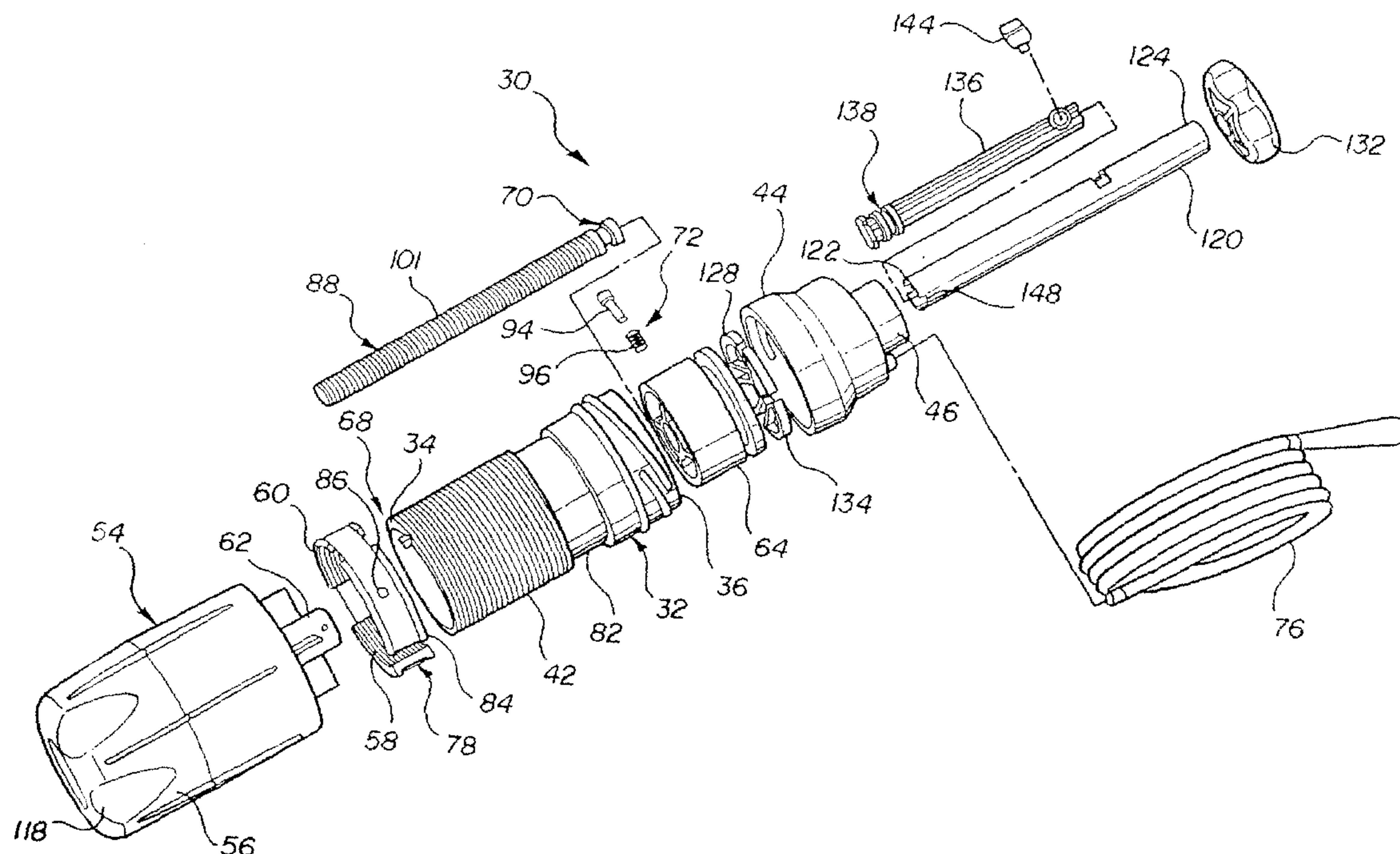




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(54) Titre : DISPOSITIF D'ADMINISTRATION ET DE MELANGE DE CIMENT OSSEUX POUR INJECTION ET
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(54) Title: BONE CEMENT MIXING AND DELIVERY DEVICE FOR INJECTION AND METHOD THEREOF



(57) **Abrégé/Abstract:**

A bone cement mixing and delivery assembly (30) is disclosed for mixing a powdered copolymer and a liquid monomer to form a bone cement and delivering the bone cement. The assembly includes a cartridge having a distal end (34) and a proximal end (36) and defining a mixing chamber (40) between the distal end and the proximal end. A transfer mechanism having a cap (52) and a stem supporting a piston (64) and a plunger is connected to the distal end. The transfer mechanism includes a first advancement mechanism (68) for advancing the piston and plunger in unison and a second advancement mechanism (70) for moving the plunger independent of the piston. The assembly further includes a removable handle (120) having a shaft for attachment of a mixing blade and a quick-release connector (142) and a release button (144) for locking and unlocking the mixing blade (128) from the removable handle.



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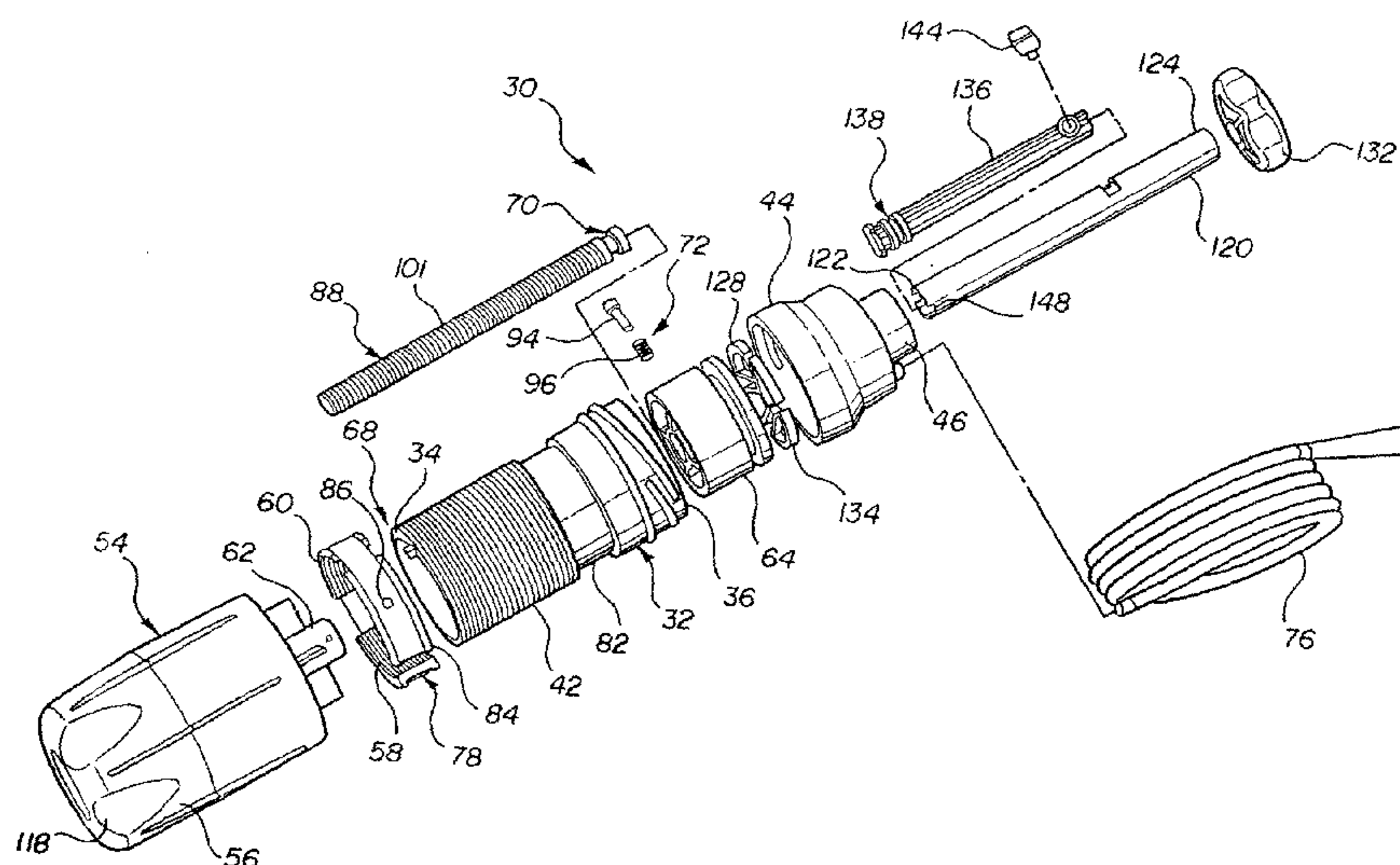
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5 **BONE CEMENT MIXING AND DELIVERY DEVICE FOR
 INJECTION AND METHOD THEREOF**

Field of the Invention

10 [0001] The present invention relates generally to a bone cement delivery assembly,
one that is particularly suited for mixing a powdered copolymer and a liquid monomer
to form a bone cement and delivering the bone cement.

Background of the Invention

15 [0002] In many surgical procedures, particularly orthopedic procedures, it is common
practice to affix a prosthesis to a bone or joint structure for improving the strength,
rigidity and movement of the bone/joint structure. Such prosthetic devices have been
widely used, hip joints and knee joints are the most common examples of areas where
prosthetic devices are used to reduce or eliminate pain and suffering that exists from
typical leg movements.

20 [0003] As part of these surgical procedures, it has become common practice to secure
the prosthesis to the bone or joint using a cement formed by mixing a polymer powder
and a liquid monomer. The two components must be thoroughly blended together to
achieve the required consistency for the fully mixed cement. The fully mixed cement is
then loaded into a separate dispensing apparatus for placement in the desired area and
25 affixing of the prosthesis to the desired site.

30 [0004] Other uses of bone cement include repairing or mending bone fractures or
shattered bone occurring from extreme trauma. Bone cement may also be used during
cosmetic or dental surgery. Moreover, bone cement may be used as a drug delivery or
release system, whereby the bone cement is mixed with antibiotics or other desired
drugs and applied to a specific surgical site such that the drugs leach out and are
delivered directly to the surgical site. Some bone cements are also designed to be
absorbed by the body over time.

35 [0005] Because of the necessity for a fairly quick setting material, the cement is
almost universally prepared by a surgical assistant during the course of the operation in
the sterile operating room. Conventional bone cements are generally polymeric
materials which are prepared by copolymerization of the components as needed. Bone
cement is prepared by copolymerizing the liquid monomer and the powdered
copolymer, such as methyl methacrylate and polymethyl methacrylate or methyl

5 methacrylate styrene. In order to provide a bone cement having the desired properties, the compounds must be uniformly and thoroughly mixed so that a homogeneous reaction product is produced.

[0006] During the mixing and subsequent chemical reaction various vapors are produced. Due to the noxious and toxic nature of such vapors, it is highly undesirable
10 to be exposed to them, particularly for extended periods of time in the course of multiple preparations. Since it is necessary that the mixing be carried out for extended periods of time to ensure a uniform reaction product and a minimum of concentration of volatile reactants, the period of exposure to harmful vapors can be substantial. Moreover, during the mixing of the constituent components of the cement, air bubbles
15 may be formed within the cement.

[0007] Most often, the two components forming the cement are mixed in a mixing vessel and, once fully mixed, the cement is manually transferred from the mixing vessel to a dispensing member of a dispensing device. Typically, devices similar to caulking
20 guns are employed for dispensing the fully mixed cement to the desired location in the patient. These devices have a piston which allows the bone cement to remain in the dispensing member.

[0008] In some other prior art systems, the cement is mixed in one vessel which is then directly connected to a feeding system that enables the mixed cement to be added to a holding tube for use with the dispensing device. The dispensing system, however,
25 is separate and exposes the mixed cement to the surrounding personnel. Furthermore, care must be exercised during the transfer of the mixed cement to the dispenser to avoid introducing air into the cement or to avoid dropping, spilling, or contaminating the cement.

[0009] Other prior art systems utilize a handle that operates mixing paddles in a closed cylinder for combining the cement constituents. Upon mixing the bone cement,
30 the handle must be removed. Conventional systems incorporate frangible handles that when broken may produce fragments that could contaminate the bone cement.

[0010] One such device is disclosed in United States Patent 5,551,778 to Hauke et al. The '778 patent discloses a device having a mixing cylinder and a mixing plunger
35 extending therethrough. The standard powder and liquid components are introduced into the chamber to form a bone cement and the mixing plunger mixes the two components. The mixing plunger has a predetermined break point for breaking the

5 mixing plunger and allowing for its removal from the mixing cylinder. A discharge nozzle is then connected to the mixing cylinder and the mixing chamber is connected to a drive mechanism. The drive mechanism includes a discharge plunger that is passed through the mixing cylinder forcing the bone cement from the mixing cylinder out the nozzle. A portion of the bone cement remains in the discharge nozzle and thus the
10 system does not ensure complete delivery of the bone cement into the patient.

[0011] Another such device is disclosed in United States Patent 5,879,116 to Barker et al. The '116 patent discloses a device having a mixing chamber integral with a delivery chamber. The bone cement components are introduced into the mixing chamber and a paddle having a handle extending from the mixing chamber is utilized to
15 mix the components and form the bone cement. Once the components are adequately mixed, a passage way is opened between the mixing chamber and the delivery chamber. The handle is actuated causing rotation of the paddle and of an auger disposed within the delivery chamber. The paddle transfers the bone cement from the mixing chamber to the auger. The auger has threads, which taper away from the
20 mixing chamber for pulling the bone cement from the mixing chamber into the delivery chamber. One disadvantage of this system is that the bone cement must have a relatively low viscosity to be pulled by the auger into the delivery chamber. Additionally, the bone cement may remain on the walls of the mixing chamber where the paddle is unable to reach it.

25 [0012] Accordingly, it would be advantageous to provide a bone cement mixing and delivery assembly that includes a mechanism to transfer all of the bone cement from a mixing chamber to an delivery cartridge and to deliver all of the bone cement from the delivery cartridge into the patient.

30 SUMMARY OF THE INVENTION AND ADVANTAGES

[0013] The present invention provides a bone cement mixing and delivery assembly for mixing a powdered copolymer and a liquid monomer to form a bone cement and delivering the bone cement . The device includes a cartridge having a distal end and a proximal end defining a mixing chamber between the distal end and the proximal end.
35 A lid is connected to the proximal end and has an aperture. A transfer mechanism is connected to the distal end and in sealing engagement with the cartridge. A piston is connected to the transfer mechanism such that movement of the transfer mechanism

5 extends the piston through the mixing chamber for transferring the bone cement from the mixing chamber to the proximal end. The device is characterized by a plunger extending from the piston for forcing the bone cement through the aperture and delivering the bone cement to the patient.

[0014] Accordingly, the subject invention proves a method comprising the steps of
10 filling a chamber having a proximal end with the bone cement, advancing a piston and a plunger in unison within the chamber for transferring the bone cement out of an aperture in the proximal end of the chamber, and the method is characterized by advancing the plunger independently of the piston to extend the plunger beyond the piston and into the aperture.

15 [0015] The subject invention provides many advantages over conventional systems. First, the bone cement is mixed and dispensed from the same container, thus eliminating the need to manually transfer the bone cement from a mixing vessel to a dispensing device. In addition, the removable handle is released rather than broken off. Thus, cost is reduced, handling is minimized and the introduction of contaminants into
20 the mixture is minimized or eliminated. Furthermore, the compound is not exposed to air, thereby reducing or eliminating exposure of noxious and toxic vapors to surrounding personnel during the surgical operation. Another advantage of the subject invention is that the compound is mixed in an environment evacuated by a vacuum. Thus, the formation of air bubbles is minimized, providing a uniform reaction product
25 and, in turn, producing a stronger bone cement compound.

[0016] Additionally, the device of the subject invention provides a mechanism for transferring all of the bone cement from the mixing chamber to the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

30 [0017] Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

[0018] Figure 1 is a perspective view of a first embodiment of a cement mixing and delivery assembly having a transfer mechanism and a removable handle designed
35 according to the present invention;

[0019] Figure 2 is an exploded perspective view of the embodiment of Figure 1;

5 [0020] Figure 3 is a cross-sectional view of a lid with an aperture having the removable handle extending therethrough designed according to the present invention;

[0021] Figure 4 is a cross-sectional view of the embodiment of Figure 1 shown in a mixing phase;

10 [0022] Figure 5 is an exploded perspective view of the embodiment of Figure 1 shown in a delivery phase;

[0023] Figure 6 is a cross-sectional view of the embodiment of Figure 1 shown at the start of the transfer stage;

[0024] Figure 7 is a cross-sectional view of the embodiment of Figure 1 shown after complete delivery of the bone cement;

15 [0025] Figure 8 is a perspective view of the lid;

[0026] Figure 9 is a perspective view of the transfer mechanism;

[0027] Figure 10 is a perspective view of a mixing blade designed according to the present invention;

20 [0028] Figure 11 is a bottom-side perspective view of a piston designed according to the present invention;

[0029] Figure 12 is a top-side perspective view of the piston designed according to the present invention;

[0030] Figure 13 is a perspective view of a cartridge designed according to the present invention;

25 [0031] Figure 14 is a perspective view of a plunger designed according to the present invention;

[0032] Figure 15 is a perspective view of a shaft designed according to the present invention;

30 [0033] Figure 16 is a perspective view of a delivery cartridge designed according to the present invention;

[0034] Figure 17 is a cross-sectional view of a second embodiment of a cement mixing and delivery assembly designed according to the present invention;

[0035] Figure 18 is a cross-sectional view of a third embodiment of a cement mixing and delivery assembly designed according to the present invention;

35 [0036] Figure 19 is a cross-sectional view of a fourth embodiment of a cement mixing and delivery assembly having multiple plungers and designed according to the present invention;

5 [0037] Figure 20A is a perspective view of a fifth embodiment of a cement mixing and delivery device designed according to the present invention;

[0038] Figure 20B is a cross-sectional view of the cement mixing and delivery device of Figure 20A;

10 [0039] Figure 21A is a perspective view of a sixth embodiment of a cement mixing and delivery device designed according to the present invention;

[0040] Figure 21B is a cross-sectional view of the cement mixing and delivery device of Figure 21A;

[0041] Figure 22 is a cross-section view of a seventh embodiment of a cement mixing and delivery device designed according to the present invention; and

15 [0042] Figure 23 is a perspective view of an alternate embodiment for a removable handle.

DETAILED DESCRIPTION OF THE INVENTION

20 [0043] Referring to the Figures, wherein like numerals indicate like or corresponding parts throughout the several views, a bone cement mixing and delivery assembly for mixing a powdered copolymer and a liquid monomer to form a bone cement and delivering the bone cement is shown generally at **30**. In one embodiment, delivery of the bone cement is performed percutaneously. Percutaneous, as used in the medical field, relates to passing or effectuating the bone cement through the skin. The mixing and delivery assembly **30** functions in three phases comprising a mixing phase, a transfer phase, and a delivery phase. All phases are described in detail below with the transfer and delivery phases described first, followed by the mixing phase. Specifically, Figures 5-7 and Figures 17-21 show the assembly **30** during the transfer and delivery phases. Figures 1-4 illustrate the assembly **30** during the mixing phase.

30 [0044] The mixing and delivery assembly **30** includes a cartridge **32** (shown separately in Figure 13) having a distal end **34** and a proximal end **36** and defining a chamber **38** between the distal end **34** and the proximal end **36**, as shown in Figures 4, 6, and 13. An external portion of the cartridge **32** adjacent the distal end **34** further includes male threads **42**. In the preferred embodiment, the chamber **38** is a mixing chamber **40** for receiving the liquid monomer and the powdered copolymer to form the bone cement. The chamber **38** may, however, receive premixed bone cement, in which case the assembly **30** is used only to deliver the premixed bone cement to the patient.

35

5 Alternatively, the chamber 38 may be packaged with the powdered copolymer. Thus, prior to use, only the liquid monomer is added.

[0045] A lid 44 is connected to the proximal end 36 and it has a first aperture 46. The lid 44 sealingly engages the proximal end 36. In the preferred embodiment, the lid 44 has threads for engaging corresponding threads on the proximal end 36 as shown in
10 Figures 2-7. The lid 44 also has a vent 48 connected to the lid 44 for allowing a vacuum (not shown) to be attached to the vent 48 with a vacuum attachment 76 for removing gas particles from the chamber 38. The vacuum may be any device capable of applying a pressure differential, as is known in the art, for removing gas particles from the mixing chamber 40. Removal of the gas creates a stronger cement. Also the
15 vacuum assists in the removal of obnoxious and potentially harmful gases produced during mixing. A filter 50 may also be disposed within the vent 48 for filtering the gas particles.

[0046] The mixing and delivery assembly 30 may further include a cooling chamber 52 positioned adjacent the mixing chamber 40 for receiving a cooling fluid (not shown) to
20 cool the mixing chamber 40. The cooling chamber 52 is capable of receiving any cooling fluid as is known in the art. As the liquid monomer and powder copolymer are mixed, an exothermic chemical reaction occurs. Illustrative examples of such a cooling fluid include ice inserted into the cooling chamber 52 or chemicals which produce an endothermic reaction for cooling the chamber 38. Alternately, the cooling chamber 52
25 could be annular and connected to a cold air or water supply for passing cold air or water through the cooling chamber 52. The bone cement remains useable for a longer period of time if the heat from the exothermic reaction is dissipated.

[0047] A transfer mechanism 54 threads onto the distal end 34, as shown in Figures 1, 2, 4-7, and 17-21. The transfer mechanism 54 includes a cap 56. The cap 56 has
30 female threads 58 for engaging the male threads 42 of the distal end 34. The cap 56, as shown in Figure 9, further includes a stem 62 extending from the cap 56. A piston 64 is rotatably supported by the stem 62 and housed within the cartridge 32. The piston 64 has a perimeter which extends to an inner wall of the chamber 38. The piston 64 is shown separately in Figures 11 and 12. The piston 64 also has a piston seal 65 between
35 the piston 64 and the chamber 38 for preventing bone cement from flowing therebetween. Preferably, the piston seal 65 comprises an O-ring.

5 [0048] The transfer mechanism 54 has a first advancement mechanism 68 and a second advancement mechanism 70. The first advancement mechanism 54 is for use in the transfer phase to advance the piston 64 through the chamber 38 and transfer the bone cement from the chamber 38 and out the aperture 46. The first advancement mechanism 68 includes a pin system 72 interconnecting the piston 64 and the stem 62
10 for preventing rotation of the piston 64 relative to the stem 62 until the piston 64 reaches a stop position 74, shown in Figure 6. The stop position 74 is defined by a channel 66 in the chamber 38 being adjacent the piston 64. The first advancement mechanism 68 further includes a disconnect system 78 disconnecting the female threads 58 from the male threads 42, as shown in Figure 7. After the female threads 58
15 and the male threads 42 are disconnected, the cap 56 can be rotated relative to the cartridge 32 without moving or rotating the piston 64.

[0049] In the preferred embodiment, the female threads 58 are formed as a plurality of circumferential segments 60. The plurality of circumferential segments 60 are connected to the transfer mechanism 54 to move axially along the male threads 42
20 thereby advancing the piston 64. The cartridge 32 includes an annular recess 82 adjacent the male threads 42. A first biasing device 84 moves the segments into the annular recess 82 once the piston 64 reaches the stop position 74. Preferably, the circumferential segments 60 are divided into sections and each section has a nipple 86 for engaging the first biasing device 84, as shown in Figure 2. Additionally, the
25 plurality of circumferential segments 60 may only encircle a portion of the threaded portion 40. Preferably, the first biasing device 84 is a metal spring band which collapses the plurality of circumferential segments 60 into the annular recess 82. As the circumferential segments 60 reach the end of the male threads 42, the first biasing device 84 forces the plurality of circumferential segments 60 into the annular recess 82.
30 As the circumferential segments 60 are forced into the annular recess 82, the circumferential segments 60 disengage from the transfer mechanism 54 which disconnects from the piston 64. When the circumferential segments 60 have entered the annular recess 82, the transfer stage is completed and the bone cement has been transferred from the chamber 38 and out the aperture 46. The first biasing device 84
35 and the annular recess 82 prevent the first advancement mechanism 68 from being able to back down the threaded portion 42. In other words, the first biasing device 84 allows the mixing and delivery assembly 30 to be used for a single application.

5 [0050] The assembly 30 also includes a plunger 88 movable relative to the piston 64 for extending from the piston 64 and into the aperture 46 for forcing the bone cement through the aperture 46. The extending of the plunger 88 from the piston 64 through the aperture 46 is the beginning of the delivery phase. The plunger 88 has a groove 90 and the stem 62 has a tongue 92 for interconnecting the plunger 88 to the
10 stem 62. The interconnection of the tongue 92 and the groove 90 allows the plunger 88 to rotate with the stem 62 and to move axially relative to the stem 62 in the delivery phase via threaded interaction between the plunger 88 and the piston 64.

[0051] The pin system 72 includes a pin 94 disposed radially to interconnect the stem 62 and the piston 64. The pin 94 has a head 95 and a tail 97 and the head 95 is larger
15 than the tail 97. A second biasing device 96, comprising a spring around the tail 97, urges the pin 94 radially outwardly against the cartridge 32. The cartridge 32 has the channel 66 adjacent the proximal end 36 for receiving the head 95. As the first advancement mechanism 68 moves the piston 64 through the chamber 38, the spring is compressed due to the head 95 engaging the inner wall of the chamber 38. When the
20 piston 64 reaches the stop position 74, the pin 94 is received by the channel 66 and the spring forces the pin 94 outward. Once this happens, the pin 94 no longer engages the stem 65 and only engages the chamber 38 and the piston 64.

[0052] The second advancement mechanism 70 includes threads 100 on the plunger 88 that engage threads 101 inside the piston 64. The second advancement mechanism 70
25 advances the plunger 88 from the piston 64 during the delivery phase. A plunger seal 103 is disposed between the plunger 88 and the piston 64 to prevent bone cement from flowing therebetween during the mixing and transfer phases. The tongue 92 and the groove 90 impart the continued rotation of the cap 56 to the plunger 88. The plunger 88 thereafter threadably engages the piston 64 such that the plunger 88 extends from
30 the piston 64. Once the piston 64 has reached the stop position 74, the plunger 88 moves independently of the piston 64 and the piston 64 acts as a nut as the cap 56 is rotated.

[0053] Alternately, and as shown in Figures 17 and 18, the second advancement mechanism 70 may include a rack 102 connected to the plunger 88 and a gear 104
35 engaging the rack 102 to advance the plunger 88 during the delivery phase. The gear 104 may be either a pinion gear 106 (Figure 17) or a worm gear 108 (Figure 18). A rod 110 is connected to the gear 104 and extends through the transfer mechanism 54 for

5 actuating the gear **104** manually or by a drive (not shown). The rod **110** is rotated causing the gear **104** to rotate causing the rack **102** to move linearly. Movement of the rack **102** extends the plunger **88** from the piston **64** and continues to deliver the bone cement through the aperture **46**.

[0054] The assembly **30** further includes a delivery cartridge **112** having a cartridge
10 end **114** connected to the aperture **46** of the lid **44** and extending to an open end **116**. The delivery cartridge **112** (shown separately in Figure 16) has a smaller diameter than the mixing chamber **40** and the plunger **88** has a smaller cross-section which allows the plunger **88** to extend through the aperture **46** and into the delivery cartridge **112**. As
15 the delivery cartridge **112** receives the plunger **88**, the bone cement is forced through the delivery cartridge **112**. The delivery cartridge **112** may also include cooling chambers **52** as discussed above for surrounding the mixing chamber **40**. For example, a water-based gel may be inserted into the cooling chamber **52** around the delivery cartridge **112** and cooled. The cooled delivery cartridge **112** allows the bone cement to
20 be available for use for longer periods of time. The delivery cartridge **112** may be permanently or removably connected to the lid **44**. Alternate embodiments may have the delivery cartridge **112** connected to the opposite end of a removable handle **120**.

[0055] The subject invention may also be utilized with more than one delivery cartridge **112**, as shown in Figure 19. Multiple delivery cartridges **112** require a plurality of plungers **88** corresponding to each of the delivery cartridges **112**. For
25 instance, two plungers **88** may extend from the piston **64**. The plungers **88** would be configured as described above with each plunger **88** engaging the second advancement mechanism **70**. Therefore, actuation of the second advancement mechanism **70** advances both plungers **88**. Alternately, the plungers **88** could have individual second advancement mechanisms such as the worm gear **108** or pinion gear **106** type of second
30 advancement mechanisms **70**. For percutaneous delivery, a flexible extension tube (not shown) is removable coupled to the open end **116**. A needle having a handle (not shown) is coupled to the extension tube for injection through the skin and into the patient.

[0056] In one embodiment, the mixing and delivery assembly **30** also includes at least
35 one indicator **118** disposed on the transfer mechanism **54** or rod **110** indicating an amount of the bone cement to be delivered into the patient upon rotation of the transfer mechanism **54** and the second advancement mechanism **70**. For instance, the indicator

5 118 on the transfer mechanism 54 may represent a quarter of a turn. The quarter of a turn may further represent two cubic centimeters of bone cement to be delivered into the patient. The indicators allow medical personnel to easily and efficiently deliver predetermined amounts of the bone cement to the patient. In another embodiment, the delivery cartridge 112 includes markings indicative of the amount of bone cement
10 delivered.

[0057] The assembly 30 of the subject invention can be used with a method of delivering the bone cement. The method includes the steps of filling the chamber 38 with the bone cement and sealing the chamber 38 by connecting the lid 44 to the proximal end 36. The preferred method includes disposing the liquid monomer and the
15 powdered copolymer into the chamber and agitating the liquid monomer and the powdered copolymer to form the bone cement as described below. However, the subject invention is particularly useful with premixed bone cement. Once the mixed bone cement is in chamber 38, the next step is actuating the transfer mechanism 54 to advance the first advancement mechanism 68. Advancing the first advancement
20 mechanism 68 includes advancing the piston 64 and the plunger 88 in unison for transferring the bone cement from the chamber 38 to the proximal end 36. In the preferred embodiment, actuation of the first advancement mechanism 68 begins by rotating the transfer mechanism 54. Rotation of the cap 56 causes the plurality of circumferential segments 60 to move along male threads 42. When the plurality of
25 circumferential segments 60 reaches the annular recess 82, the first biasing device 84 forces the plurality of circumferential segments 60 radially inward and into the annular recess 82 thereby separating the plurality of circumferential segments 60 from the cap 56.

[0058] The method is then characterized by actuating the second advancement
30 mechanism 70 and advancing the plunger 88 independently of the piston 64 to extend the plunger 88 beyond the piston 64 thereby delivering the bone cement into the patient. Specifically, in a preferred embodiment, once the plurality of circumferential segments 60 is recessed, the pin 94 engages the channel 66 in the mixing chamber 40 which fixes the position of the piston 64. Continued rotation of the cap 56 causes the
35 plunger 88 to rotate within the piston 64 and extend therefrom. The cap 56 is rotated until the plunger 88 has moved into the delivery cartridge 112 to force the bone cement completely from the mixing chamber 40.

5 [0059] In alternate embodiments, the second advancement mechanism 70 has the rod 110 extending from the cartridge 32 and engaging the gear 104. After the piston 64 is locked in place, the rod 110 is rotated causing the plunger 88 to extend from the piston 64. Alternate aspects of the assembly 30, as described above, further include the steps of venting the chamber 38, removing gas particles from the chamber 38, and filtering
10 the gas particles as the gas particles are removed from the chamber 38.

[0060] The assembly 30 preferably is further used to mix the liquid monomer and powder copolymer in the mixing chamber 40, as shown in Figures 1-4. In the mixing phase, the assembly 30 includes a removable handle 120 extending through the aperture 46 and having a first end 122 and a second end 124 defining a hollow cavity 126
15 therebetween. Other embodiments may include the removable handle 120 extending through the cap 56. The removable handle 120 may also be used to move the plunger 88 through the aperture 46. One such removable handle 120 is illustrated in Figure 22. The removable handle 120 includes a pivot 121 for engaging a cap stop 123. While in the transfer phase, the removable handle 120 pivots and is at a right angle with the
20 plunger 88. The removable handle 120 can be used to rotate the cap 56 during this stage. During the delivery phase, the removable handle 120 is pivoted and coextensive with said plunger 88. Rotation of the removable handle 120 extends the plunger 88 from the piston 64.

[0061] A mixing blade 128 (shown separately in Figure 10) has a bore 130 for
25 receiving the first end 122 of the removable handle 120. The second end 124 of the removable handle 120 allows a knob 132 to be attached for rotating and moving the mixing blade 128 through the mixing chamber 40. The mixing blade 128 may be any blade used for mixing, but is preferably a circular blade or a circular disc that is able to slide within the mixing chamber 40. The mixing blade 128 has a circumference which
30 extends to the inner wall of the mixing chamber 40, while still allowing for movement of the mixing blade 128. The mixing blade 128 may further include slots 134 for increasing the efficiency of the mixing. A shaft 136 (shown separately in Figure 15) is disposed within the hollow cavity 126 and has a blade attachment end 138 with
35 projections 140 extending from the first end 122. A shaft seal 141 is disposed between the shaft 136 and the removable handle 120 for preventing cement from flowing therebetween.

5 [0062] A quick-release bayonet-type connector 142 is located between the mixing blade 128 and the shaft 136 such that the mixing blade 128 is releasably connected to the removable handle 120. A release button 144 engages the shaft 136 and is movable between a locked position and an unlocked position. The quick-release connector 142 further includes flanges 146 extending inward from the bore 130 of the mixing blade
10 128 and a pair of flange recesses 148 disposed within the first end 122 of the removable handle 120. In the unlocked position, the projections 140 are offset from the flange recesses 148 such that the flange 146 can be received by the flange recess 148. Movement of the release button 144 causes the shaft 136 to rotate while the removable handle 120 remains still. The shaft 136 rotates causing the projections 140 to engage
15 the flanges 146 and force the flanges 146 into the flange recess 148. Once the release button 144 is in the locked position, the mixing blade 54 is locked to the removable handle 120. The removable handle 120 is manipulated manually or by a motor (not shown) to move the mixing blade 54 through the mixing chamber 40 and mix the cement components. The removable handle 120 is of sufficient length to extend the
20 mixing blade 128 through the entire length of the mixing chamber 40 and rotate the mixing blade 128 to ensure complete mixing.

[0063] An alternate quick-release connector 142 is shown in Figure 23. A collapsible ball 143 is connected to the first end 122 of the removable handle 120. When the release button 144 is in the unlocked position, the collapsible ball 143 is collapsed and
25 can be inserted into the bore 130. The release button 143 is moved to the locked position and the collapsible ball 143 engages the bore 130 thereby locking the mixing blade 128 to the removable handle 120.

[0064] The assembly 30, as utilized in the mixing phase, includes a method of mixing the powdered copolymer and the liquid monomer to form the bone cement. The
30 method includes the steps of disposing the powdered copolymer and the liquid monomer into the mixing chamber 40 and connecting the lid 44 to the proximal end 36 to seal the mixing chamber 40 having the mixing blade 128 disposed within the mixing chamber 40. Preferably, the removable handle 120 is inserted through the aperture 46 of the lid 44 while the lid 44 is not connected to the cartridge 32. However, the quick-
35 release connector 142 allows for the mixing blade 128 to be initially within the mixing chamber 40 and the lid 44 attached when inserting the removable handle 120 through the aperture 46. Additionally, the two components may be added with the lid 44

5 already connected and the mixing blade **128** disposed within the mixing chamber **40**. The removable handle **120** is manipulated moving the mixing blade **128** and agitating the powdered copolymer and the liquid monomer to form the bone cement. As the components are mixed together, a chemical reaction ensues, producing a gas that may be harmful if inhaled by the medical personnel. The vacuum is applied to the vent **48**
10 to remove gas particles from the mixing chamber **40** preventing the gas from being inhaled. The removal of the gas also ensures that the bone cement will be formed without gas bubbles providing a stronger cement. Additionally, the filter **50** may be utilized for filtering the gas particles as the gas particles are being removed from the mixing chamber **40**.

15 **[0065]** Once mixing is complete, the release button **144** is moved to the unlocked position thereby releasing the mixing blade **128** from the quick-release connector **142** such that the removable handle **120** is removable through the aperture **46** and the mixing blade **128** remains in the mixing chamber **40**. When the release button **144** is moved to the unlocked position, the shaft **136** is rotated causing the projections **140** of
20 the blade attachment end **138** to be offset from the flanges **146** of the bore **130**. The removable handle **120** is then removed from the bore **130** of the mixing blade **128** and through the aperture **46**. Since the mixing blade **128** is released without having to break the removable handle **120**, the bone cement does not become contaminated with fragments.

25 **[0066]** Figures 20A & B illustrate another embodiment of the cement mixing and delivery assembly **30**. The first advancement mechanism **54** is actuated by rotating the cap **56** to move the piston **64** through the mixing chamber **40** along the male threads **42**. The assembly **30** allows the removable handle **120** to remain in the mixing chamber **40** while the second advancement mechanism **70** is operated. The second advancement
30 mechanism **70** includes the plunger **88** extending through the removable handle **120** and through the mixing blade **128**. The delivery cartridge **112** extends from the lid **44** while the plunger **88** and the removable handle **120** extend through the cap **56**. The second advancement mechanism **70** is actuated by forcing the plunger **88** through the delivery cartridge **112** to deliver the bone cement by applying a force to the knob **132**
35 of the removable handle **120**. In this embodiment, the mixing blade **128** has tapered slots **134** to ensure better mixing and to assist in transferring the bone cement.

5 [0067] Figures 21A & B illustrate yet another embodiment of the cement mixing and delivery assembly 30. The mixing handle 120 and the delivery cartridge 112 both extend from the lid 44. The first advancement mechanism 54 is actuated by rotating the cap 56 to move the piston 64 through the mixing chamber 40 along the male threads 42. The second advancement mechanism 70 includes the rod 110 extending from the
10 cartridge 32 and the gear 104 engaging the plunger 88. When the rod 110 is rotated, the plunger 88 moves linearly through the mixing blade 128 and through the delivery cartridge 112 to deliver the bone cement.

[0068] Obviously, many modifications and variations of the present invention are possible in light of the above teachings. The invention may be practiced otherwise than
15 as specifically described within the scope of the appended claims.

5

CLAIMS

What is claimed is:

1. A bone cement mixing and delivery assembly for delivering a bone cement, said assembly comprising:

10 a cartridge having a distal end and a proximal end and defining a chamber between said distal end and said proximal end;

a lid connected to said proximal end and having an aperture;

a piston disposed in said chamber for transferring said bone cement from said chamber to said proximal end;

15 a transfer mechanism adjacent to said distal end and in sealing engagement with said cartridge, said transfer mechanism moving said piston through said chamber; and

a plunger extendable from said piston for forcing said bone cement through said aperture.

20

2. An assembly as set forth in claim 1 wherein said transfer mechanism includes a first advancement mechanism for advancing said piston and said plunger in unison.

25 3. An assembly as set forth in claim 2 wherein said transfer mechanism includes a second advancement mechanism for advancing said plunger relative to said piston.

4. An assembly as set forth in claim 3 further including an delivery cartridge
30 having a cartridge end connected to said aperture and extending to an open end with a smaller diameter than said chamber, said plunger having a cross section permitting the plunger to extend through said aperture and into said delivery cartridge.

5. A bone cement mixing and delivery assembly for mixing a powdered
35 copolymer and a liquid monomer to form a bone cement and delivering the bone cement, said assembly comprising:

5 a cartridge having a distal end and a proximal end and defining a chamber between said distal end and said proximal end;

 a lid connected to said proximal end and having an aperture;

 a piston disposed in said chamber and presenting a face for transferring the bone cement from said chamber to said proximal end;

10 a plunger moveable relative to said piston for extending from said piston and into said aperture for forcing the bone cement through said aperture; and

 a transfer mechanism connected to said distal end of said cartridge for moving said piston and said plunger in unison to a stop position that limits further movement of said piston and thereafter moves said plunger relative to said piston and
15 into said aperture.

6. An assembly as set forth in claim 5 wherein said transfer mechanism includes a cap surrounding said distal end and a first advancement mechanism interconnected between said cap and said distal end for moving said piston and said
20 plunger in unison and a second advancement mechanism for moving said plunger relative to said piston.

7. An assembly as set forth in claim 6 wherein said first advancement mechanism includes male threads on said distal end and female threads inside said cap
25 threadably engaging said male threads for moving said cap axially over said cartridge upon rotation of said cap relative to said cartridge.

8. An assembly as set forth in claim 6 wherein said second advancement mechanism includes coaxing threads interconnecting said plunger and said piston for
30 moving said plunger axially relative to said piston in response to rotation of said cap at said stop position.

9. An assembly as set forth in claim 7 wherein said second advancement mechanism includes a rack on said plunger and a gear engaging said rack to move said
35 plunger relative to said piston upon rotation of said gear.

5 10. An assembly as set forth in claim 7 wherein said cap includes a stem and
said piston is rotatably supported on said stem, a pin system interconnecting said piston
and said stem for preventing relative rotation between said piston and said stem until
said piston moves to said stop position, said first advancement mechanism includes a
10 disconnect system for disconnecting said female threads from said male threads for
allowing rotation of said cap relative to said cartridge without relative axial movement
therebetween at said stop position.

 11. An assembly as set forth in claim 10 wherein said disconnect system
includes an annular recess in said cartridge adjacent said male threads and a plurality of
15 circumferential segments forming said female threads and a first biasing device for
moving said segments radially into said annular recess at said stop position.

 12. An assembly as set forth in claim 10 wherein said first advancement
mechanism includes a tongue and a groove interconnecting said plunger and said stem
20 for rotating said plunger with said stem while allowing said plunger to move axially
relative to said stem.

 13. An assembly as set forth in claim 10 wherein said pin is disposed radially
to interconnect said stem and said piston, a second biasing device for urging said pin
25 out radially and into engagement with said cartridge, said cartridge having a channel
adjacent said proximal end for receiving said pin at said stop position to prevent
rotation of said piston and thereby to cause axial movement of said plunger relative to
said piston in response to rotation of said cap at said stop position.

30 14. An assembly as set forth in claim 5 further comprising at least one indicator
indicating an amount of the bone cement to be delivered upon rotation of said second
advancement mechanism.

 15. An assembly as set forth in claim 5 further comprising a vent connected to
35 said lid for removing gas particles from said chamber.

5 16. An assembly as set forth in claim 15 further comprising a filter disposed within said vent for filtering said gas particles.

 17. An assembly as set forth in claim 5 further comprising a cooling chamber positioned adjacent said chamber for receiving a cooling fluid to cool said chamber.

10

 18. An assembly as set forth in claim 5 further comprising a removable handle extending through said aperture and having a first end and a second end.

 19. An assembly as set forth in claim 18 wherein said removable handle is
15 coextensive with said plunger whereby actuation of said transfer mechanism extends said plunger from said piston.

 20. An assembly as set forth in claim 19 further comprising a pivot
interconnecting said plunger and said removable handle for allowing said removable
20 handle to extend at a right angle from said plunger.

 21. An assembly as set forth in claim 20 further comprising a cap stop
extending from said transfer mechanism and positioned for engagement with said
removable handle when said removable handle is positioned at a right angle to said
25 plunger whereby said removable handle aids in rotation of said transfer mechanism.

 22. An assembly as set forth in claim 18 further comprising a mixing blade releasably attached to said removable handle.

30 23. An assembly as set forth in claim 22 further comprising a quick-release connector between said mixing blade and said removable handle.

 24. A method of delivering a bone cement from a cartridge having a distal end and a proximal end defining a chamber therebetween and an aperture in the proximal
35 end, said method comprising the steps of:

 filing a chamber having a proximal end with the bone cement;

5 advancing a piston and a plunger in unison within the chamber for
transferring the bone cement out of an aperture in the proximal end of the chamber; and
 advancing the plunger independently of the piston to extend the plunger
beyond the piston and into the aperture.

10 25. A method as set forth in claim 24 wherein the bone cement further includes
a liquid monomer and a powdered copolymer and further including the step of
disposing the liquid monomer and the powdered copolymer into the chamber.

 26. A method as set forth in claim 25 further including the step of agitating the
15 liquid monomer and the powdered copolymer to form the bone cement.

 27. A method set forth in claim 24 further including the step of venting the
chamber and removing gas particles from the chamber.

20 28. A method set forth in claim 27 further including the step of filtering the gas
particles as the gas particles are removed from the chamber.

 29. A bone cement mixing and delivery assembly for mixing a powdered
copolymer with a liquid monomer to form a bone cement and delivering the bone
cement, said device comprising:

25 a cartridge having a distal end and a proximal end and defining a mixing
chamber between said distal end and said proximal end;

 a lid connected to said proximal end and having an aperture;

 a removable handle extending through said aperture and having a first end
and a second end defining a hollow cavity between said first end and said second end;

30 a shaft disposed within said hollow cavity and extending from said first end
of said removable handle;

 a mixing blade having a bore and said bore receiving said first end of said
removable handle; and

 a quick-release connector between said mixing blade and said shaft such
35 that said mixing blade is releasable from said removable handle.

5 30. An assembly as set forth in claim 29 wherein said quick-release connector further comprises a release button engaging said shaft and being moveable between a locked and an unlocked position for locking and unlocking said mixing blade to said removable handle.

10 31. An assembly as set forth in claim 30 wherein said quick-release connector further comprises a flange extending from said bore of said mixing blade and a flange recess disposed in said first end of said removable handle such that in said unlocked position said flange engages said flange recess.

15 32. An assembly as set forth in claim 31 wherein said shaft further comprises a blade attachment end extending through said bore, said blade attachment end having a projection for engaging said flange wherein engagement of said flange occurs when said release button is in said locked position and said flange is in said flange recess.

20 33. An assembly as set forth in claim 32 further including a piston disposed in said mixing chamber and presenting a face for transferring the bone cement from said mixing chamber to said proximal end.

25 34. An assembly as set forth in claim 33 further including a plunger moveable relative to said piston for extending from said piston and into said aperture for forcing the bone cement through said aperture.

30 35. An assembly as set forth in claim 34 further including a transfer mechanism connected to said distal end of said cartridge for moving said piston and said plunger in unison to a stop position that limits further movement of said piston and thereafter moves said plunger relative to said piston and into said aperture.

35 36. An assembly as set forth in claim 35 wherein said transfer mechanism includes a cap surrounding said distal end and a first advancement mechanism interconnected between said cap and said distal end for moving said piston and said plunger in unison and a second advancement mechanism for moving said plunger relative to said piston.

5

37. An assembly as set forth in claim 36 wherein said first advancement mechanism includes male threads on said distal end and female threads inside said cap threadably engaging said male threads for moving said cap axially over said cartridge upon rotation of said cap relative to said cartridge.

10

38. An assembly as set forth in claim 37 wherein said second advancement mechanism includes coacting threads interconnecting said plunger and said piston for moving said plunger axially relative to said piston in response to rotation of said cap at said stop position.

15

39. An assembly as set forth in claim 29 further comprising a vent connected to said lid for removing gas particles from said mixing chamber.

40. An assembly as set forth in claim 39 further comprising a filter disposed within said vent for filtering said gas particles.

41. An assembly as set forth in claim 29 further comprising a cooling chamber positioned adjacent said mixing chamber for receiving a cooling fluid to cool said mixing chamber.

25

42. An assembly as set forth in claim 30 wherein said quick-release connector further comprises a collapsible ball extending from said first end of said removable handle and engaging said mixing blade such that in said unlocked position said collapsible ball collapses thereby releasing said mixing blade.

30

43. A method of mixing a powdered copolymer and a liquid monomer to form a bone cement in a cartridge having a distal end and a proximal end defining a mixing chamber therebetween with a removable handle having a release button and a quick-release connector for attachment to a mixing blade and a lid having an aperture connected to the proximal end, said method comprising the steps of:

35

disposing the powdered copolymer and the liquid monomer into the mixing chamber;

5 connecting the lid to the proximal end to seal the mixing chamber having the mixing blade disposed within the mixing chamber;

 agitating the powdered copolymer and the liquid monomer with the mixing blade by manipulating the removable handle to form the bone cement; and

 actuating the release button and releasing the mixing blade from the quick-
10 release connector such that the removable handle is removable through the aperture and the mixing blade remains in the mixing chamber.

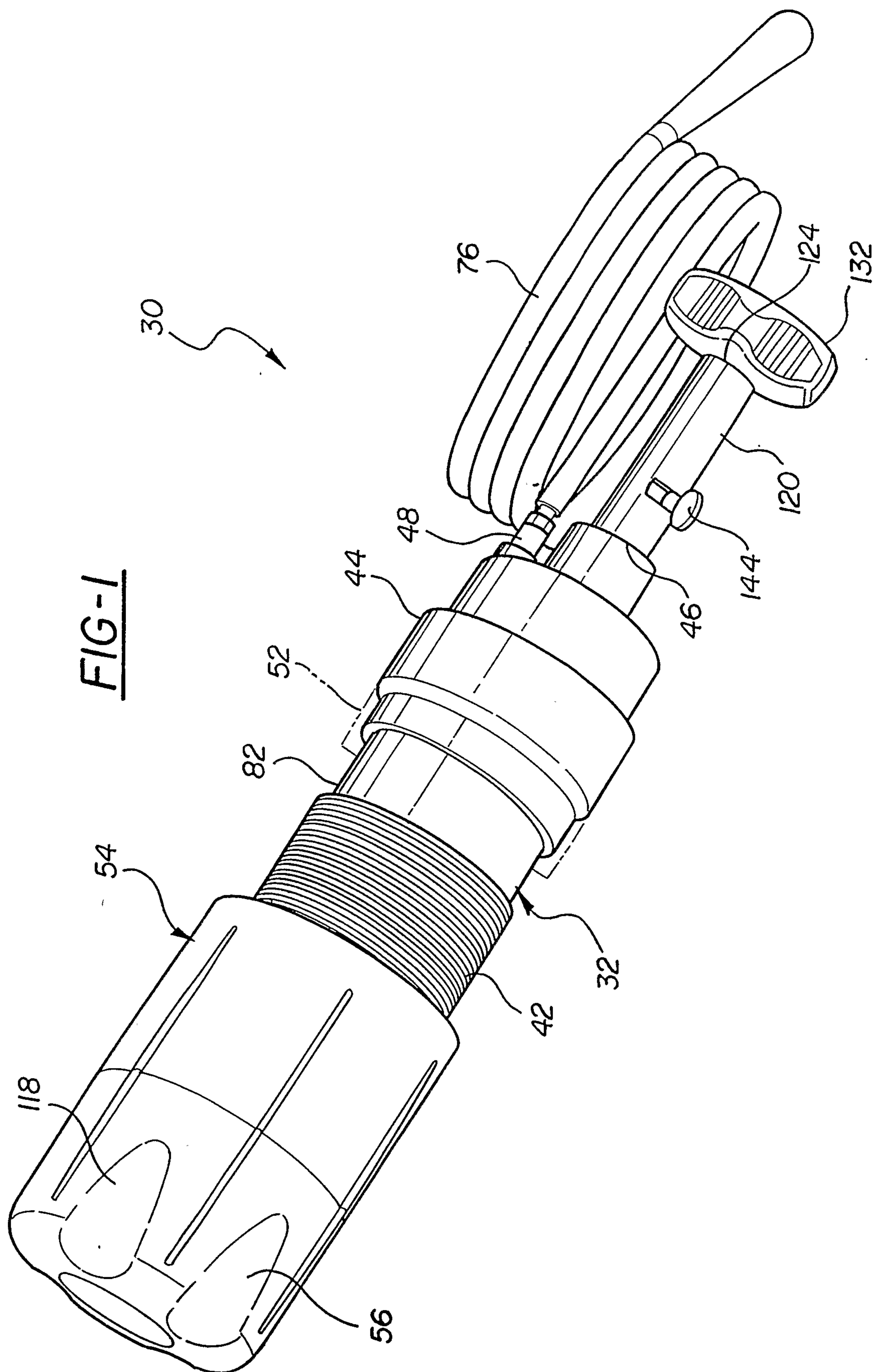
 44. A method as set forth in claim 43 wherein the quick-release connector further includes a shaft disposed within the removable handle and connected to the
15 release button and wherein the step of actuating the release button further comprises the step of sliding the release button and rotating the shaft to unlock the mixing blade from the removable handle.

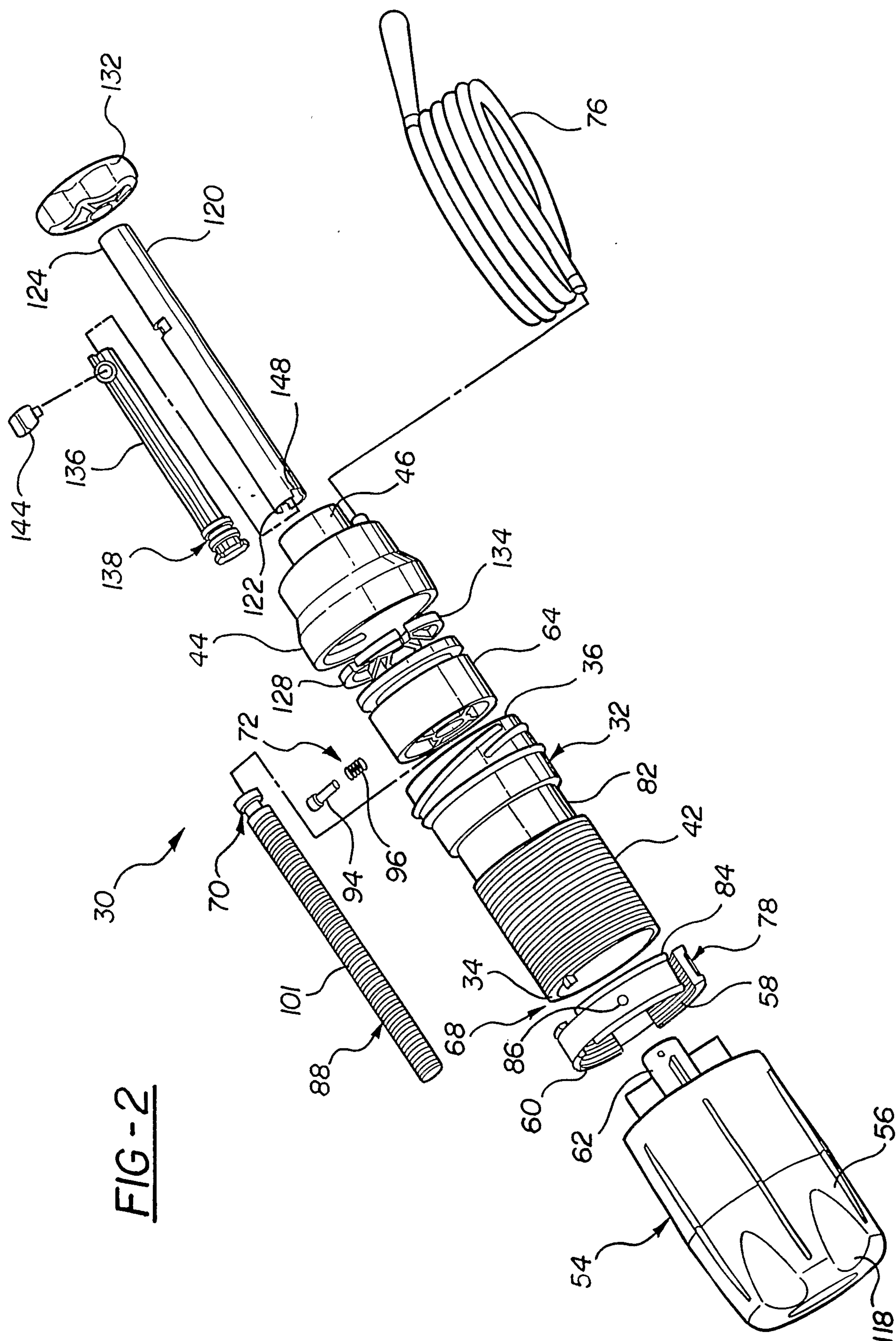
 45. A method as set forth in claim 43 wherein the step of connecting the lid
20 further comprises the step of inserting the removable handle through the aperture of the lid prior to connecting the lid to the proximal end.

 46. A method as set forth in claim 45 wherein the step of connecting the lid further comprises the step of attaching the mixing blade to the shaft while the release
25 button is in the unlocked position and sliding the release button to a locked position for locking the mixing blade to the removable handle such that mixing blade is on one side of the lid, and it enters the mixing chamber as the lid is connected.

 47. A method as set forth in claim 43 further comprising the step of removing
30 gas particles from the mixing chamber.

 48. A method as set forth in claim 47 further comprising the step of filtering the gas particles as the gas particles are being removed from the mixing chamber.





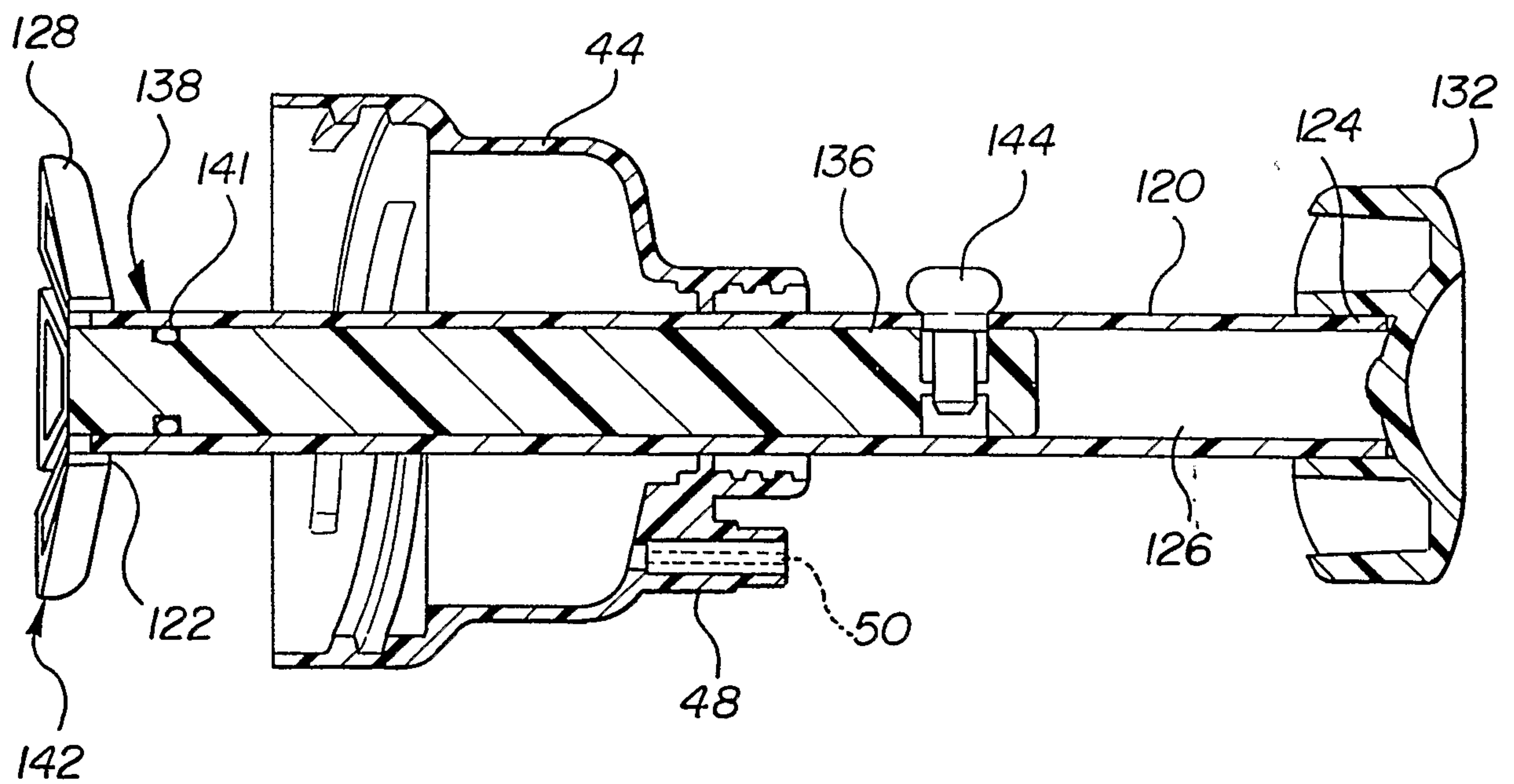
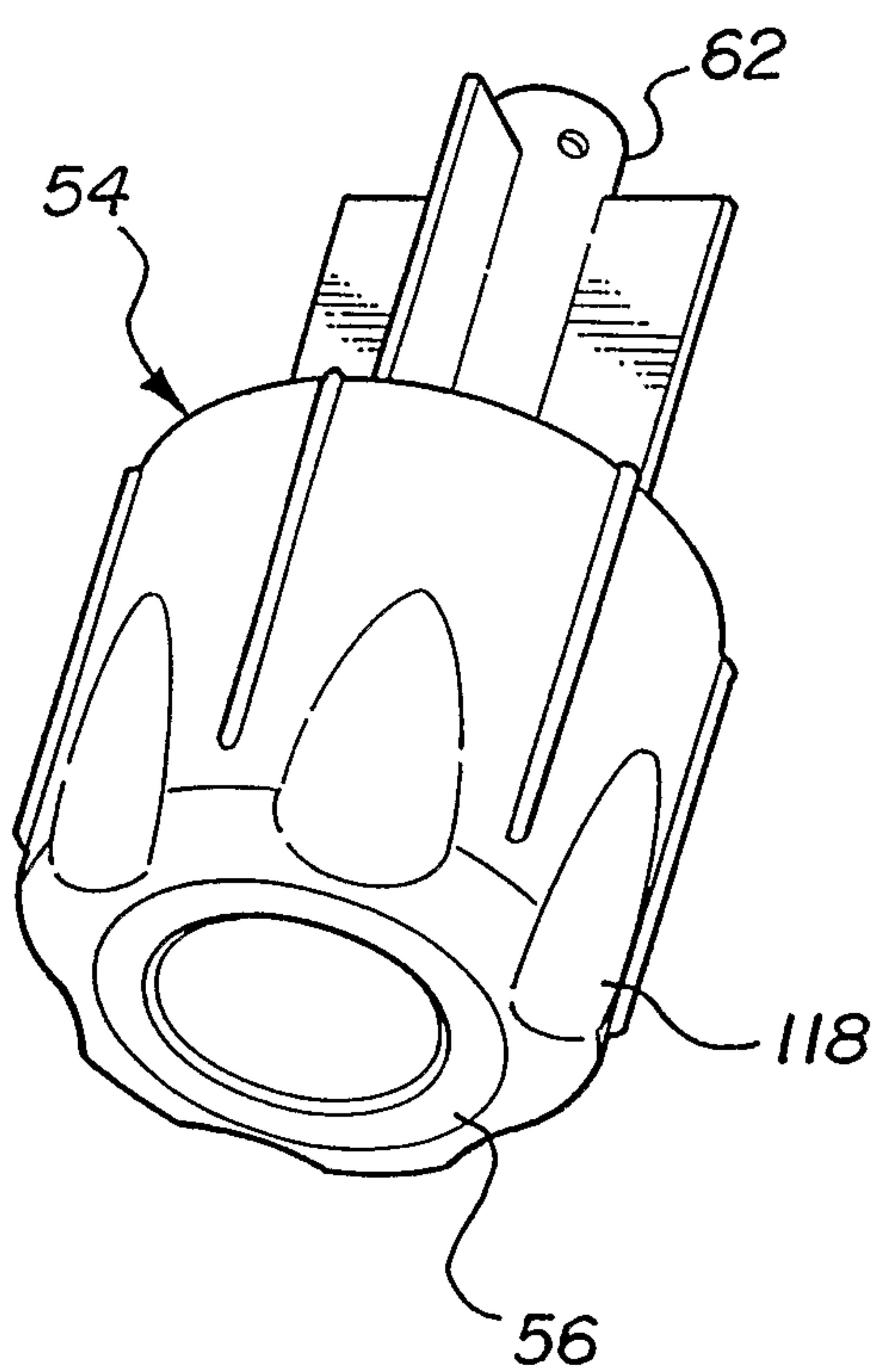
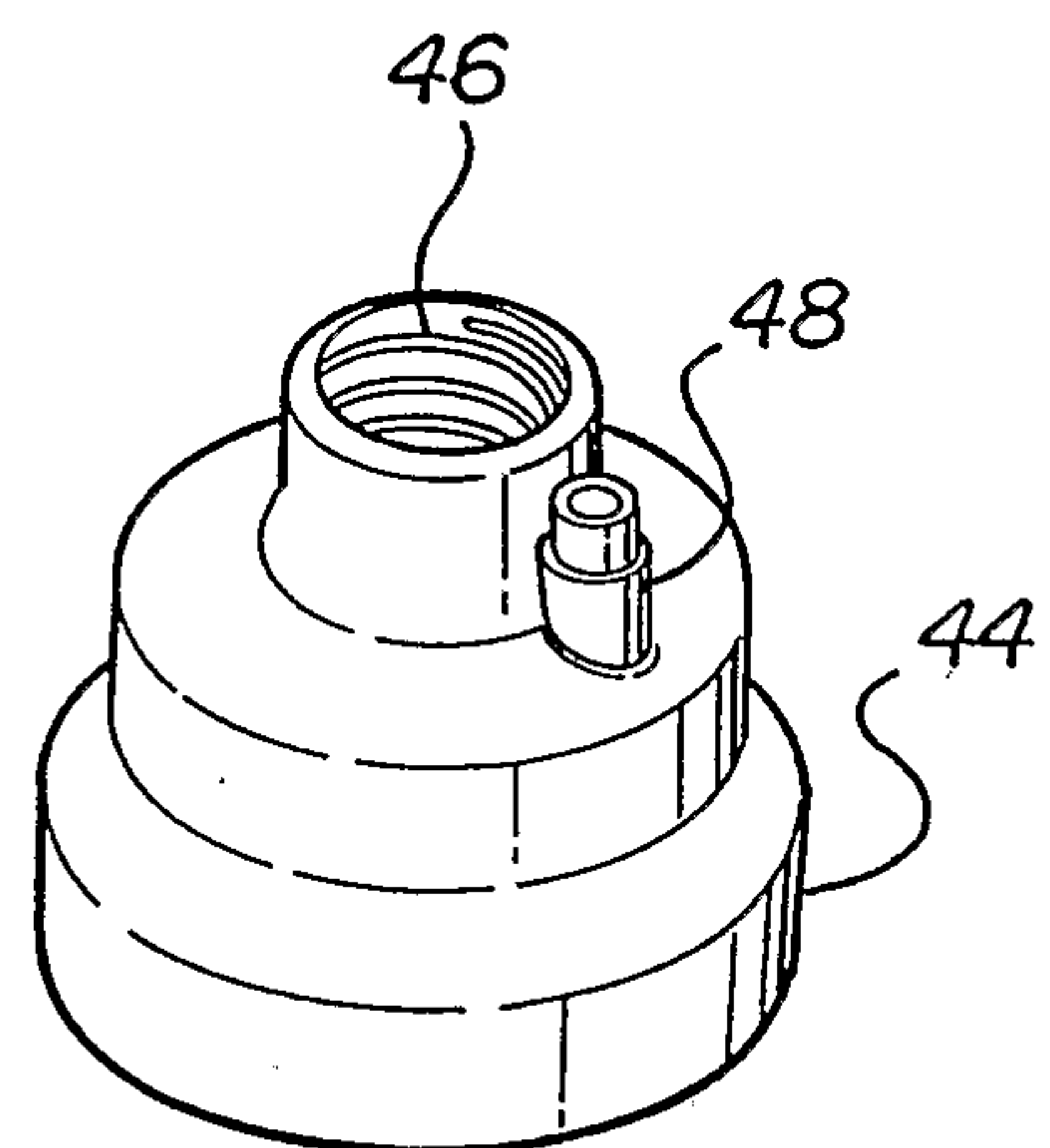
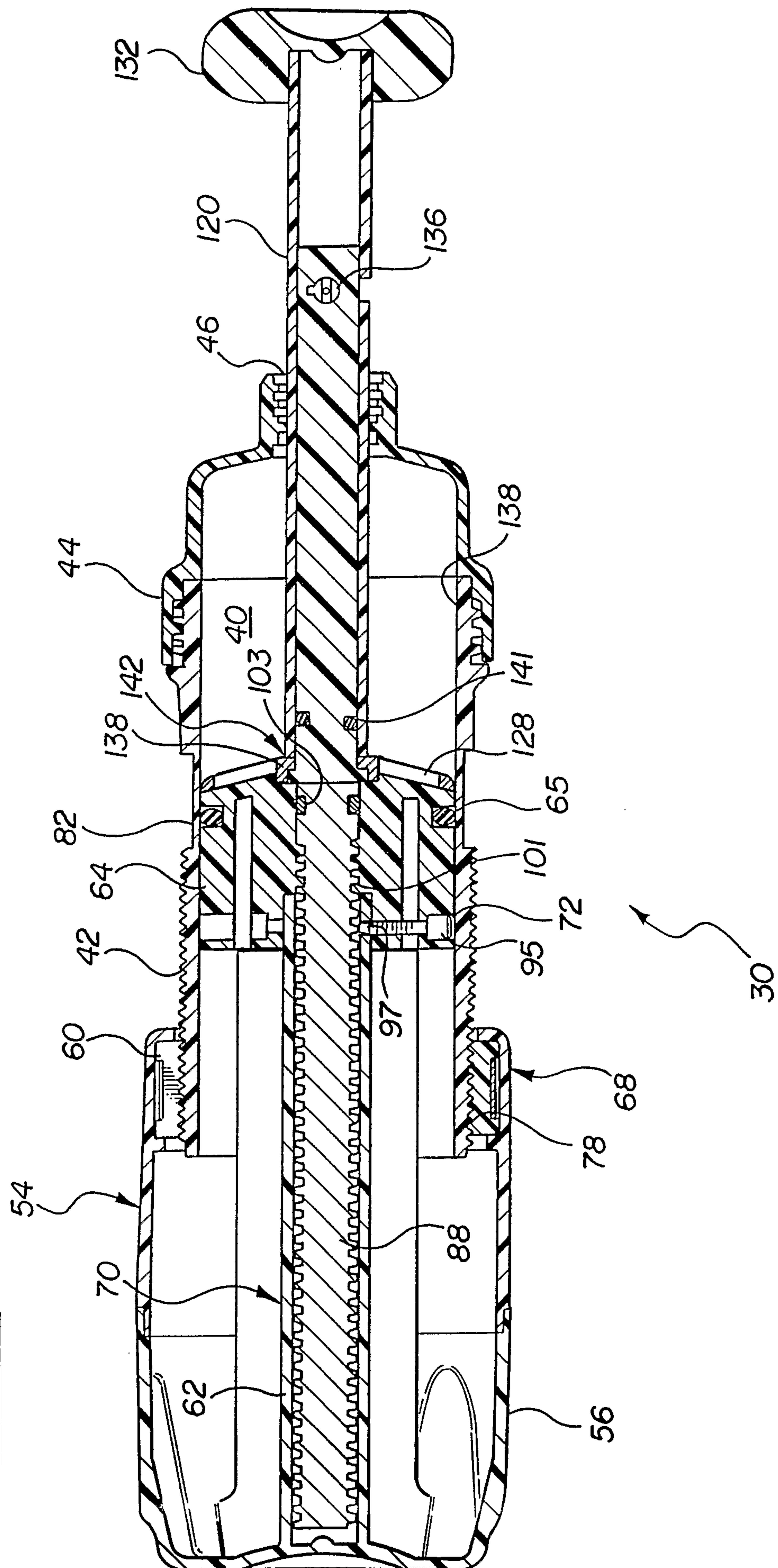
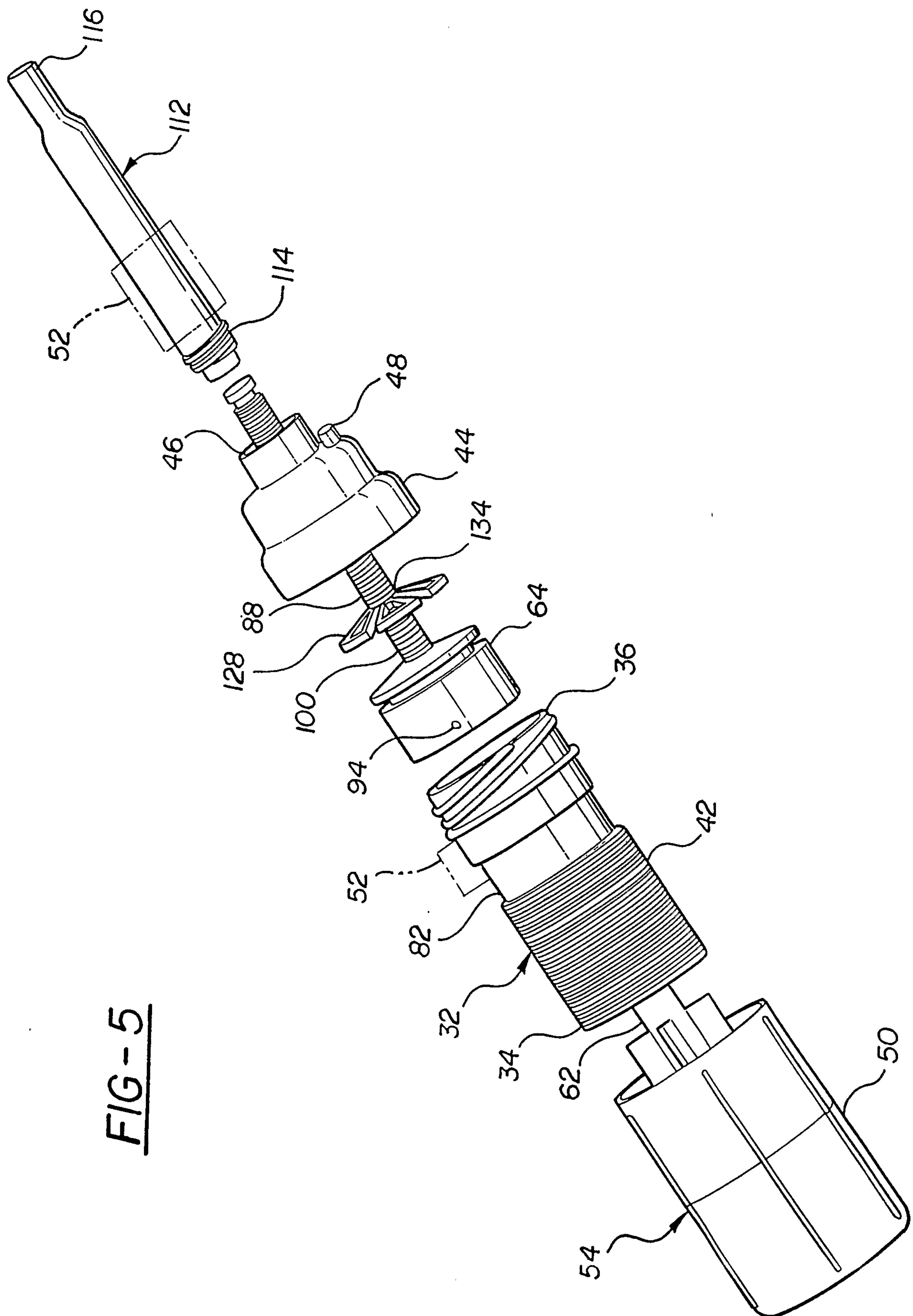
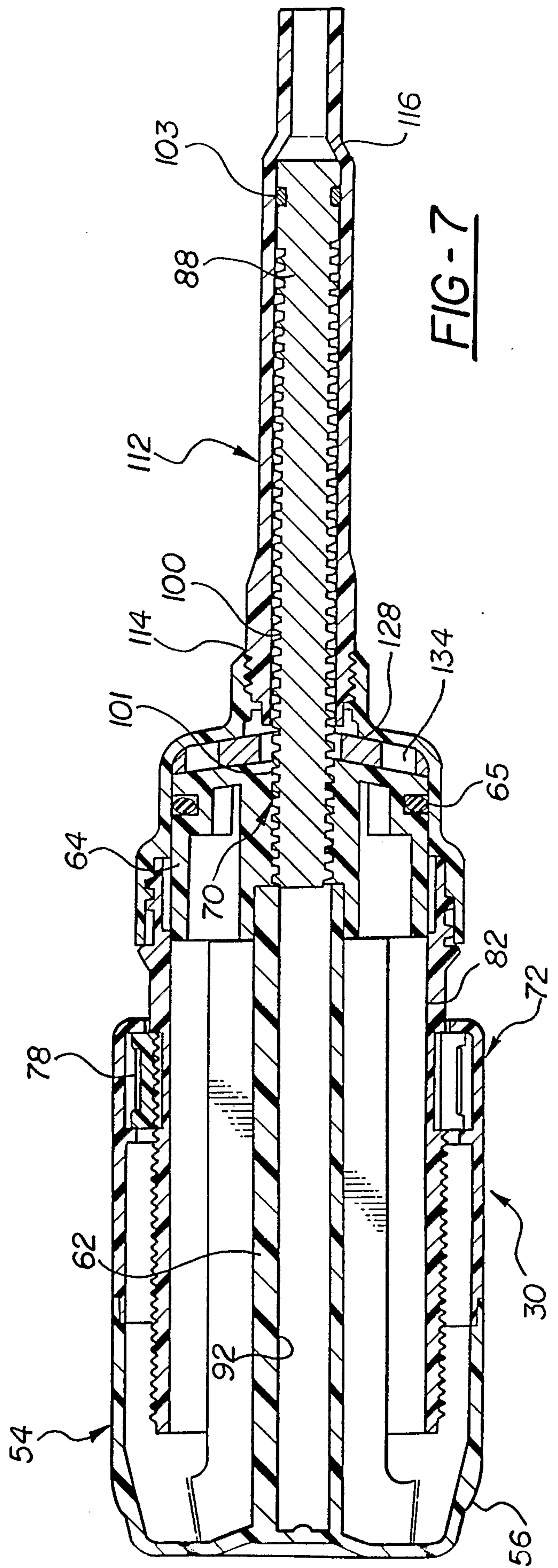
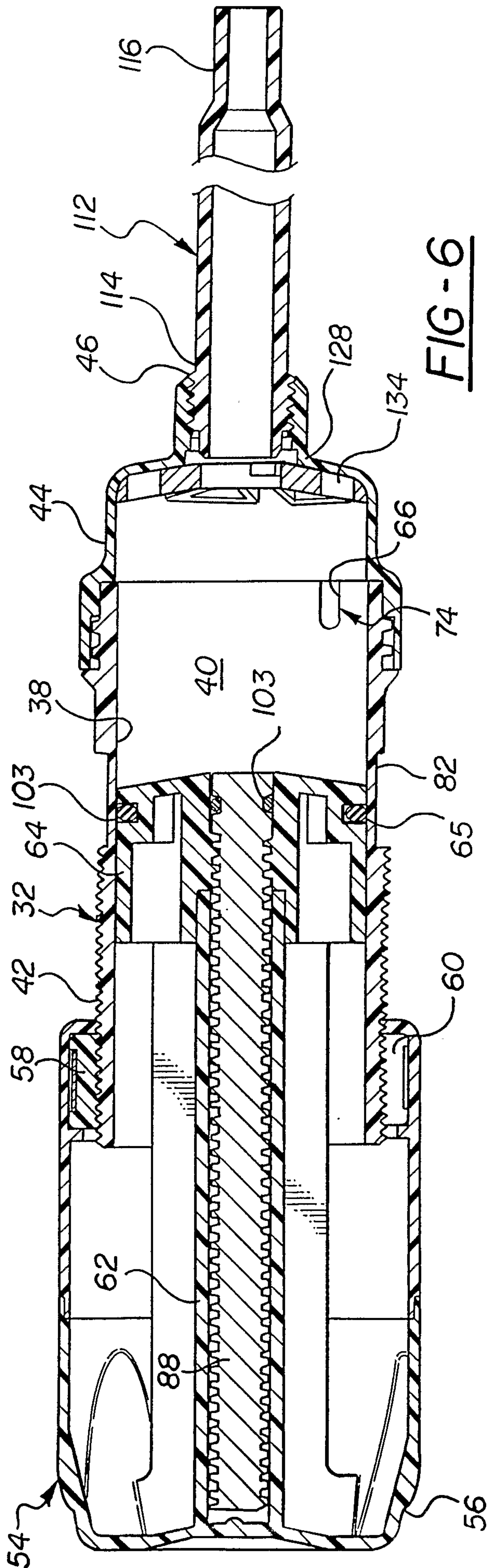
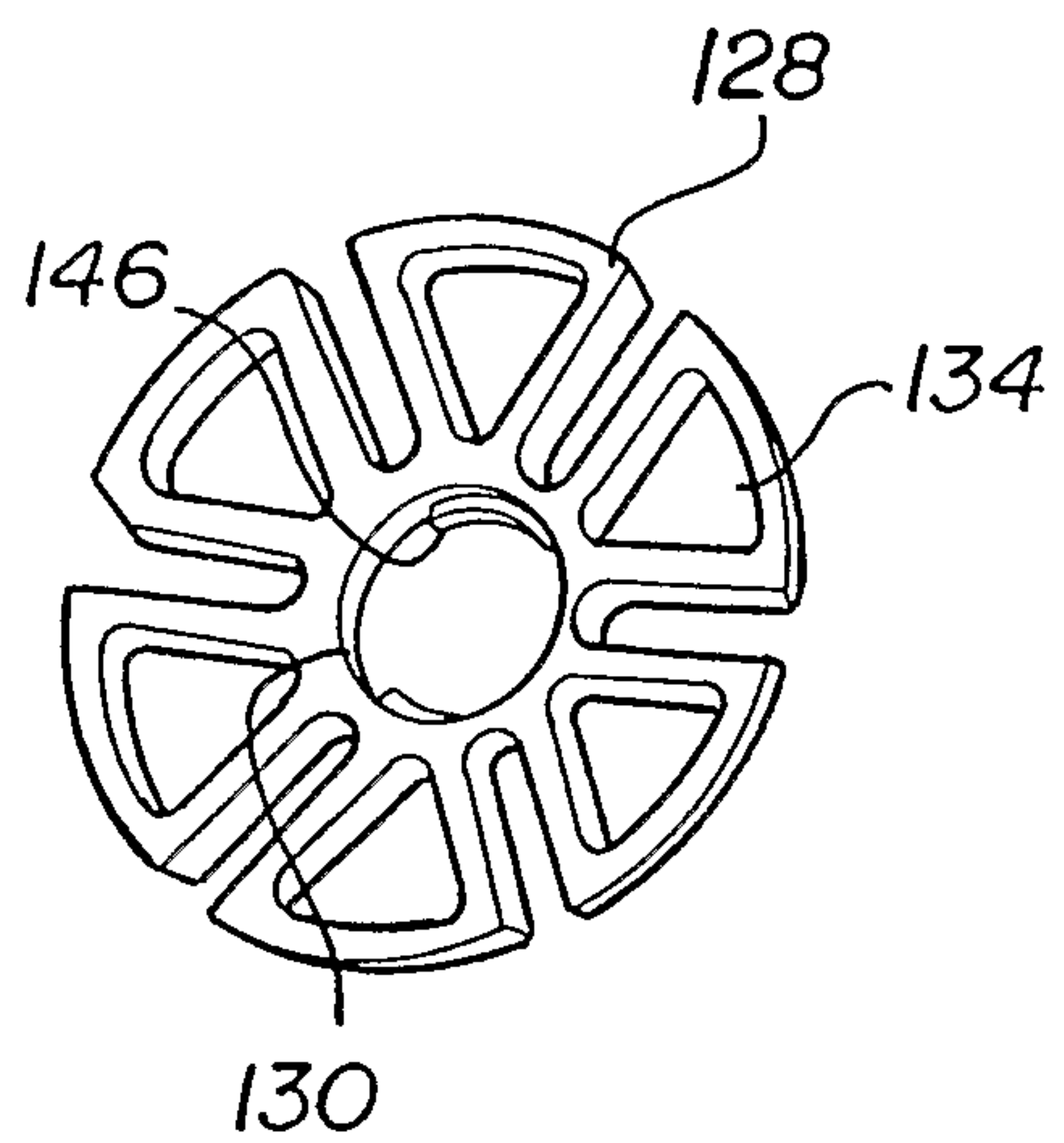
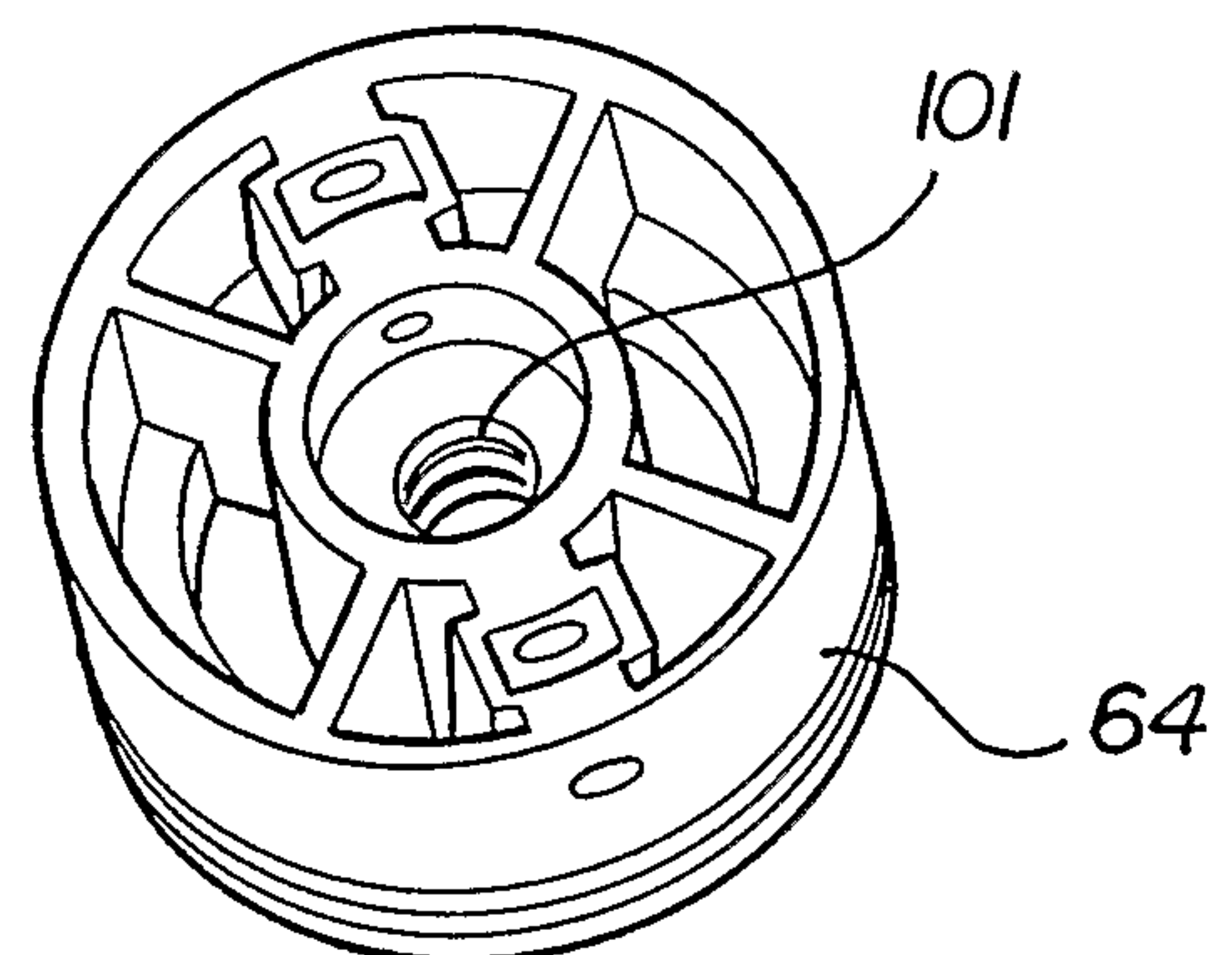
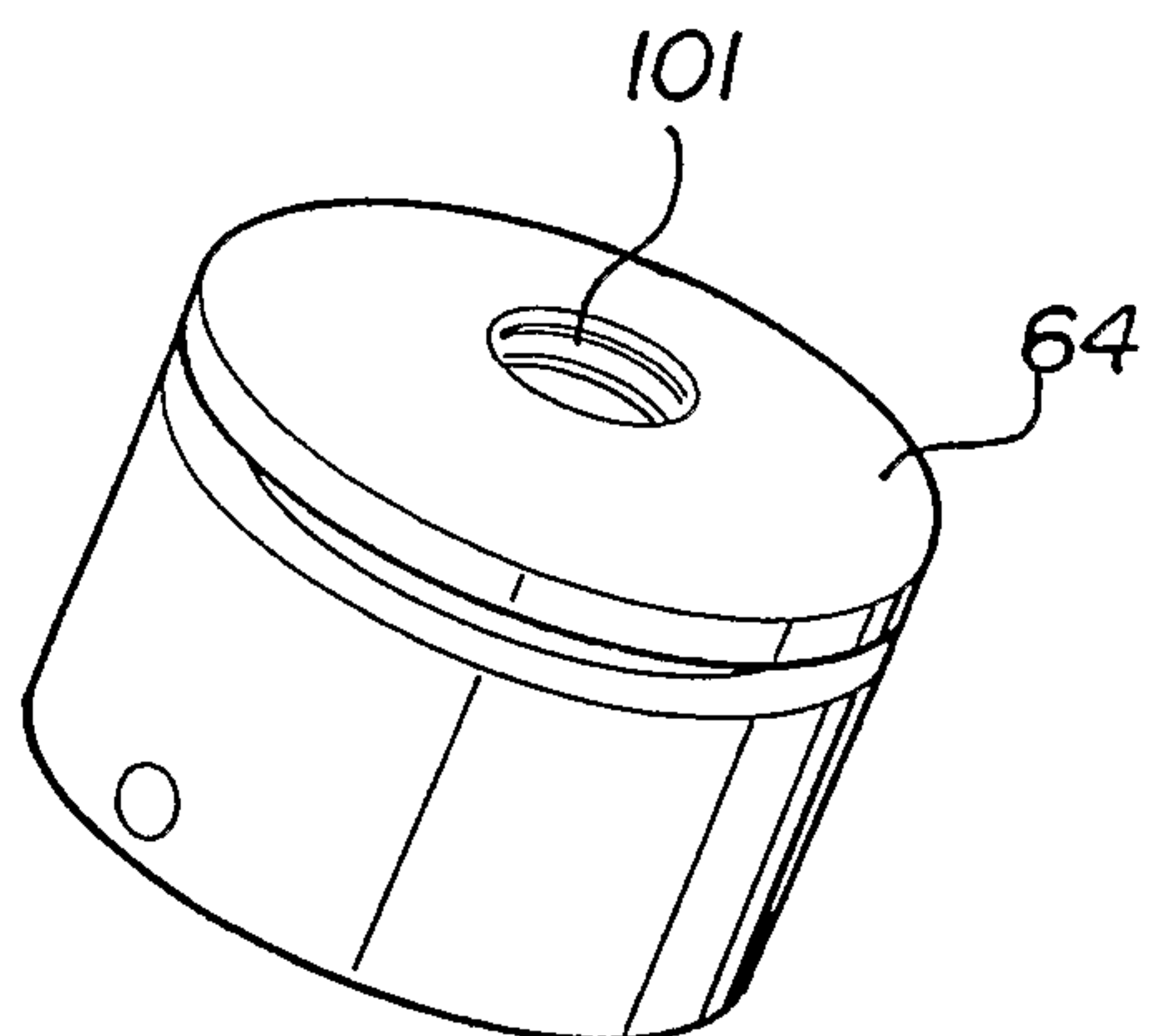
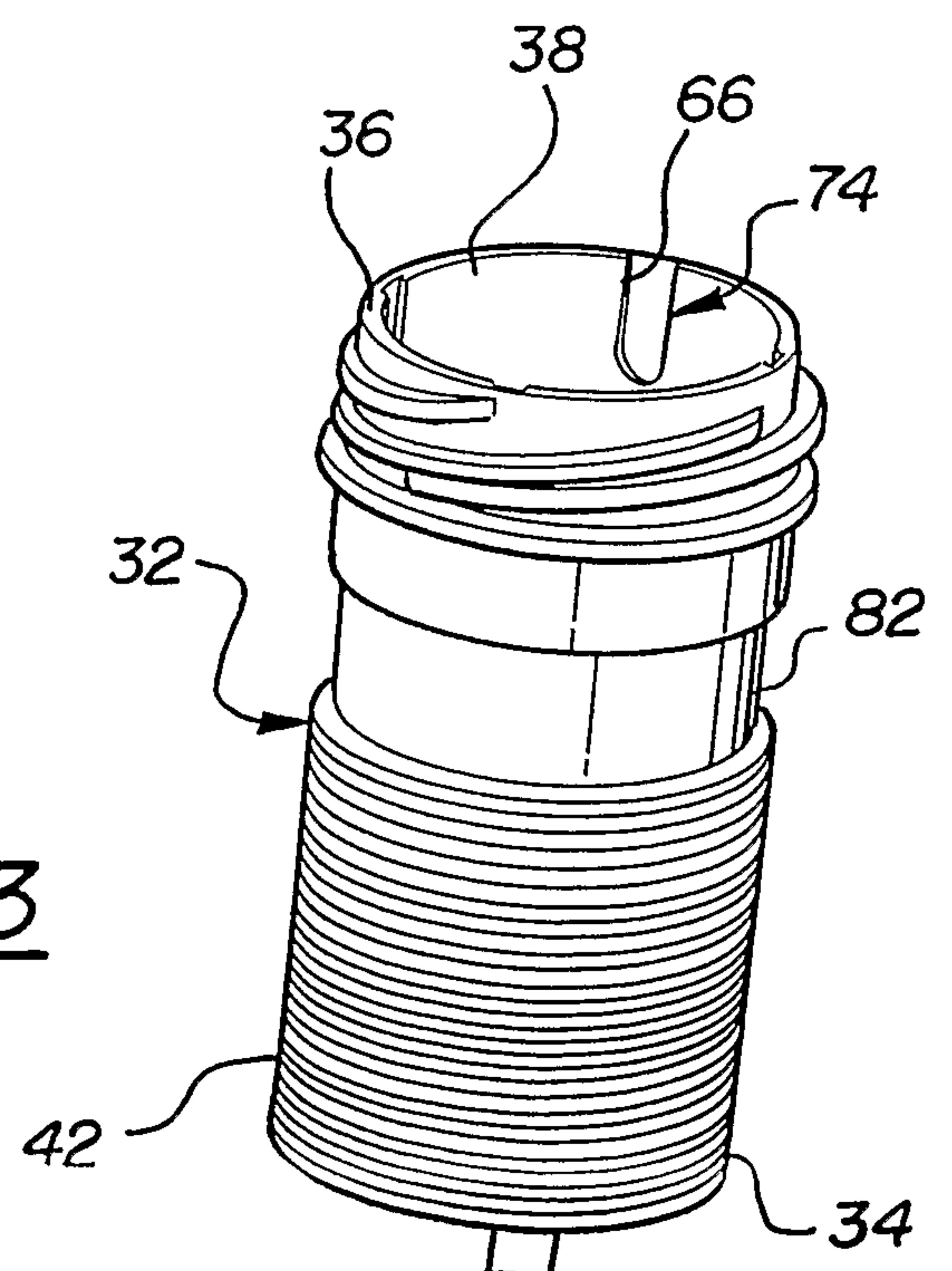
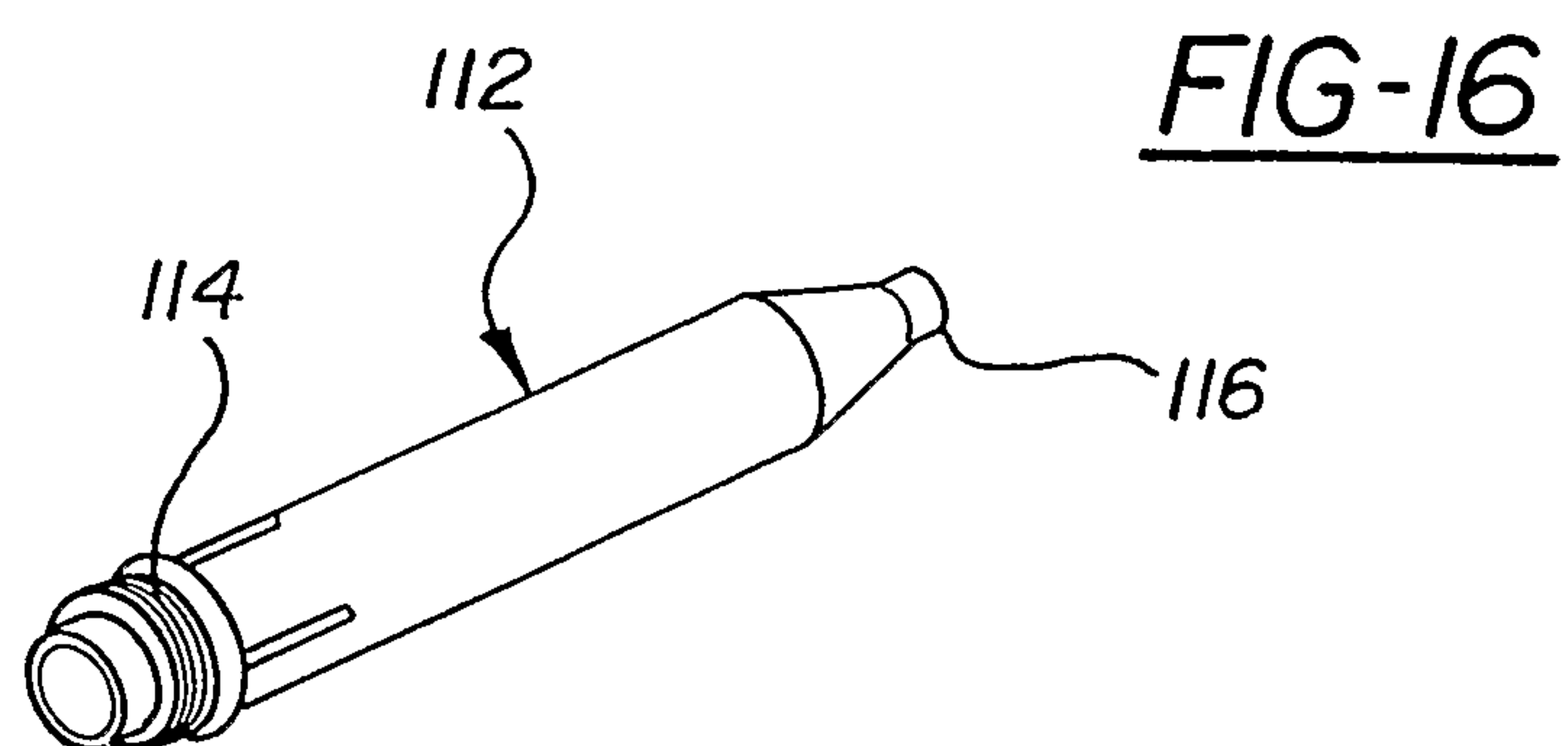
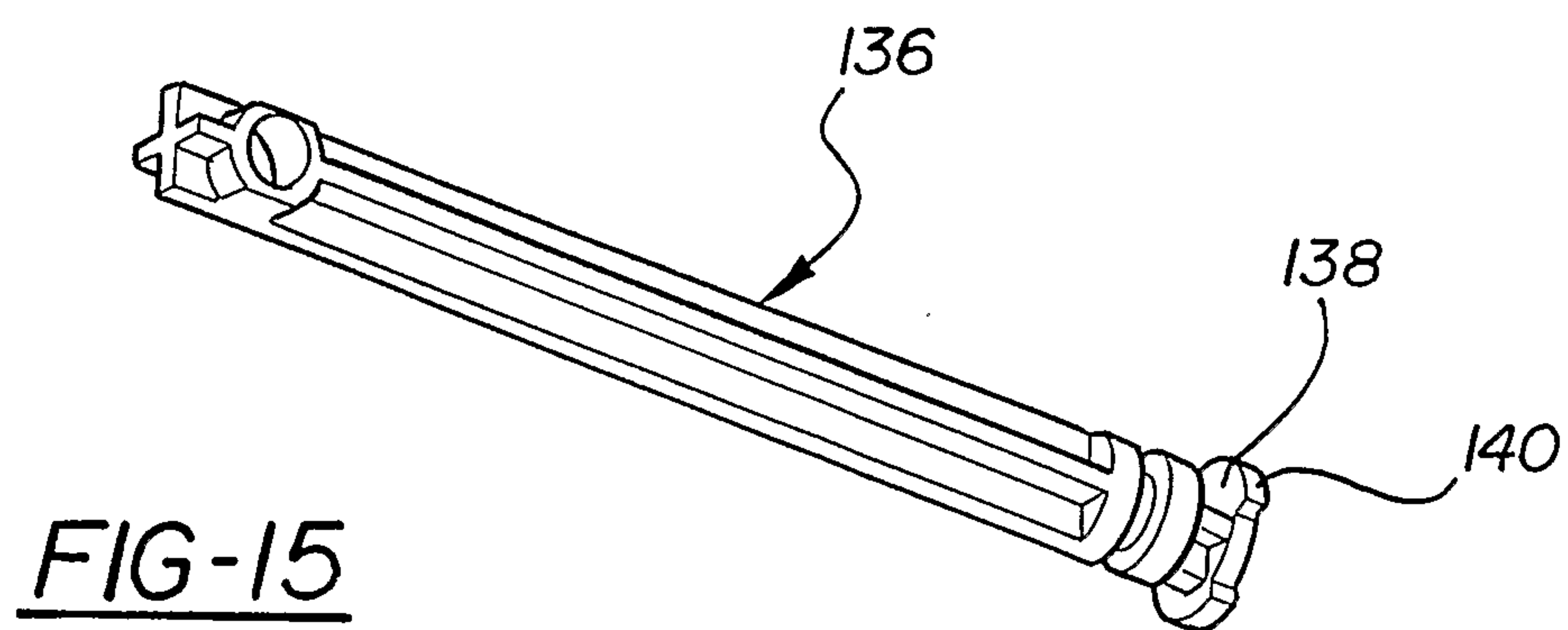
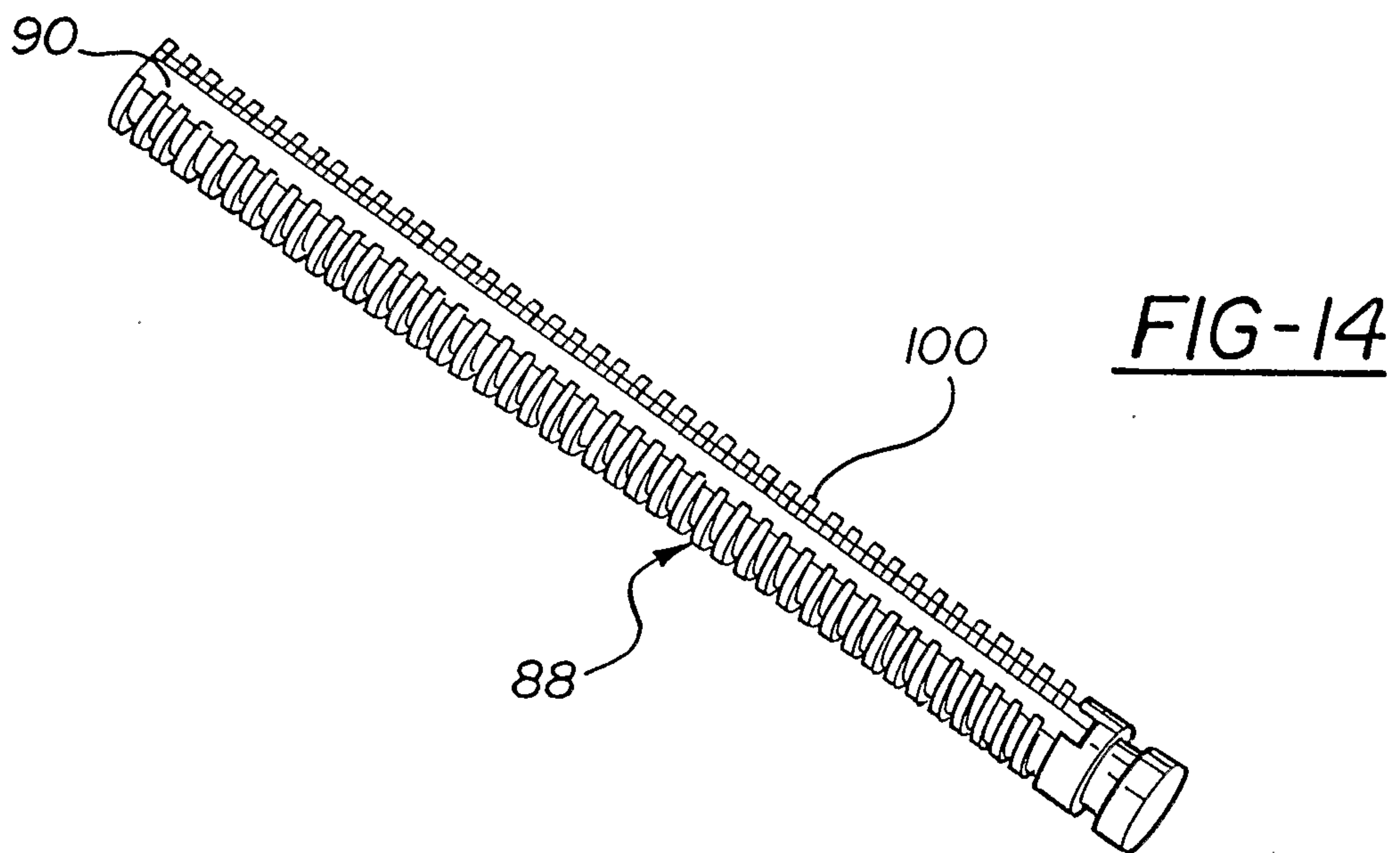
FIG-3FIG-9FIG-8

FIG-4





FIG-10FIG-11FIG-12FIG-13



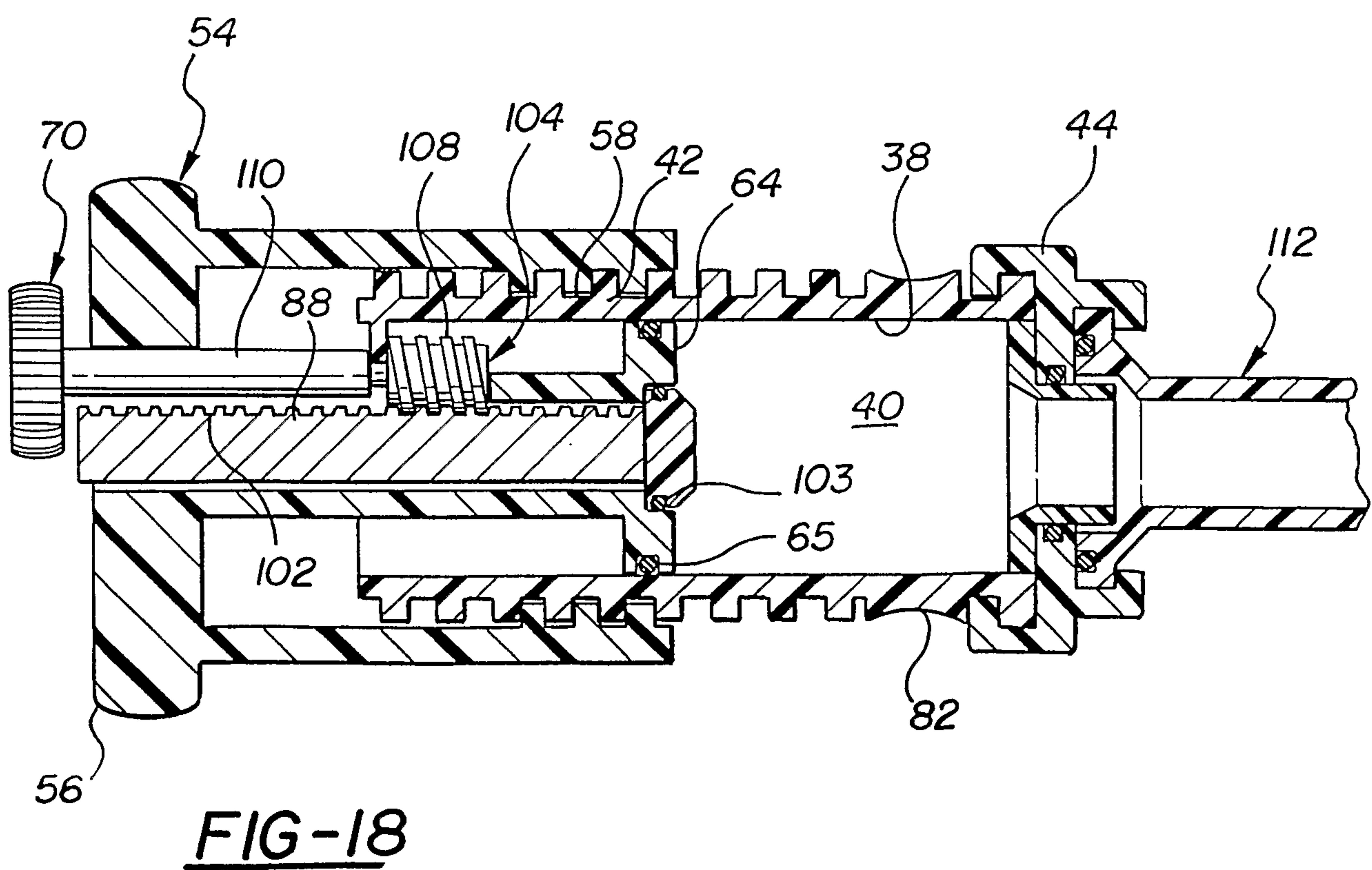
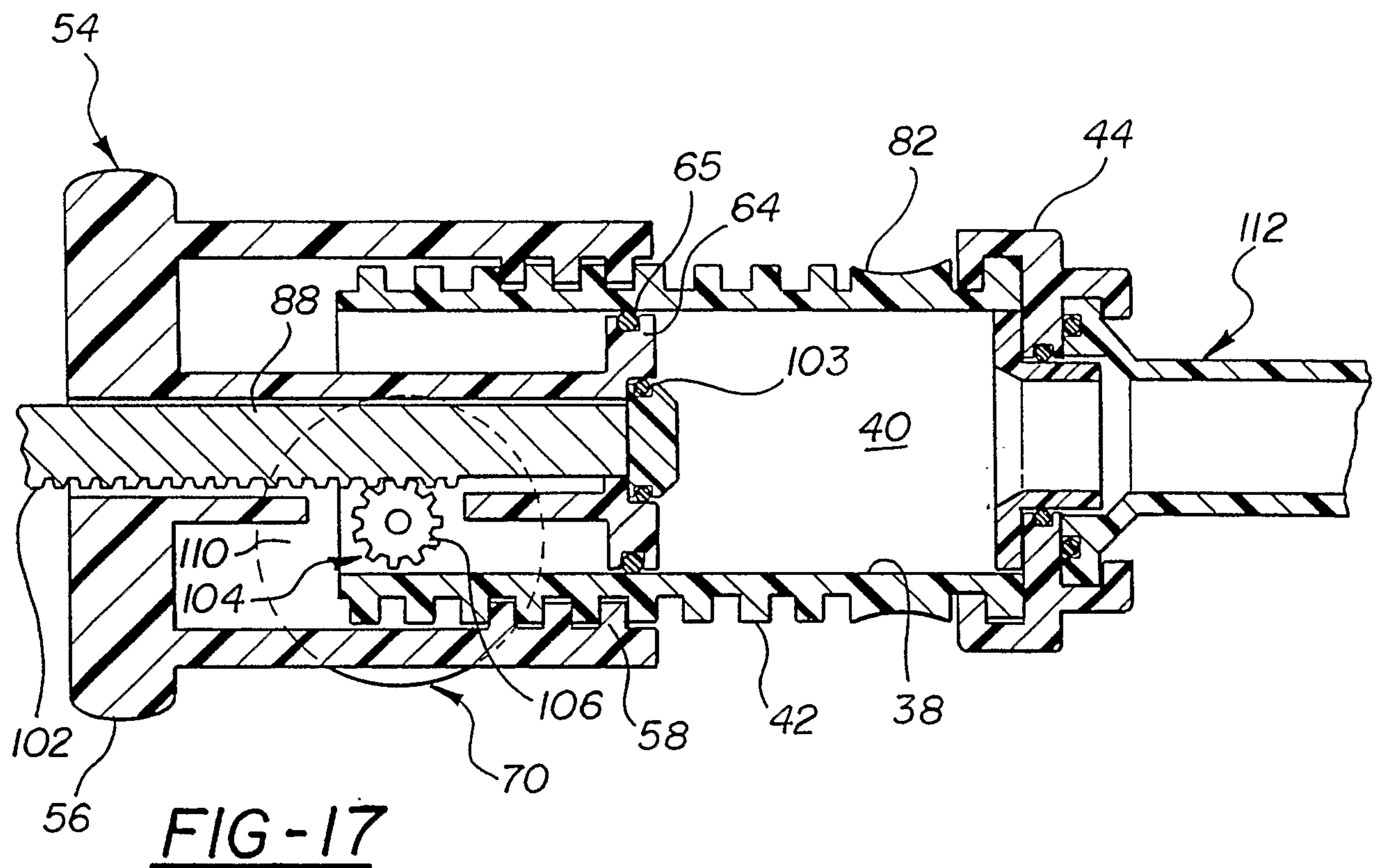
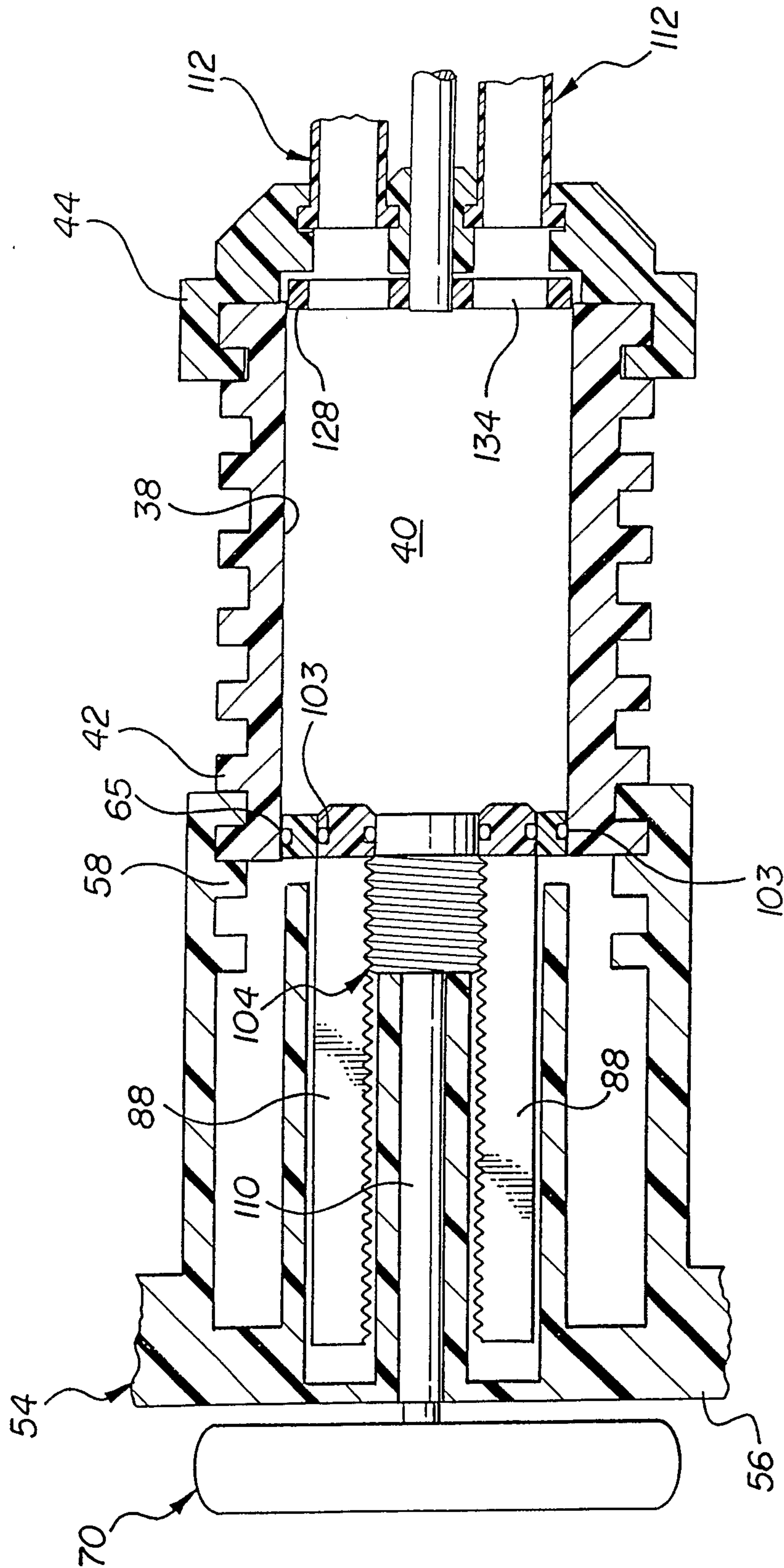
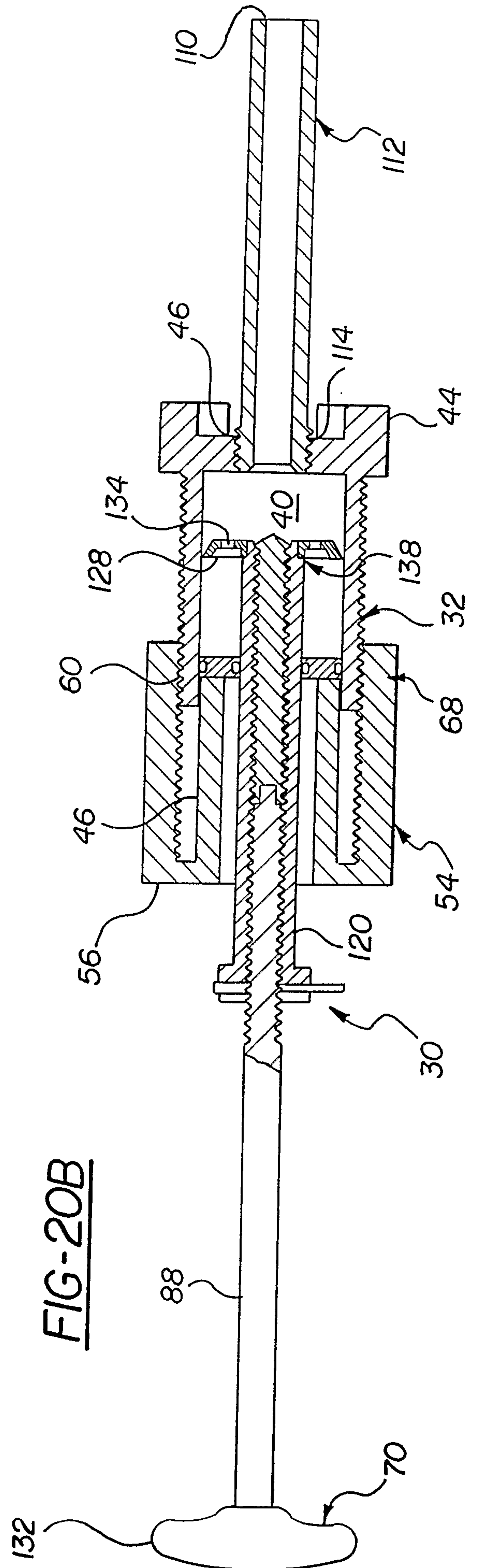
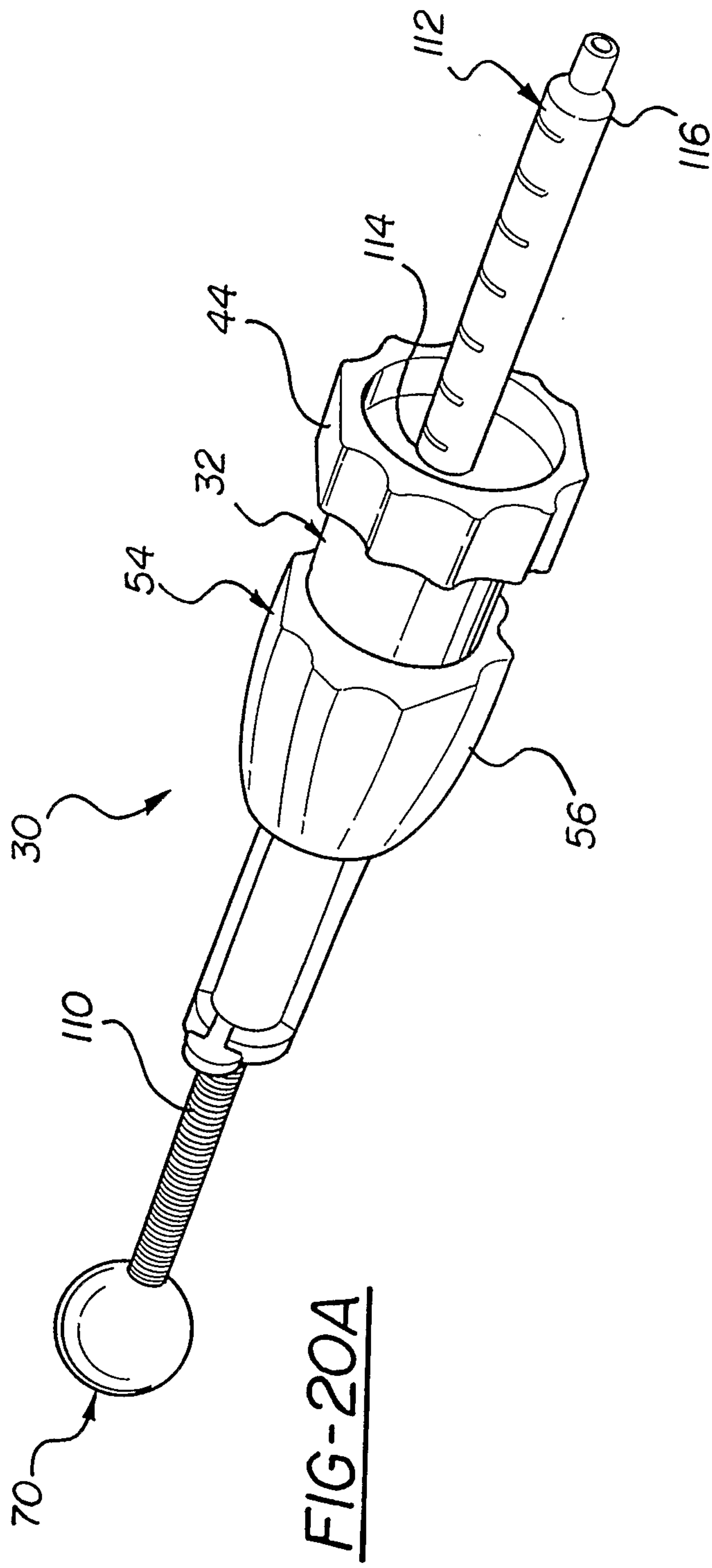
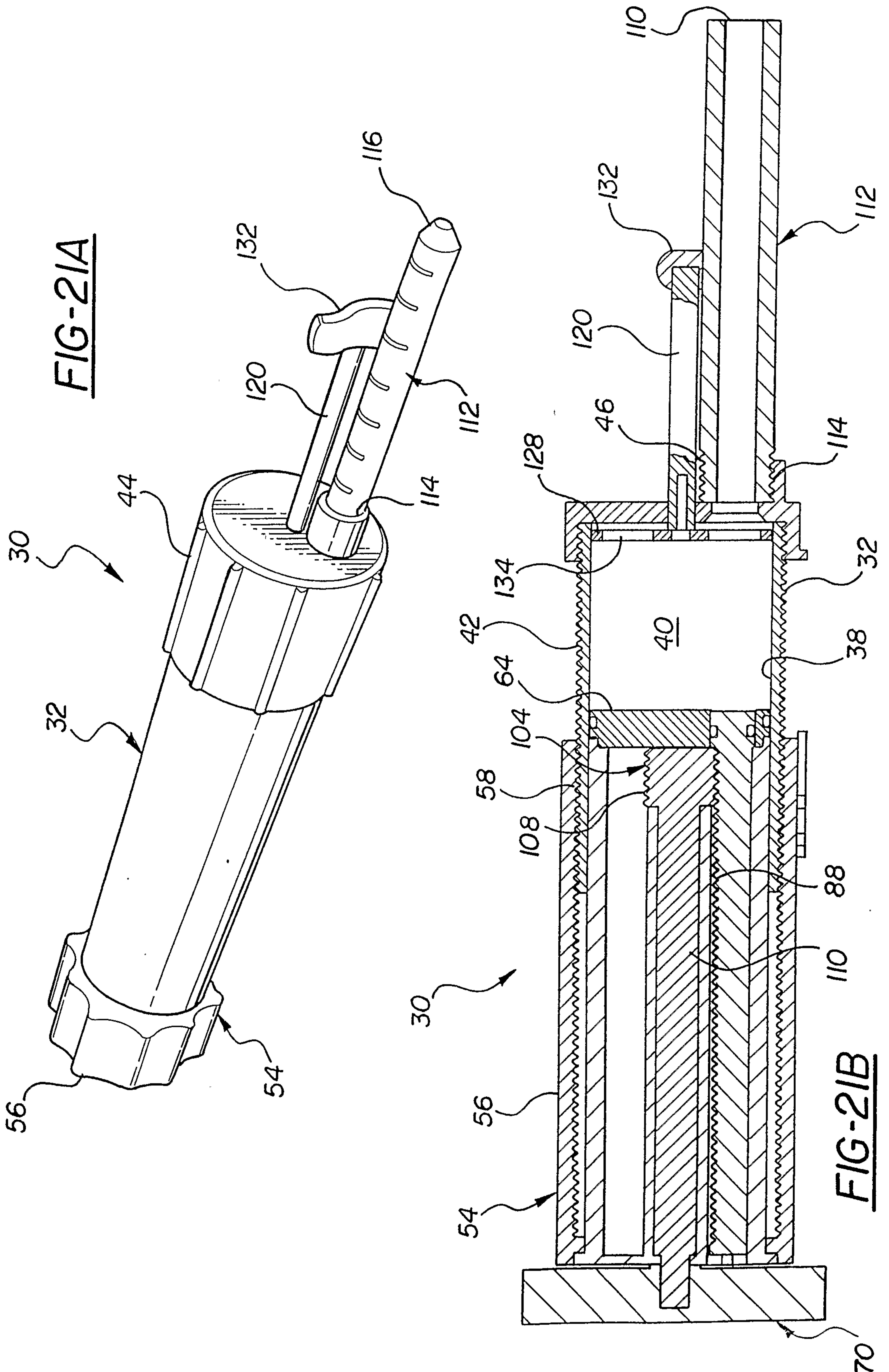


FIG-19







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