adjust the direction of bending. The gripper is therefore gimbaled. The gripper is also completely balanced *around* its centers of motion. All three bearings are designed to cause very low friction, and three axes are equipped with contact-free rotary encoders. If the gripper

clamps onto the wire, and no external force is applied to the gripper, the rotational angles of the three axes (provided by the rotary encoders) will precisely document the passive or relaxed shape of the wire. If the present shape is not within the tolerances of the nominal shape, corrective movements are to be made by the gripper. These movements can be initiated
5 manually or by actuators. If actuators are used, and the signals of the rotational encoders are processed accordingly, the process shaping the wire could be fully automated, provided that additional means for feeding the wire are present and that the clamping functionality of the gripper is also actuated. In a preferred embodiment, the actuators can be coupled to the axes and fully decoupled while the measurement of the actual wire shape is performed.

10 **(13a)** A preferred aspect of the invention is a method of bending an orthodontic archwire, including the steps of determining an optimal shape of a portion of an archwire positioned between a pair of orthodontic bracket receiving segments with the optimal shape including at least one pair of nominal bends. The location of a first nominal bend of the at least one pair of nominal bends is substantially spaced apart from a location of a second nominal bend of the at
15 least one pair of nominal bends. The method also includes the steps of applying an actual bend to the archwire at a location coinciding with the location of the first nominal bend, measuring the actual bend to the archwire responsive to the actual bend being applied, comparing the actual bend to the first nominal bend to determine an amount of deviation of the actual bend from the first nominal bend, determining corrective movements to substantially eliminate the
20 deviation between the actual bend and the nominal bend, iteratively re-executing the applying, measuring, comparing, and determining steps until the deviation is within a predefined tolerance, the deviation then defining a remaining deviation, and recalculating a value of the subsequent second nominal bend of the pair of nominal bends responsive to the remaining deviation of the actual bend to the archwire from the first nominal bend to thereby compensate
25 for the remaining deviation therebetween.

(13b) In a further aspect, the invention is a method of bending an orthodontic wire that includes the steps of calculating a plurality of nominal bends describing a desired design shape of a portion of an orthodontic archwire positioned between a pair of orthodontic bracket slot segments where the plurality of nominal bends including a first nominal bend having a first
30 location and a second nominal bend having a second location that is spaced apart from a first

location of the first nominal bend, placing a first bend in the archwire where the first placed bend represents the first nominal bend of the plurality of nominal bends at the first location, measuring a deviation between the first placed bend and the first nominal bend being represented by the first placed bend, calculating an offset to the second nominal bend of the plurality of nominal bends by a computer where the offset represents a correction to the second nominal bend to thereby compensate at least partially for the deviation in the first placed bend determined in the measuring step, deriving an updated value for the second nominal bend at the second location by the computer using the offset calculated in the calculating step to thereby define a modified second nominal bend, and placing a subsequent second bend in the archwire where the subsequent second placed bend represents the modified second nominal bend at the second location and the subsequent second placed bend provides at least partial compensation for the determined deviation in the first placed bend.

(13c) In yet a further aspect, the invention is a manufacturing method to shape an orthodontic archwire in consecutive steps in response to numerical control data derived from design data of a desired shape of the orthodontic archwire that includes the steps of placing a first bend in a first portion of an orthodontic archwire positioned between a pair of orthodontic bracket slot segments to be positioned in a corresponding pair of brackets slots of a corresponding pair of orthodontic brackets to be employed to straighten teeth of a patient, generating measurement data of the first portion of the archwire having the first placed bend, determining an amount of deviation between the measurement data of the first portion of the archwire and a first portion of the design data representing a design of the first portion of the archwire where the design of the first portion of the archwire comprises a first nominal bend at a first location, deriving updated numerical control data representing an update to a second portion of the design data responsive to the amount of deviation where the second portion of the design data represents an initial design of a second portion of the archwire and the initial design of the second portion of the archwire comprises a second nominal bend having a second location that is spaced apart from the first location of the first nominal bend. The update to the second portion of the design data represents a modified design of the second portion of the archwire and the modified design of the second portion of the archwire comprises the second nominal bend having an updated value to thereby define a modified second nominal bend. Also included is the step of shaping a second portion of the archwire to include placing a subsequent second bend representing the

modified second nominal bend in the second portion of the archwire in response to the updated numerical control data to thereby provide at least partial compensation for the determined deviation in the first placed bend.

(13d) In another aspect, the invention contemplates a method of placing a bend in an orthodontic wire having a cross-section having at least two main axes. The method includes the steps of a) bending the wire in a first direction where the bending axis is substantially parallel to one of the main axes, b) bending the wire in a second direction where the bending axis is substantially parallel to one of the other main axes wherein the place of the bend of step a) is substantially equal to the place of the bend of step b) in the longitudinal direction of the wire.

10 BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING

(14) FIG. 1 illustrates a straight piece of wire being held by two grippers. The calculated consumed wire length for the bend is indicated in the center of the wire and equals the distance between the end of the first gripper and the beginning of the second gripper.

(15) FIG. 2 illustrates how a wire is bulged if the actual consumed wire length for the bend is shorter than the calculated length represented by the original distance between the two grippers.

(16) FIG. 3 illustrates a straight piece of wire being held by a bushing and a gripper. The calculated consumed wire length for the bend is indicated in the center of the wire and equals the distance between the end of the bushing and the beginning of the gripper.

(17) FIG. 4 illustrates that the wire has slipped through the bushing, and this wire motion has relaxed the bended portion. There is a noticeable difference between the originally calculated consumed wire length for the bend, indicated by the line in the center of the wire, and the actually consumed wire length.

(18) FIG. 5 is a perspective view of a piece of wire that has been bent around two axes at mainly the same wire position.

(19) FIG. 6 is a perspective view of a wire segment that has been bent according to the classic algorithm, having two bends and three twists.

(20) FIG. 7 is a perspective view of a wire segment that has been bent according to the method disclosed in this application, having four bends and one twist.

(21) FIG. 8A is a view onto a wire that has already been bent in one direction. The end points of the line of impact for application of the second bend are located on both
5 sides of the midline.

(22) FIG. 8B is a side view onto a wire that has already been bent and illustrates the bending finger contacting the wire for the second bend.

(23) FIG. 9 is a view onto a wire that has already been bent in one direction. Both end points of the line of impact for application of the second bend are located on one
10 side of the midline.

(24) FIG. 10 is a perspective view of a group of wire segments that are connecting two slot segments according to the method disclosed in this application, having four bends and one twist.

(25) FIG. 11 is a flow diagram of calculating the required bends and twists according
15 to the method disclosed in this application.

(26) FIG. 12 displays an iterative optimization of two angles in a simplified manner.

(27) FIG. 13 is a cross-sectional view of a device for shaping orthodontic wires.

(28) FIG. 14 is a cross-sectional top view of the device of FIG. 13, seen from view
20 line A in FIG. 13.

(29) FIG. 15 displays an alternate layout of the device of FIG. 13.

(30) FIG. 16 displays a portion of a wire having a bend deviating from the desired angle.

(31) FIG. 17 displays the wire of FIG 16 with a second bend, the second bend
25 compensating the deviation of the first bend.

DETAILED DESCRIPTION OF THE INVENTION

Six Axis Robot Having One Gripper

(32) The robot as disclosed in U.S. Patent No. 6,612,143 comprises two grippers, one of the grippers being mounted to a six-axis-robot arm and thus moveable in all six
30 degrees of freedom. The other gripper is fixed to the base plate of the robot. The gripping tools preferably incorporate force sensors which are used to determine

overbends needed to get the desired final shape of the archwire. The manufacturing process uses straight pieces of wire and step by step applies bends and/or twists to the wire, thus forming an archwire. The process as described in the '143 patent requires the calculation of the consumed wire length for a bend. In column 16 line 64 ff. it is described how such a calculation can be performed. Also, FIG. 20B displays a proposed algorithm. From the specification it becomes obvious that the exact calculation of the required straight wire length is not possible. Even a slight miscalculation of the consumed wire length for a bend generates significant forces along the longitudinal axis of the wire, since a wire as used for orthodontics purposes may be flexible in the direction transversal to its longitudinal axis, but is extremely stiff in the longitudinal axis. Depending on the veracity of the calculations, the forces generated by estimating an improper consumed wire length for a bend can significantly exceed the forces actually required for bending the wire. This is a very undesired side effect since the whole concept of the '143 patent bases on the precise measurement of forces generated by bending the wire. The high forces arising by estimating an improper consumed wire length for a bend will superimpose the bending forces and significantly disturb the desired measurements of those forces.

(33) The term "bend" as used in this specification and the claims can mean a pure bend, a pure twist or a combination of both. This is in line with the general usage of the term "bend" in orthodontics. A pure twist is referred to as a "3rd order bend" by orthodontists.

(34) Patent '143 describes in great detail the usage of force sensors in order to determine the required overbending of the wire. From the specification it becomes obvious that the proposed process is not very fault tolerant. It can easily be imagined that various influences like longitudinal forces as described above or the mechanical flexibility of an off-the-shelf six-axis-robot will be highly disturbing and may even corrupt proper function.

(35) The calculated length consumed for a bend reflects the distance between the two grippers before the bending process starts, in other words while the wire is still straight.

(36) An exact calculation of the straight wire length consumed for a bend has not yet been introduced. The reason is that if a significant amount of bending forces is

applied to a wire, not only bending but also shearing deformations will occur, and accordingly the cross section of the wire will change. Only slightest changes in the cross section can have a great effect on the exact location of the neutral axis. The neutral axis is the zone where no tensile forces and no compression forces are active.

5 Theoretically, the length of the neutral axis as a first approximation is equal to the consumed wire length. However, all calculations and approximations do typically not exactly reflect the true outcome, and toolmakers will always run a couple of tests with the nominal material before they start designing a tool.

(37) The disadvantage of performing a calculation is that due to the longitudinal
10 stiffness of a wire, even a slight miscalculation of the consumed wire length leads to significant longitudinal forces. For instance, if the required wire length for a bend would be 3mm, and the calculation produces a result of 2.9mm, an error of 0.1mm would result. The longitudinal force within a wire portion of stainless steel having a length of 3mm and a cross section of 0.017" x 0.125" resulting from compression or
15 elongation of 0.1 mm will be approx. 1700N. This exceeds by far the forces that are active in order to bend the wire. The true forces may be lower because the wire will not actually be compressed but bulge, and the mechanical structures of the bending robot will also have certain flexibility. It is obvious, however, that the bending process itself and all force measurements will be significantly superimposed and
20 disturbed by the longitudinal forces.

(38) The solution to this problem is to clamp the wire only on one side of the deformation zone. In a preferred embodiment, a gripper that is mounted to the arm of the six-axis-robot will clamp the wire and perform the bending and twisting movement. On the opposite side of the deformation zone, a low friction guiding
25 bushing will support the wire in order to maintain the integrity of the desired deformation, but will restrict longitudinal movements as little as possible. The calculations of the consumed wire length for a bend can be executed as taught in the '143 patent. However, while the bending and twisting process is performed, the wire can slip through the bushing in order to compensate for any error in the calculation.

30 (39) FIG. 1 shows a straight piece of wire 1 held by a fixed gripper 18 and a moveable gripper 4. Line 3 illustrates the calculated wire length that will be consumed for the bend according to the calculations. FIG. 2 illustrates the result of the

deformation if the calculated consumed wire length is longer than the actually consumed length. The wire will show a bulge. The actual shape of the bulge depends widely on the deformation, the cross section and material of the wire, the distance between the grippers and the flexibility of the 6-axis-robot.

5 (40) FIG. 3 shows a straight piece of wire 1 supported by a bushing 2 and a moveable gripper 4. Line 3 illustrates the calculated wire length that will be consumed for the bend according to the calculations. FIG. 4 illustrates the result of the deformation. The wire 1 has slipped through bushing 2. This movement compensates the discrepancy between the calculated consumed wire length and the actually
10 consumed length. Precise knowledge of the amount of the wire length that has slipped through the bushing is not required. For obtaining a precise wire shape, only the wire between the bushing and the gripper is relevant. The wire portion that has slipped will either add to the straight length ready to be fed for the next bends and twists or will be subtracted from that straight length, depending of the mathematical sign of the
15 discrepancy. As long as enough straight wire length remains to be fed through the bushing for consecutive bends, the exact amount of the remaining straight wire length must not be known. Assuming that the calculations *are* reasonably precise, the summarized overall discrepancy between calculated and actually consumed length will not exceed 5mm, so it is sufficient to provide a straight wire length at the
20 beginning of the bending process showing this additional safety margin in length.

(41) The design of the bushing must ensure low friction between the wire and its support. There are several options. One option is to have a bushing that is coated with polytetrafluoroethylene or another plastic designed for low friction bearings. Another option is to add oil to the contact surface. In both cases, the slipping movement can be
25 also supported by temporarily applying vibrations to the bushing. This is a common approach in industrial automation when parts for instance are supposed to slide down a chute. If the parts tend to get stuck because the angle of the chute being too flat, a vibrating device is mounted to the chute. Another option is to use roller bearings. The four walls of the bushing could be substituted by eight needles that would be located
30 at the edges of the bushing. Each needle would be pivoted by roller bearings. Also, a combination of roller bearings and plain bearings can be appropriate.

Alternative Implementation of Bending: Robot According to Orthuber

(42) Another implementation of the present invention uses a bending robot as disclosed by Orthuber et al. in U.S. Patent No. 4,656,860. A device according to the invention has been built and distributed as part of their "bending art system" by Geyer
5 Medizintechnik GmbH in Berlin, Germany, in close cooperation with Dr. Orthuber. The "bending art system" came complete with software for designing the wire shape and for controlling the robot. The robot as disclosed in the '860 patent consists of two characteristic design features: a bending finger (a partial cone) that can move forwards and backwards to bend the wire, and a rotating cone that can twist the wire.
10 The wire is held during both bending and twisting operations by the outer clamping cone.

(43) Since the robot as disclosed by Orthuber et al. in the '860 patent produces a wire consisting of straight portions, bent portions and twisted portions, it is obvious to assign straight portions to bracket slots. In other word, a specific straight portion of
15 the wire is supposed to be located within the slot of a specific brackets slot either during treatment or at the end of treatment. The portions between two adjacent slots can be used to apply twists and bends to the wire in order to obtain a spatial shape dictated by the therapeutic task. The spatial relationship between two adjacent slots will typically be defined in mathematical terms in the numeric wire description.

(44) The device has several restrictions. Bends and twists have to be applied to
20 separate locations along the wire. Also, the portion of the wire extending beyond the cone is free and unconstrained, and therefore only bends over the two main axes of a cross section of a rectangular shaped wire can be applied. A bend in any direction other than one of the main axes would create side effects due to oblique bending.

(45) Geyer Medizintechnik GmbH has solved this problem by introducing an
25 algorithm comprising a series of three twists and two bends. FIG. 6 shows an exemplary wire section. The wire section has two segments 8 and 14 that are assigned to bracket slots. The relative spatial location and orientation between these two segments is therefore given. A portion of an orthodontic wire being assigned to a slot
30 is referred to as "slot segment" in this application. Segment 8 is accordingly referred to as first slot segment and segment 14 second slot segment. Also, the bend adjacent to the first slot segment is named "first" bend. This *order* has been selected

arbitrarily and does not imply the order of manufacturing. Basically, both slot segments have to be connected by a piece of wire. The first bend 10 can be understood as the beginning of the connecting segment, while the second bend 12 is the end of the connecting segment. In order to adjust the direction of bend 10 with respect to the orientation of the first bracket slot, a first twist 9 is required. Likewise, the third twist 13 adjusts the direction of bend 12 with respect to the orientation of the second bracket slot. Yet another twist 11 is required in order to compensate for the discrepancy of the orientation of the main axes of both bends.

(46) While this concept represents a universal approach, it has significant disadvantages and limitations. Firstly, the distance between a bend and a twist is dictated by the design and the dimensions of the robot. The devices sold by Geyer Medizintechnik GmbH required a minimal distance of 0.7mm between a bend and a consecutive twist and a minimal distance of 0.9mm between a twist and a consecutive bend. It is easily understood that the series of twists and bends therefore required as much as 5 mm of wire length between adjacent brackets. This length of wire is greater than that available for closely spaced teeth, especially in lingual orthodontics. Secondly, relevant twists are present in the wire simply to adjust the desired direction of a bend. Depending on the individual geometry, twists up to 90° can be required for a rectangular wire. In order to consume little wire length for twists, the devices sold by Geyer Medizintechnik GmbH show a distance between the twisting clamps of less than 0.3mm. Even for ductile materials, a 90° twist applied to a wire portion shorter than the side length of the cross section is a challenge. Many materials used for orthodontic wires like shape memory alloys or beta-titanium break instantaneously when exposed to such stress.

(47) This invention introduces a new method for bending and twisting a wire using the device as disclosed in the '860 patent. Instead of applying one bend and one twist in order to adjust the direction of the bend, two bends in the directions of the two main axes are applied. Since orthodontic archwires are typically smoothly curved, following the form of the jaw, only relatively small bends are required in most cases. Even if individual adjustments are required in order to adapt a wire to a misplaced bracket or in order to re-adjust the treatment goal, the required steps in the wire are typically below 1mm. Therefore, it is often possible to bend the wire in one direction,

then turn it 90° around its longitudinal axis and apply a second bend at the same position. FIG. 5 shows a wire having two bends at one location. The bending axis for bend 7 is the Y-axis. Bend 6 has been applied around the Z-axis.

(48) FIG. 7 shows the same slot segments 8 and 14 as in FIG. 6. However, bend 10 and twist 9 of FIG. 6 are substituted by bends 6 and 7. Accordingly, bend 12 and twist 13 of FIG. 6 are substituted by bends 16 and 17. Similar to the method used in FIG. 6, a twist 15 is required between the bends in order to compensate for the discrepancy of the orientation of the main axes of the bends. By comparing FIGS. 6 and 7, the advantage of the proposed method is evident. The overall length of required deformations is much shorter, and the amount of deformations is reduced. Only one twist is required, having a much lower value than required by the old method.

(49) Placing two bends at one location is possible as long as the first bend is not too large. When the bending finger of the device according to the '860 patent touches the wire, the contacting forces are applied along a line. FIG. 8A shows a wire 42 that has already been bent in one direction. Line 40 is the top edge of the outer clamping cone. The portion of the wire 42 that is extending above the cone is to be bent in the second direction. The contacting line of the bending finger has a specified height 37 above the top edge of the outer clamping cone. The robots delivered by Geyer Medizintechnik GmbH show a dimension of 0.9mm. Both endpoints 38 and 39 of the contacting line are located on opposite sides of the center line. FIG. 8B shows a side view of the situation displayed in FIG. 8A. A forward movement of the bending finger 41 will induce a proper bend.

(50) FIG. 9 shows a wire 42 that has a first bend of a significantly higher angle. In this case, both endpoints of the contacting line are located on the same side of the center line. A forward movement of the bending finger will also induce a twisting movement onto the wire, since both force transmission points are placed asymmetrically on one side of the center line. The result will be an undefined mixture of bend and twist. To solve this problem, the order of the bends can be changed. If the second bend is smaller, it would be useful to apply that bend first and then the other, larger bend.

(51) In case both bends are too large, a feed motion of the wire is required before the second bend is applied. In other words, the second bend is placed a short distance

away from the first bend. This does obviously consume some wire length, but is still more efficient than having a twist instead of the bend.

(52) In order to determine the required commands for the bending robot, it would be possible to use an analytic approach. Due to the various constraints and options regarding the order of bends, an iterative approach seems more adequate. FIG. 11 shows a flow chart of a preferred embodiment of method steps for calculating the command sequence for the robot. In order to obtain a good starting point for the iterative optimization, it is useful to execute step 20 and calculate four angles as starting points by virtually connecting the two slot segments by a line and projecting the connecting line onto the main planes. If this calculation is not performed, this does not have any negative effect on the end result, it just slows the calculation down by adding more iterative steps. Step 21 is the beginning of an outer loop, and step 22 is the beginning of an inner loop. In steps 23 to 26, the angles of the bends are gradually modified, together with the length of the straight wire segments (the process of gradually modifying and optimizing an angle is demonstrated in a simplified manner in FIG. 12). In step 27, the twist angle is obtained by calculating the angles between the edges of the wire segments adjacent to the twist (see segments 33 and 34 in FIG. 10). Now the remaining error is determined. One option is to calculate the normal vector for each surface terminating a segment (as shown in FIG. 12), and to determine the error in parallelism of both terminating surfaces of each segment. If a predefined value is exceeded, a new iterative loop is executed. Otherwise, the iterative loop is left (step 28). In step 29, the constraints are checked. If a bending angle is too large so that both endpoints of the contacting line of the bending finger are located on the same side of the center line, another order of bends is tested or, if all orders have been tested, the distance between paired bends is increased (step 30). In each case, a new iterative process for re-calculating the angles is required. Finally, the result is exported as ASCII file. The robots sold by Geyer Medizintechnik GmbH are fed with files having a simple format. Each line has a specific command type, indicated by a number (feed: 10; bend: 12; turn: 15; twist: 11), followed by one or more blanks and the value (with a maximum resolution of two digits after the decimal point).

(53) FIG. 10 shows a perspective view of the straight segments of a wire portion extending from one slot segment 31 to the next slot segment 36. Segment 31 is

followed by a bend, and the adjacent segment 32 provides the necessary distance between the two bends (both bends are very large and need to be separated from each other). Segment 32 is followed by the second bend and then by segment 33, which actually embodies one part of the connecting segment which virtually connects the slot segments. Adjacent segment 34 embodies the other part, both segments being separated respectively joined by the twist (that is displayed with a length of zero for a better understanding of the underlying geometry). Segment 34 is followed by the third bend and by another separating segment 35. The length of segment 35 is shorter because the third bending angle is much smaller than the first angle and requires less feed until the endpoints of the contact line of the bending finger are located on both sides of the center line. Segment 35 is followed by the fourth bend and is adjacent to slot segment 36.

(54) FIG. 12 displays in a simplified manner the iterative process of optimizing angles. In this drawing, only two angles are to be optimized. Step I shows the initial situation. In step H, the first angle is optimized in a resolution of 5° in a manner that the normal vector on the angled surface passes the center of the opposite angled surface as close as possible. The result in this example is 45° . In step III, the opposite surface is optimized in the same manner, ending up with 20° . In further loops, the angles are iteratively optimized one by one, while the resolution is increased. After performing step IX, the first bend has 46.48° and the second bend 17.26° . The length L of the virtual connecting segment can also easily be calculated basing on the spatial arrangement of the two segments to be connected.

Apparatus for Bending Orthodontic Wires

(55) In yet another implementation of the invention, an optimized apparatus is used. It has been explained earlier that the apparatus disclosed in U.S. Patent No. 6,612,143 has the advantage of shaping the wire portion between two slot segments in one section, but the verification of the accuracy of the deformation requires significant efforts and is prone to errors. The device disclosed in U.S. Patent No. 4,656,860 is stiff and robust, but requires up to five independent deformations to be applied one after another and has no means for a verification of the accuracy of the deformation, thus requires the use of calibrated wire materials.

(56) This application presents a device that allows shaping a wire by applying two deformations in order to connect to slot segments. Each deformation consists of a combined bend and twist. This is achieved by clamping the wire with one moveable gripper and a fixed gripper or a fixed guiding bushing. The moveable gripper is
5 gimbal-mounted and has three degrees of freedom. This limits the scope of deformations, but allows for a robust and stiff design of the apparatus. The stiff design is a valuable precondition for verification of the applied deformation. In a preferred embodiment, the device measures directly the resulting deformation by decoupling the gripper from any external forces and measuring the angles of the three axes with the
10 wire dictating the spatial orientation of the gimbal axes.

(57) FIG. 13 shows a preferred embodiment of the invention. A wire feeding mechanism 58 is mounted to a base plate 55. A plurality of options is applicable. Friction rollers can be used as well as a mechanism which clamps the wire and moves in incremental steps. The feeding mechanism can be activated for instance by steppers
15 or servo motors. In addition to feeding the wire, the wire feeding mechanism 58 should also mechanically guide the wire at its outlet. This is to ensure that the deformation zone of the wire is well defined and limited to the portion of the wire extending from the feed mechanism. One option to support and guide the wire would be a clamping mechanism that clamps the wire after the feeding movement is
20 finished. Another option is a low friction bushing. This second option is favorable in light of the problems arising when the consumed length has been calculated imprecisely, and high longitudinal forces develop.

(58) The first axis of the gimbal-mount could be named "rotational axis". The term "axis", as used in the specification and the claims, when directed to an
25 apparatus, shall mean a configuration of means of the apparatus allowing a directed movement of portions of such means; including but not limited to rotational and translational movements.

(59) The first axis or rotational axis is realized by ball bearing 56. The rotational base 51 can accordingly rotate around this axis, which is in line with the longitudinal
30 wire axis of the undeformed wire inside the feeding mechanism. Rotational base 51 carries ball bearings 52, embodying the second gimbal axis that could be named "bending axis". The rotational base 51 carries also the encoding disk 64 of rotary

encoder 50. Ball bearings 52 carry the bending base 59 which accordingly rotates around the bending axis. Bending base 59 holds ball bearing 63 which incorporates the third gimbal axis, the "twist axis". The names for the axes have been selected in order to improve descriptiveness. The bending base 59 carries also the encoding disk 53 of rotary encoder 54. Ball bearing 63 -incorporating the twist axis - holds twist base 60. Twist base 60 carries the encoding disk 62 of rotary encoder 57. It also holds gripper unit 61. Gripper unit 61 has the task of clamping the wire with gripper fingers 66 during the deformation process and, if applicable, also during the verification process.

10 (60) Again, a wide variety of design principles is applicable. Possible implementations for actuating the gripper fingers include, but are not limited to solenoids, pressurized air and electric motors.

(61) FIG. 14 shows the apparatus in a cross-sectional top view. The line of view is indicated in FIG. 13 by arrows A. Deviating from FIG. 13, bending base 59 is tilted around the bending axis. Also, a wire 65 that is currently being bent is displayed. The deformation is applied to the wire zone between feeding mechanism 58 and gripper fingers 66. After the deformation is applied and, if applicable, verified, the gripper unit is released, all three gimbal axes are reset to zero, and the wire is moved forward in order to apply deformations to the next wire section.

20 (62) A preferred method of operating the device is to obtain a numeric wire description similar to the one that was used by Geyer Medizintechnik GmbH to operate the robot of the '860 patent. The appropriate bends and twists that need to be applied to the wire can be calculated as described above. The main advantage of the new design is that the two bends that are placed in close proximity or at the same location can now be substituted by one bend, Since the wire is restrained on both sides of the deformation zone, an oblique bend, that is a bend where the bending axis is not identical to one of the main axes of the cross section, can be applied. The direction of the bend can be adjusted by rotating rotational base 51 to the correct position. As explained in FIGS. 7 and 10, an additional twist is typically required between two slot segments. This twist can be applied to the wire by rotating the gripper unit 61 around the twist axis. The twisting deformation is applied to the same zone as the bending deformation. With respect to the amount of torque, it is possible to apply the complete

twisting angle to one deformation, but the twist can also be distributed over both deformation zones that are located between two slot segments. Temporally, the twisting deformation can be applied before the bend, simultaneously or after the bend.

5 (63) The forces for bending and twisting the wire can be applied manually by an operator, or by using actuators. Applicable actuators include, but are not limited to steppers and servo motors. In a preferred environment, also the feeding mechanism 58 is controlled by a computer, so that the process of bending and twisting the wire can be fully automated.

10 (64) The device as disclosed has several significant advantages. The design is simple and can be realized by using mainly inexpensive off-the-shelf components. Since only two deformations are required to shape the wire between two slot segments, the operation is much faster compared to the operation of the device of the '860 patent, where five deforming operations and several feed operations are required. Due to its stiff design and the option to have completely balanced axes with very low friction, a very reliable feedback loop for verification of the true wire shape as described below can be easily integrated.

15 (65) FIG. 15 shows an alternate layout of the apparatus. Here, the bending axis is attached directly to base plate 55. The rotational axis is realized by mounting wire feeding mechanism 58 to bearings 56. In this way, the relative rotational movements between bending base 59 and wire feeding mechanism 58 are enabled in the same manner as in FIG. 13. The advantage of this layout is that gripper unit 61 has only two degrees of freedom with respect to the base plate. This eases routing the umbilicals for energy supply and sensor signals.

Method for Verifying the Actually Bent Shape of an Orthodontic Wire

25 (66) The method disclosed in this application requires an apparatus having at least two tools that can either grip the wire or at least partially embrace the wire in order to fully adapt to the spatial position of a portion of the wire at two different locations. The term "position" as used in this specification and the claims shall mean either a location or an orientation or a combination of a location and orientation.

30 (67) Then, the spatial position of each tool is measured. In order to fully reflect the orientation and location of the wire portion being held by the tool, it is important that

the bearings holding the tools are designed for extra low friction. Also, no relevant external forces must be acting onto the tools. Forces like gravity must be compensated by using for instance counter weights or springs. Now only the remaining forces in the wire will drive the location and orientation of the tools. The tools will move until
 5 the wire is in its relaxed situation. If the internal damping properties of the wire material should be too low, it may be desirable to use additional damping elements in order to calm oscillations.

(68) In a preferred embodiment, the apparatus used for the method will be an apparatus also used to bend the wire. The tools will be identical to the tools used for
 10 holding the wire when performing the desired deformation. In this way, the actual wire shape can be measured directly after the bend has been applied. This shape can be compared to the nominal shape with the help of a computer. In a preferred embodiment, the computer calculates corrective movements in order to eliminate remaining deviations from the ideal shape. These movements are executed either
 15 manually by an operator that receives respective instructions from the computer, or the computer has direct control over actuators that are coupled to the gimbal axes, and executes the necessary movements automatically. When the errors do not exceed predefined tolerances, the deformation process is regarded as successful, and the gripper is released and the gimbal axes are reset.

(69) The remaining deviation of an actual bend from the nominal value can be used for recalculating the subsequent bends. FIG. 16 displays a wire 68 having a first bend
 20 69. This bend deviates from the nominal bend represented by the nominal midline 67. FIG. 17 displays the wire after the second bend 70 has been applied. The distance between both bends has been slightly shortened, and the angle has been increased.
 25 Thus the original error in bend 69 has been compensated. Depending on the specific configuration of bends, a full compensation as demonstrated in FIGS 16 and 17 may not be possible, but a partial compensation can be performed. Again, the error in the second bend 70 will be measured, and a compensation of the determined deviation from the nominal value will be performed on subsequent bends.

(70) It is obvious that an apparatus as shown in FIG. 13 or 15 with a gimbal-mounted moveable gripper is perfectly suited for measuring the actual shape of the wire. The moveable components of such an apparatus can be perfectly balanced. Also,

measuring the actual angles can be performed by contact-free rotary encoders 50, 54 and 57. During the measuring process the wire is held, but no forces are applied onto the wire. In a preferred embodiment, all actuators that are used to drive the axes are completely decoupled from the axes.

5 (71) The words used in this specification to describe the invention and its various embodiments are to be understood not only in the sense of their commonly defined meanings, but to include by special definition in this specification structure, material or acts beyond the scope of the commonly defined meanings. Thus if an element can be understood in the context of this specification as including more than one meaning,
10 then its use in a claim must be understood as being generic to all possible meanings supported by the specification and by the word itself

(72) Insubstantial changes from the claimed subject matter as viewed by a person with ordinary skill in the art, now known or later devised, are expressly contemplated as being equivalent within the scope of the claims. Therefore, obvious substitutions
15 now or later known to one with ordinary skill in the art are defined to be within the scope of the defined elements.

(73) The scope of the claims should not be limited by the preferred embodiments set forth in the description, but should be given the broadest interpretation consistent with the description as a whole.

20 (74) In the claims which follow, reference characters used to designate claim steps are provided for convenience of description only, and are not intended to imply any particular order for performing the steps.

25

What is claimed is:

1. A method of bending an orthodontic archwire, comprising the steps of:

determining an optimal shape of a portion of an archwire positioned between a pair of orthodontic bracket receiving segments, the optimal shape including at least one pair of nominal bends, a location of a first nominal bend of the at least one pair of nominal bends substantially spaced apart from a location of a second nominal bend of the at least one pair of nominal bends;

applying an actual bend to the archwire at a location coinciding with the location of the first nominal bend;

measuring the actual bend to the archwire responsive to the actual bend being applied;

comparing the actual bend to the first nominal bend to determine an amount of deviation of the actual bend from the first nominal bend;

determining corrective movements to substantially eliminate the deviation between the actual bend and the nominal bend;

iteratively re-executing the applying, measuring, comparing, and determining steps until the deviation is within a predefined tolerance, the deviation then defining a remaining deviation; and

recalculating a value of the subsequent second nominal bend of the pair of nominal bends responsive to the remaining deviation of the actual bend to the archwire from the first nominal bend to thereby compensate for the remaining deviation therebetween.

2. The method as defined in claim 1, wherein the step of determining an optimal shape of a portion of an archwire includes the steps of determining a value for each of the at least one pair of nominal bends and determining a location of each of the at least one pair of nominal bends.

3. The method as defined in claim 1, wherein the step of determining an optimal shape of a portion of an archwire, and the step of determining corrective movements, are each performed by a computer in communication with an archwire bending apparatus.

4. The method as defined in claim 1, wherein the step of applying an actual bend to the archwire is performed by an archwire bending apparatus including at least two tools positioned to hold separate portions of the archwire, at least one of the tools positioned to adapt to a spatial position of a portion of the archwire.

5. The method as defined in claim 4, wherein the step of measuring the actual bend includes the steps of:

compensating for external forces to include gravity acting upon the at least one of the tools; and

performing automated positioning of the at least one of the tools responsive to forces in the archwire, the forces in the archwire driving at least an orientation of the at least one of the tools until the archwire is in a substantially relaxed state.

6. The method as defined in claim 5,

wherein the at least one tool of the archwire bending apparatus is a gimbal-mounted movable gripper; and

wherein the archwire bending apparatus includes at least one contact-free rotary encoder positioned to measure an angle of the actual bend.

7. The method as defined in claim 1, wherein the actual bend is a first actual bend, and wherein the step of determining an optimal shape of a portion of an archwire includes determining a value and a location for a third nominal bend, the method further comprising the steps of:

applying a second actual bend to the archwire at a location coinciding with the location of the second nominal bend;

measuring the second actual bend responsive to the second actual bend being applied;

comparing the second actual bend to the second nominal bend to determine an amount of deviation of the second actual bend from the second nominal bend;

determining corrective movements to substantially eliminate the deviation between the second actual bend and the second nominal bend;

iteratively re-executing the applying, measuring, comparing, and determining steps on the second actual bend until the deviation of the second actual bend is within a predefined tolerance, the deviation then defining a remaining deviation for the second actual bend; and

recalculating a value of the subsequent third nominal bend responsive to the remaining deviation of the second actual bend from the second nominal bend to thereby compensate for the remaining deviation therebetween.

8. A method of bending an orthodontic wire, comprising the steps of:

calculating a plurality of nominal bends describing a desired design shape of a portion of an orthodontic archwire positioned between a pair of orthodontic bracket slot segments, the plurality of nominal bends including a first nominal bend having a first location and a second nominal bend having a second location that is spaced apart from a first location of the first nominal bend;

placing a first bend in the archwire, the first placed bend representing the first nominal bend of the plurality of nominal bends at the first location;

measuring a deviation between the first placed bend and the first nominal bend being represented by the first placed bend;

calculating an offset to the second nominal bend of the plurality of nominal bends by a computer, the offset representing a correction to the second nominal bend to thereby compensate at least partially for the deviation in the first placed bend determined in the measuring step;

deriving an updated value for the second nominal bend at the second location by the computer using the offset calculated in the calculating step to thereby define a modified second nominal bend; and

placing a subsequent second bend in the archwire, the subsequent second placed bend representing the modified second nominal bend at the second location, the subsequent second placed bend providing at least partial compensation for the determined deviation in the first placed bend.

9. The method as defined in claim **8**, wherein the term bend includes either one of the following: one straight bend, a plurality of straight bends, one straight twist, a plurality of straight twists and any combination thereof.

10. The method as defined in claim **8**, wherein the plurality of nominal bends includes a third nominal bend having a third location that is spaced apart from the second location of the second nominal bend, the method further comprising:

measuring a deviation between the second placed bend and the modified second nominal bend being represented by the second placed bend;

calculating an offset to the third nominal bend of the plurality of nominal bends, the offset representing a correction to the third nominal bend to thereby compensate at least partially for the deviation in the second placed bend determined in the measuring step;

deriving an updated value for the third nominal bend using the offset calculated in the calculating step to thereby define a modified third nominal bend; and

placing a subsequent third bend in the archwire, the subsequent third placed bend representing the modified third nominal bend at the third location, the subsequent third placed bend providing at least partial compensation for the determined deviation in the second placed bend.

11. The method as defined in claim **8**, wherein the step of calculating an offset and the step of deriving an updated value are each performed by a computer, the method

further comprising generating a numerical set of data readable by an archwire bending apparatus positioned to execute the placing steps.

12. The method as defined in claim **8**, wherein the step of placing a bend is performed by an archwire bending apparatus including at least two tools positioned to hold separate portions of the archwire, at least one of the tools positioned to adapt to a spatial position of a portion of the archwire, at least one of the tools adapted to allow substantially unrestricted longitudinal movement of the portion of the archwire held therein.

13. The method as defined in claim **12**, wherein the step of measuring a deviation includes the steps of:

compensating for external forces to include gravity acting upon the at least one of the tools; and

performing automated positioning of the at least one of the tools responsive to forces in the archwire, the forces in the archwire driving at least an orientation of the at least one of the tools until the archwire is in a substantially relaxed state.

14. A manufacturing method to shape an orthodontic archwire in consecutive steps in response to numerical control data derived from design data of a desired shape of the orthodontic archwire, comprising the steps of:

placing a first bend in a first portion of an orthodontic archwire positioned between a pair of orthodontic bracket slot segments to be positioned in a corresponding pair of brackets slots of a corresponding pair of orthodontic brackets to be employed to straighten teeth of a patient;

generating measurement data of the first portion of the archwire having the first placed bend;

determining an amount of deviation between the measurement data of the first portion of the archwire and a first portion of the design data representing a design of the

first portion of the archwire, the design of the first portion of the archwire comprising a first nominal bend at a first location;

deriving updated numerical control data representing an update to a second portion of the design data responsive to the amount of deviation, the second portion of the design data representing an initial design of a second portion of the archwire, the initial design of the second portion of the archwire comprising a second nominal bend having a second location that is spaced apart from the first location of the first nominal bend, the update to the second portion of the design data representing a modified design of the second portion of the archwire, the modified design of the second portion of the archwire comprising the second nominal bend having an updated value to thereby define a modified second nominal bend; and

shaping a second portion of the archwire to include placing a subsequent second bend representing the modified second nominal bend, in the second portion of the archwire in response to the updated numerical control data to thereby provide at least partial compensation for the determined deviation in the first placed bend.

15. The method as defined in claim **14**, further comprising the step of comparing the measurement data to at least the first portion of the design data to determine the amount of deviation between the measurement data and the first portion of the design data.

16. The method as defined in claim **14**, wherein the step of determining an amount of deviation between the measurement data of the first portion of the archwire and the first portion of the design data includes the step of comparing the measurement data to at least a first portion of the numerical control data.

17. The method as defined in claim **14**, wherein the deriving and shaping steps are performed repeatedly on subsequent portions of the design data and subsequent portions of the archwire in at least two iterations so as to place at least three bends in the archwire to thereby compensate for an associated error function and to increase overall shape accuracy with respect to the desired shape.

18. The method as defined in claim **14**, wherein the steps of placing a bend at the first portion of the archwire and shaping a second portion of the archwire are performed by an archwire bending apparatus including at least two tools positioned to hold separate portions of the archwire, at least one of the tools positioned to adapt to a spatial position of a portion of the archwire, at least one of the tools adapted to allow unrestricted longitudinal movement of the portion of the archwire held therein.

19. The method as defined in claim **18**, wherein the step of generating measurement data includes the steps of:

compensating for external forces to include gravity acting upon the at least one of the tools; and

performing automated positioning of the at least one of the tools responsive to forces in the archwire, the forces in the archwire driving at least an orientation of the at least one of the tools until the archwire is in a substantially relaxed state.

20. The method as defined in claim **16**, wherein the step of comparing the measurement data and the step of deriving updated numerical control data are each performed by a computer, the method further comprising generating a set of numerical data readable by an archwire bending apparatus positioned to execute the shaping step.

21. A method of placing a bend in an orthodontic wire having a cross-section having at least two main axes, comprising the steps of:

a) bending the wire in a first direction where the bending axis is substantially parallel to one of the main axes;

b) bending the wire in a second direction where the bending axis is substantially parallel to one of the other main axes;

wherein the place of the bend of step a) is substantially equal to the place of the bend of step b) in the longitudinal direction of the wire.

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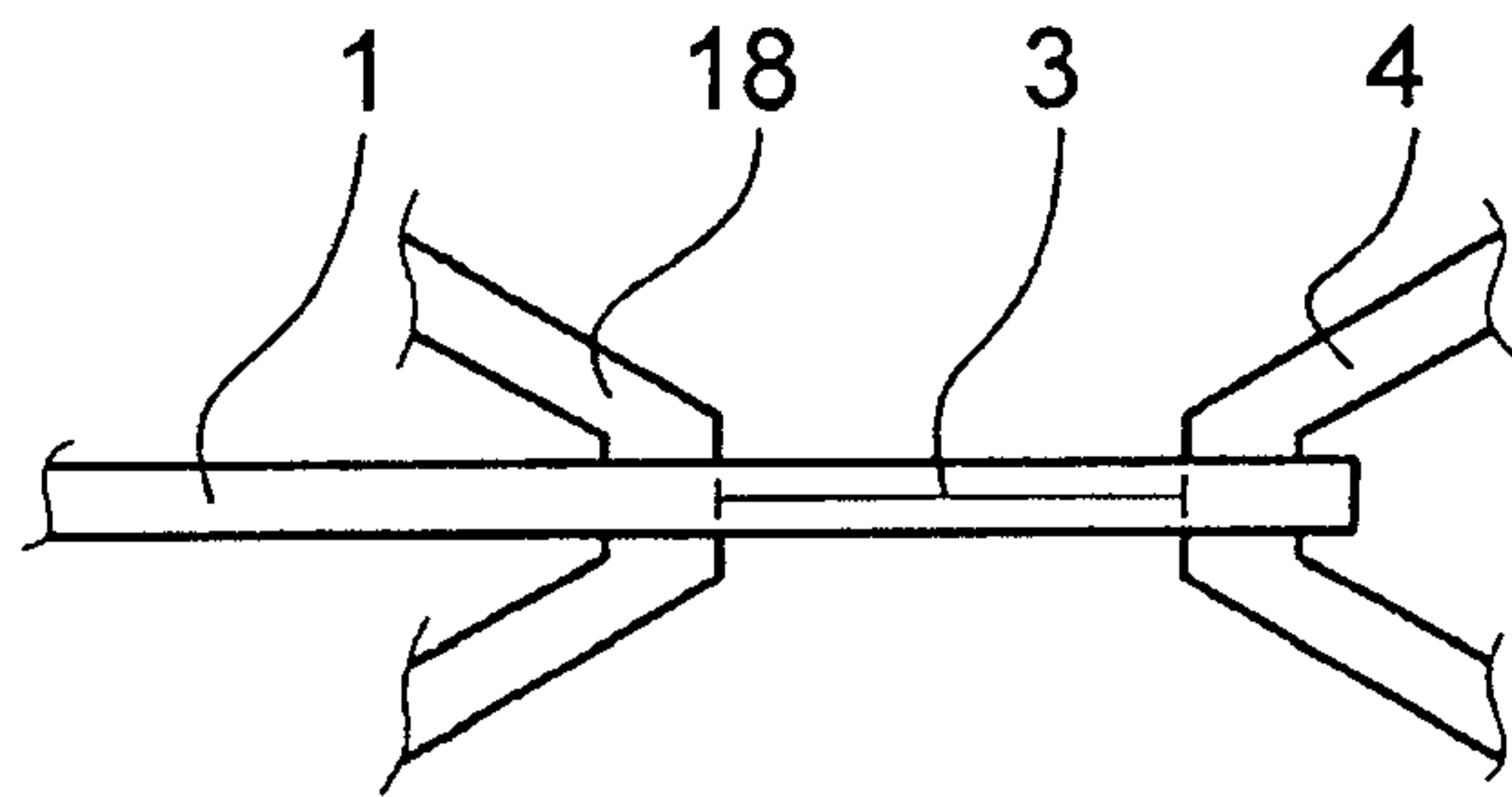


FIG. 1

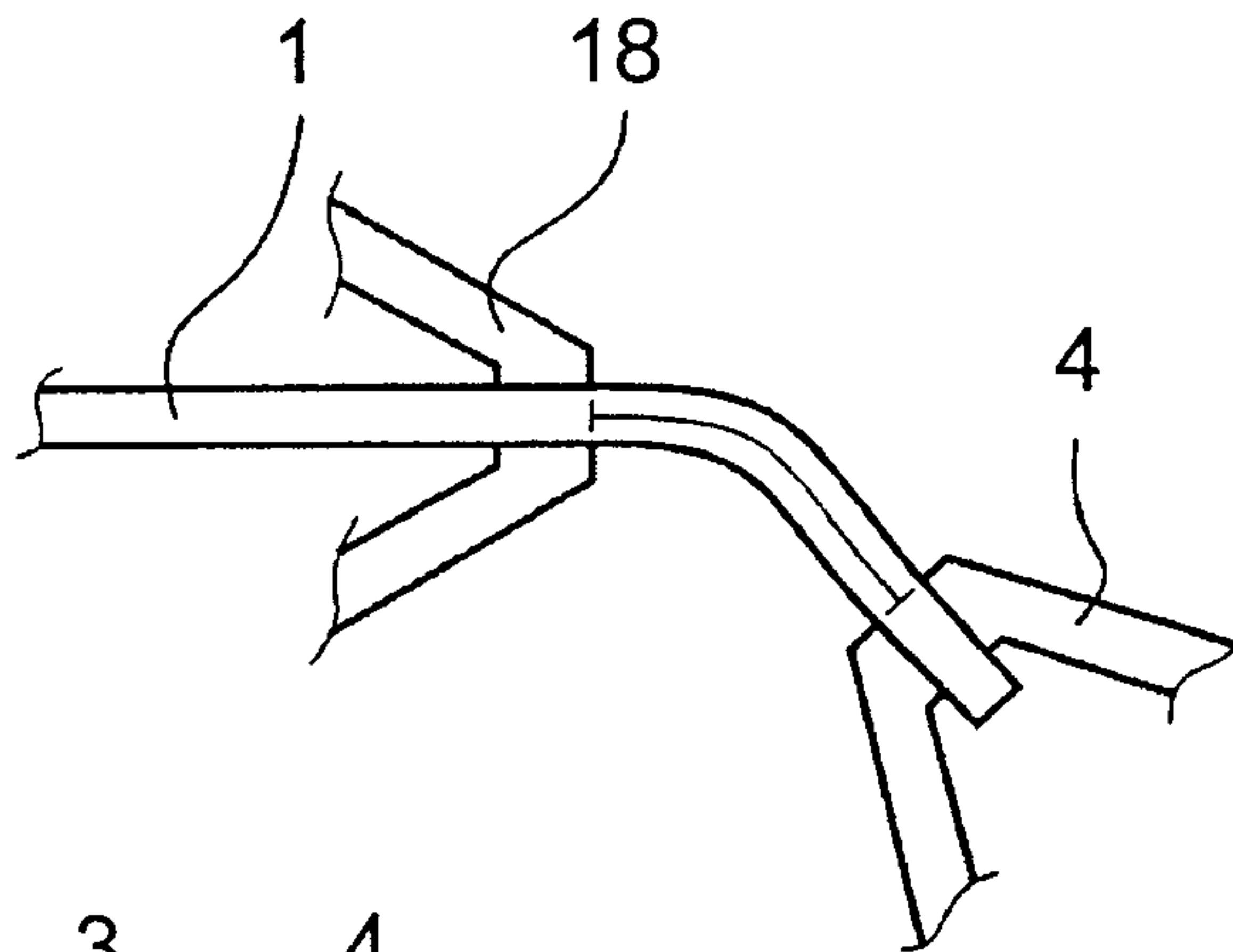


FIG. 2

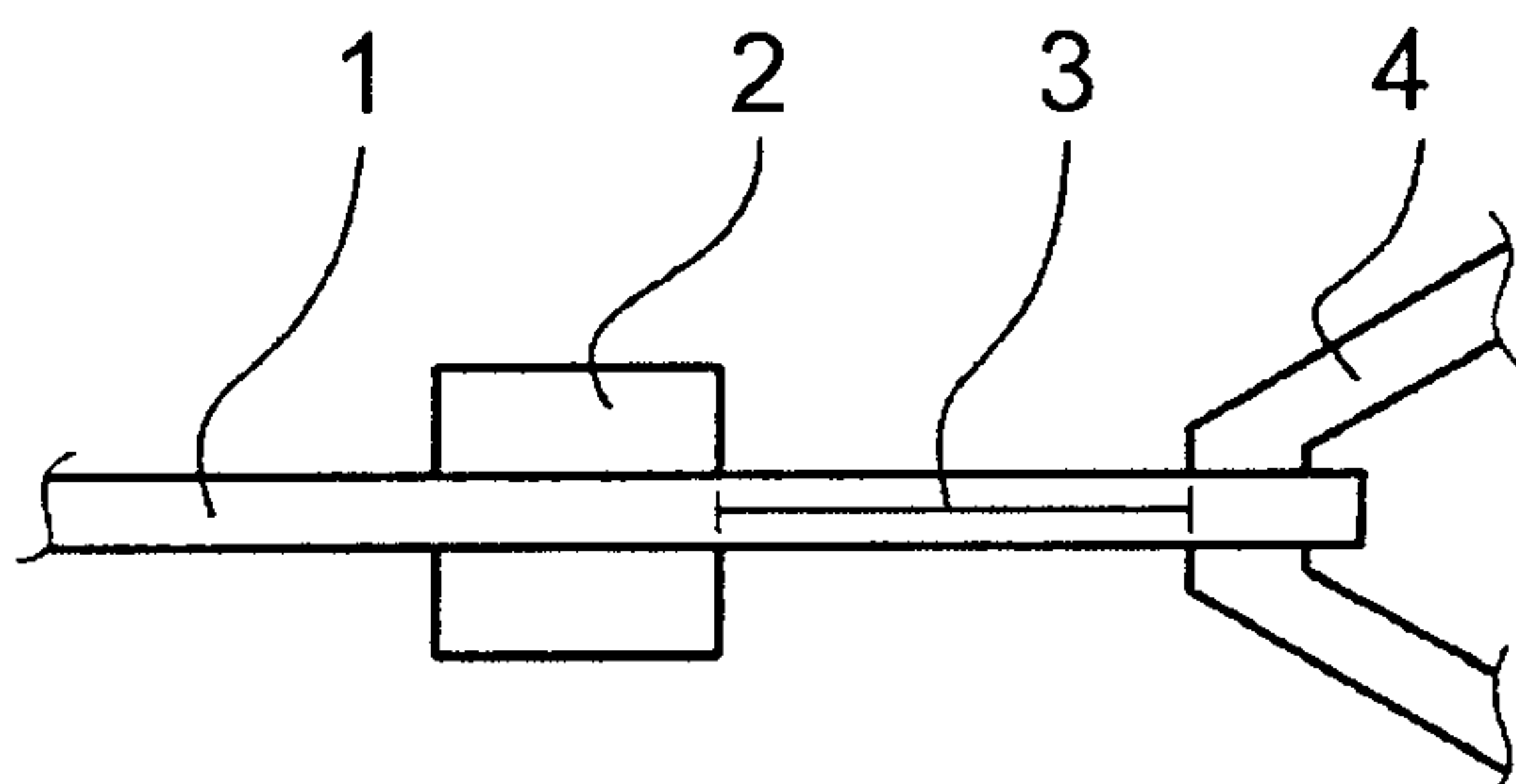


FIG. 3

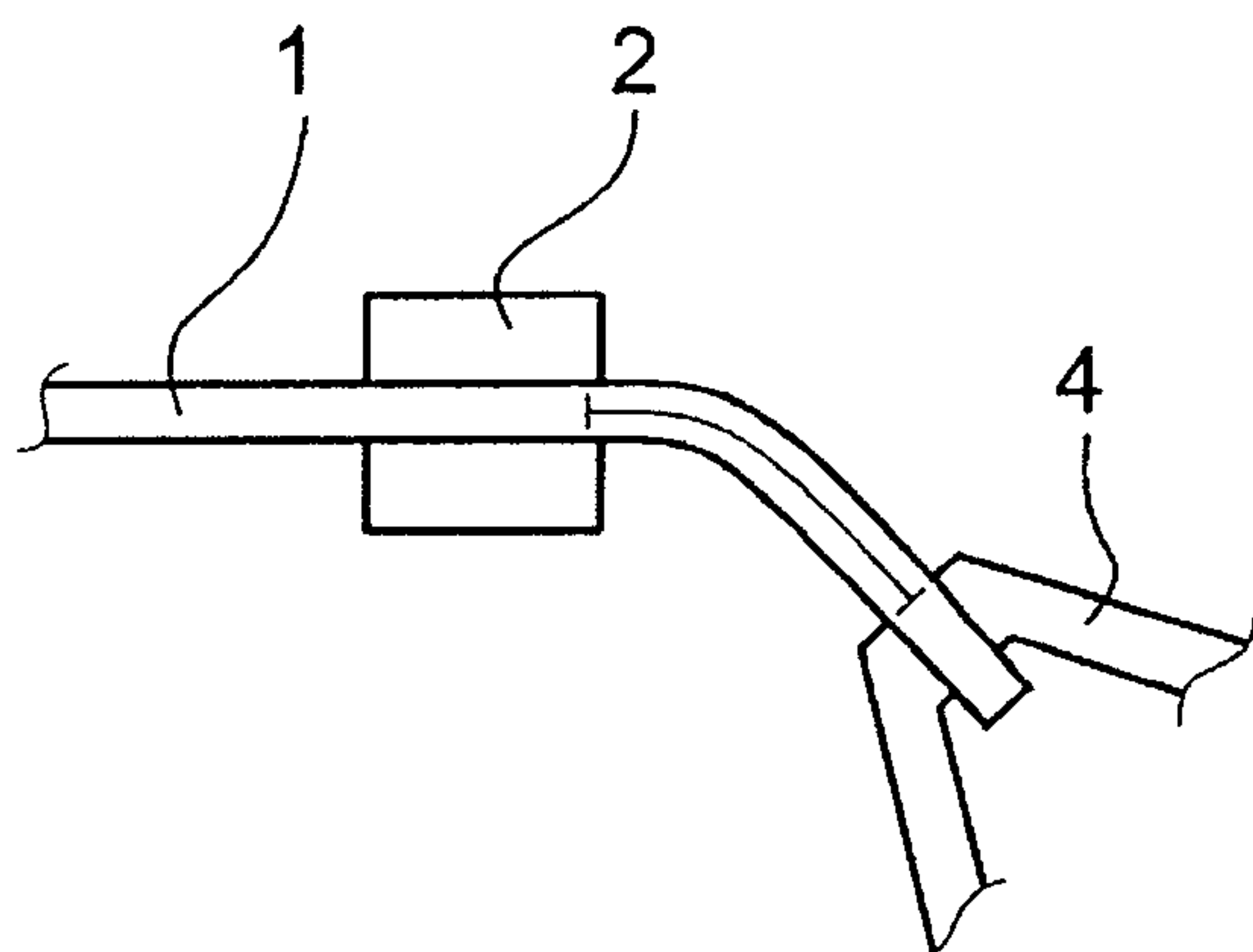


FIG. 4

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FIG. 5

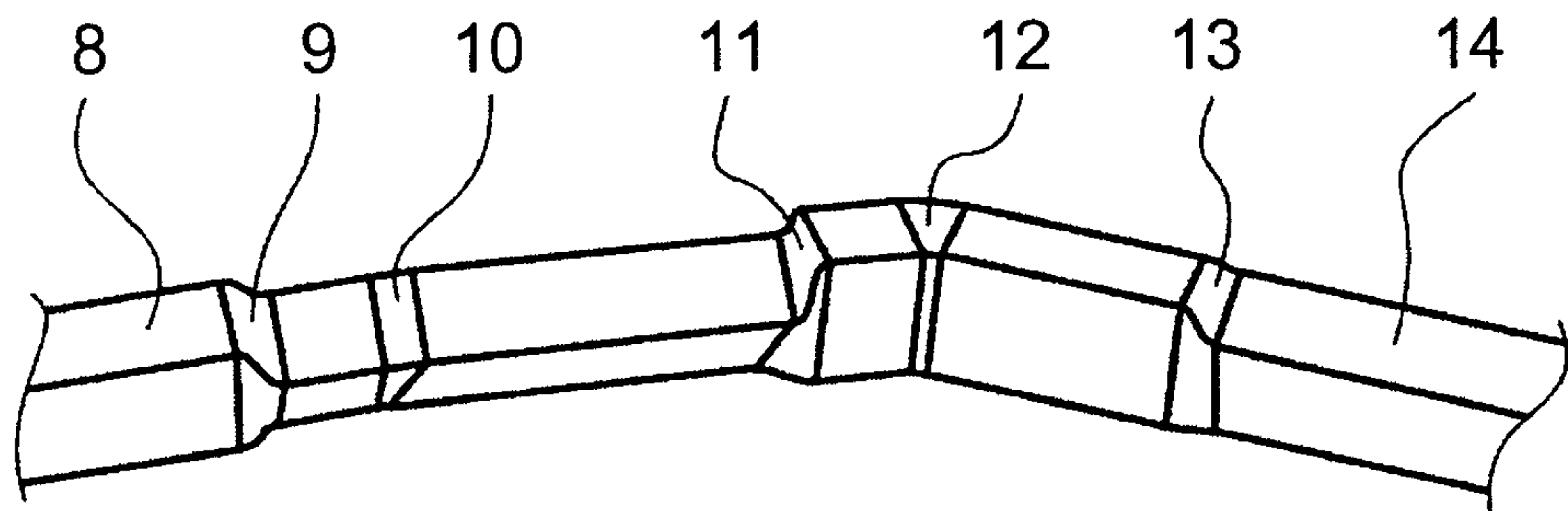
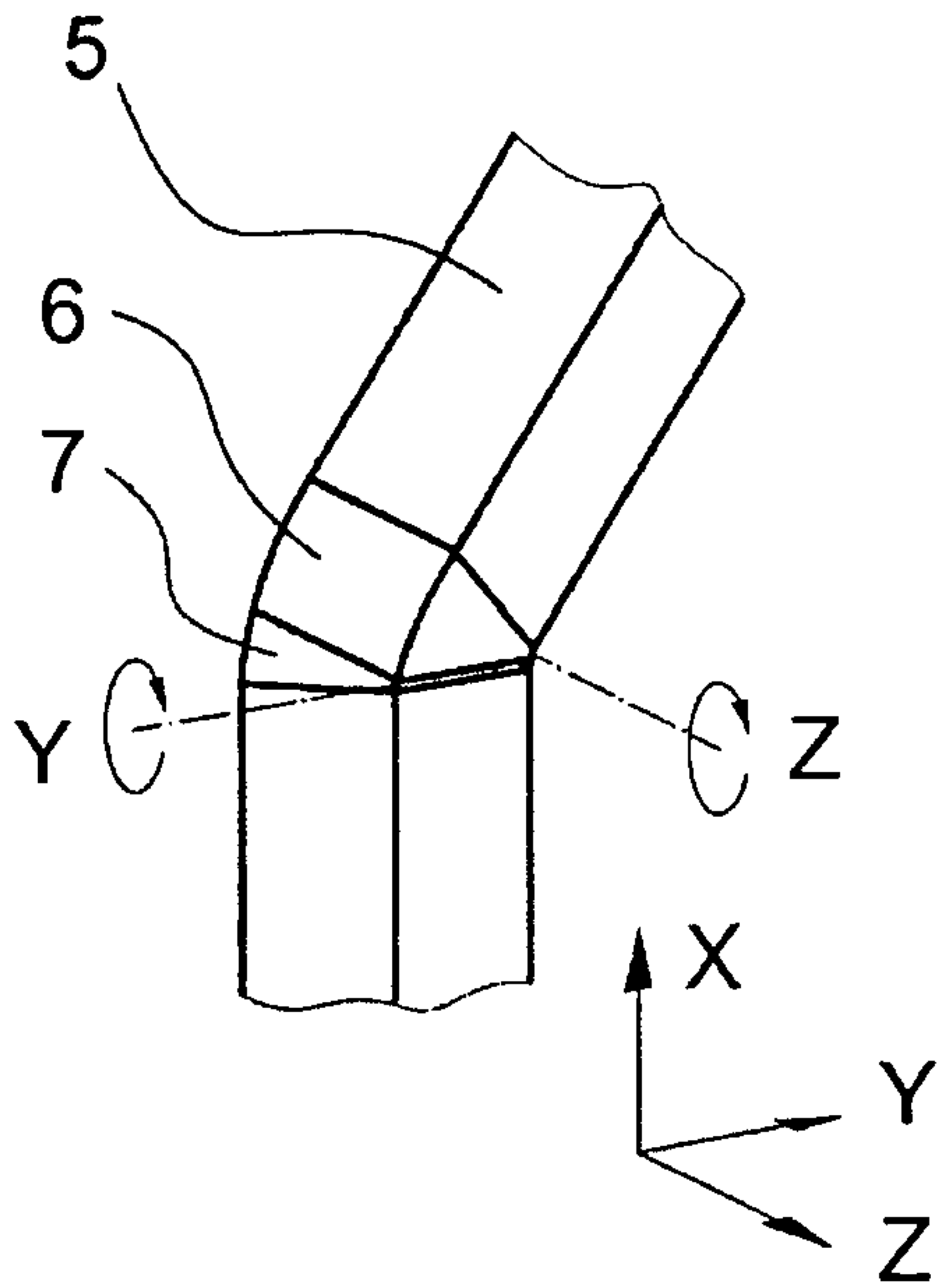


FIG. 6

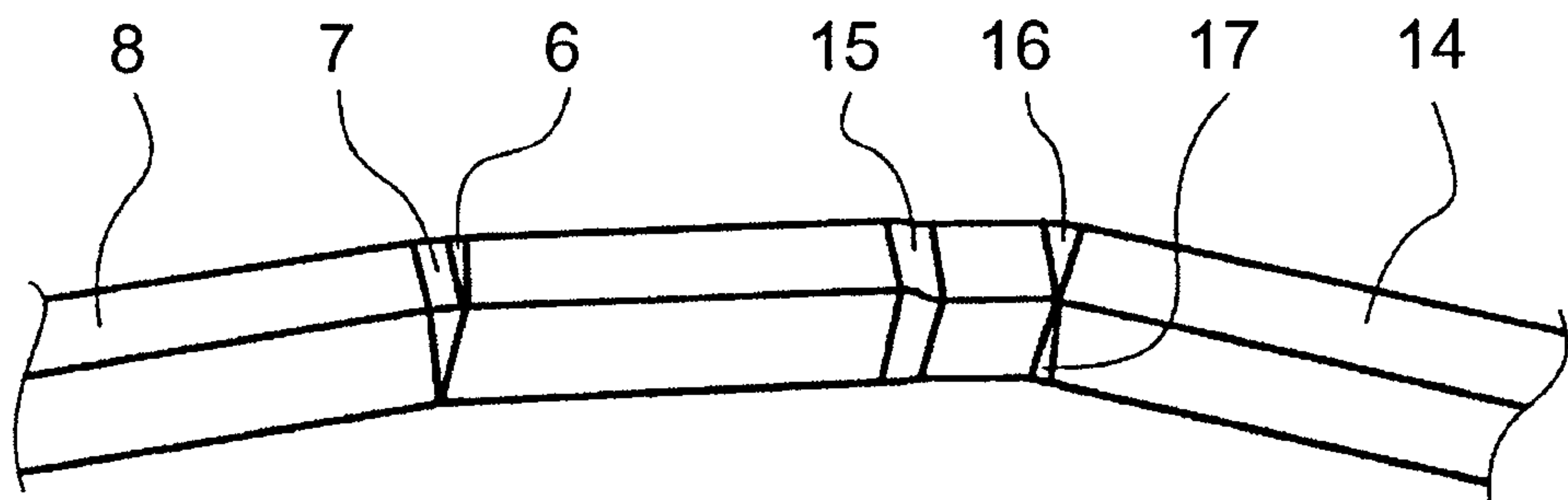


FIG. 7

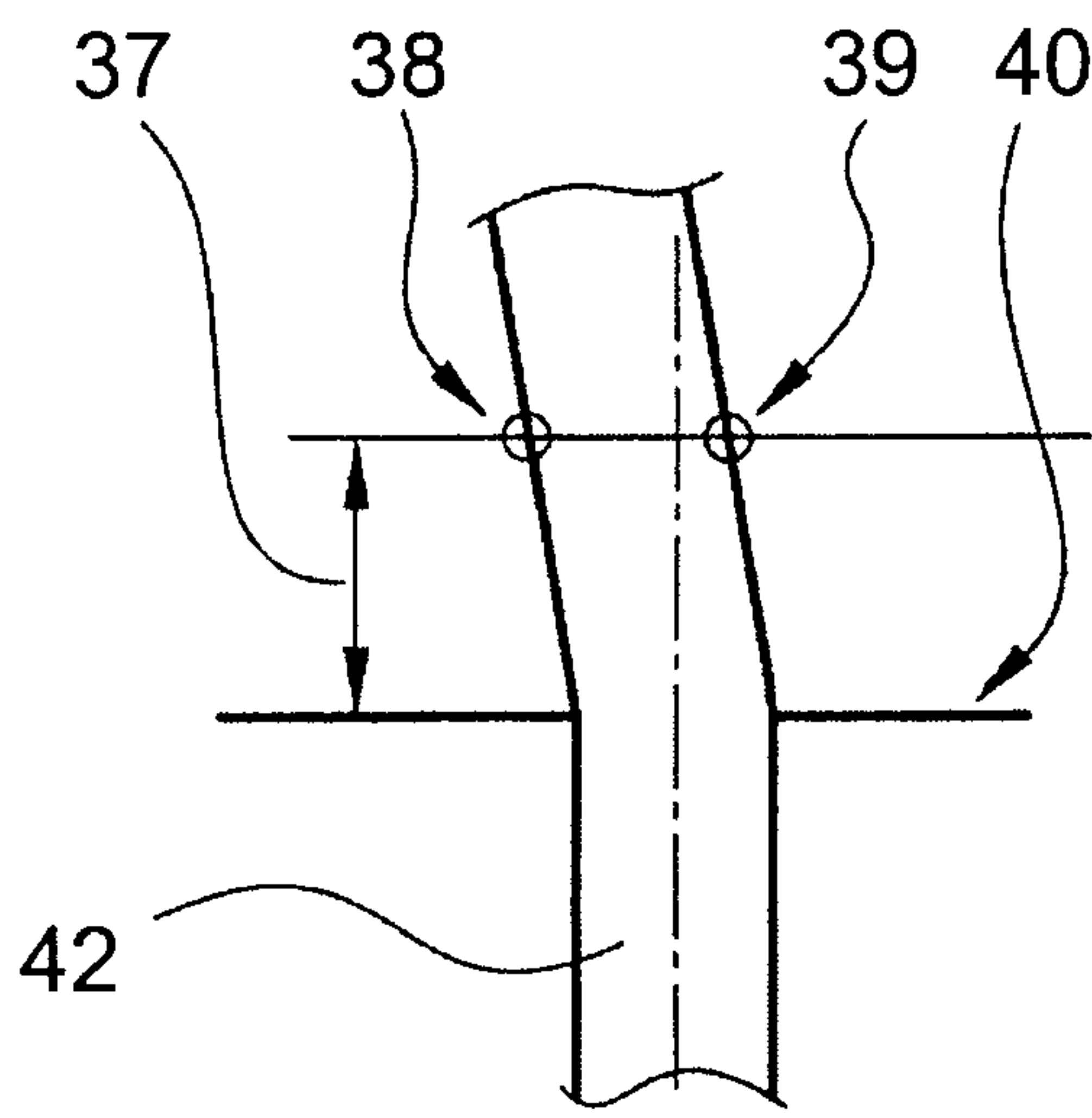


FIG. 8A

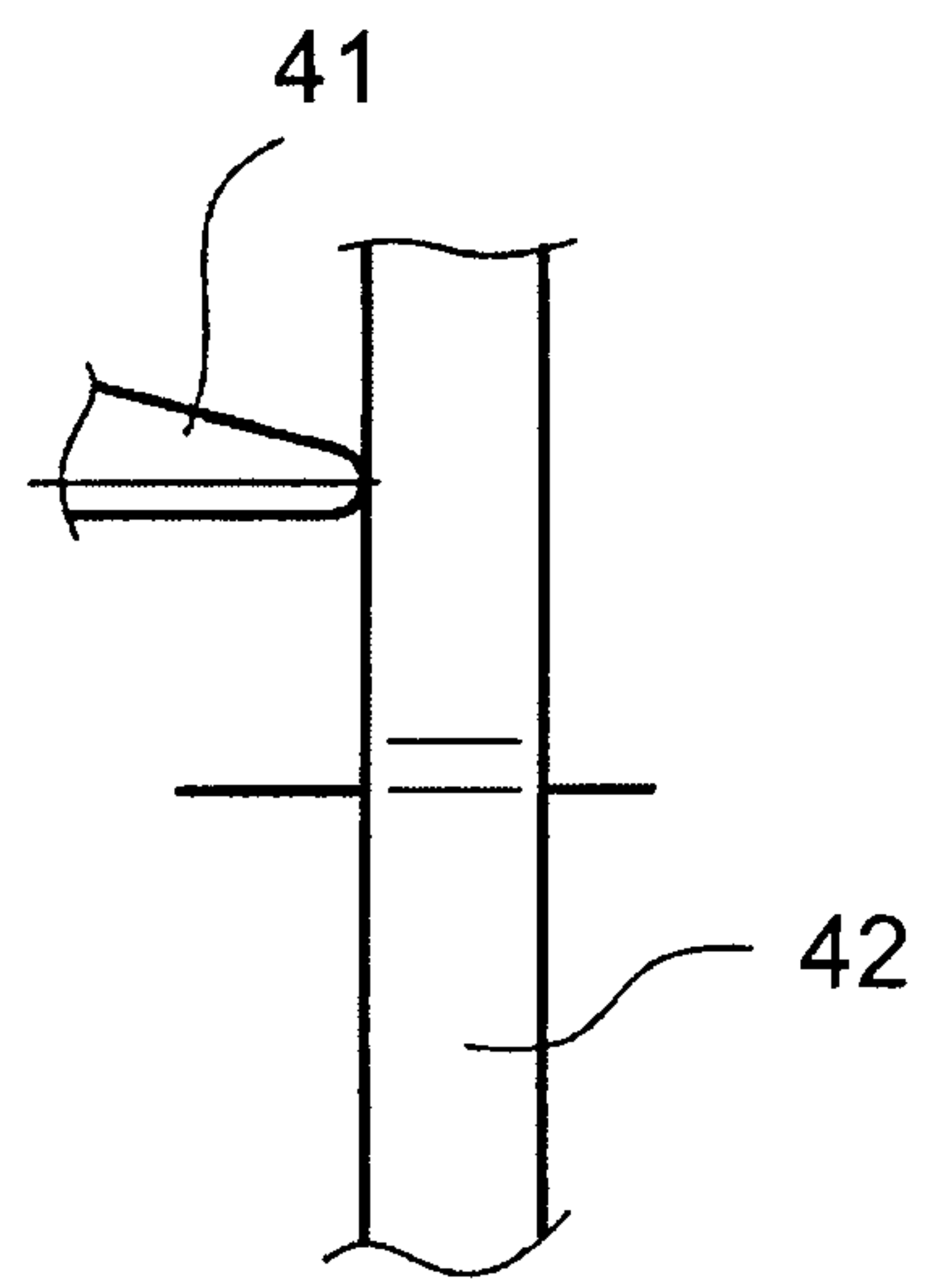


FIG. 8B

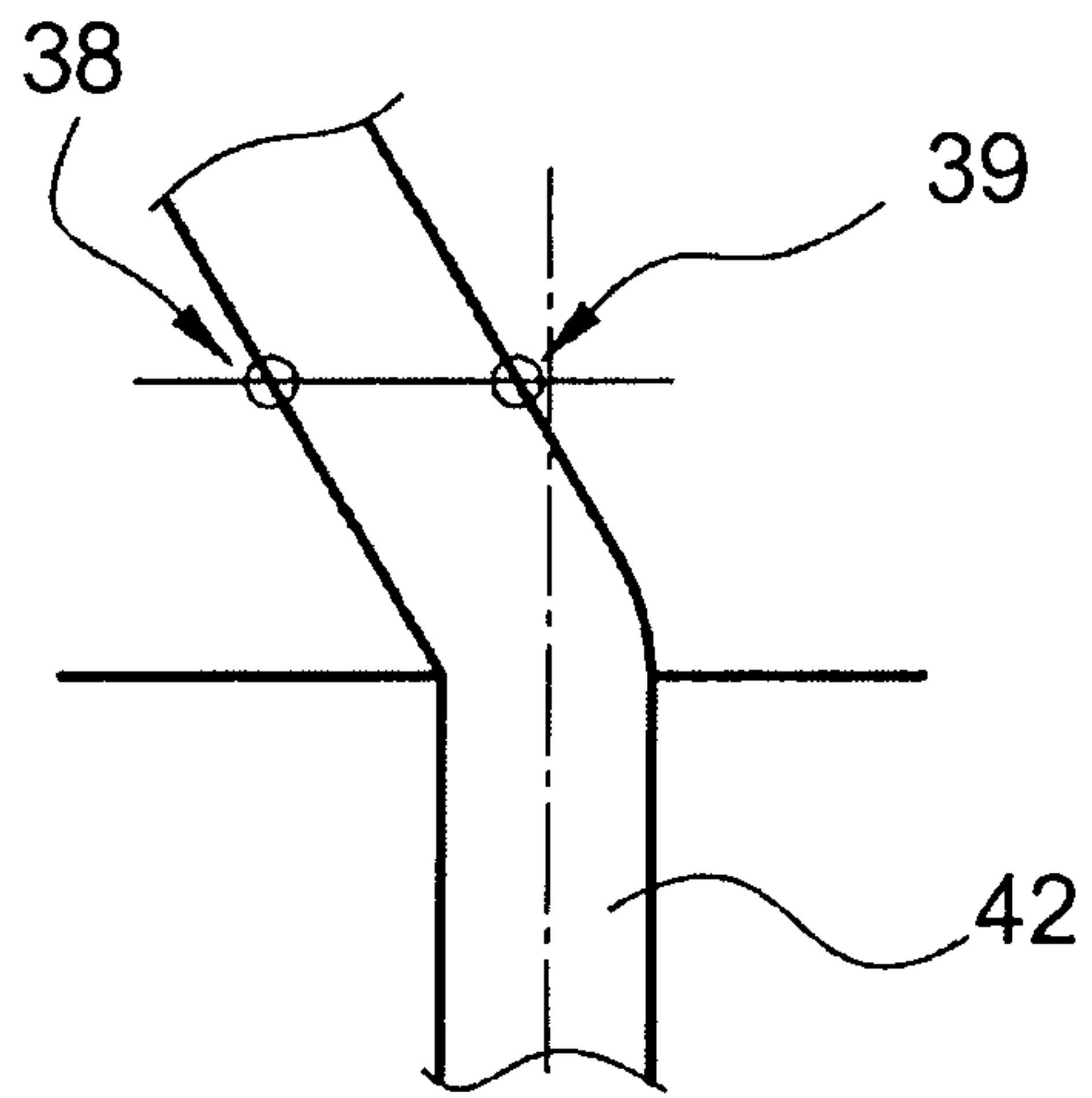


FIG. 9

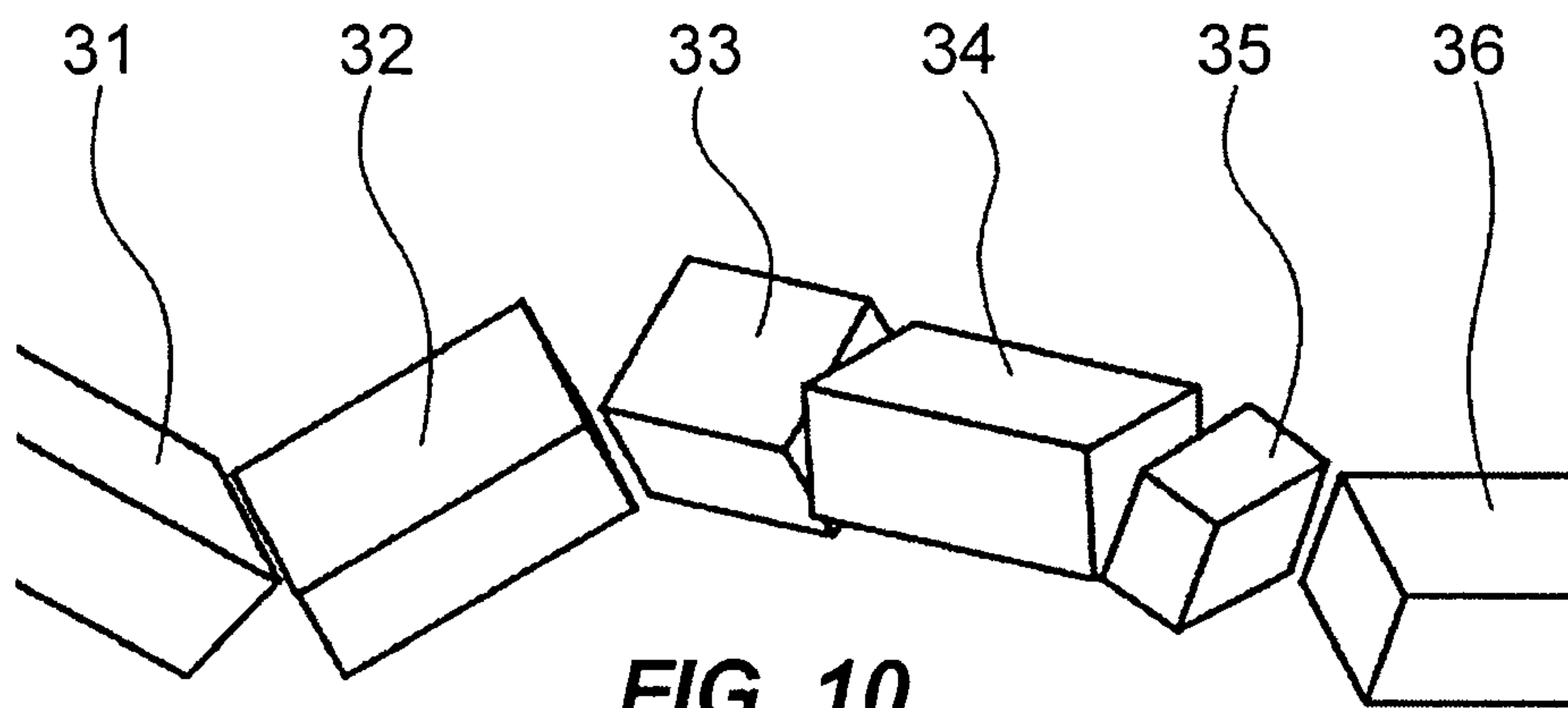
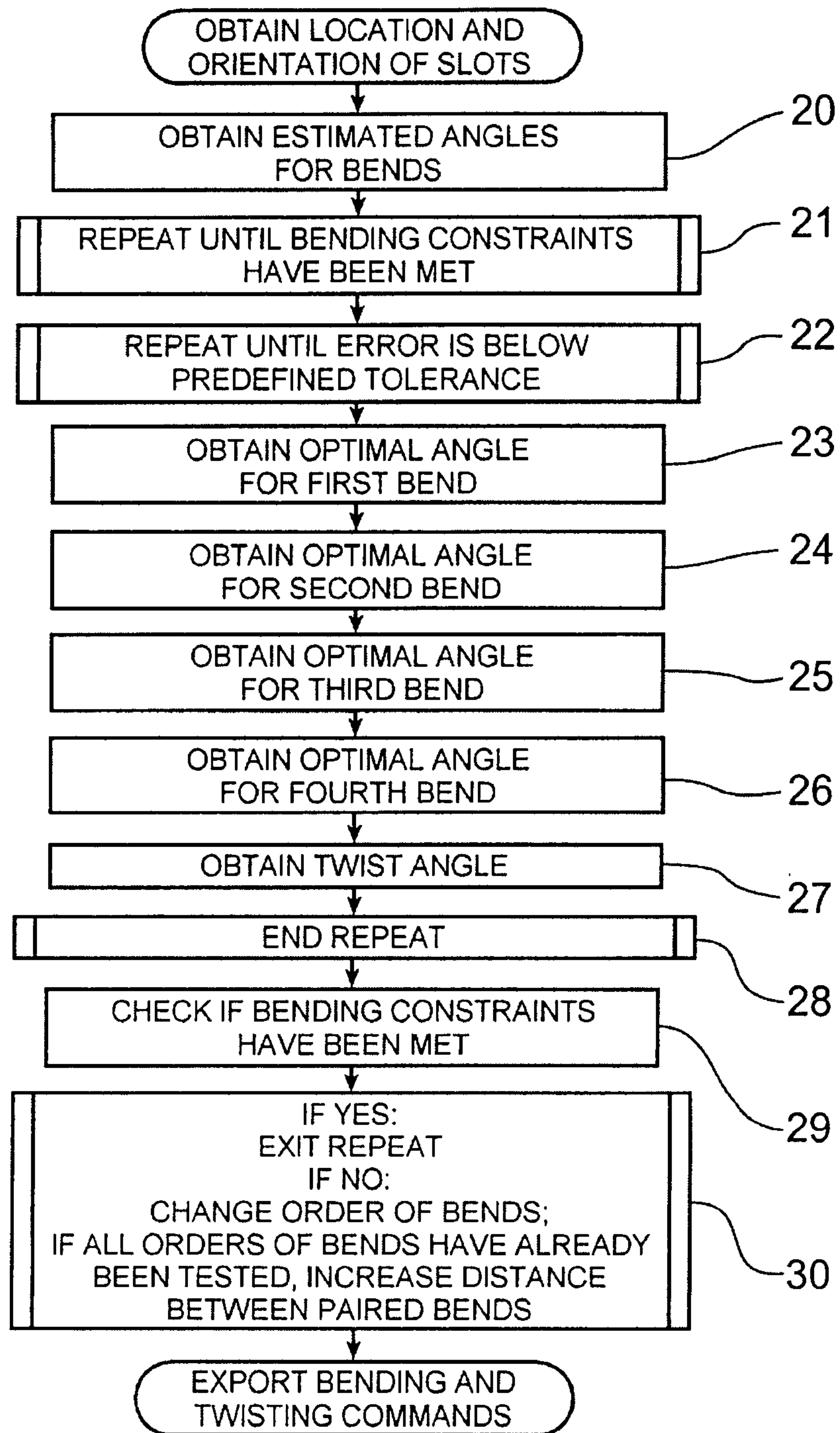


FIG. 10

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**FIG. 11**

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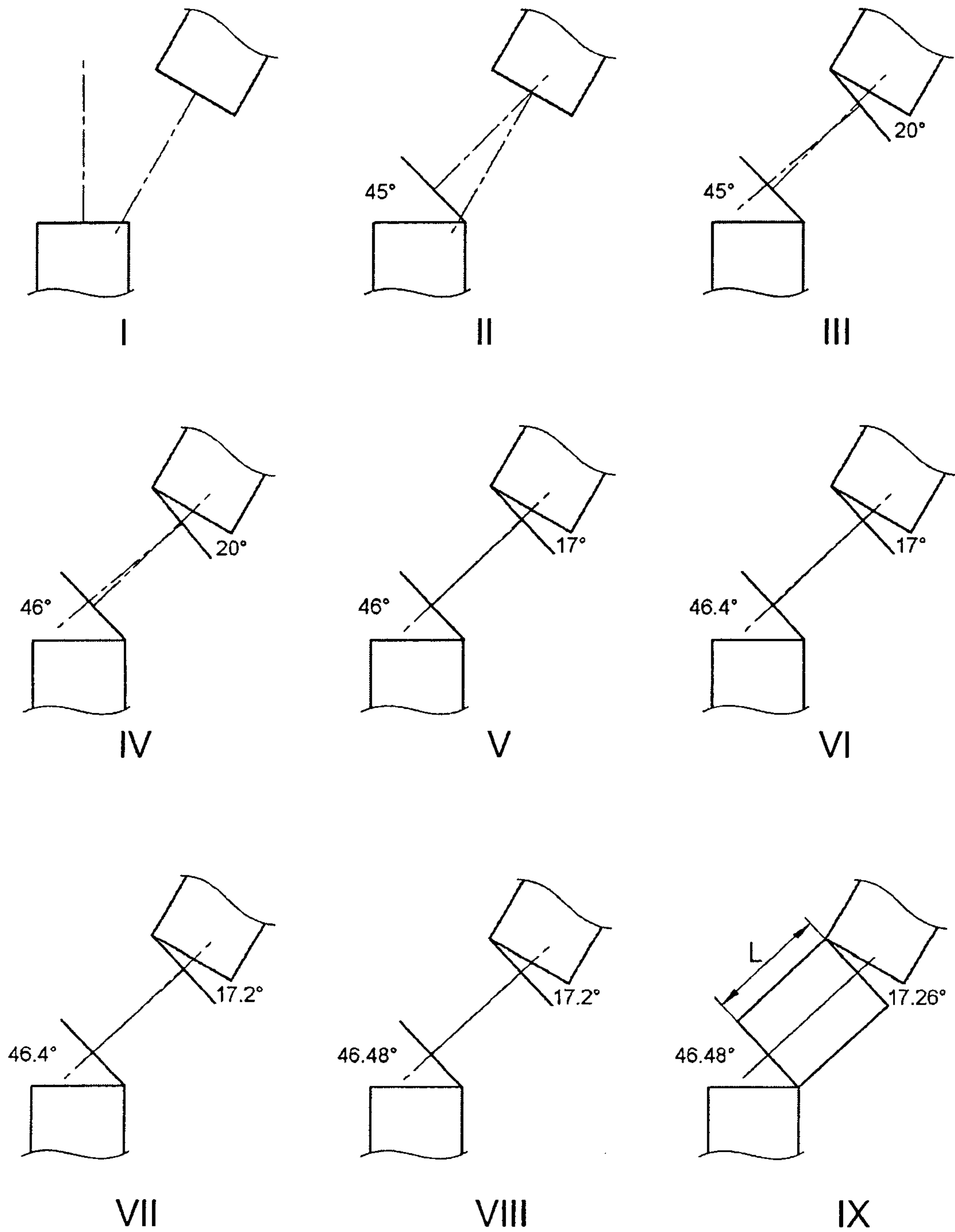


FIG. 12

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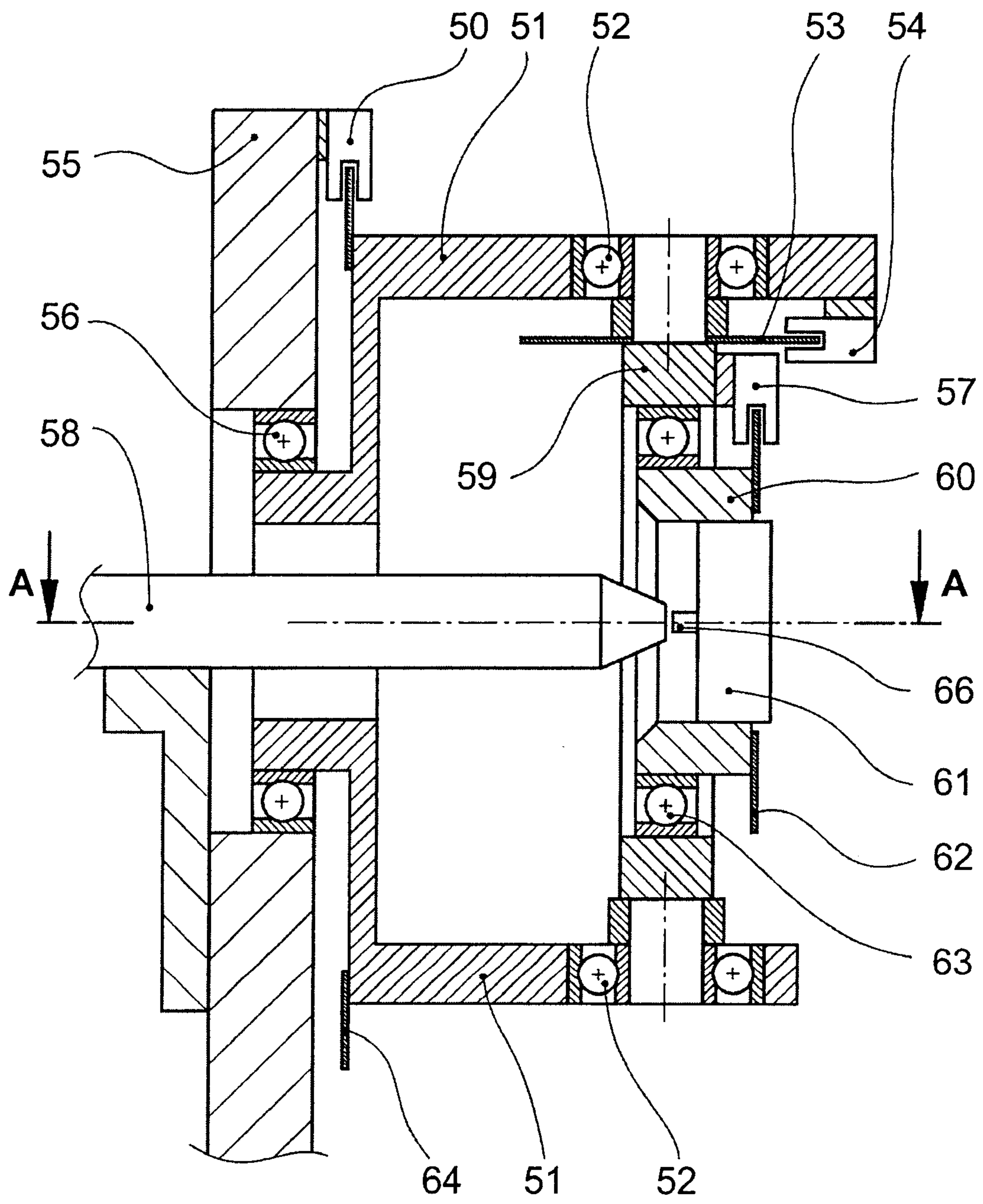


FIG. 13

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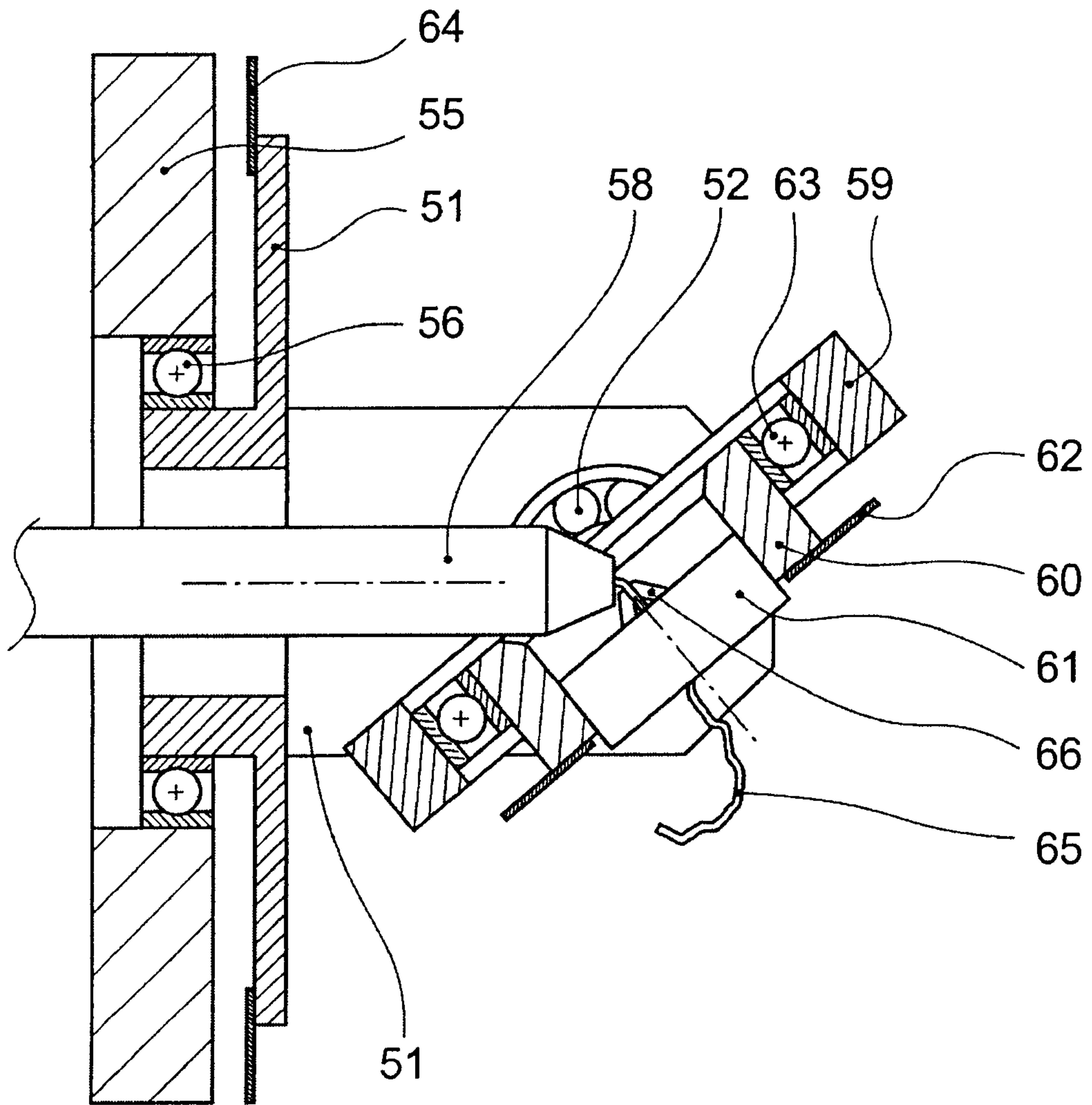


FIG. 14

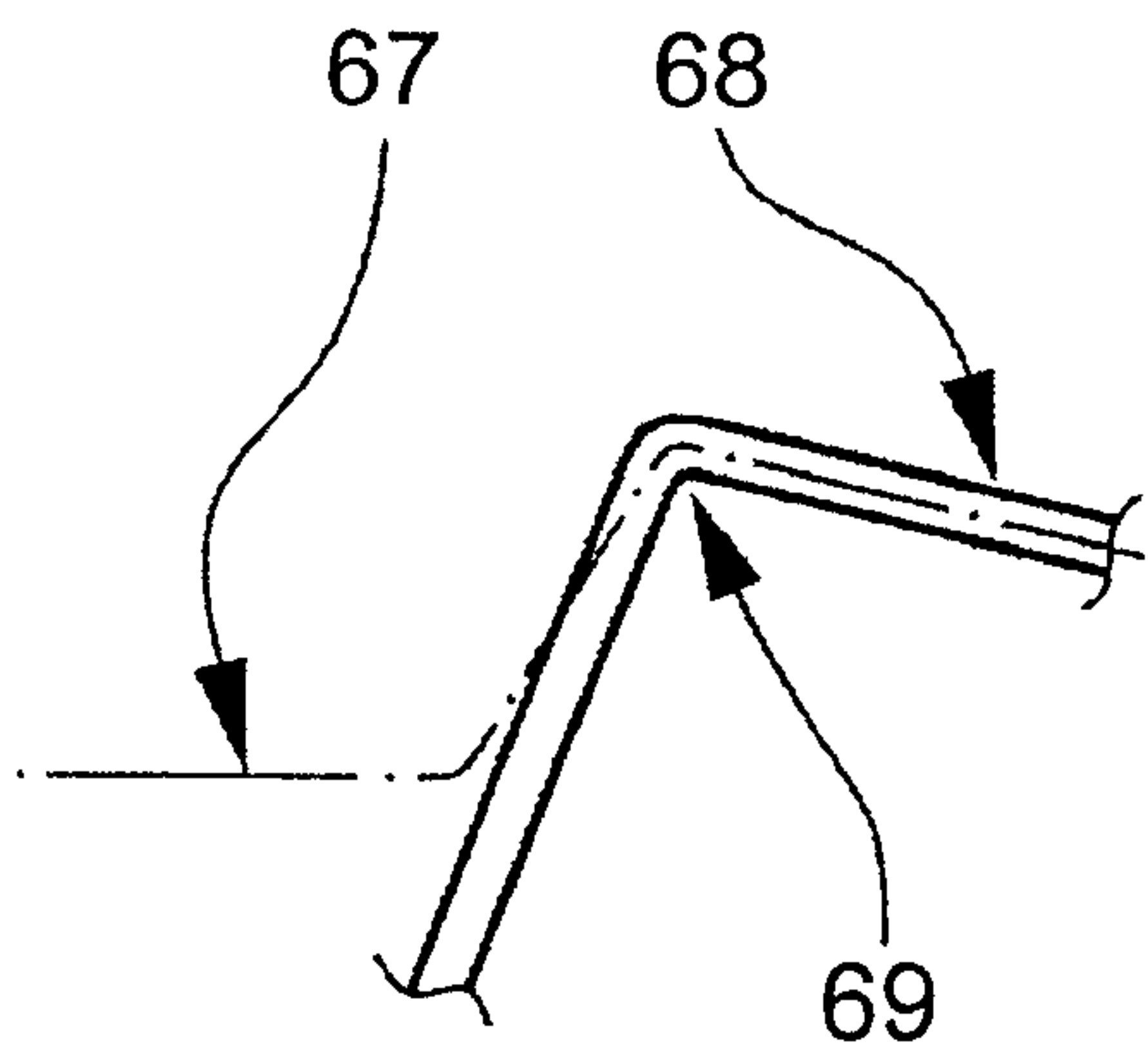
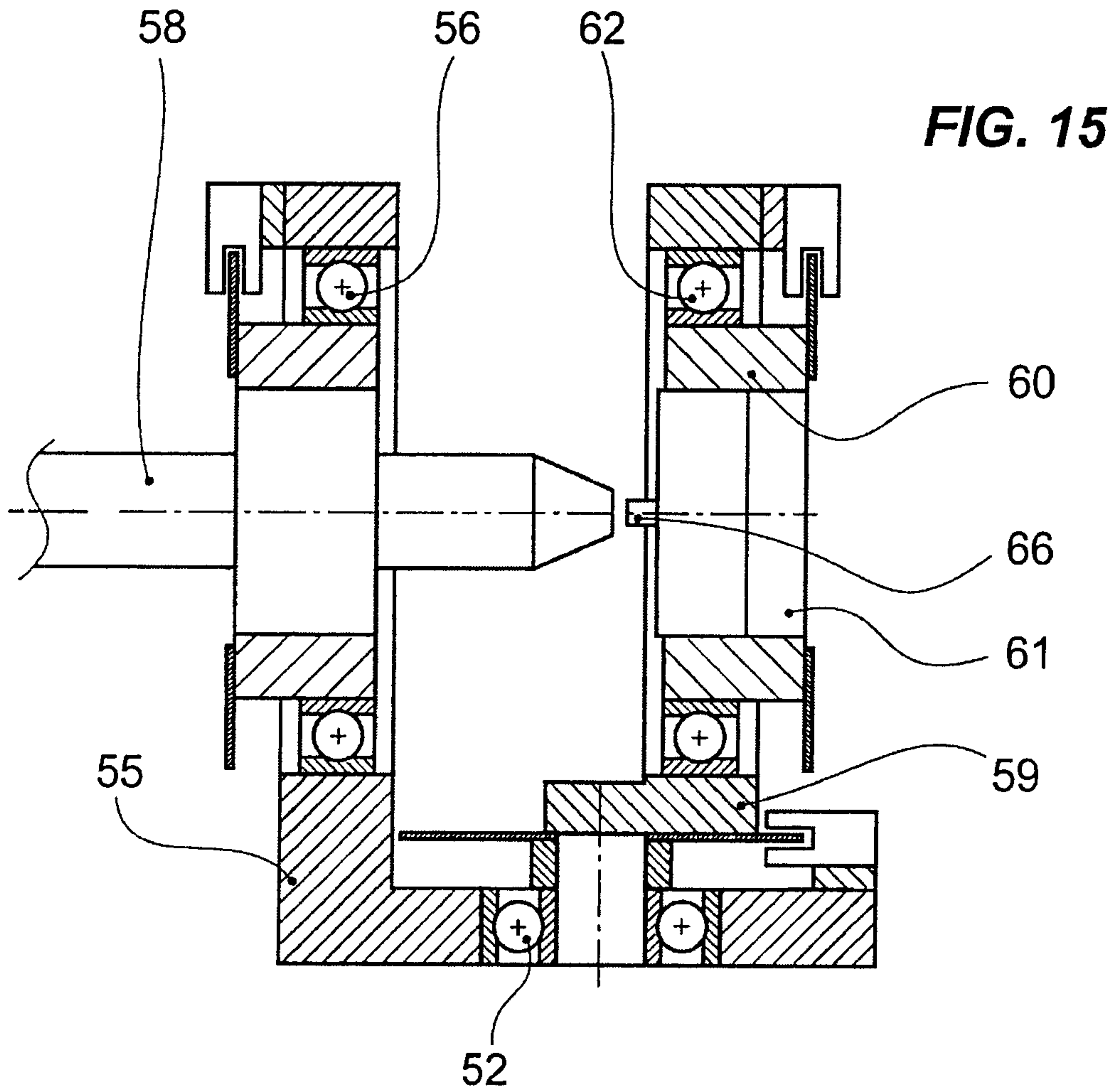


FIG. 16

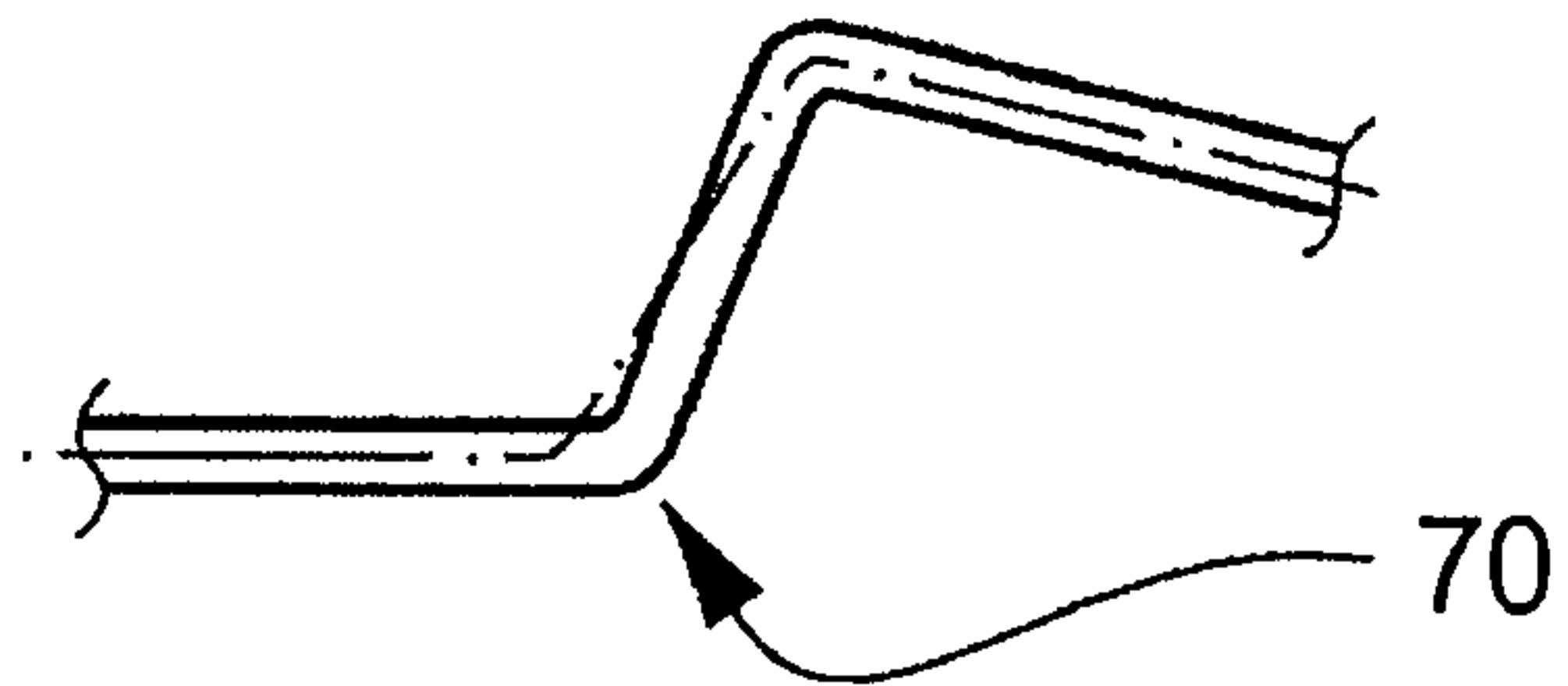


FIG. 17

