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(54) **SINGLE LUMEN TO MULTIPLE LUMEN  
TRANSITION CATHETER AND METHOD**

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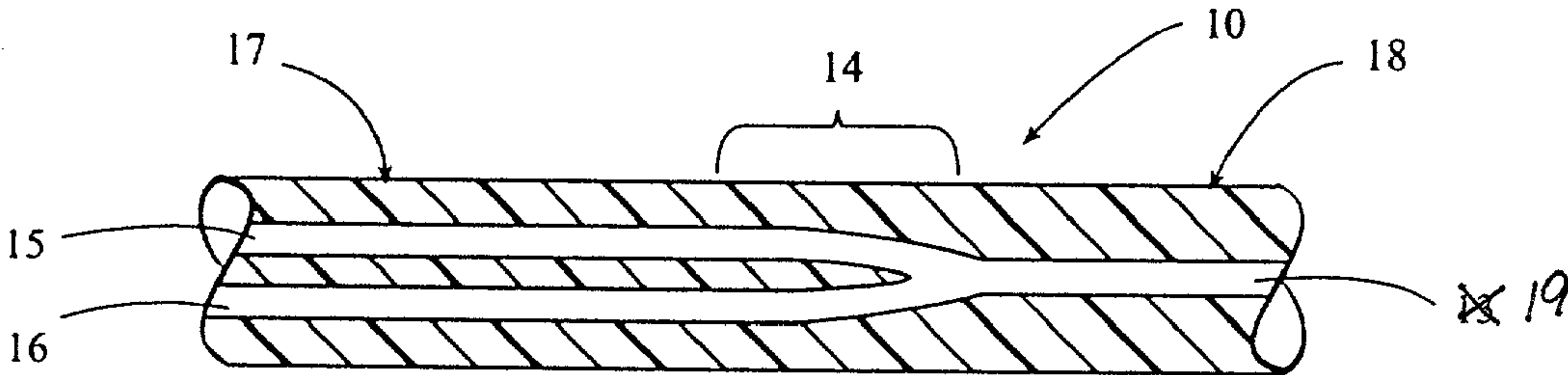
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**Related U.S. Application Data**

(63) Continuation-in-part of application No. 09/131,487,  
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(57) **ABSTRACT**

A tubing having unitary construction and having a single lumen portion, a multilumen portion and a transition portion therebetween. The single lumen is in fluid communication with each and every lumen comprising the multilumen portion. The tubing may be made in any desired length by means of extrusion. The outer surface of the tubing may be either smooth or grooved and have any desired cross-sectional geometry. Similarly, any of the lumens can be made to have a desired cross-sectional shape and size. Although the tubing can be made from any extrudable material, a preferred material is medical grade silicone elastomer. An extrusion apparatus and a method for making the tubing in a continuous process is described.



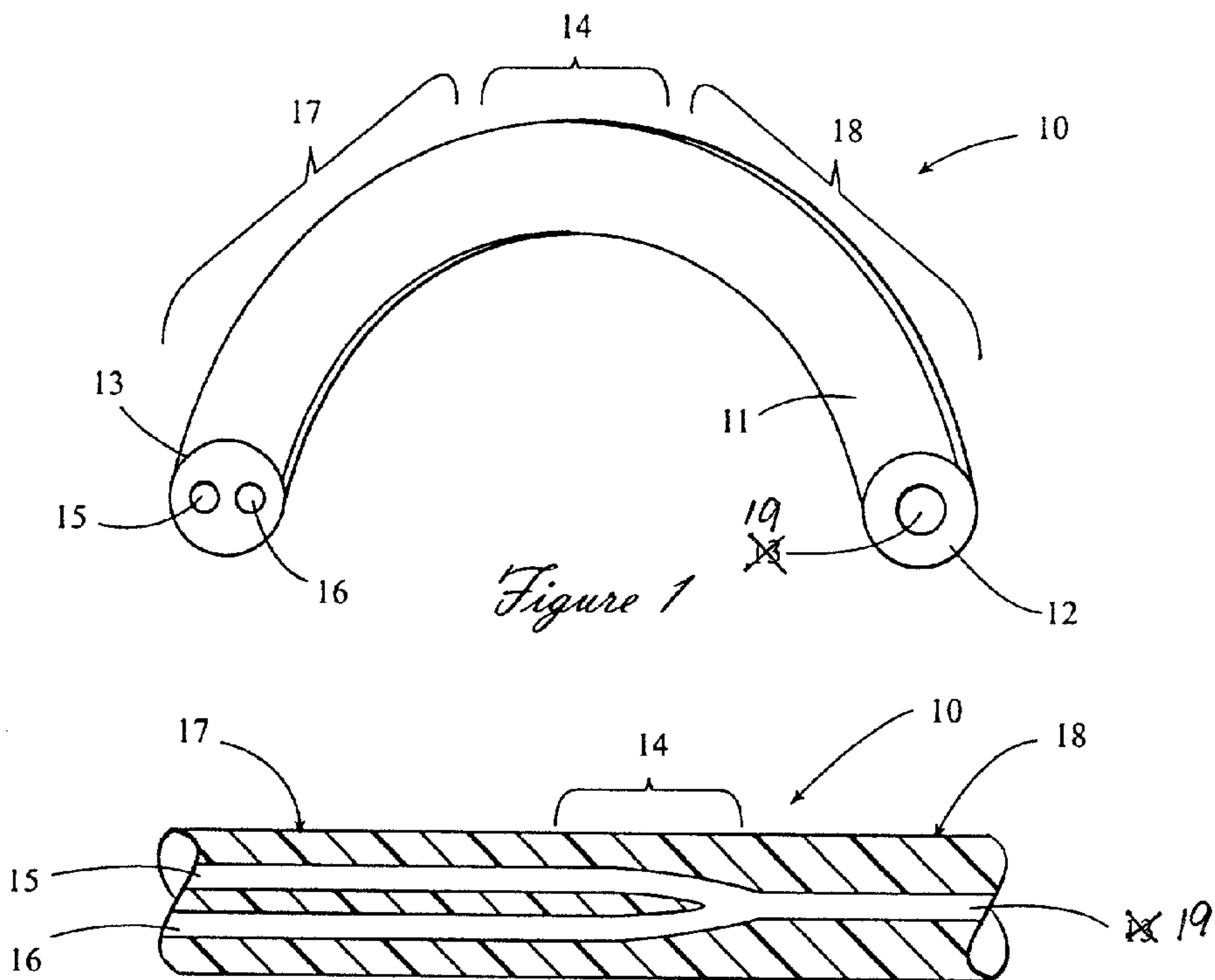
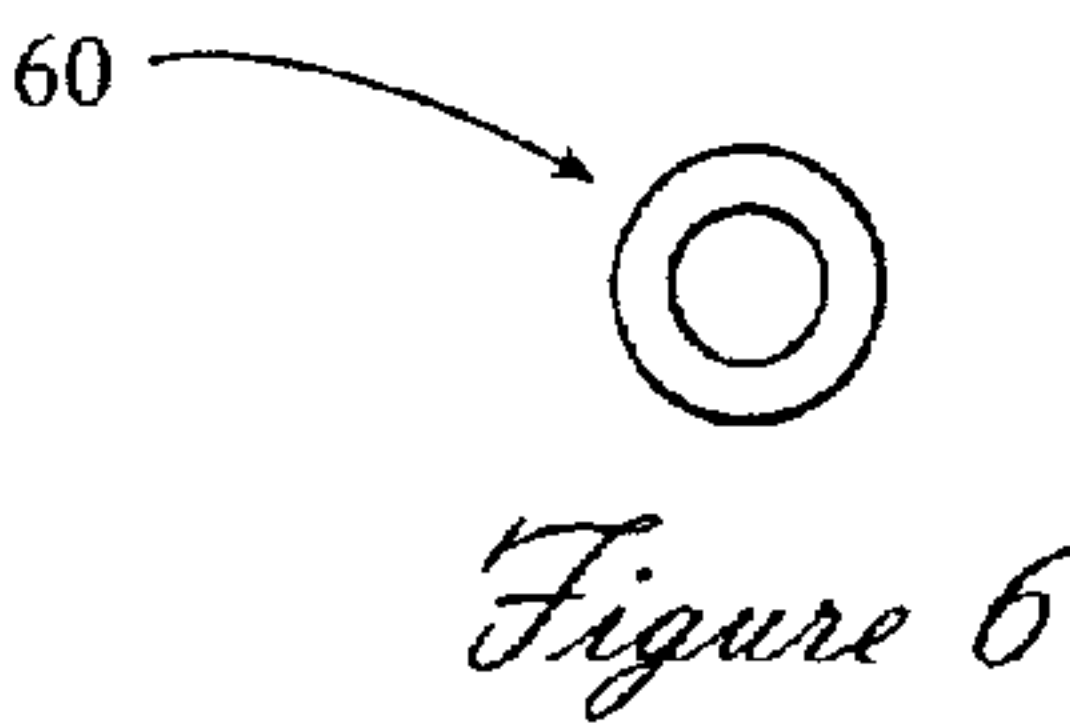
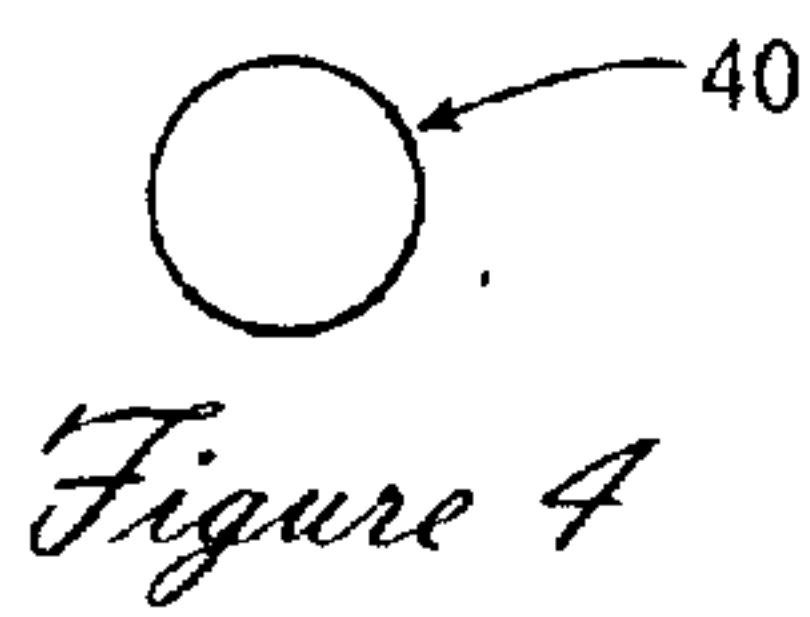
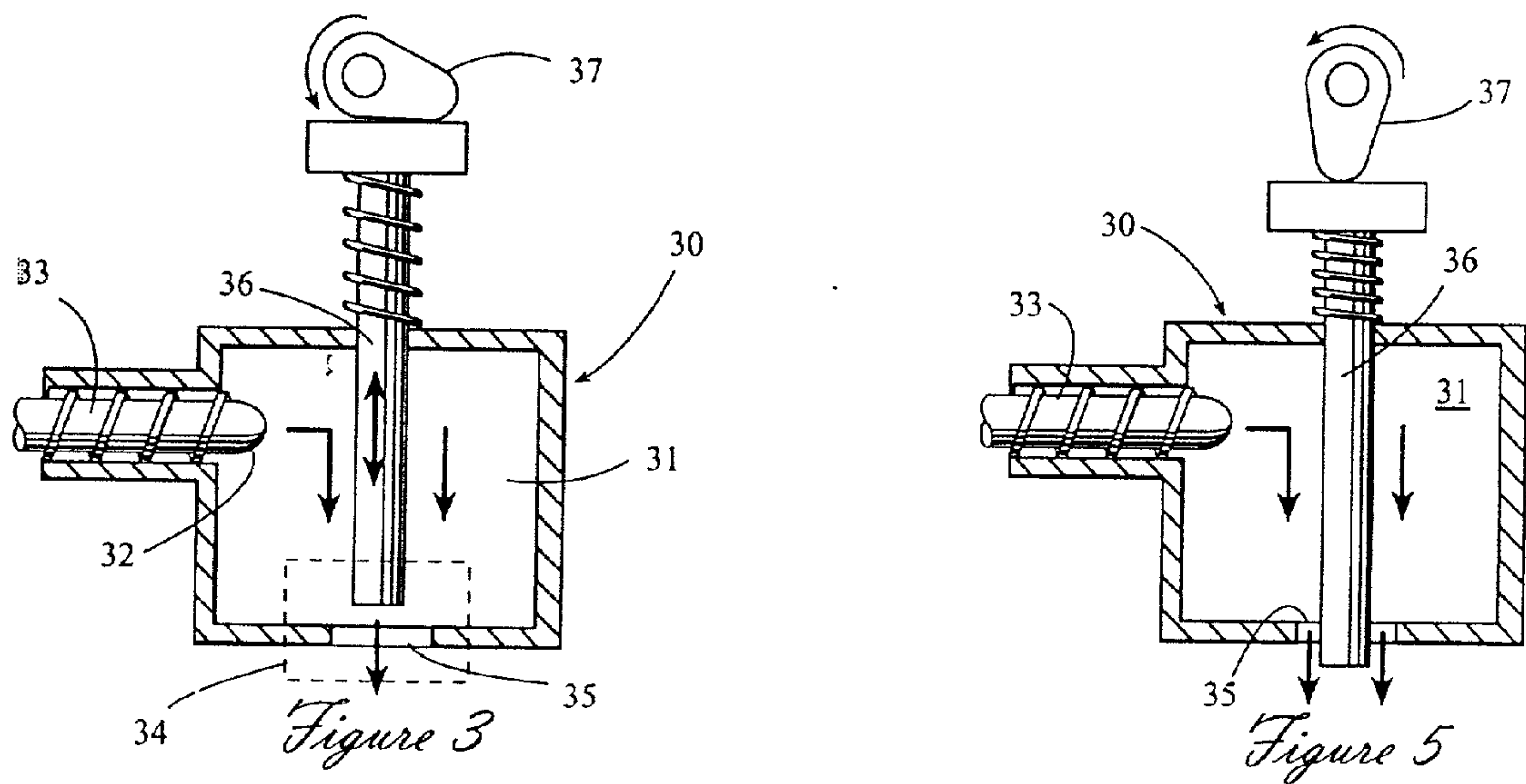
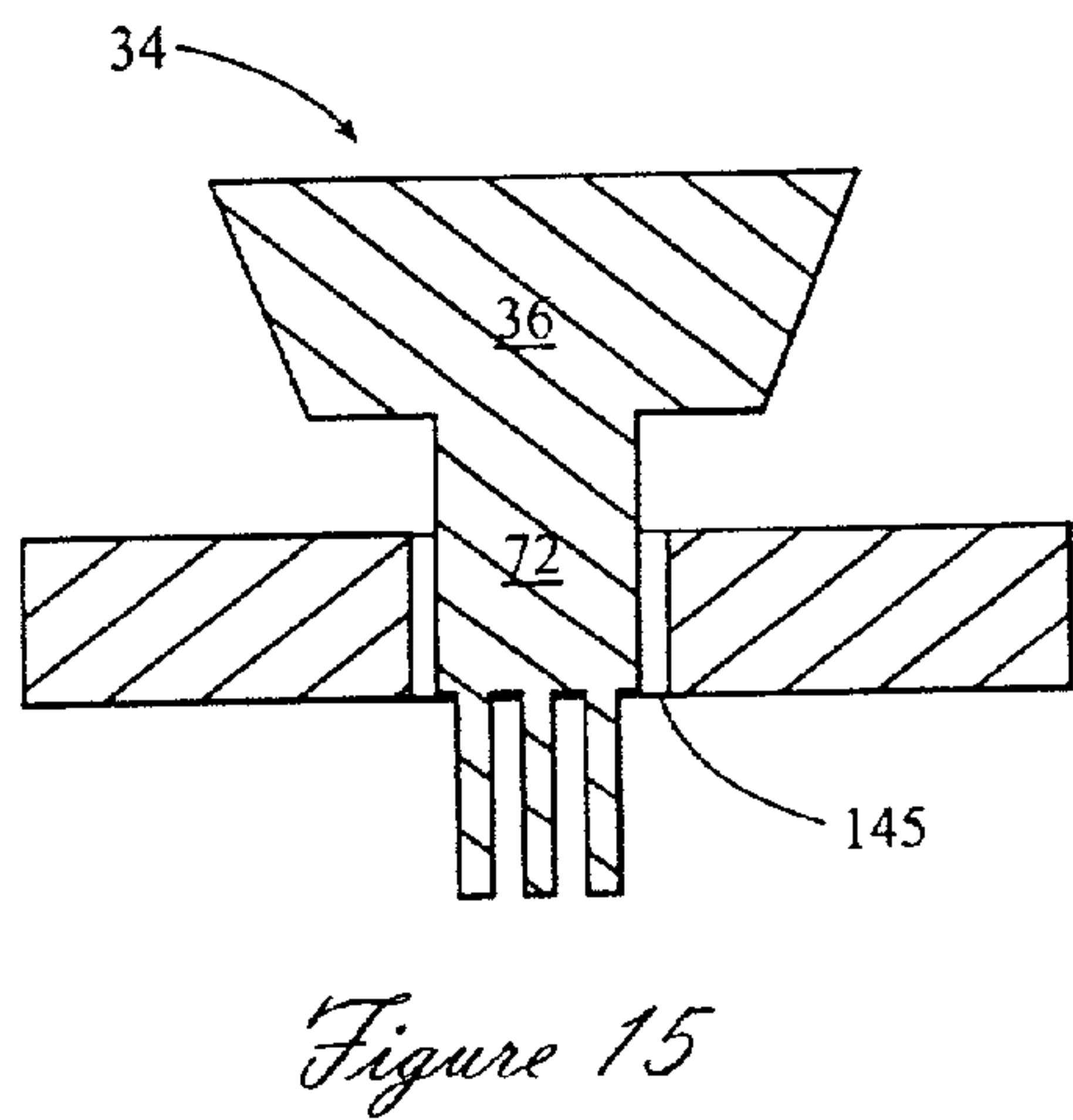
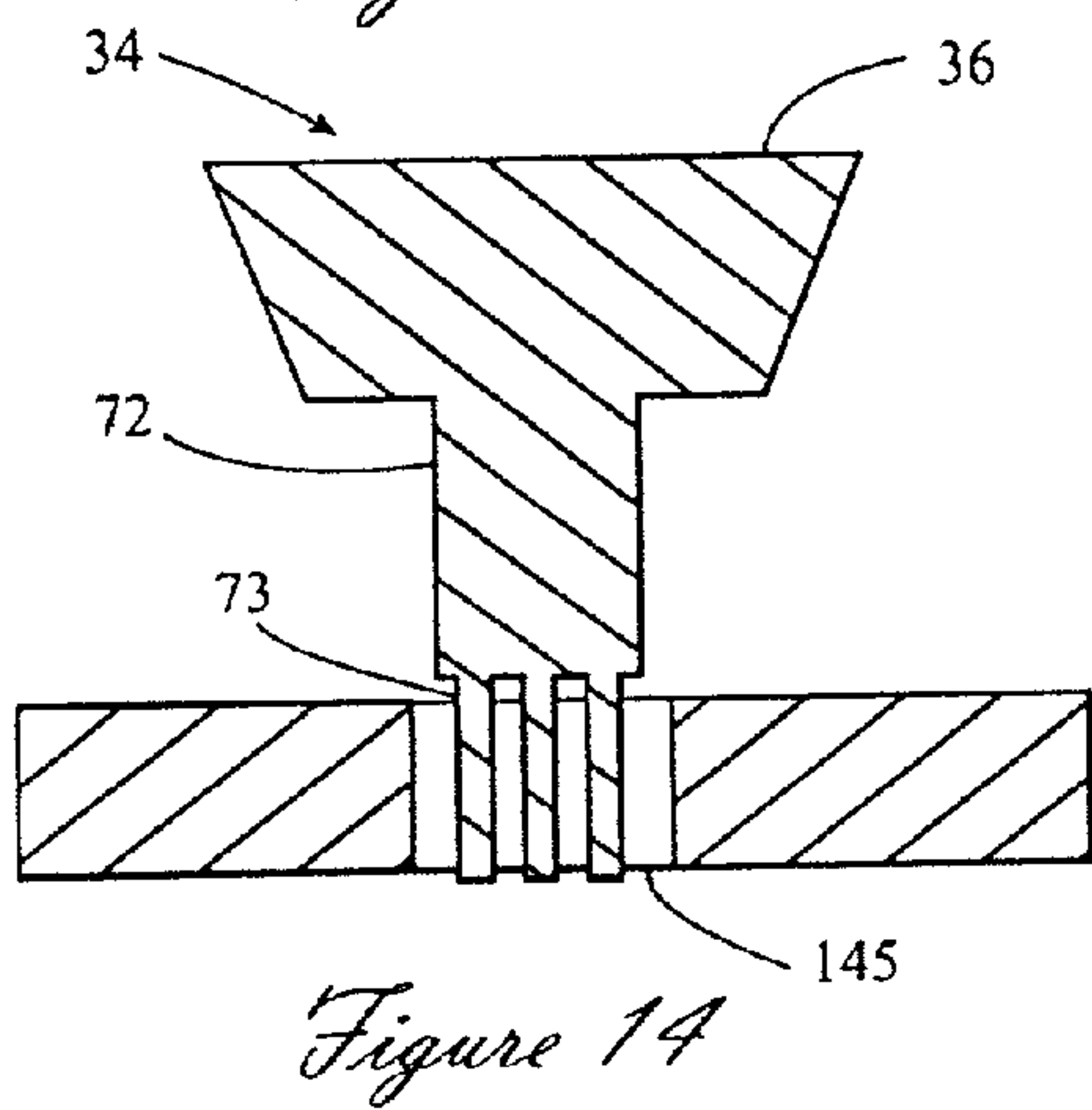
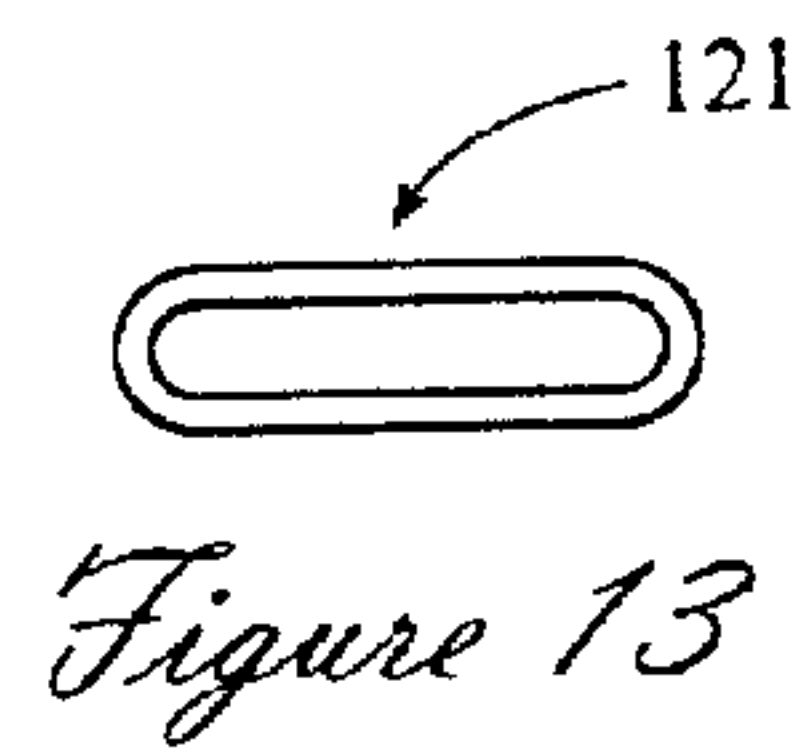
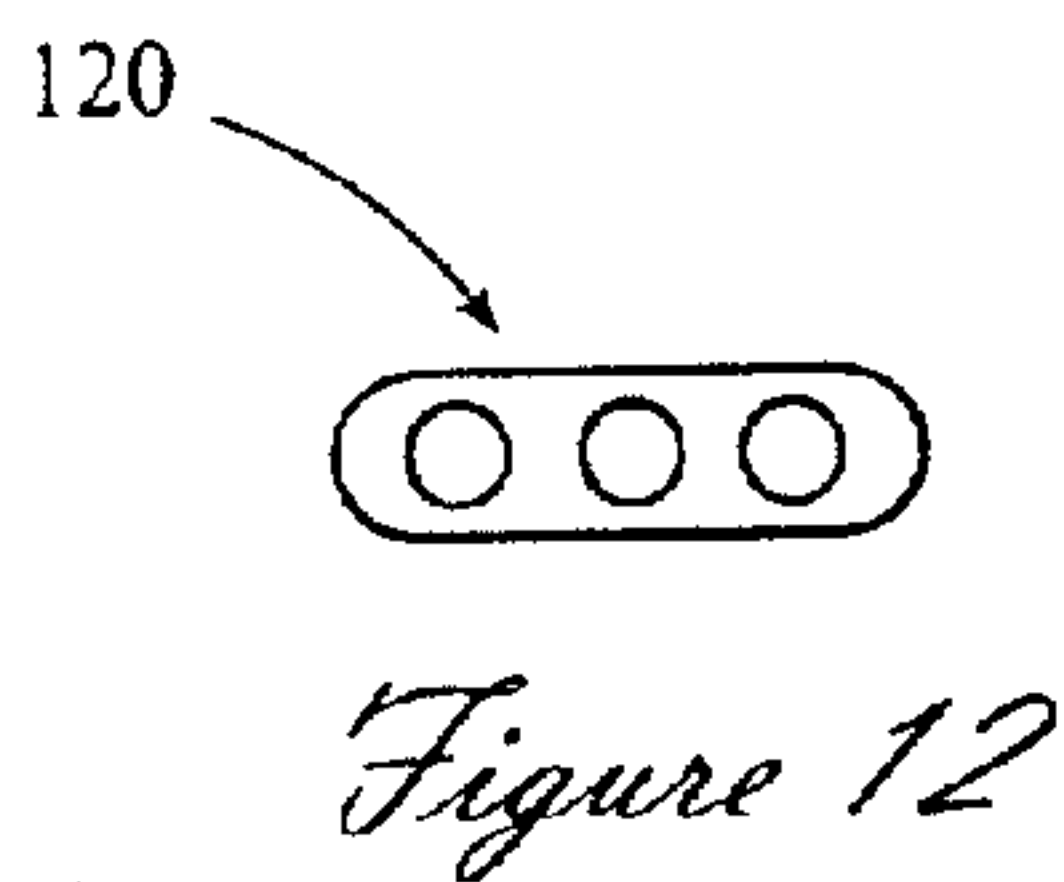
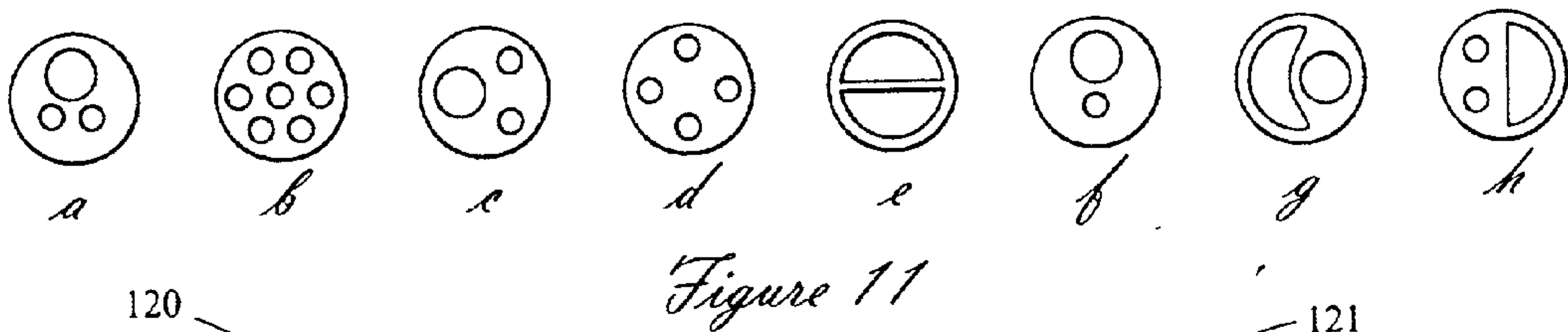
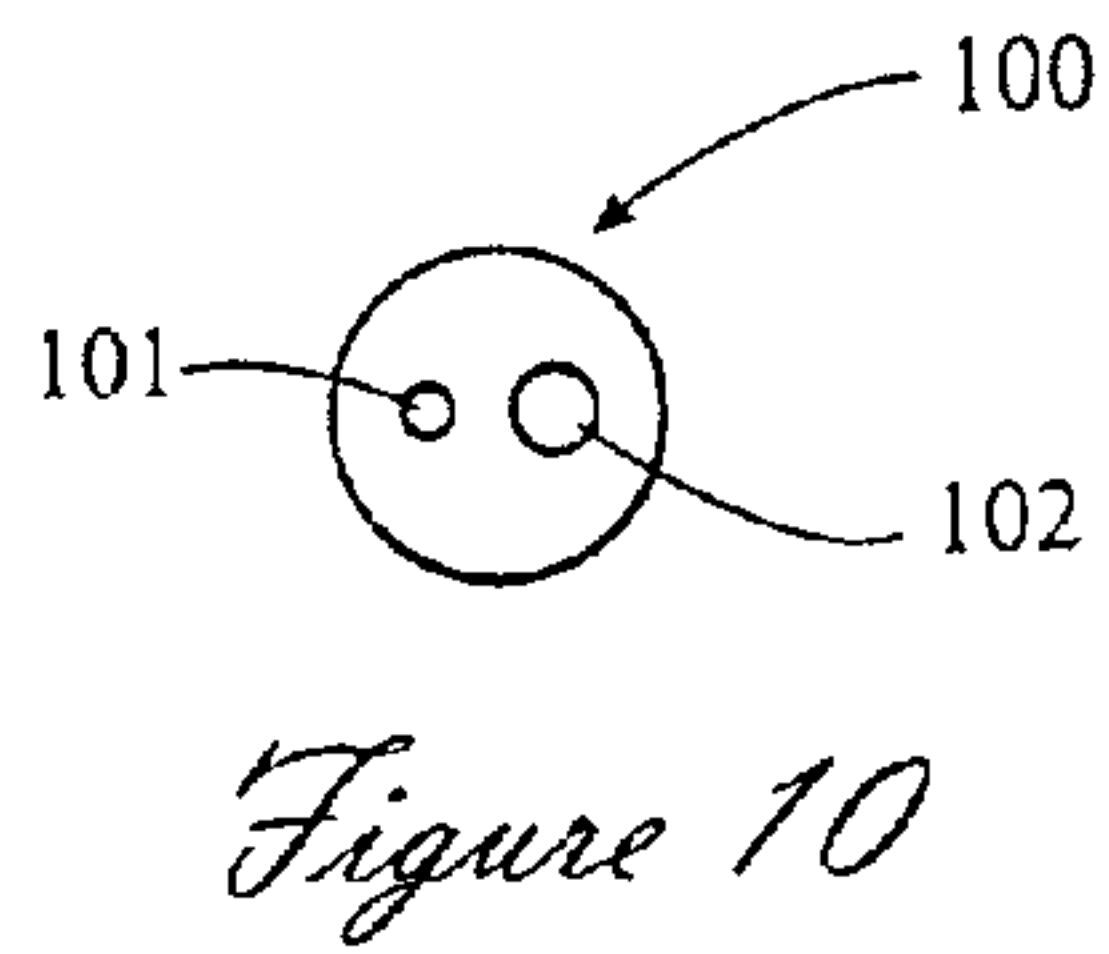
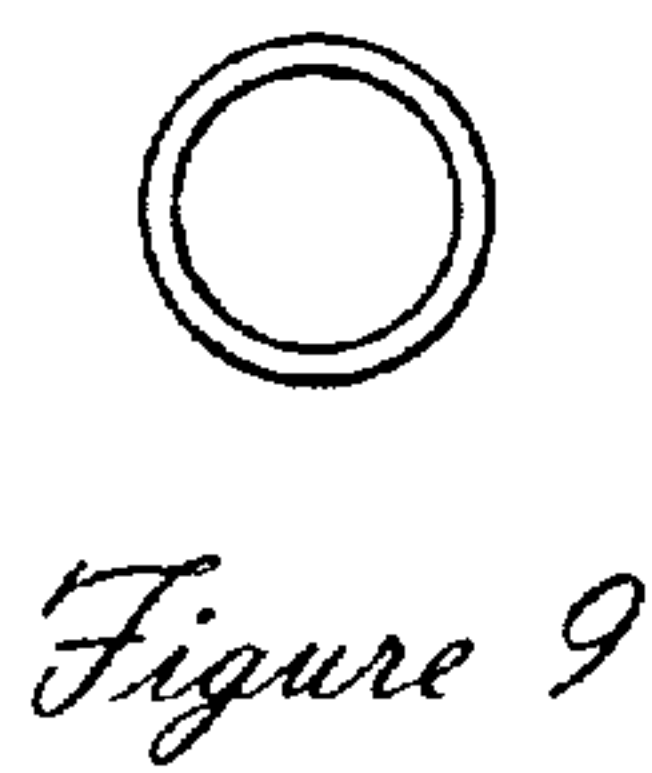
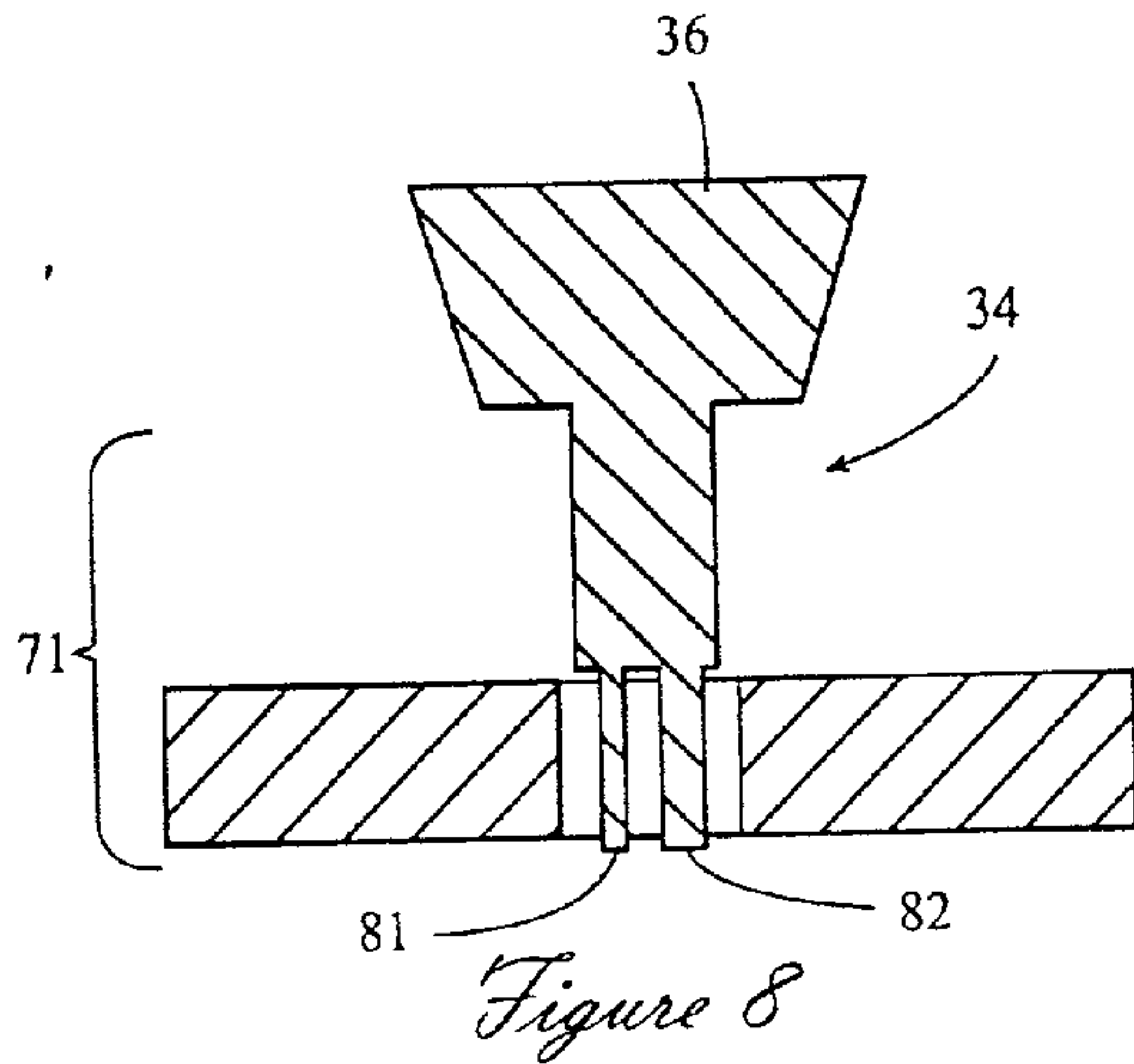
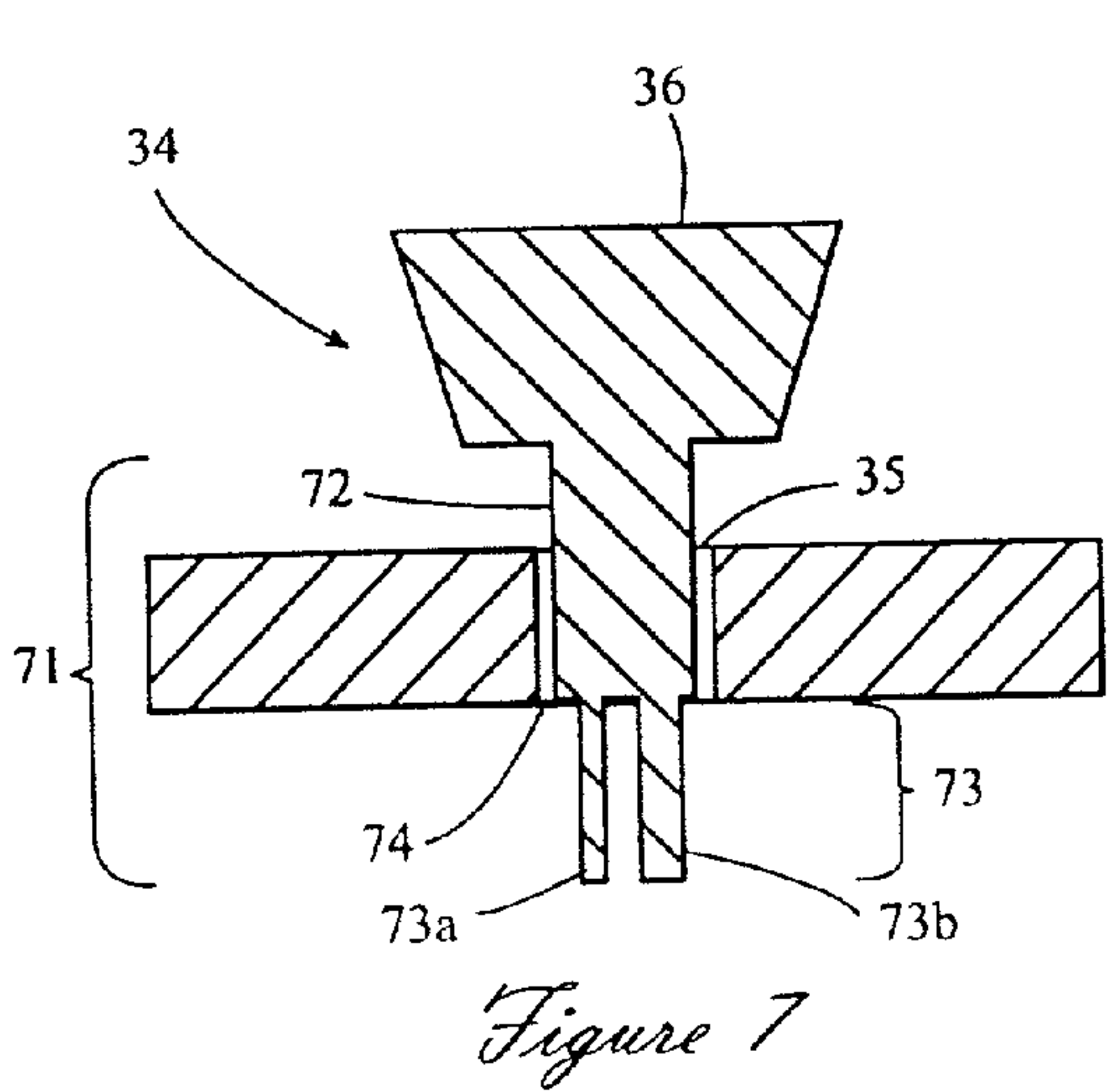
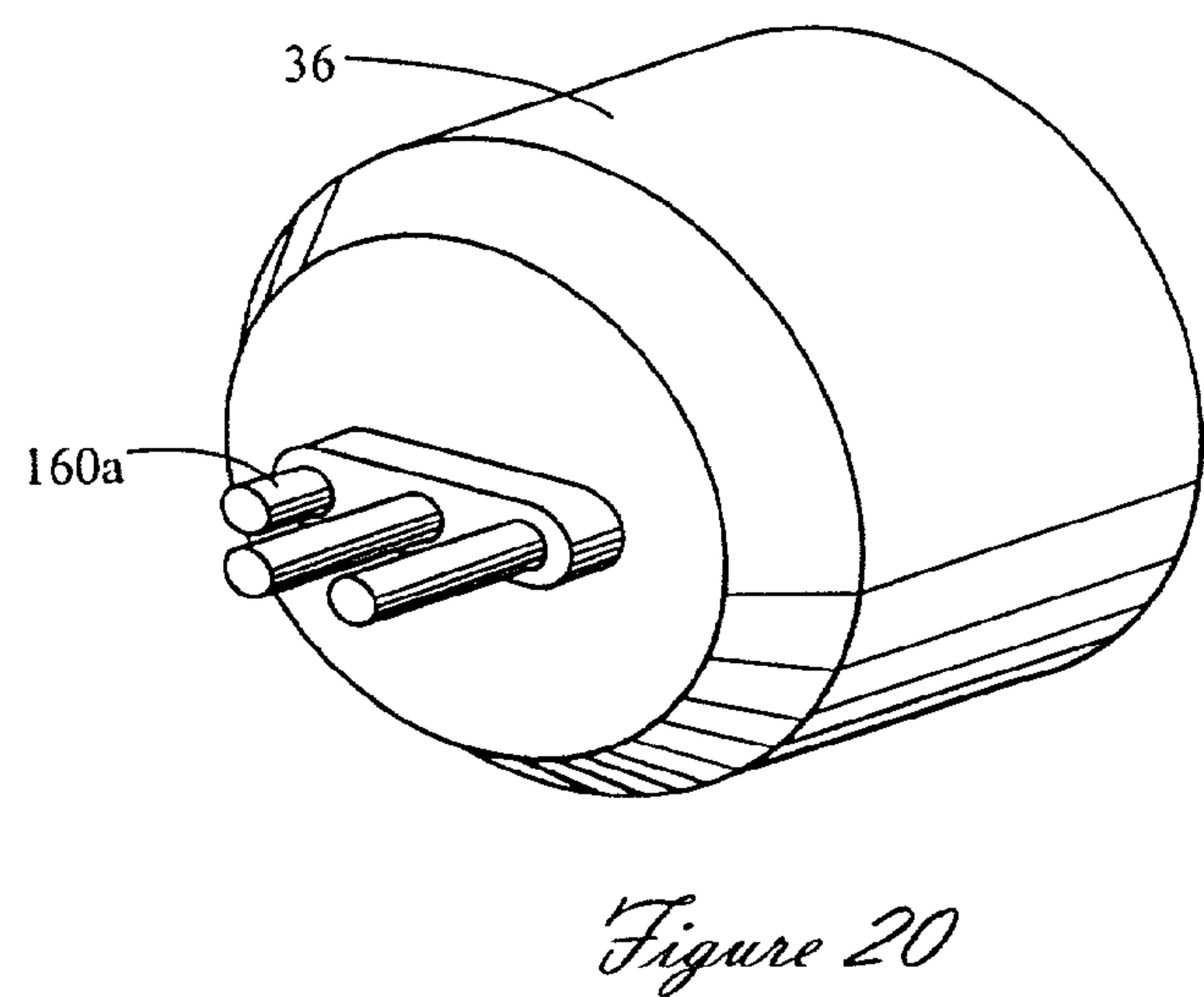
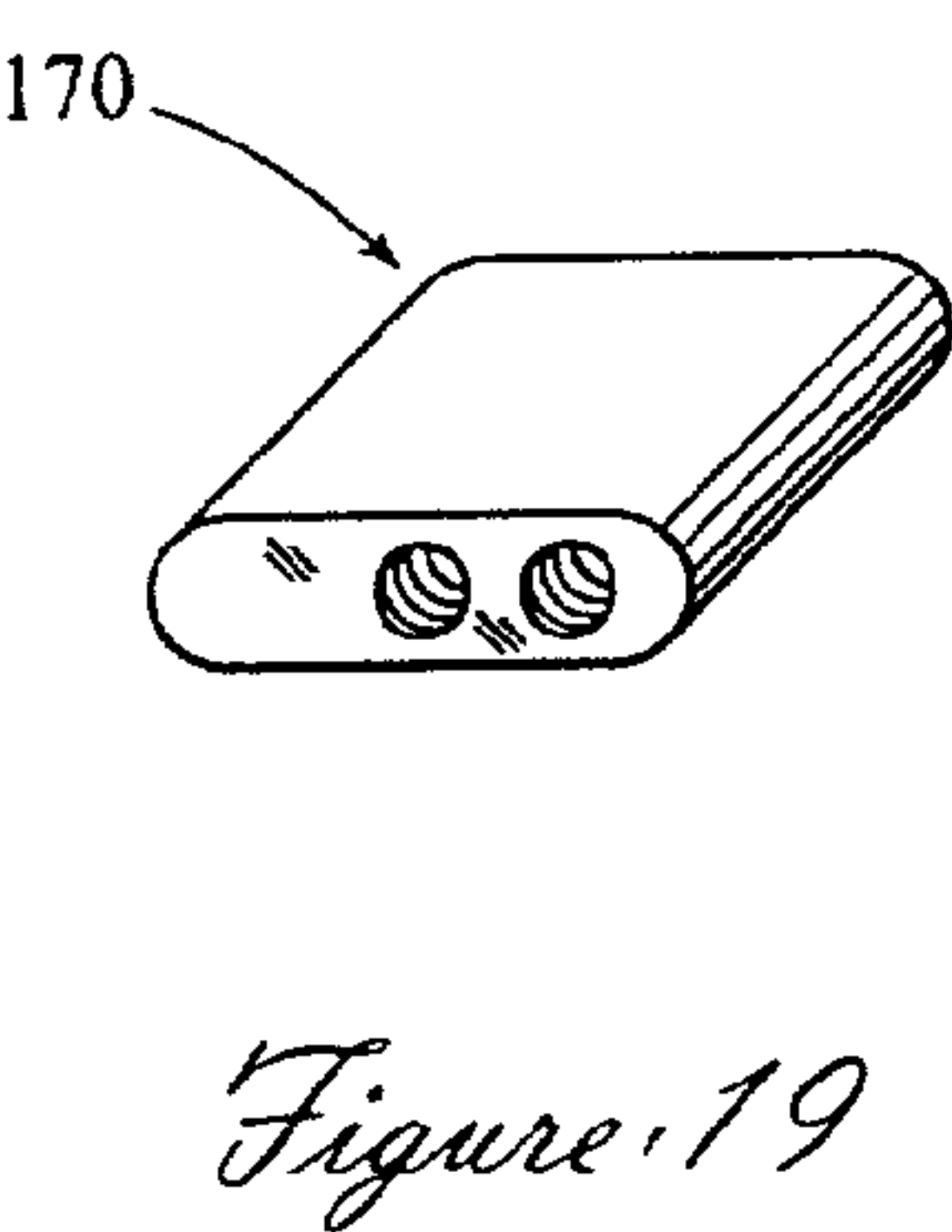
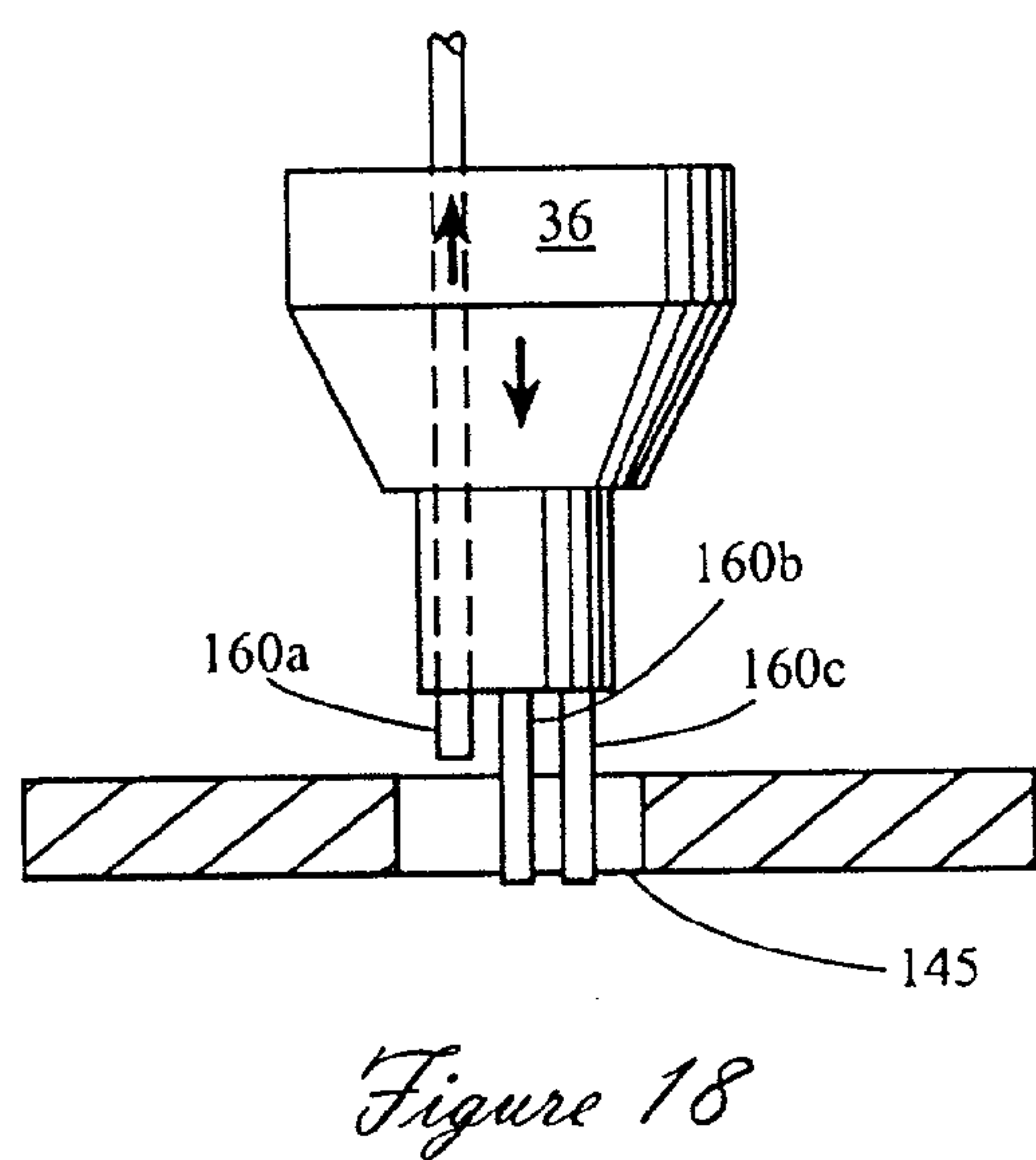
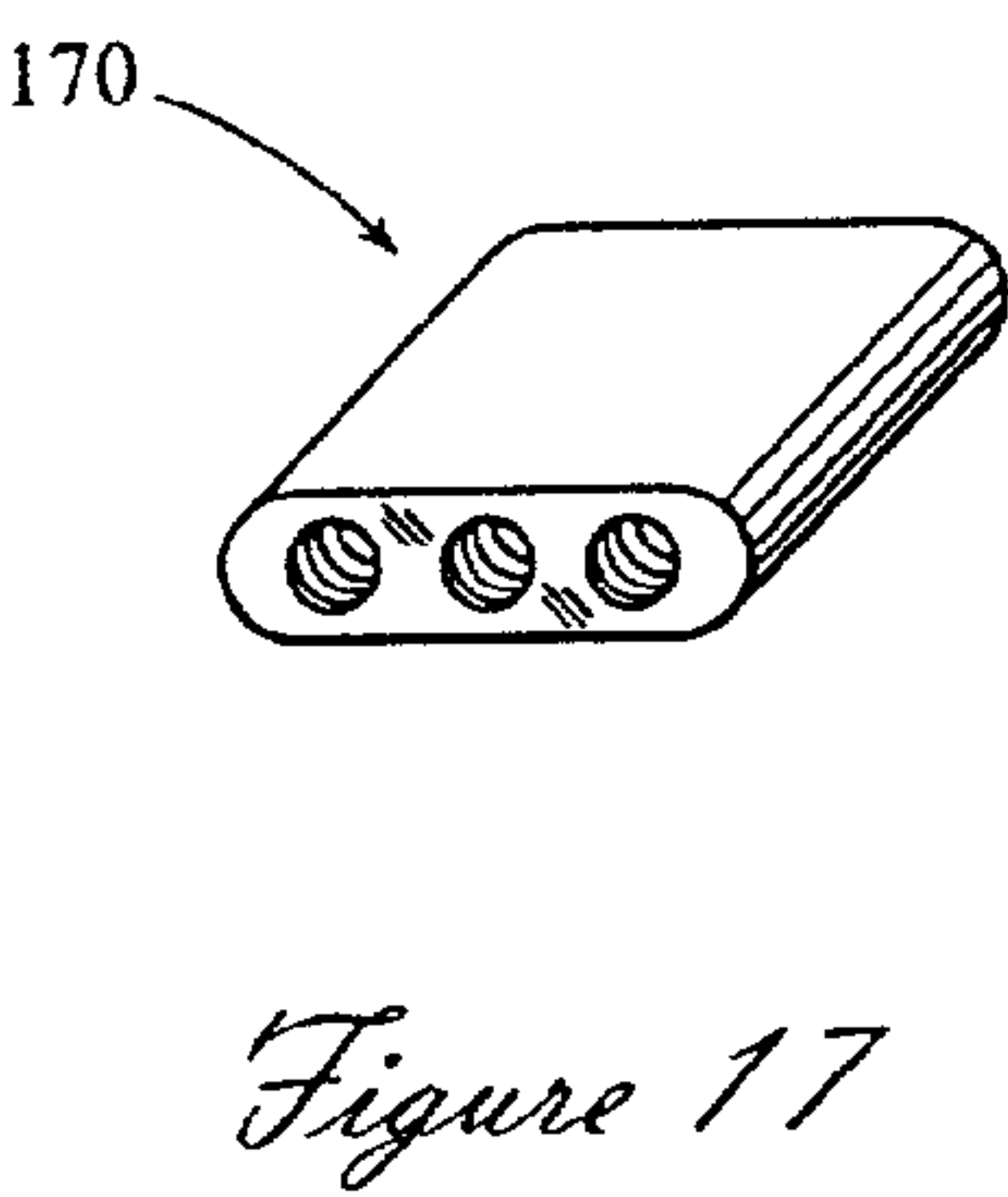
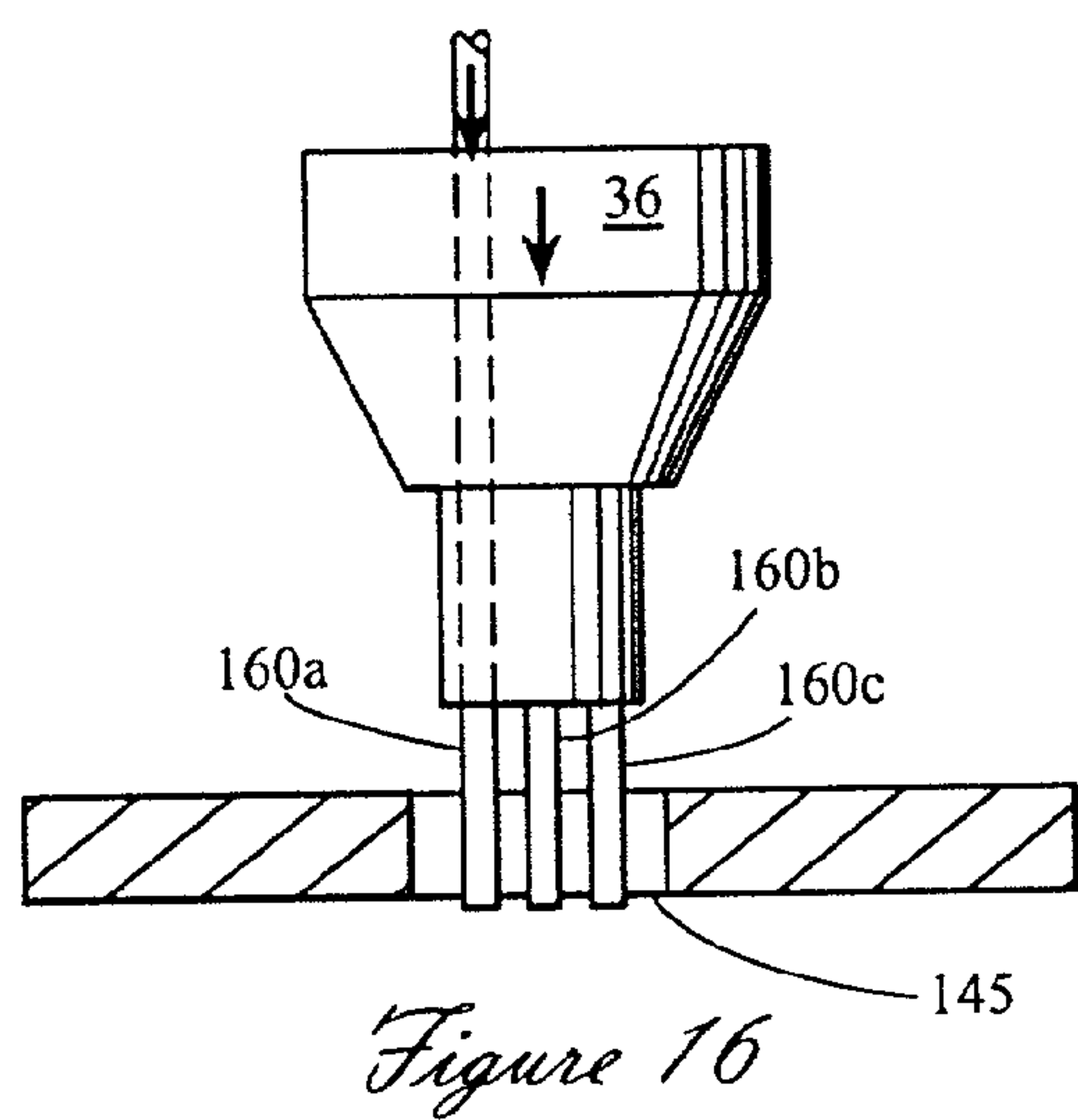


Figure 2









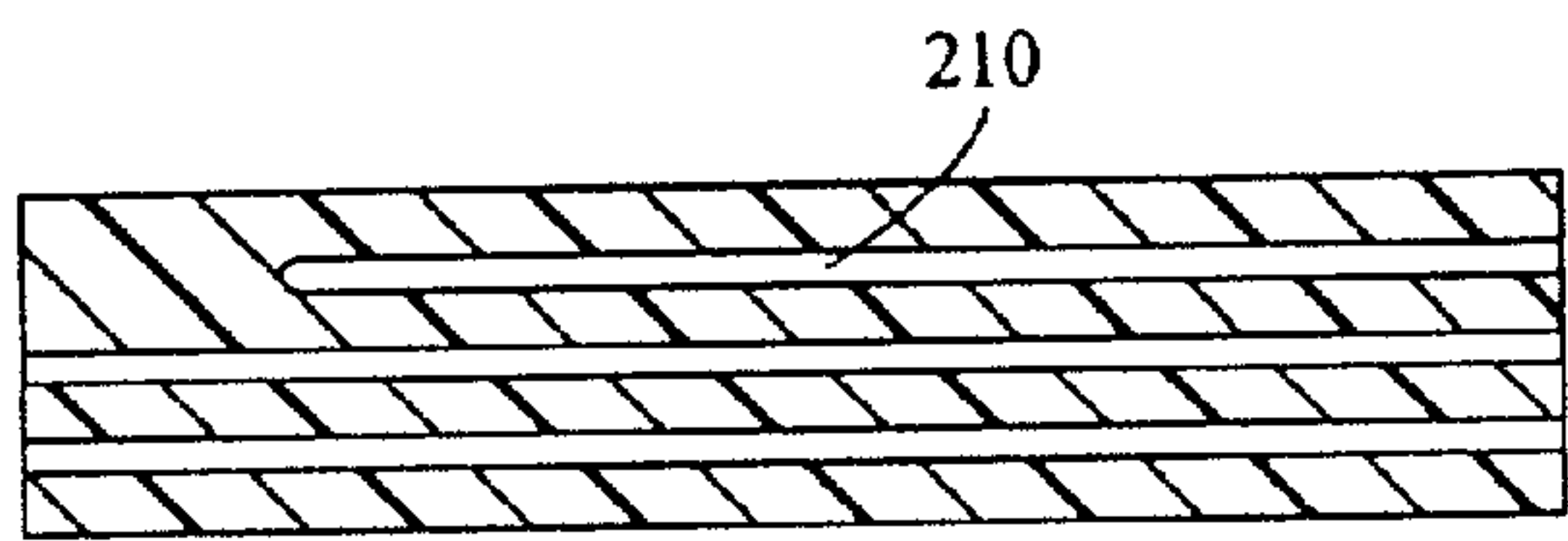


Figure 21

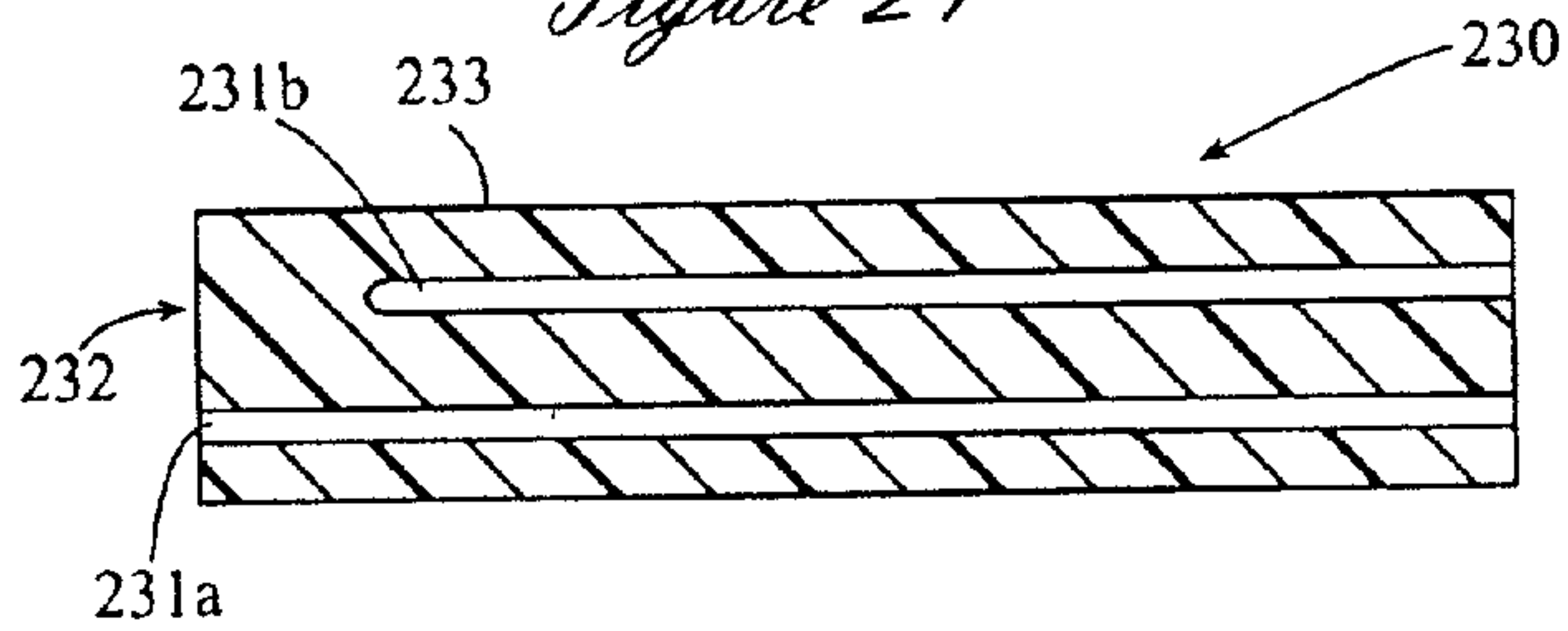


Figure 23

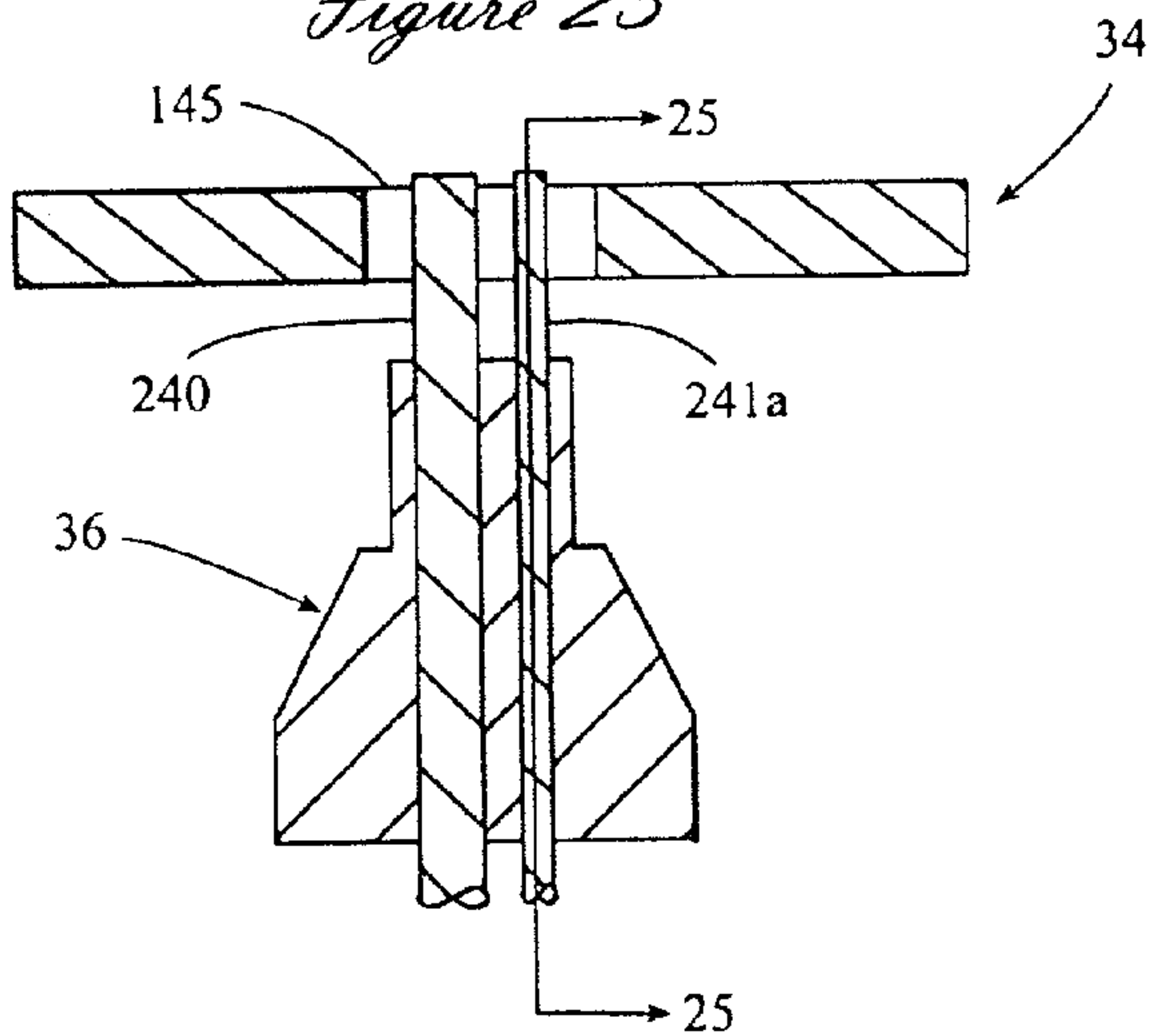


Figure 24

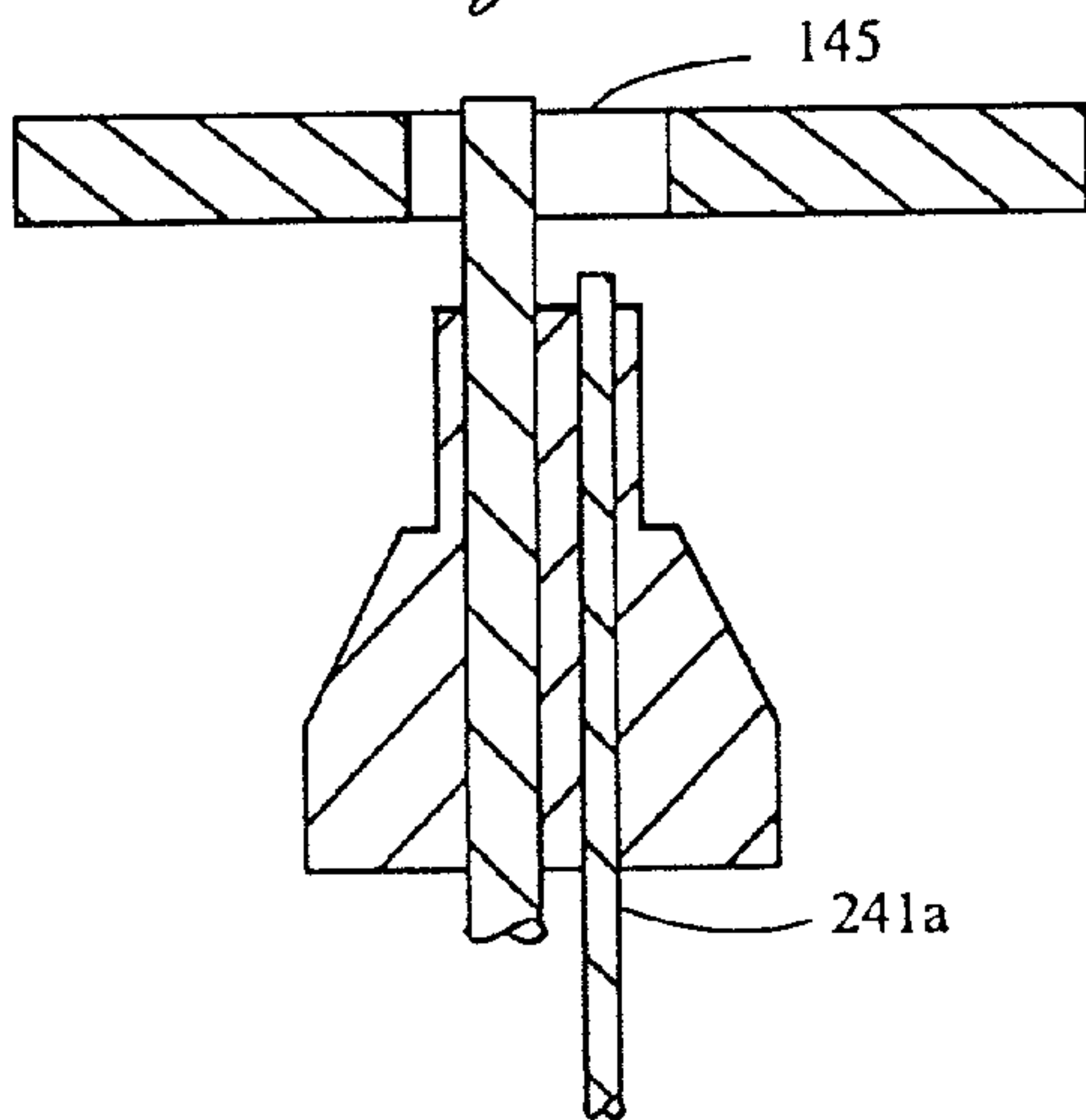


Figure 27

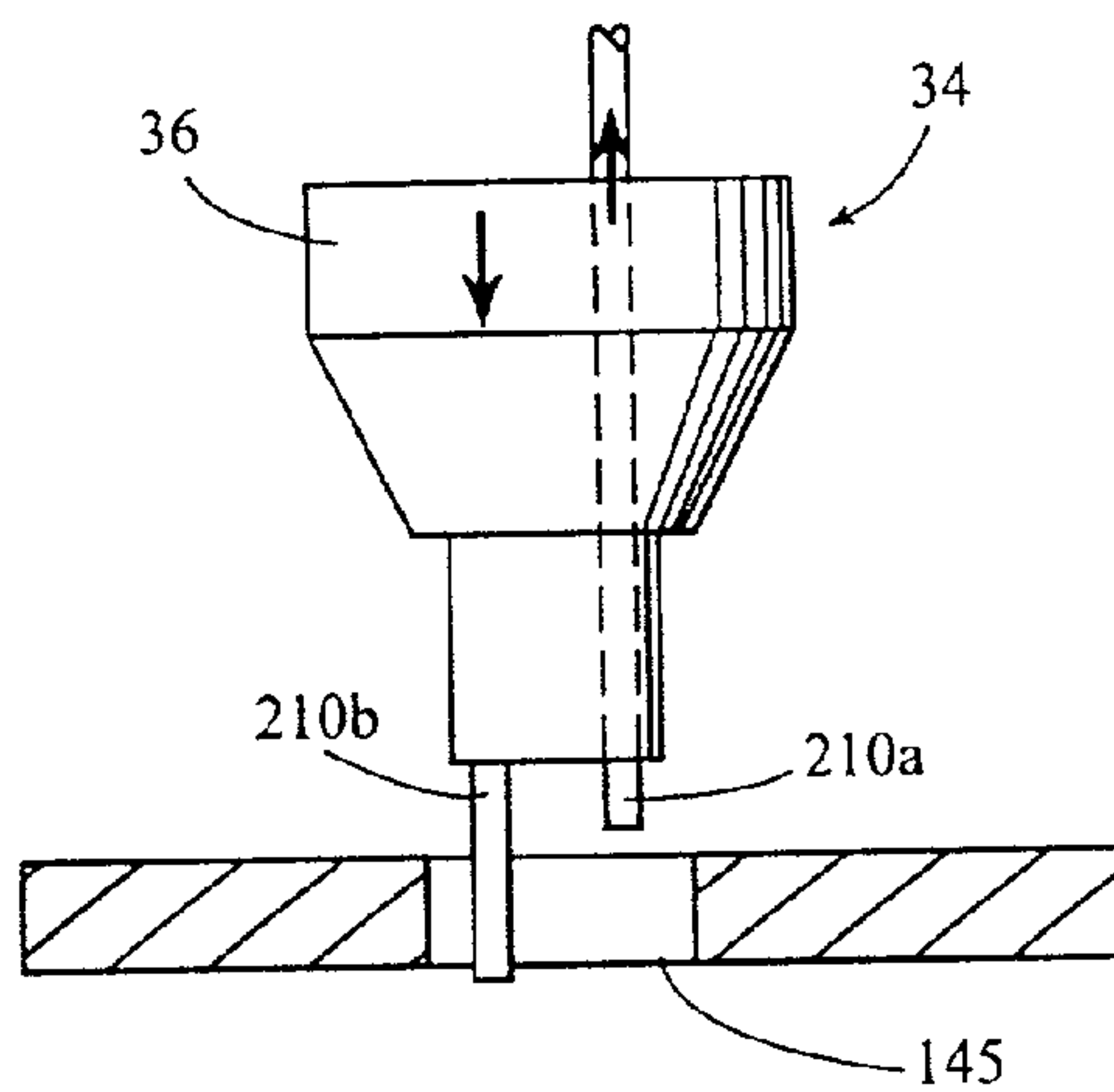


Figure 22

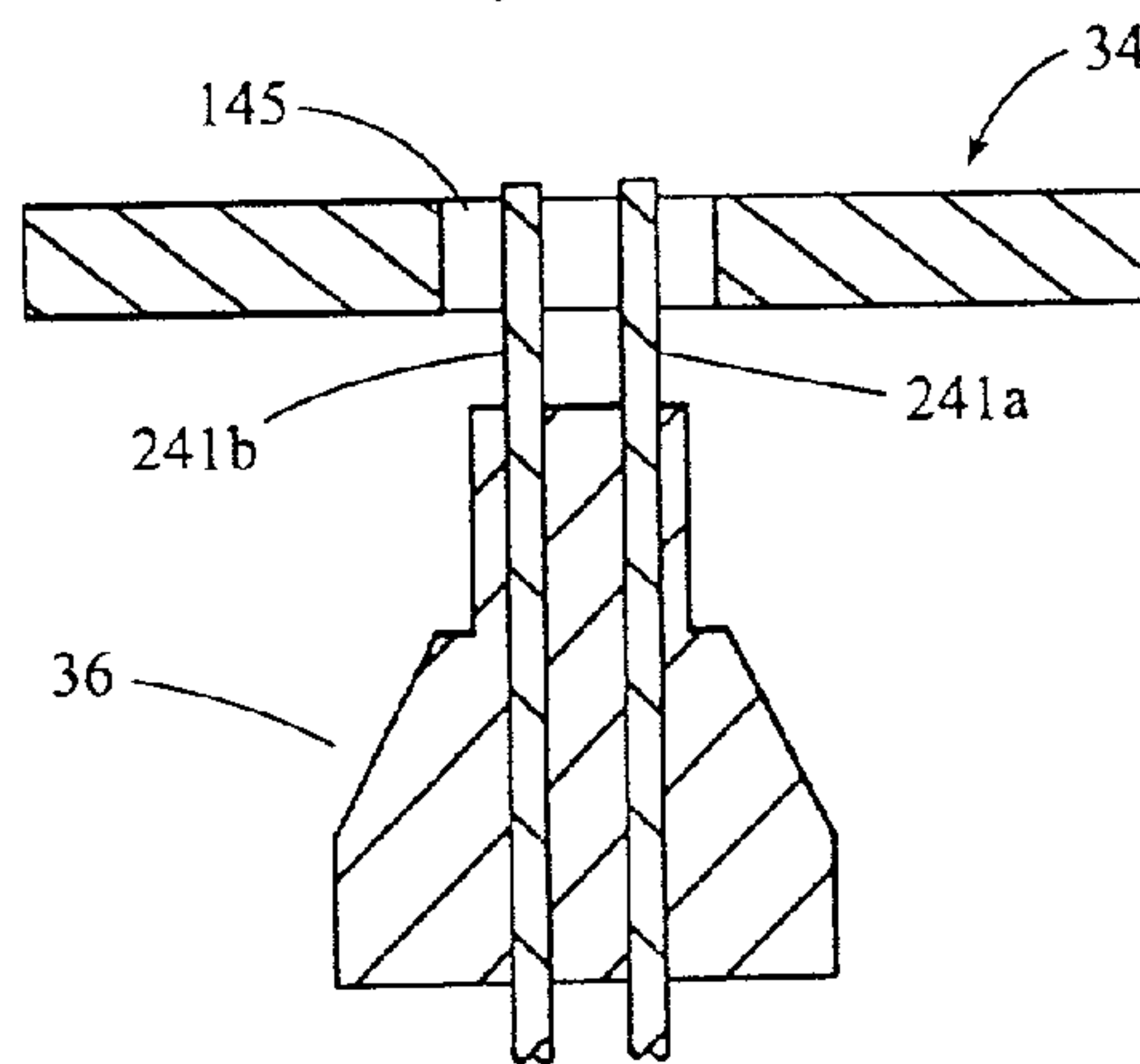


Figure 25

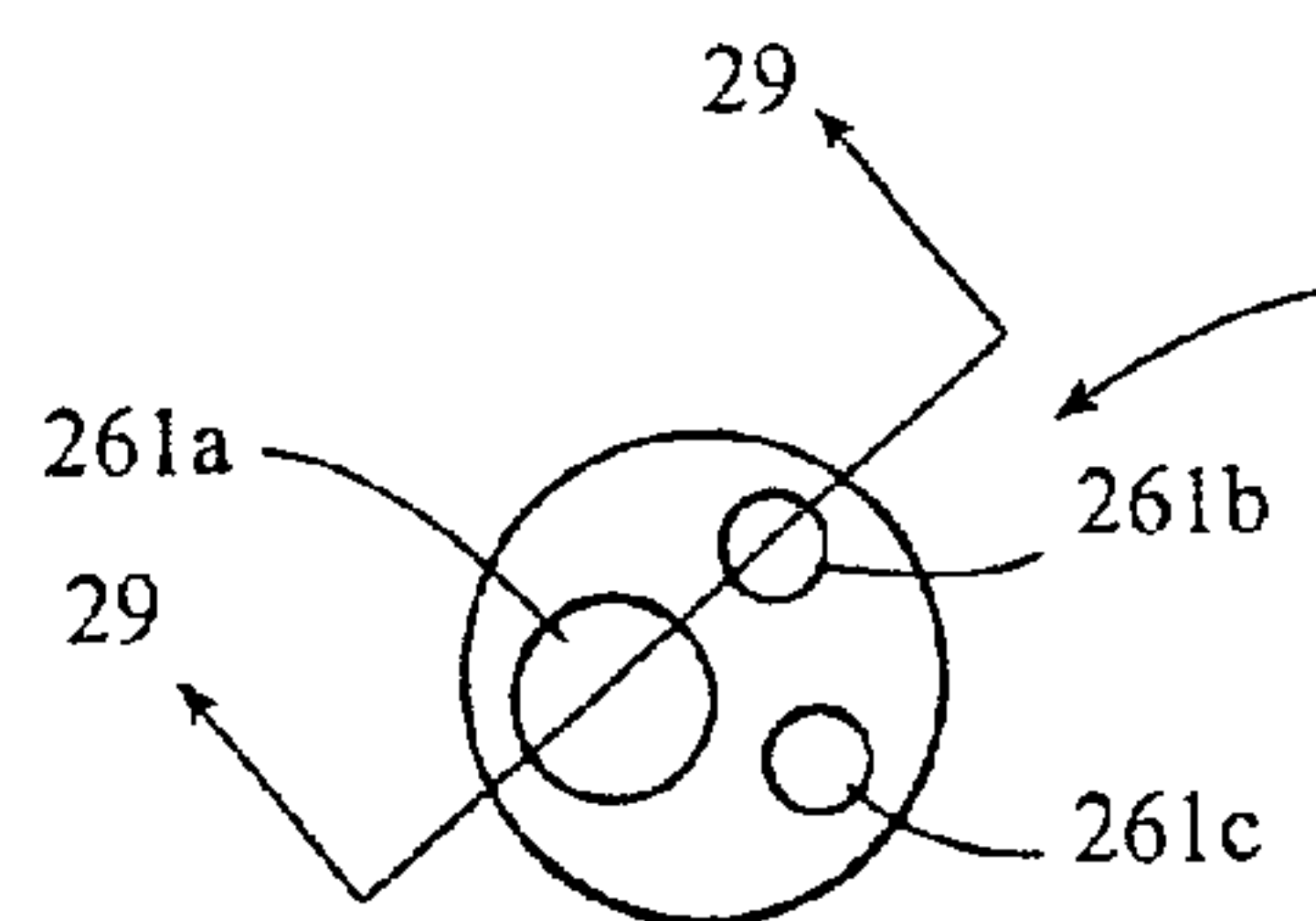


Figure 26

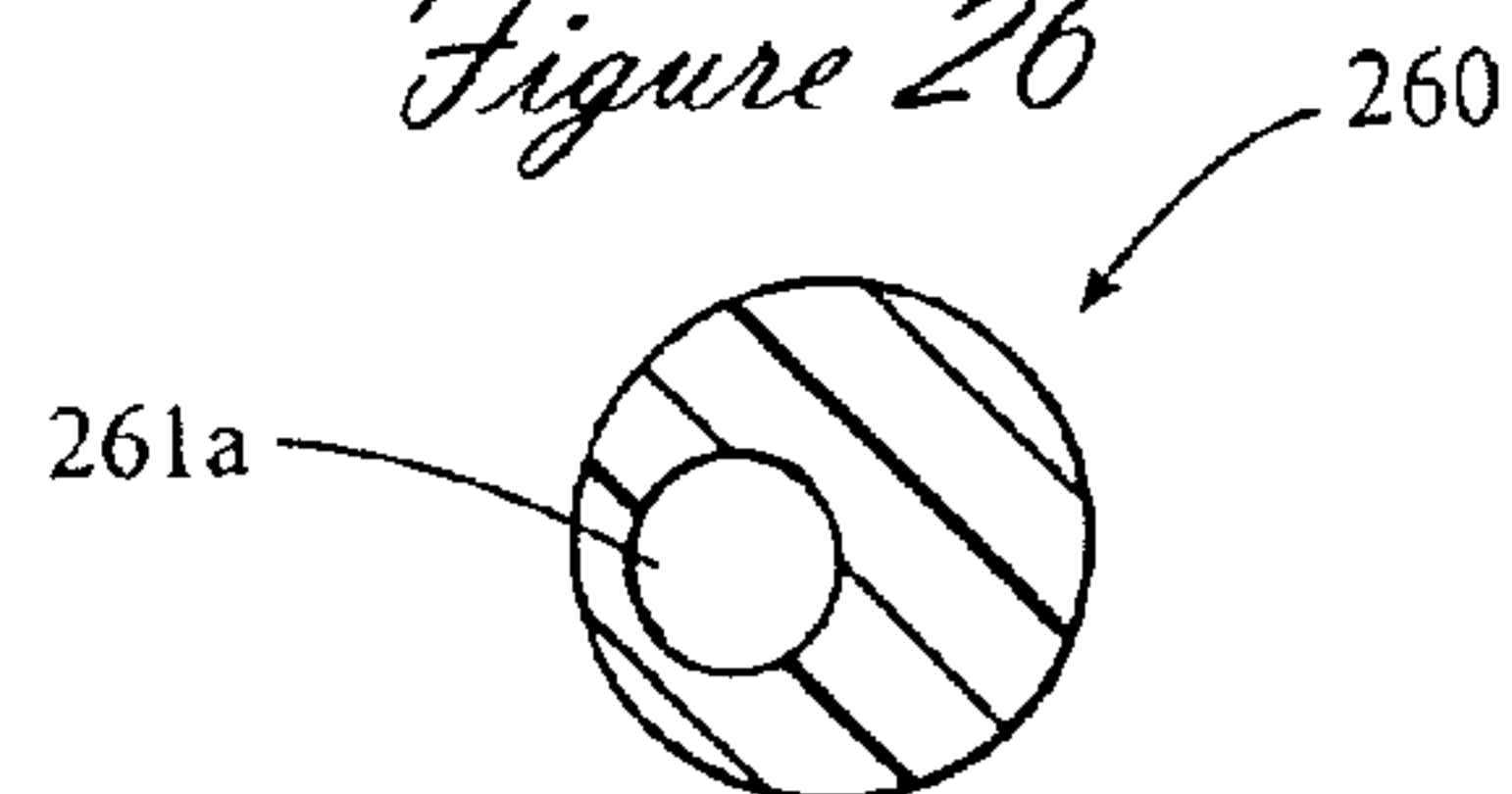


Figure 28

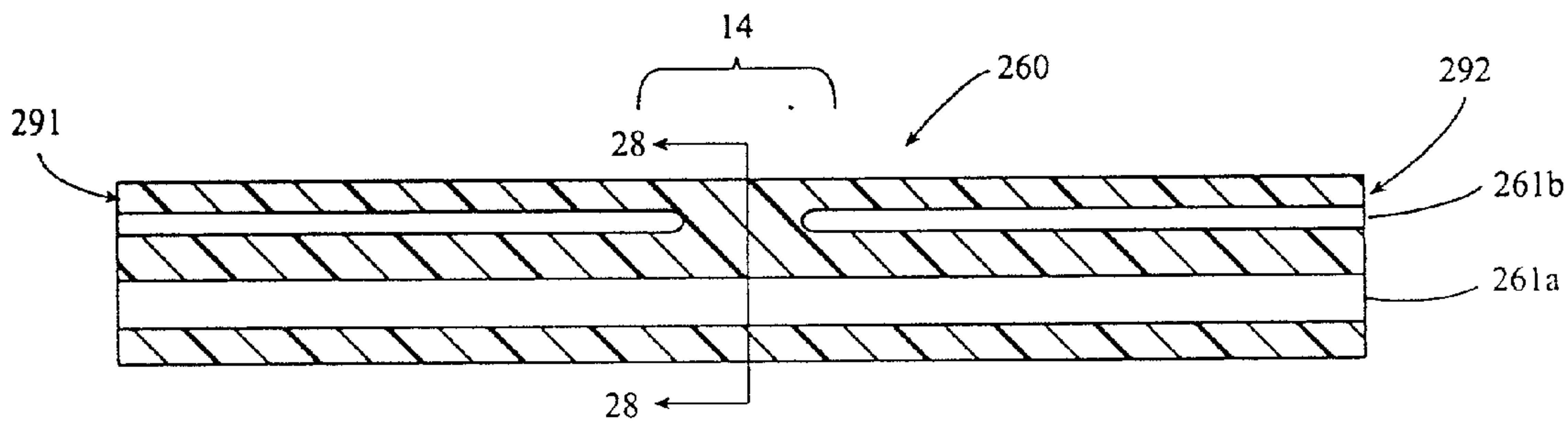


Figure 29

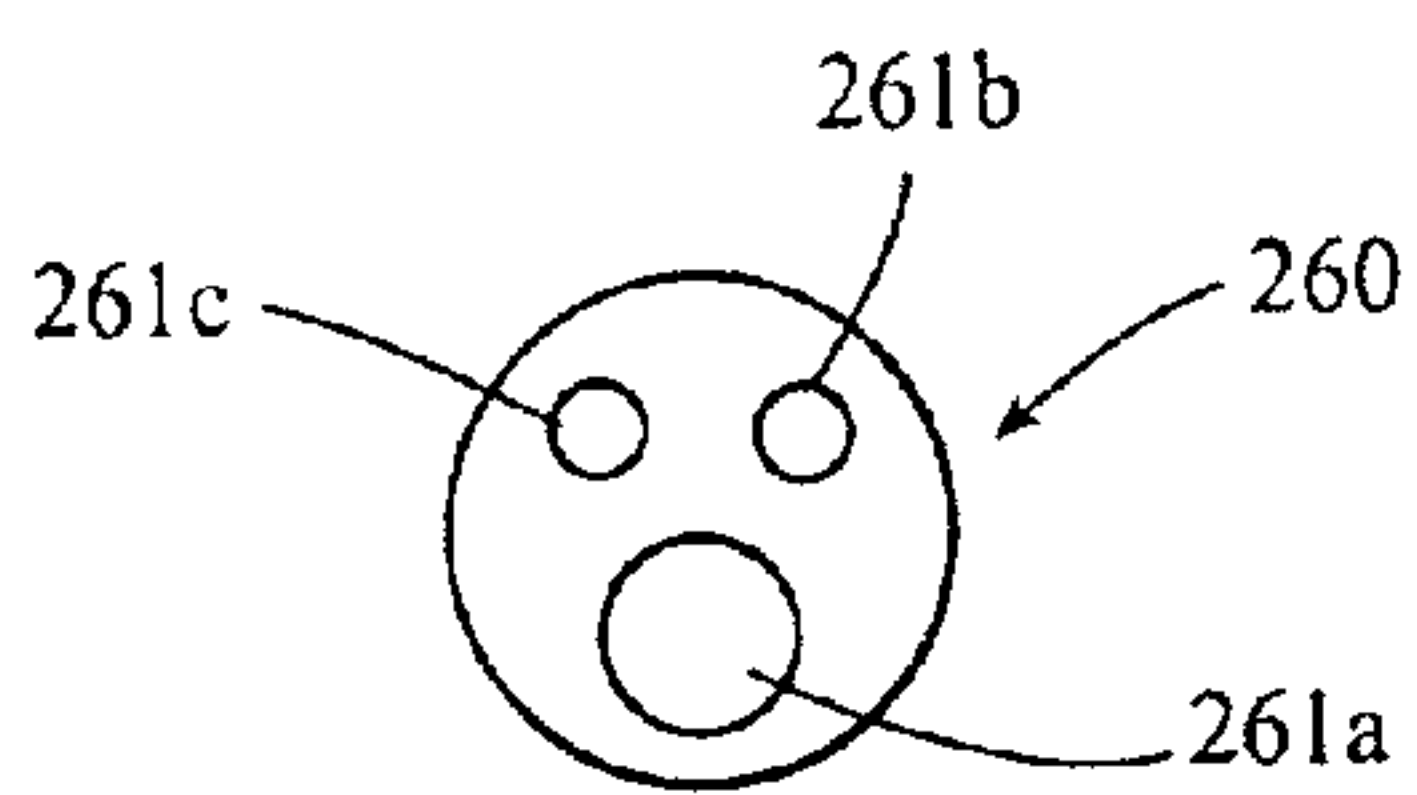


Figure 30

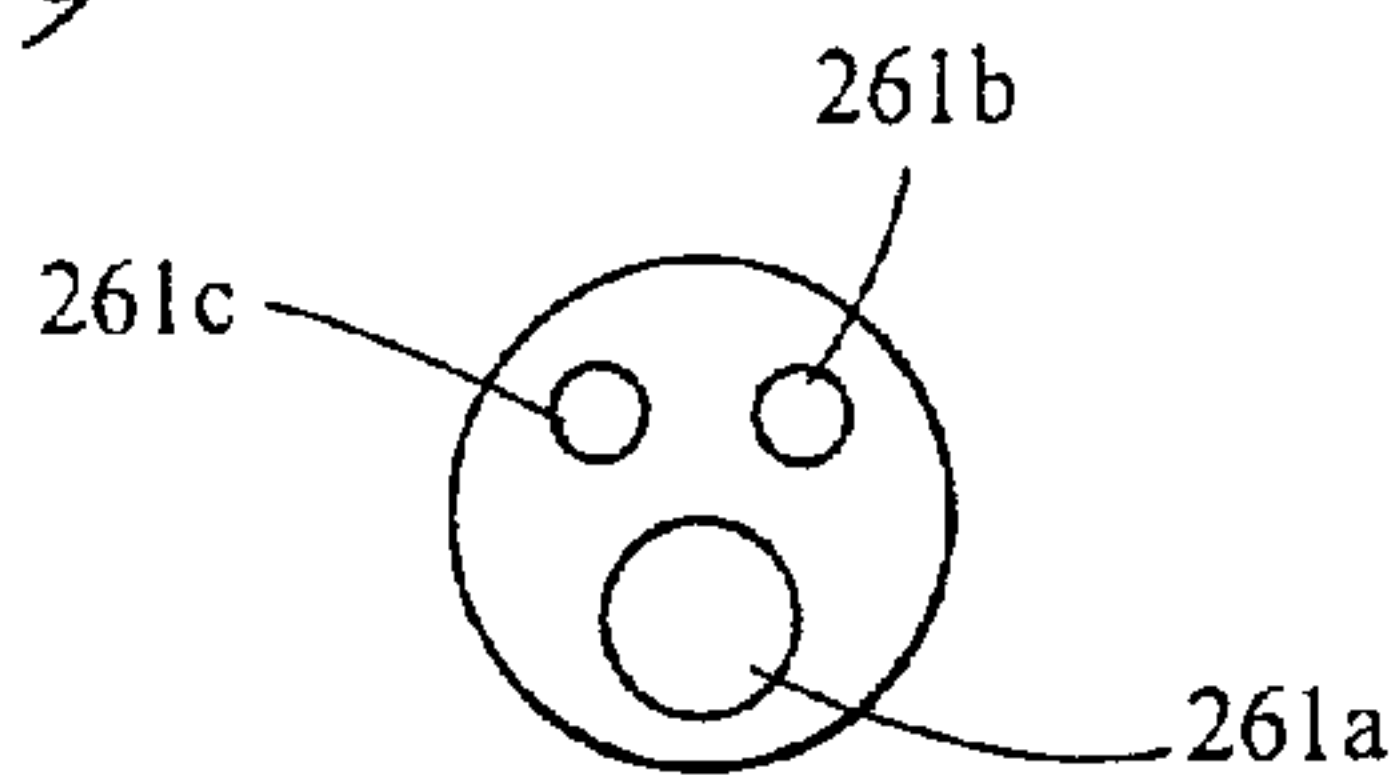
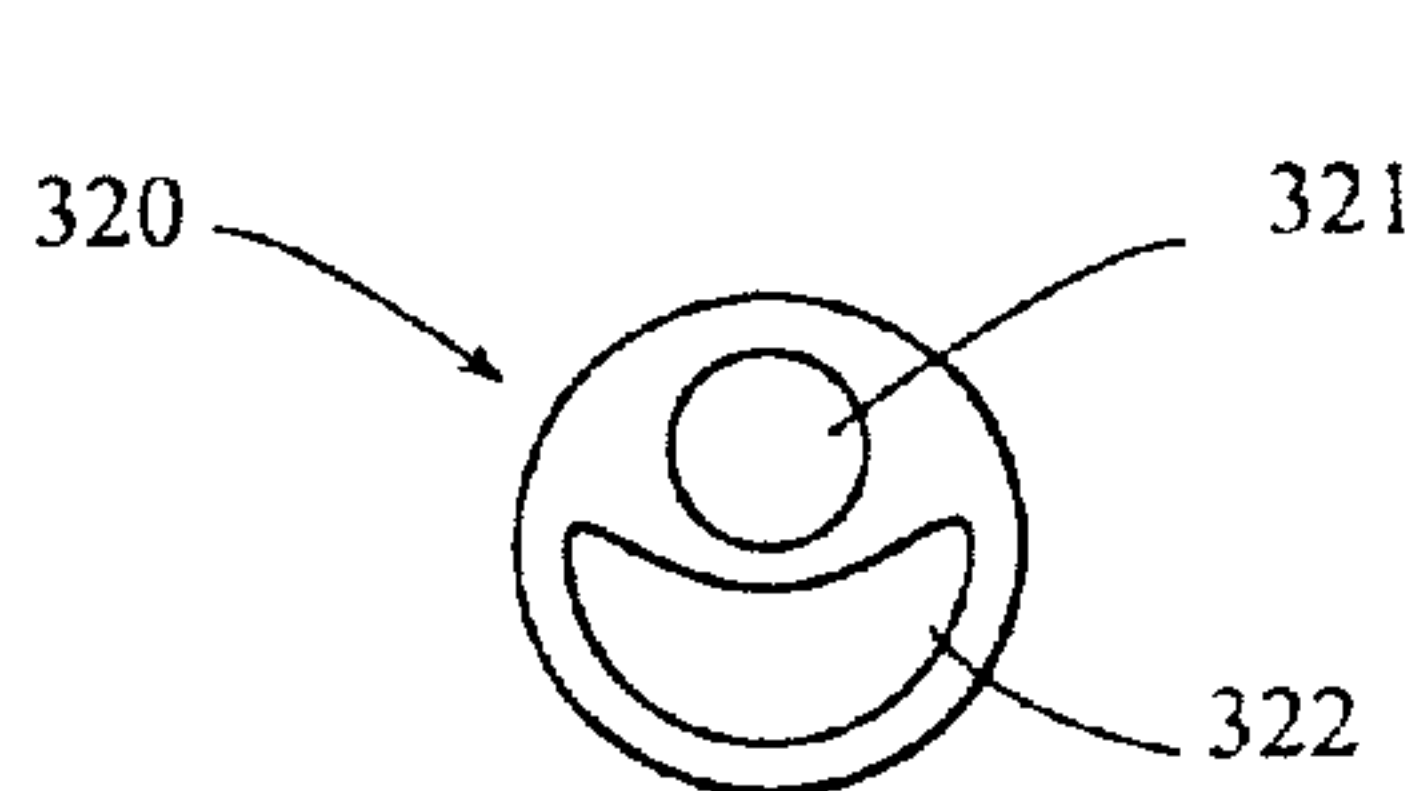
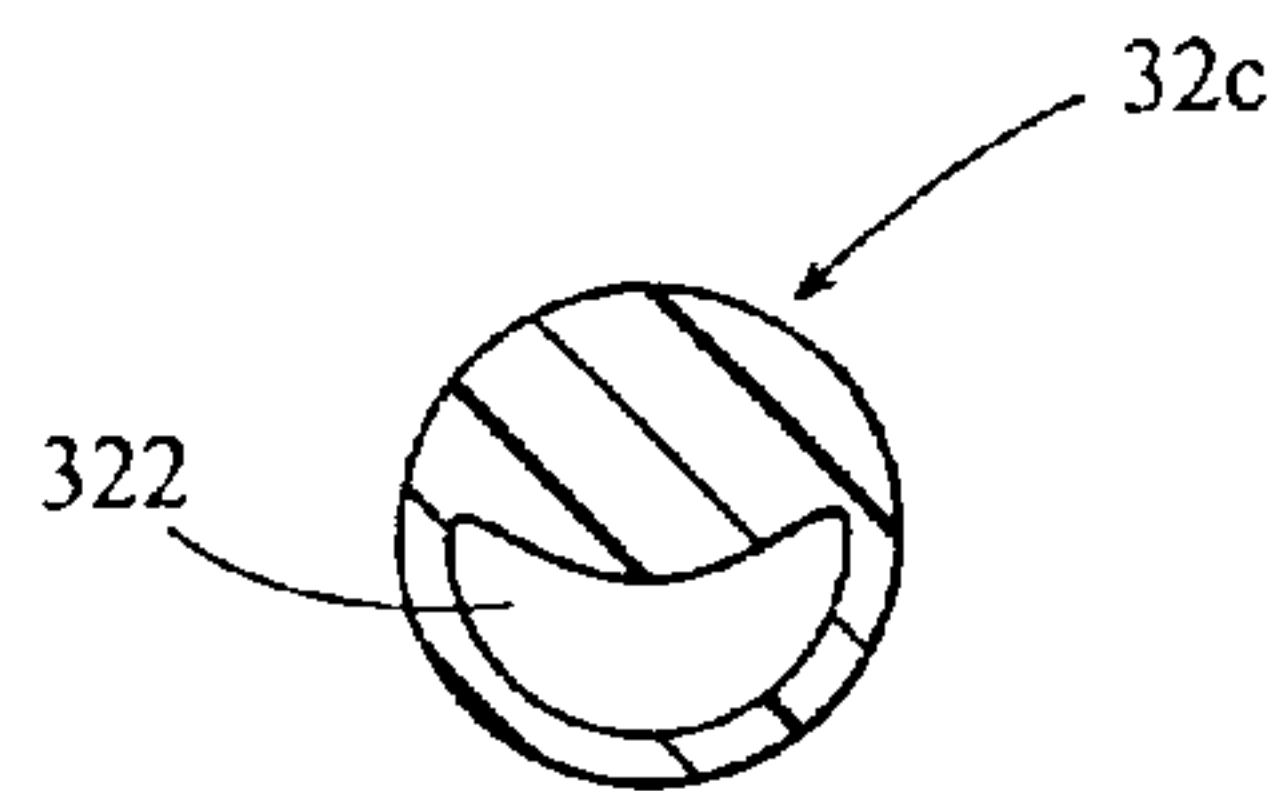


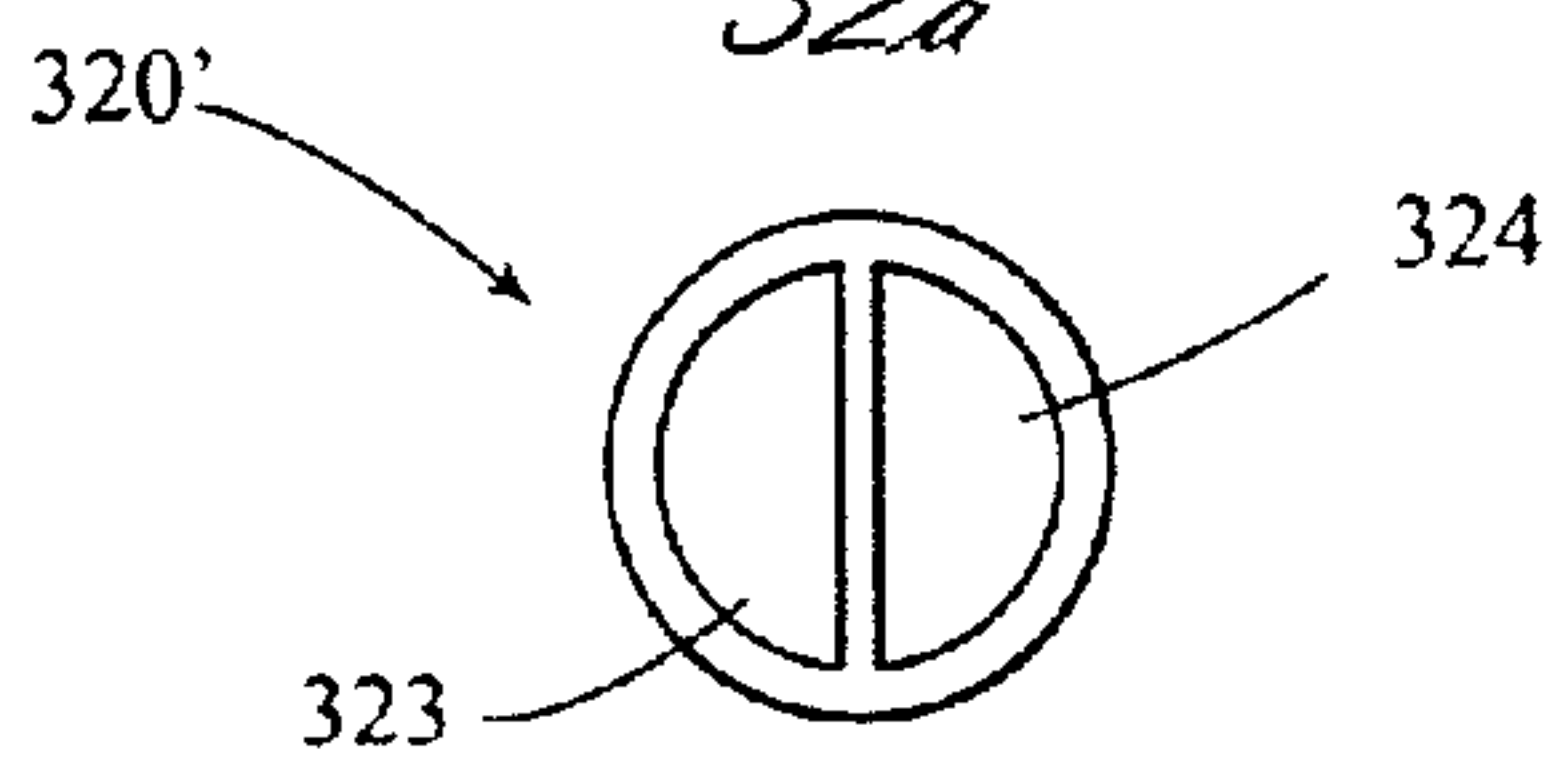
Figure 31



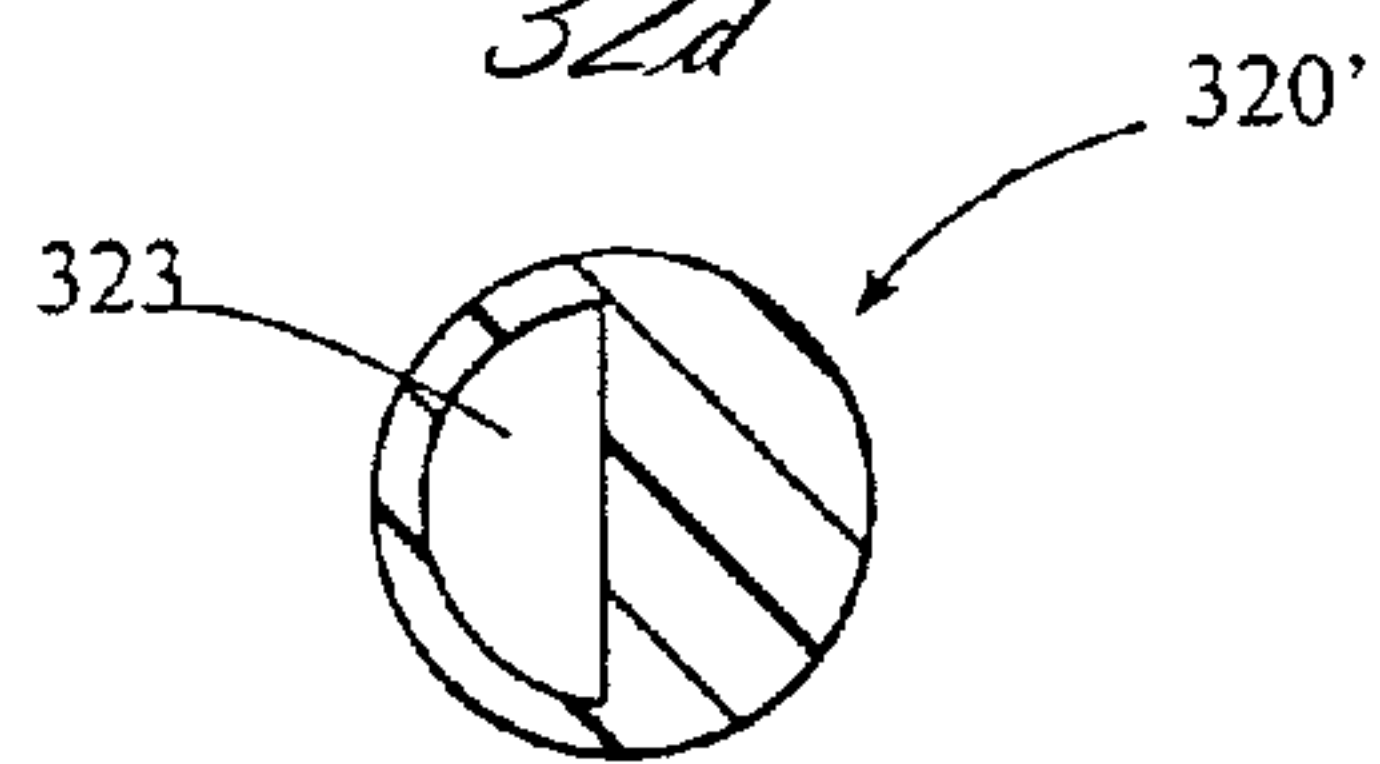
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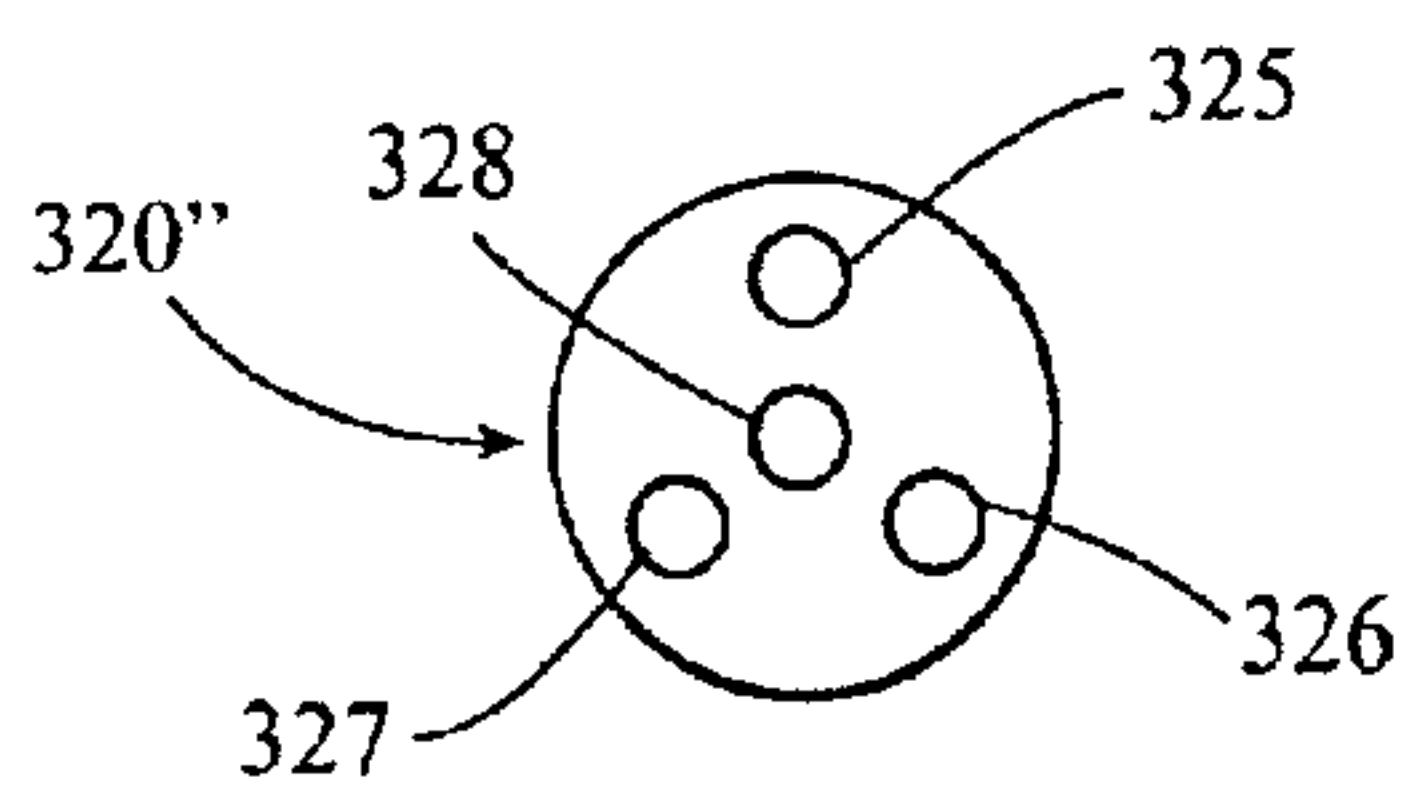
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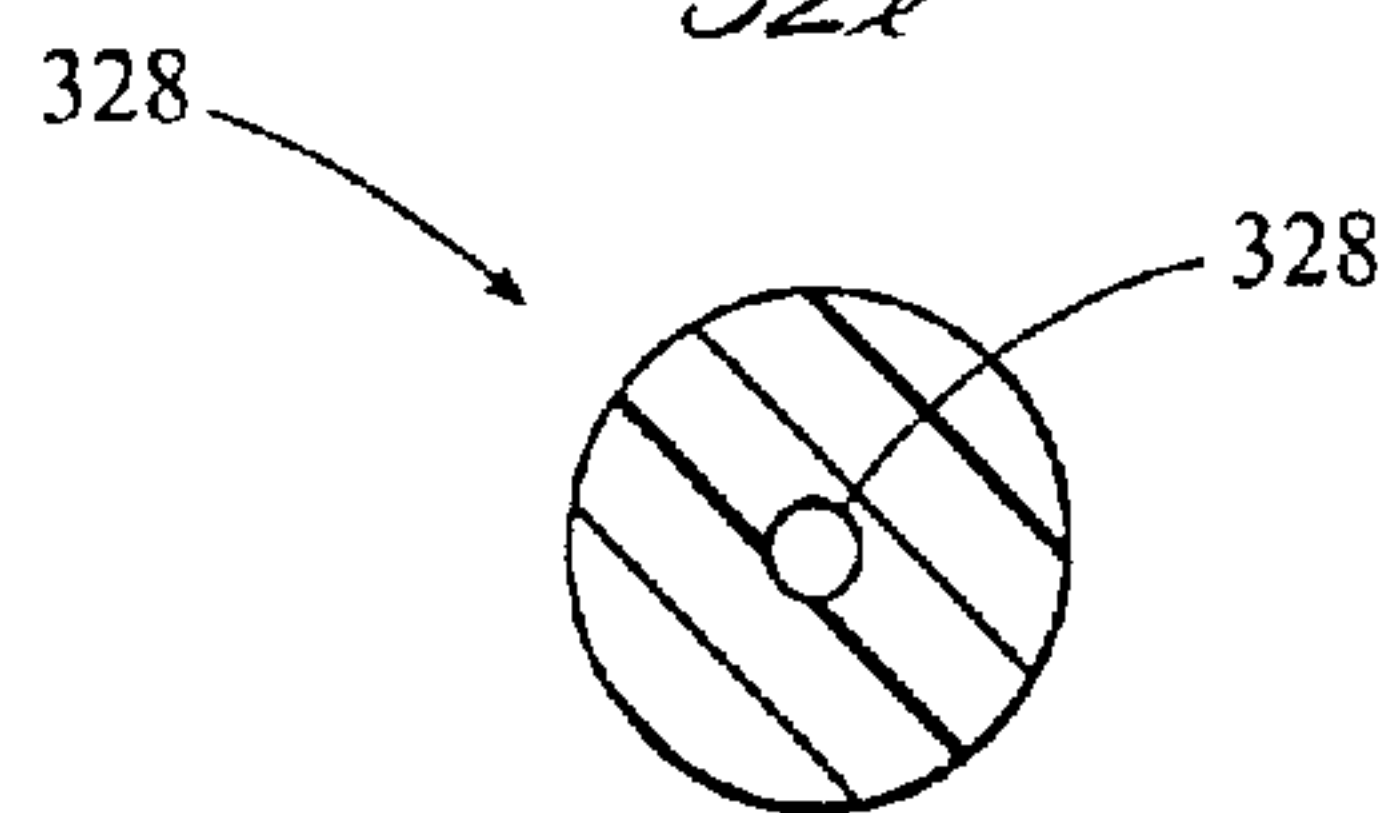
32b



32d



32e



32f

Figure 32



## SINGLE LUMEN TO MULTIPLE LUMEN TRANSITION CATHETER AND METHOD

### BACKGROUND OF THE INVENTION

#### [0001] 1. Field of the Invention

[0002] A multilumen tubing, and more particularly, a tubing having a multilumen portion in fluid communication with a single lumen portion and having unitary construction.

#### [0003] 2. Prior Art

[0004] A variety of multilumen catheters and similar tubing is well established in the prior art. Chee, et al., in U.S. Pat. No. 5,542,937, discloses a multilumen catheter made by an extrusion process wherein the lumens are coextensive with the length of the catheter. Means for changing the composition of the elastomer comprising the catheter body during the extruded elongation of the catheter is discussed.

[0005] Miller et al., in U.S. Pat. No. 5,683,640, discloses a dual lumen catheter wherein a first lumen is coextensive with the length of the catheter and a second lumen, parallel to the first lumen, is shorter than the first lumen and exits the catheter via a port in the catheter wall. A hollow hub is affixed to one end of the catheter and is in fluid communication with both the first and second lumen. Medical applications of the catheter include infusion of fluids and peritoneal dialysis.

[0006] The attachment of a hub to a multilumen tubing, or any tubing, compromises the structural integrity of the assembly. Either axial or lateral tension on the hub may cause it to separate from the catheter. This problem can be overcome by providing a multilumen catheter having unitary construction, wherein multiple lumens, terminating at one end of a catheter, are in fluid communication with a single lumen terminating at the opposing end of the catheter.

### SUMMARY OF THE INVENTION

[0007] It is a first object of the invention to provide a unitary tubing having a multilumen end and a single lumen end wherein fluid communication between the single lumen and the multiple lumens is established by means of a transition portion disposed therebetween.

[0008] It is another object of the invention to provide a medical catheter meeting the above-stated objective in any desired length and diameter.

[0009] It is still a further object of the invention to provide an apparatus and method for making a multilumen tubing meeting the objectives stated above.

[0010] The features of the invention believed to be novel are set forth with particularity in the appended claims. However the invention itself, both as to organization and method of operation, together with further objects and advantages thereof may be best understood by reference to the following description taken in conjunction with the accompanying drawings in which:

### BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 is a perspective view of a length of tubing wherein one end of the tube is characterized by a single lumen therein and the opposing end by the presence of dual

lumens therein and wherein the single lumen is in fluid communication with the dual lumens.

[0012] FIG. 2 is a longitudinal cross-sectional view of the transition portion of the tubing in accordance with FIG. 1 illustrating the multiple lumen-single lumen transition.

[0013] FIG. 3 is a cutaway partially cross-sectional view of an extrusion apparatus showing the axially mounted mandrel retracted from within the extruder's outlet aperture.

[0014] FIG. 4 is an end view of an article extruded with the mandrel retracted from the extruder's circular outlet aperture.

[0015] FIG. 5 is a cutaway partially cross-sectional view of an extrusion apparatus in accordance with FIG. 3, showing a lumen-forming end on the axially mounted mandrel, thrust into, and partially obstructing, the extruder's outlet aperture.

[0016] FIG. 6 is an end view of a tubular article made using the extruder shown in FIG. 5 when the portion of the mandrel projecting within the outlet aperture has a cylindrical cross-section.

[0017] FIG. 7 is a cross-sectional view of a portion of an extruder die showing an outlet aperture and mandrel in accordance with the invention, wherein the mandrel includes a cylindrical upper portion and a configured lower portion with the upper cylindrical portion of the mandrel partially obstructing the extruder's outlet aperture.

[0018] FIG. 8 illustrates the relationship between the mandrel and outlet aperture within the extruder die of FIG. 7 with the lower configured portion of the mandrel partially obstructing the outlet aperture.

[0019] FIG. 9 is an end view of a portion of tubing extruded when the upper portion of a mandrel is cylindrical and partially obstructs the extruder's outlet aperture as illustrated in FIG. 7.

[0020] FIG. 10 is an end view of a portion of tubing extruded when the lower portion of a mandrel is comprised of two cylindrical pins which partially obstruct the extruder's outlet aperture as illustrated in FIG. 8

[0021] FIGS. 11a-h are a series of end views of a tubing extruded when the configured lower portion of a mandrel is partially obstructs the extruder's outlet aperture as illustrated in FIG. 8 illustrating a variety of multilumen configurations corresponding to various configurations of the lower mandrel.

[0022] FIG. 12 is an end view of a triple lumen tubing extruded through a die with the mandrel positioned as shown in FIG. 8, wherein both the outlet aperture and the upper portion of the mandrel are oval and the lower configured portion of the mandrel comprises three cylindrical pins affixed to the upper portion.

[0023] FIG. 13 is an opposing end view of a single lumen portion of the triple lumen tubing shown in FIG. 12, extruded when the upper oval portion of the mandrel partially obstructs the oval outlet aperture as shown in FIG. 7.

[0024] FIG. 14 is a cross-sectional view of a portion of the extruder die illustrating the position of the mandrel within the outlet aperture during extrusion of the triple lumen portion of the tubing shown in FIG. 12.



[0025] FIG. 15 is a cross-sectional view of a portion of the extruder die illustrating the position of the mandrel within the outlet aperture during extrusion of the single lumen portion of the tubing shown in FIG. 12.

[0026] FIG. 16 is a partially cross-sectional side view of a extrusion die wherein the mandrel comprises a retractable tine on the lumen-forming portion thereof wherein the retractable tine is in an extended position.

[0027] FIG. 17 is a perspective view showing the end portion of an extruded tubing exiting the outlet aperture of an extrusion die when the configuration of the mandrel and tines are in accordance with the extrusion die shown in FIG. 16.

[0028] FIG. 18 is a partially cross-sectional side view of a extrusion die wherein the mandrel comprises a retractable tine on the lumen-forming portion thereof wherein the retractable tine is in a retracted position.

[0029] FIG. 19 is a perspective view showing the end portion of an extruded tubing exiting the outlet aperture of an extrusion die when the configuration of the mandrel and tines are in accordance with the extrusion die shown in FIG. 18.

[0030] FIG. 20 is a perspective view of the mandrel shown in FIG. 18 showing the retractable tine on the lumen-forming portion of the mandrel in a retracted position.

[0031] FIG. 21 is a top cross-sectional view of the unitary triple lumen portion of the extruded tubing of FIG. 19 showing termination of one of the lumens.

[0032] FIG. 22 is a partially cross-sectional side view of a extrusion die wherein the mandrel comprises two tines on the lumen-forming portion thereof wherein one of the two tines is retractable and the retractable tine is in a retracted position.

[0033] FIG. 23 is a top cross-sectional view of a unitary double lumen portion of an extruded tubing made using the mandrel/aperture configuration of FIG. 22 showing termination of only one of the two lumens.

[0034] FIG. 24 is a side cross-sectional view of an extrusion die operable for extruding the triple-lumen tubing shown in FIGS. 26 and 28-31, wherein all lumen-forming tines comprising the mandrel are fully extended to partially occlude the die outlet aperture.

[0035] FIG. 25 is a side cross-sectional view of the extrusion die of FIG. 24 taken along section line 25-25.

[0036] FIG. 26 is an end view of a portion of triple-lumen tubing extruded through the extrusion die shown in FIGS. 24 and 25 wherein all three lumen-forming tines on the mandrel partially occlude the die outlet aperture.

[0037] FIG. 27 is a side cross-sectional view of the extrusion die of FIG. 24, operable for extruding the triple-lumen tubing shown in FIGS. 26 and 28-31, wherein two of the three lumen-forming tines on the mandrel are retracted so that only a single lumen-forming tine partially occludes the die outlet aperture.

[0038] FIG. 28 is a cross-sectional view, taken along section line 28-28 of FIG. 29, of the single lumen transition portion of the triple-lumen tubing extruded through the

extrusion die shown in FIGS. 24 and 25, formed when two of the three lumen-forming tines on the mandrel are retracted so that only a single lumen-forming tine partially occludes the die outlet aperture.

[0039] FIG. 29 is a cross-sectional view of a length of triple-lumen transition tubing, viewed along section line 29-29 of FIG. 26, which has been extruded through an extrusion die in accordance with FIGS. 24 and 27 in a continuous extrusion process.

[0040] FIG. 30 is a proximal end view of the length of triple-lumen transition tubing shown in FIG. 29.

[0041] FIG. 31 is a distal end view of the length of triple-lumen transition tubing shown in FIG. 29.

[0042] FIGS. 32a-c are end views of three multi-lumen transition tubes, made in accordance with the present invention, illustrating three examples of multi-lumen configurations which can be made using an extrusion die in accordance with the present invention.

[0043] FIGS. 32d-f are transverse cross-sectional views, taken across the transition portion of the three respective multi-lumen transition tubes having end views as shown in FIGS. 32a-c.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0044] The words: "catheter" and "tube" or "tubing", are used interchangeably in the following discussion. The choice of one word rather than the others for use in a particular context should not be construed as limiting. Turning now to FIG. 1, a tube 10 is shown in perspective view. The tube 10 has an outer surface 11, a single lumen end 12 and a multilumen end 13. The tube 10 further includes a transition portion 14 disposed between the single lumen end 12 and the multilumen end 13. In FIG. 1, the multilumen end 13 is shown with two lumens 15 and 16 for the purpose of example. The segment of the tube 10 between the multilumen end 13 and the transition portion 14 is referred to hereinafter as the multilumen portion 17, whereas the segment of the tube 10 between the transition portion 14 and the single lumen end 12 is referred to as the single lumen portion 18.

[0045] With reference now to FIG. 2, a segment of the tube 10 containing the transition portion 14 is shown in longitudinal cross-section. The single lumen 13 bifurcates within the transition portion 14 to form a smooth union with lumens 15 and 16 comprising the multilumen portion 17 of the tube 10. The transition portion 14 is unitary with both the single lumen portion 18 and the multilumen portion 17 thereby providing a unitary tube which will not separate even when the tube 10 is stretched.

[0046] An extrusion chamber is illustrated in cross-sectional view in FIGS. 3 and 5. With reference first to FIG. 3, the extrusion chamber 30 includes a hollow interior cavity 31 having a extrudable material injection port 32 opening thereinto through which an extrudable material (not shown) is transported into the cavity 31 under pressure in the direction of the unnumbered single-headed arrows. The pressure may be provided by mechanical means, such as the auger 33 shown in FIG. 3, or by a hydraulically or pneu-



matically driven piston. The extrudable material (not shown) exits the cavity **31** through an extrusion die **34** to form an extruded article.

[0047] The extrusion die **34** is comprised of a die aperture **35** and a moveable mandrel **36**. The mandrel **36** is reciprocally driven in the direction indicated by the double-headed arrow by a programmable mandrel positioning mechanism **37** such as, for example, a cam, as shown in **FIGS. 3 and 5**, which may be driven by a stepper motor (not shown). Pneumatic, hydraulic and electromagnetic solenoids may also be employed for positioning the mandrel **36**. When the mandrel **36** is retracted so as not to obstruct the flow of extrudable material through the die aperture **35**, as shown in **FIG. 3**, the extruded material exits the cavity **31** through the die aperture **35** to form a rod **40** (**FIG. 4**) having a transverse cross-sectional shape which conforms to the shape of the die aperture.

[0048] **FIG. 5** illustrates, in longitudinal cross-sectional view, the extruder head **30** of **FIG. 3** wherein the mandrel **36** is advanced to partially obstruct the outlet aperture **35**. In this configuration, the extruded material is forced to exit the cavity **31** through the (cylindrical) space between the mandrel and the wall of the outlet aperture. In the configuration shown in **FIG. 5**, wherein the mandrel **36** projects within, and partially obstructs, the outlet aperture, the extruded article emerging from the outlet aperture will be a tube **60** having a transverse cross-sectional shape conforming to the corresponding shape of the outlet aperture with the mandrel therewithin as shown in **FIG. 6**. The shape and size of the lumen **61** is determined by the transverse cross-sectional shape and size of the portion of the mandrel within the outlet aperture.

[0049] **FIGS. 7 and 8** are cross-sectional longitudinal views of a portion of an extruder head showing the mandrel and the outlet aperture in enlarged view. The mandrel **36** has a lower end **70** with a lumen forming portion **71** affixed thereto. The lumen forming portion **71** of the mandrel **36** is comprised of a single lumen forming portion **72** affixed to the lower end **70** of the mandrel **36**, and a multilumen forming portion **73** rigidly affixed to the lower surface **74** of the single lumen forming portion **72**. The single lumen forming portion **72** preferably has a continuous outer surface facing the wall of the outlet aperture **35**. If the outlet aperture **35** is circular, and the single lumen forming portion **72** of the mandrel has a circular transverse cross-section, an article extruded through the outlet aperture **35**, configured as shown in **FIG. 7**, will be a tube **90** (**FIG. 9**) having an outer diameter equal to the diameter of the outlet aperture and a circular lumen having a diameter equal to the diameter of the single lumen forming portion **72** of the mandrel.

[0050] If, during extrusion of a tubing through the extrusion die shown in **FIG. 7**, the mandrel **36** is retracted and repositioned such that the multilumen forming portion **73** is disposed within the outlet aperture, as shown in **FIG. 8**, the lumen must also change to conform to the change in shape of the opening in the outlet aperture. Thus, for example, if the multilumen forming portion **73** is comprised of a plurality of cylindrical pins **81** and **82**, the extruded tubing **100** will have a transverse cross-section as shown in **FIG. 10**. The multiple lumens **101** and **102** will have the same diameter as the lumen-forming pins **81** and **82** corresponding thereto. Since either the single lumen forming portion **72**

and/or the multilumen forming portion **73** of the mandrel partially obstructs the flow of extrudate through the die aperture, the transition portion is formed as the mandrel changes position within the die aperture. If the repositioning occurs quickly, the transition portion of the extruded tubing will be relatively short. Conversely, when repositioning occurs slowly, the transition portion will be relatively long. **FIG. 11a-h** provide some examples of multilumen configurations which can be manufactured in accordance with the present extrusion apparatus. In each embodiment of the multilumen portion of the tubing, shown in transverse cross-section in **FIGS. 11a-h**, the transition portion **14** of the tubing **10** provides fluid communication between the single lumen portion **18** of the extruded tubing and each and every lumen comprising the multilumen portion **17** of the tubing **10**.

[0051] The die outlet aperture **35** in the extrusion chamber **30** need not be round, but may, in general, be made in any desired shape. For example, a tube **120** of unitary construction, having a oblong lumen **121** in the single lumen portion thereof, shown in transverse cross-section in **FIG. 12**, with the multilumen portion shown in similar sectional view in **FIG. 13**, can be made in a continuous process using a mandrel **36** having a lumen forming portion **73** as shown in **FIG. 14**; and an oblong aperture **145** having the same shape as the outer surface of the tubing **120**. In addition, by completely retracting the mandrel such that no portion of the mandrel obstructs the die aperture **145**, the end of the lumens can be sealed.

[0052] The axially movable mandrel **36** may also be used for extruding a catheter having either single or multiple lumens wherein any one or all of the lumens are plugged at one or both ends of the catheter. Returning to **FIG. 3** to illustrate this lumen-sealing feature, it is seen that when the mandrel **36** is retracted from the extrusion die outlet aperture **35**, the extruded article **40**, shown in end view in **FIG. 4**, is a solid rod. Similarly, if the lumen forming portion **73** of a mandrel comprises a plurality of lumen-forming tines, one or all of which are slidably mounted within the mandrel, such a slidably mounted lumen-forming tine can be repositioned independently from the mandrel, to seal and/or open a lumen within the extruded tubing. For example, the mandrel, shown at **36** in **FIGS. 14 and 15**, can be modified such that one of the tines in the lumen forming portion **73** is mobilized, as shown in **FIG. 16**.

[0053] With reference to **FIG. 16**, the lumen-forming portion **73** of the mandrel **36** comprises three tines **160a-c**. One of the tines is slidably mounted to move reciprocally in an axial direction (i.e. in a direction which is orthogonal to the plane defined by the die aperture which is parallel to the direction of flow of extruded material emerging from the die aperture). When both the mandrel **36** and the tine **160a** are fully extended, as shown in **FIG. 16**, and partially occludes the die aperture **145**, a tubing **170** extruded through the die aperture **145** will have a transverse geometry as shown in **FIG. 17**. If the movable tine **160a** is retracted without moving the mandrel **36** and the stationary tines **160b** and **160c**, an extruded tubing emerging from the aperture **145** will have a transverse cross-section as shown in **FIG. 19** wherein the lumen corresponding to tine **160a** is sealed. A perspective view of the mandrel **36** of **FIG. 18**, with tine **160a** in a retracted position, is shown in **FIG. 20**. **FIG. 21**



is a top cross-sectional view of the tubing 170 of FIG. 19 illustrating the sealed lumen 210.

[0054] FIG. 22 illustrates, in partial cross-section, an extrusion die 34 having a mandrel 36 which may be used to extrude a double lumen catheter 230, shown in FIG. 23. One of the lumens 231a of the dual lumen tubing 230 opens at the distal end 232 of the catheter 230 whereas the other lumen, 231b, terminates proximal to the distal end 232 of the catheter 230. If a perforation 233 is made in the side of the tube 230 adjacent to the terminus of lumen 231b, lumen 231b can be used, for example, for inflating and deflating a balloon (not shown) affixed to the outer surface of the unitary dual lumen tubing 230.

[0055] As a further example of the application of the present invention, FIGS. 24, 25 and 27 illustrate an extrusion die which may be used in cooperation with an extrusion apparatus for making a multi-lumen transition tubing wherein one or more lumens open or close in a continuous extrusion process. FIGS. 24, 25 and 27 collectively illustrate, in cross-section, an extrusion die 34 having a mandrel 36 which may be used to extrude a triple lumen catheter 260, shown in FIG. 26 and FIGS. 28-31. In FIG. 24, all three tines 240, 241a and 241b (not visible in FIG. 24) comprising the mandrel 36 extend into the die outlet aperture 145 and are flush with the uppermost surface of the outlet aperture. When the tines 140 and 141a and 141b are positioned within the die outlet aperture in accordance with FIGS. 24 and 25, a multi-lumen transition tubing 260 extruded through the die outlet aperture 145 will have a transverse lumen configuration as shown in FIG. 26. When the tines 241a and 241b are retracted to reposition the tines so as to not obstruct the die outlet aperture, as shown in FIG. 27, a multi-lumen transition tubing 260 extruded through the die outlet aperture 145 will have a lumen configuration as shown in transverse cross-section in FIG. 28. With reference to FIG. 29, lumen 261a is coextensive with the length of the triple-lumen transition tubing 260, whereas the other two lumens 261b and 261c (not visible in FIG. 29) terminate between the proximal end 291 and the distal end 292 of the catheter 260. The lumen configuration at the proximal end 291 and distal end 292 of the multi-lumen transition tubing 260 is shown in FIGS. 30 and 31 respectively. The transverse cross-section of the transition portion 14 of the tubing 260, viewed along section line 28-28, will have the lumen configuration shown in FIG. 28.

[0056] FIGS. 32a-c are exemplary, showing in end view, three of the many possible lumen configurations which may be embodied in an extruded multi-lumen tubing using an extrusion die in accordance with the present invention. FIGS. 32d-f illustrate, in cross-sectional view, the lumen configuration of the transition portion of the respective multi-lumen transition tubes shown in FIGS. 32a-c. In FIG. 32a, an end view of a multi-lumen transition tubing 320 is configured to include two lumens 321 and 322, only one of which lumens (322) is present in the transition portion as shown in FIG. 32d. Similarly, of the two lumens 323 and 324, present in the multi-lumen portion of a multilumen tubing 320', shown in FIG. 32b, only lumen 323 traverses the transition portion as shown in FIG. 32e. In the quadruple-lumen transition tubing 320'', shown in end view in FIG. 32c, there are four lumens, 325, 326, 327 and 328,

present. FIG. 32f shows that only one lumen, lumen 328, traverses the transition portion of the multi-lumen transition tubing 320''.

[0057] It should now be clear that the extrusion die construction and operation, described above, can be employed to make a unitary tubing in any desired length and lumen configuration. For example, the mandrel 34 can be replaced with a plurality of mandrels adjacent to one another, any one of which may be independently repositionable. Any or all of the mandrels may, in turn, have any number of tines of any shape on the lumen-forming portions thereof. In addition, any or all of the tines may be retractably mounted within their respective mandrels. It is possible to make a unitary tubing having a first portion with m lumens therein, where  $m=0,1,2,3 \dots, \infty$ , and a second portion having n lumens therewithin, where  $n=1,2,3,4 \dots, \infty$ , with any one or all of the n lumens in fluid communication with one of the m lumens via the transition portion. It is, therefore, intended that all such embodiments of tubing and all such changes and modifications of the mandrel as required to make such multi-lumen tubing are within the scope of this invention.

[0058] While particular embodiments of the present invention have been illustrated and described, it would be obvious to those skilled in the art that various other changes and modifications can be made without departing from the spirit and scope of the invention. For example, although medical grade silicone elastomer is a preferred extrudable material for tubing having medical applications, other extrudable materials may be preferred for other applications as a design choice. Similarly, as stated above, while the invention has been described using a tubing having a single lumen portion and a multilumen portion with a transition portion therebetween as exemplars, it is clear that bifurcation, trifurcation and further division of the mandrel, together with independently retractable or extendable tines, can be used to produce a unitary tubing having two portions spaced by a transition portion with any desired number of lumens in the two portion, the transition portion providing fluid communication between any of the lumens of the first portion with any of the lumens of the second portion. It is, therefore, intended to cover in the appended claims all such changes and modifications that are within the scope of this invention.

What we claim is:

1. A tubing having unitary construction comprising a single lumen portion having a first length and a single lumen therewithin coextensive with said first length, a multiple lumen portion having a second length and at least two lumens therewithin coextensive with said second length wherein said first lumen is in fluid communication with two lumens comprising said multiple lumen portion.

2. The tubing having unitary construction in accordance with claim 1, further comprising a transition portion disposed between said single lumen portion and said multiple lumen portion, said transition portion providing fluid communication between said single lumen and lumens comprising the multiple lumen portion.

3. A tubing of unitary construction having a tube length comprising a first portion having a first length and a first number of lumens therewithin coextensive with said first length, a second portion having a second length and a second



number of lumens coextensive with said second length, wherein said second number of lumens is greater than said first number of lumens.

4. The tubing of unitary construction in accordance with claim 3 wherein one lumen comprising said first number of lumens is in fluid communication with at least two lumens comprising said second number of lumens.

5. An extruder die for use with an extrusion apparatus having an extrusion chamber, the extruder die being operable for forming a shaped aperture through which an extrudable material is transported to form a tubing having a length and a shaped transverse cross-section wherein the shape of the transverse cross-section changes along the length of the tubing, comprising:

- (a) a die aperture portion comprising a planar sheet of a rigid material affixed to the extrusion chamber and having an aperture therein through which an extrudable material contained within the extrusion chamber is transported in a flow direction to form the tubing; and
- (b) a mandrel slidably mounted within the extrusion chamber and adapted to move reciprocally in said flow direction, said mandrel comprising an elongate rod having a lumen forming portion on a lower end thereof, at least a portion of said lumen forming portion projecting into said die aperture and partially obstructing the flow of extrudable material through said die aperture, said lumen forming portion comprising a first portion having a first transverse cross-sectional shape

and a second portion having a transverse cross-sectional shape which is different from said first transverse cross-sectional shape; and

(c) means for reciprocally moving said mandrel to position either said first portion or said second portion of said lumen forming portion within said die aperture.

6. A method for making a unitary tubing comprising a single lumen portion having a first length and a single lumen coextensive with said first length, a multiple lumen portion having a second length and at least two lumens coextensive with said second length, wherein said first lumen is in fluid communication with two lumens comprising said multiple lumen portion, comprising the steps of:

- (a) presenting an extrusion apparatus having an extrusion chamber comprising an extrusion die in accordance with claim 5; then
- (b) positioning the mandrel such that at least a portion of the first portion of the lumen forming portion projects into and is enclosed by the die aperture; then
- (c) forcing an extrudable material through the die aperture; then
- (d) repositioning the mandrel such that at least a portion of the second portion of the lumen forming portion of the mandrel projects into and is encircled by the die aperture while continuing to force extrudable material through the die aperture.

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