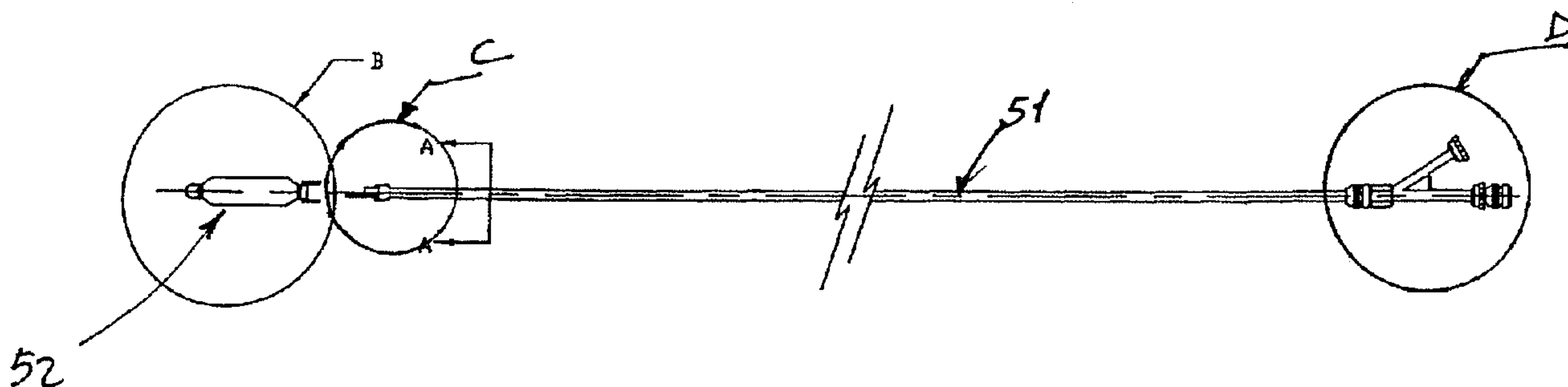




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(54) Titre : ENSEMBLE ENDOPROTHESE POUVANT ETRE EXTRAIT PAR VOIE PERCUTANEE A CAPACITE DE DRAINAGE DE FLUIDE
 (54) Title: PERCUTANEOUSLY RETRIEVABLE STENT ASSEMBLY WITH FLUID DRAINING CAPABILITY



(57) Abrégé/Abstract:

The present invention provides a stent assembly for expanding a bodily passage in a patient and draining a fluid therefrom. The assembly comprises at least one expandable stent and an elongated carrier for delivery or retrieval of the stent. The stent is circumferentially attached to a distal end of the carrier. The carrier defines at least two concentric lumens therethrough, a drainage lumen in fluid communication with the bodily passage for drainage of the fluid and an inflation lumen in fluid communication with the expandable stent. The invention also provides a method of expanding a bodily passage in a patient and draining a fluid therefrom. The method comprises providing a stent assembly of the present invention; inserting a guidewire into the bodily passage through the drainage lumen of the carrier; advancing the assembly along the guidewire until the assembly reaches a desired location; expanding the stent; and draining the fluid through drainage lumen of the carrier.

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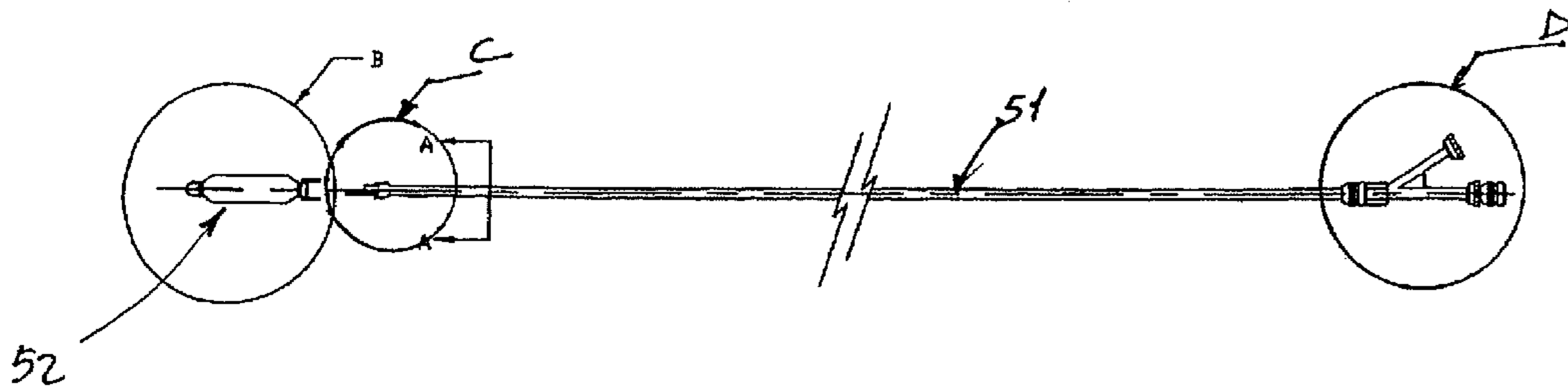
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(54) Title: PERCUTANEOUSLY RETRIEVABLE STENT ASSEMBLY WITH FLUID DRAINING CAPABILITY



(57) Abstract: The present invention provides a stent assembly for expanding a bodily passage in a patient and draining a fluid therefrom. The assembly comprises at least one expandable stent and an elongated carrier for delivery or retrieval of the stent. The stent is circumferentially attached to a distal end of the carrier. The carrier defines at least two concentric lumens therethrough, a drainage lumen in fluid communication with the bodily passage for drainage of the fluid and an inflation lumen in fluid communication with the expandable stent. The invention also provides a method of expanding a bodily passage in a patient and draining a fluid therefrom. The method comprises providing a stent assembly of the present invention; inserting a guidewire into the bodily passage through the drainage lumen of the carrier; advancing the assembly along the guidewire until the assembly reaches a desired location; expanding the stent; and draining the fluid through drainage lumen of the carrier.



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PERCUTANEOUSLY RETRIEVABLE STENT ASSEMBLY
WITH FLUID DRAINING CAPABILITY

This application claims priority to the U.S. Provisional Patent Application No.
5 60/591,787, filed on July 27, 2004.

Field of the Invention

This invention relates to devices and methods for expanding a bodily passage in a patient and draining a fluid therefrom. In particular, the invention is directed to percutaneously retrievable stent assemblies with expandable stents.

10 Background of the Invention

A number of disorders are characterized by formation of stenosis, strictures, or aneurysms that prevent normal passage and draining of fluids in body blood vessels and other tubular body structures, such as the esophagus, bile and kidney ducts, urinary tract, gastrointestinal (GI) tract, sinus pathway, and the tracheo-bronchial tree. When a
15 tubular body structure becomes occluded, it is often desirable to dilate the occluded area and facilitate drainage of fluids therethrough. Although surgical methods are available for removing an occlusion or for a complete removal of a narrowed area and restoring normal fluid flow, it involves general anesthesia that may not be suitable for all patients and may also result in formation of secondary strictures from local surgical
20 scars. Some of such secondary strictures may not be amendable to further surgery due to their difficult location or due to the underlying patient condition.

An alternative treatment that avoids many complications of a surgery, involves a two-step procedure in which stricture is first dilated and then a stent is inserted. Typically, stents are longitudinal cylindrical devices formed of biocompatible material,
25 such as metal or plastic. Although conventional stents usually allow a patient to avoid a surgical treatment, they have several limitations. For example, when metal stents are used to treat occlusions in biliary or procreatic ducts, they cannot be removed or replaced. When left in place, they often lead to development of sludge and epithelial proliferation that result in severe stricture and restenosis of the biliary system at the
30 stent site. Accordingly, conventional metal stents are usually used in patients with malignant tumors who are not expected to survive for a prolonged period of time.

The presently available plastic stents for treatment of occlusions in biliary or procreatic ducts also have significant limitations. They are stiff and once inserted percutaneously, the drain usually runs in the intercoastal space and leads to a significant

discomfort to the patient. Furthermore, similarly to the metal stents, plastic stents often cause a premature occlusion from sludge and stone formation, which may result in a biliary infection. Although these stents provide significant dilatation of the biliary system, they lead to significant recurrence of the stricture in over 50% of the patients.

5 Summary of the Invention

As it becomes apparent from the discussion above, both metal and plastic conventional stents suffer from a number of shortcomings. Additionally, although conventional stents may be used for draining fluids, such as bile, they cannot be used for a stricture dilation. Usually, a separate balloon catheter is used to dilate a stricture
10 prior to an insertion of a stent. Once inserted, the catheter does not provide any further increase in size of the narrowing without further intervention. Furthermore, because the diameter of the catheter used to maintain the dilatation of the narrowed area is the same throughout the length of the catheter, a larger passage in the body is required, which may lead to complications, including infections and formation of secondary
15 strictures.

Accordingly, it is an object of the present invention to provide an improved stent assembly, which can be placed atraumatically within an occluded bodily passage to provide both dilation of the passage and draining of a fluid therefrom, and which further can be removed without damaging the passage. It is also an object of the
20 present invention to provide a convenient method of expanding a bodily passage in a patient and draining a fluid therefrom.

These and other objects and advantages are achieved in a stent assembly of the present invention. The assembly comprises at least one expandable stent and an elongated carrier for delivery or retrieval of the stent. The stent is circumferentially
25 attached to a distal end of the carrier. The carrier defines at least two concentric lumens therethrough, a drainage lumen in fluid communication with the bodily passage for drainage of the fluid and an inflation lumen in fluid communication with the expandable stent. In one embodiment, the drainage lumen is sized to accommodate a removable guidewire. In another embodiment, the carrier further comprises a separate
30 guidewire lumen sized to accommodate a guidewire.

The inflation lumen may further include inflation holes located within an orthogonal projection of the stent onto the inflation lumen of the carrier. The drainage lumen may communicate with the bodily passage through a plurality of drainage holes connecting an outer surface of the carrier with the drainage lumen.

In one embodiment, the stent forms a spiral about the carrier. In another embodiment, a plurality of expandable stents is circumferentially attached to the distal end of the carrier. The stent may be permanently affixed to or be detachable from the carrier.

5 In another aspect, the present invention provides a method of expanding a bodily passage in a patient and draining a fluid therefrom. The method comprises: (a) providing a stent assembly of the present invention; (b) inserting a guidewire into the bodily passage through the drainage lumen of the carrier; (c) advancing the assembly along the guidewire until the assembly reaches a desired location; (d) expanding the
10 stent; and (e) draining the fluid through drainage lumen of the carrier. In one embodiment, the method further comprises a step of retrieving the stent percutaneously. The retrieved stent may be replaced with a new stent, such that the new stent, when expanded, has a size that is larger than the size of the retrieved stent.

In one embodiment, the stent is permanently affixed to the carrier and the
15 method further comprises steps of deflating the stent, removing the assembly over the guidewire, inserting a new assembly over the guidewire, and expanding a new stent of the new assembly. In another embodiment, the stent is detachable from the carrier and the method further comprises a step of disengaging the carrier from the stent after the stent is inflated and removing the carrier over the guidewire. In case of a treatment of a
20 biliary stricture, the stent assembly of the present invention may be inserted into a biliary duct using conventional techniques such as Percutaneous Transhepatic Cholangiography (PTC) or Endoscopic Retrograde Cholangio-pancreatography (ERCP).

The stent assembly of the present invention and methods of its use provide a
25 number of advantages over conventional stents and methods, including a lower risk of stricture recurrence. By combining both the dilatation and draining capabilities, the stent assemblies of the present invention are safer and easier to use. For example, when used to treat stricture of a biliary duct, the stent assembly of the present invention allows to maintain the stricture with gradual continuous or intermittent expansion of the
30 stent without the need for repetitive stent removal and reinsertion procedures. When such removal and reinsertion is required, the stent assembly of the present invention allows to replace a stent with a minimal discomfort to the patient by deflating the original stent to remove it and by inflating a new stent only after it is in a desired location inside the passage. Furthermore, because an expandable stent itself is used to

dilate the stricture instead of a separate balloon catheter, a soft catheter with a smaller than conventional diameter may be used to provide drainage of bile fluid.

In sum, stent assemblies of the present invention result in better dilatation, less sludge formation, lower risk of infection, and minimal pain since the exteriorized
5 portion is soft and small in size regardless of the size of the stent. These superior results are obtained by combining the two functions of dilatation and drainage, and by allowing progressive and continuous dilatation without the need of repetitive radiological or endoscopic interventions. Once the treatment objective is achieved,
10 usually within a few months, the stent can be removed through the same approach (ERCP or PTC) using the guide wire.

Description of the Figures:

The above-mentioned and other features of this invention and the manner of obtaining them will become more apparent, and will be best understood by reference to the following description, taken in conjunction with the accompanying drawings.
15 These drawings depict only a typical embodiment of the invention and do not therefore limit its scope. They serve to add specificity and detail.

Figures 1a-1d depict a stent assembly for expanding a bodily passage in a patient and draining a fluid therefrom, in which the stent is permanently attached to the carrier, in accordance with one embodiment of the present invention.

20 Figures 2a-2d show cross sections of the carrier with several possible configurations of lumens according to various embodiments of the present invention.

Figures 3a and 3b show an embodiment in which the stent forms a spiral about the carrier. Figure 3c shows an embodiment, in which a plurality of expandable stents are circumferentially attached to the distal end of the carrier.

25 Figures 4a – 4c depict further detail of the embodiment shown in Figures 3a and 3b, in which the stent forms a spiral about the carrier.

Figures 5a – 5e show a stent assembly for expanding a bodily passage in a patient and draining a fluid therefrom, in which the stent is detachable from the carrier in accordance with one embodiment of the present invention.

30 Figures 6a -6c show a stent with net and barb structures in accordance with another embodiment of the present invention.

Figures 7a and 7b schematically illustrate introduction of the stent assembly of the present invention into a patient.

Figures 8 a and 8b schematically illustrate increasing the size of the stent without removing it from the bodily passage in accordance with an embodiment of the present invention.

Detailed Description of the Preferred Embodiments

5 For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any alterations and further modifications in the described device, and any further
10 applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the invention relates. The drawings show relative sizes only; measurements and positions are exaggerated for purposes of illustration.

Referring to Figures 1a-1d, the present invention provides a stent assembly
15 for expanding a bodily passage 1 in a patient and draining a fluid therefrom. The assembly 10 comprises at least one expandable stent 12 having a first end 13 and a second end 14. The assembly also includes an elongated carrier 11 for delivery or retrieval of the stent 12. The carrier has a distal end 2 and a proximal end 3. The stent
20 12 is circumferentially attached to the distal end 2 of the carrier 11. The carrier defines at least two concentric lumens therethrough, a drainage lumen 17 in fluid communication with the bodily passage 1 and an inflation lumen 19 in fluid communication with the expandable stent 12. In one embodiment, the drainage lumen
25 17 is sized to accommodate a removable guidewire, such as a 0.035" Teflon-coated guidewire or any other suitable guidewire. In another embodiment, the carrier 11 further comprises a separate guidewire lumen 18 sized to accommodate a guidewire.

The expandable stent 12 may be made from a polymeric material such as polyethylene (PE), nylon or any other resilient material that could be formed into an expandable balloon-shaped vessel with a non-compliant form. In one embodiment, an
30 outer diameter of the stent 12, when expanded, is larger than an internal diameter of the bodily passage 1 to be treated.

The stent assembly 10 of the present invention may be used to treat stenosis, strictures, or aneurysms that prevent normal passage and draining of fluids in body blood vessels and any other tubular body structures including, but not limited to esophagus, bile and kidney ducts, urinary tract, gastrointestinal (GI) tract, sinus

pathway, and the tracheo-bronchial tree. The stent assembly 10 of the present invention may also be used in intercrainal applications, such as treatment of brain trauma.

Generally, the size of the carrier and the stent is selected to match the size of the bodily passage being treated. Preferably, an outer diameter of the stent 12, when expanded, is larger than an internal diameter of the bodily passage 1 to be treated. In one embodiment, an outer diameter of the stent 12, when expanded, is larger than an internal diameter of the bodily passage by about 1 - 2 mm. For example, in one embodiment, the stent assembly 10 is used for treatment of a biliary stricture and to drain biliary tract. In this embodiment, the stent is designed to be larger by 1-2 mm than the diameter of the biliary duct to be treated. An outer diameter of the stent 12 may be from 4 to 12 mm and its length is from 20 to 100 mm, when expanded, and the carrier 11 is a catheter with an outer diameter from 8 to 18 French (2.7 to 6 mm). In another embodiment, in which the stent assembly is used intracranially, an outer diameter of the stent 12 is from 3 to 5 French, when expanded, and the carrier is a catheter with an outer diameter from 2 to 3 French. Those skilled in the art will be able to select appropriate sizes of the stent and the carrier suitable for other applications taking into consideration patient's diagnosis and size of the bodily passage to be treated.

The stent 12 could be expanded by any suitable means, including, but not limited to use of various solutions, air, and shape memory materials. In one embodiment, the expandable stent is inflated with a solution of contrast media (Renografin or equivalent 50-50% dilution) at the prescribed pressure (in the range of 10-20 ata).

The carrier may be made from any suitable biocompatible material, including, but not limited to PE, Polyethylene Terephthalate (PET), or polyether block amides, such as Pebax® (Arkema, France) with hardness in the range of 80A to 50D (Shore hardness).

The first end 13 and a second end 14 of the stent 12 may have radiopaque marker bands 5, 6 including, but not limited to, those made from heavy metals such as gold, platinum or tantalum. The markers 5 and 6 help to visualize the exact position of the stent 12 under fluoroscopic guidance.

In one embodiment, the inflation lumen 19 communicates with an internal cavity of the stent 12 through inflation skive(s) 7 and/or inflation holes 8 located within

an orthogonal projection α of the stent 12 onto the inflation lumen of the carrier. The drainage lumen 17 may communicate with the bodily passage 1 through a plurality of drainage holes 9 connecting an outer surface of the carrier 11 with the drainage lumen 17.

5 The proximal end 3 of the carrier may be attached to a connector 4 that allows bifurcation of the main shaft lumens into separate side arms. In one embodiment, the connector has a first side arm 103 in a communication with the drainage lumen 17 and a second side arm 101 in a communication with the inflation lumen 19. The free end 106 of the first side arm 103 may be further connected to a fluid collection container,
10 such as a collection bag (not shown).

The free end 107 of the second side arm 101 may be further removably connected to an inflation device (not shown) for inflation or deflation of the stent via a valve connector or a three-way stopcock 109. Such inflation devices are well-known to those skilled in the art. For example, a digital or analog inflation device used
15 routinely in the field of angioplasty may be used. Once the desired inflation pressure within the expandable stent has been achieved, the valve connector may be locked and the inflation device may be disconnected. Preferably, the valve connector allows injection of a solution into the expandable stent while preventing retrograde flow of the solution from the stent when stent is attached to or disattached from the carrier 11.

20 In an embodiment, where the carrier further comprises a separate guidewire lumen, the connector 4 further comprises a third side arm 102 in a communication with the guidewire lumen 18 of the carrier. The side arm 102 may be connected to the guidewire lumen via a tapered connector 111.

The number, shape, and size of lumens of the present invention are not
25 particularly limited as long as they are capable of performing the assigned function (draining fluid, inflating stent, or providing a passage for a guidewire). In Figures 2a-2d, which depict cross section of the carrier, several possible configurations of lumens are exemplified. In an embodiment shown in Figure 2a, there is a drainage lumen 27, inflation lumen 29, and a guidewire lumen 28. Figures 2b and 2c show multi-lumen
30 carriers. The central lumen 28 may be used as a guidewire lumen. Some of lumens 21 may be used as drainage lumens and some as inflation lumens. In certain applications, some of the lumens 21 may be used for any other desirable function. In an embodiment shown in Figure 2d, the drainage lumen 27 is also used as a guidewire lumen.

The expandable stent of the present invention can be implemented in a variety of configurations as long as, when expanded, they sufficiently engage the bodily passage from within to remain in the desired location while dilating the passage and draining a fluid therefrom. Referring to Figures 3a, 3b, 4a, 4b, and 4c, in one embodiment, the stent **42** forms a spiral about the carrier **41**. The stent **42** may be fused or glued to an outer surface of the carrier at multiple points **33** of their junction. In this embodiment, the stent **42**, when expanded, forms a spiral with an outer diameter preferably exceeding the diameter of the bodily passage. Referring to Figure 4b, the proximal end **45** of the spiral expandable stent **42** may be connected to an inflation lumen **49** of the carrier or to an external inflation tube running along the carrier.

Referring to Figure 3c, in another embodiment, a plurality of expandable stents **35** are circumferentially attached to the distal end of the carrier **41**. These multiple stents are designed to "hug" the carrier **41** during insertion and withdrawal of the stent assembly. The central lumen **37** may be used as a guidewire lumen during insertion and withdrawal of the stent assembly and as a fluid discharge lumen when the stent is inside the patient. The stents **35** may be fused with or glued to the carrier. This embodiment allows an improved attachment within passage being treated. Additionally, loss of pressure in one individual stent will not render the whole assembly dysfunctional.

As shown in Figures 1 a-d, the stent **12** may be mounted permanently on the carrier. Those familiar with catheter engineering techniques will recognize numerous methods that can be used to securely and permanently attach the stent **12** to the carrier **11**. For example, the stent may be fused with or glued to the carrier.

Alternatively, as shown in Figures 5a-5e, the stent **52** may be detachable from the carrier **51**. The expandable stent **52** is mounted onto the carrier **51** prior to the insertion into the patient. The stent **52** is designed to be disengaged from the carrier **51** or left engaged with the carrier **51** after it is placed inside the bodily passage. This embodiment allows a withdrawal of the carrier, such as a bulky catheter, from the patient and leaving the expandable stent along with a very small tubing with double function: a) to be acting as a bile discharge tube and b) to be used as a guidewire lumen once the withdrawal of the stent is desired.

The stent used in this embodiment may be made of a material and have a size similar to those described above in reference to permanently attached stents. In one embodiment, the stent **52** has a central tube **55** that serves as a conduit for introduction

of the carrier's guidewire/fluid discharge tube. The central tube 55 may be made of thin poly-tetra-fluoroethylene (PTFE). In one embodiment, central tube 55 has an outside diameter in the range of 0.052"-0.056" and inside diameter in the range of 0.048"-0.052".

5 In one embodiment, the proximal end 54 of the stent houses a valve assembly 56 connected to a port 57. The combination of the valve assembly 56 and the port 57 provides a fluid communication between the internal cavity 501 of the expandable stent 52 and inflation lumen of the carrier 51 for inflation/deflation of the stent. The valve assembly 56 is designed to allow injection of a solution, such as a contrast media into
10 the expandable stent while preventing retrograde flow from the stent when the carrier 51 is disengaged from the stent 52. In one embodiment, the port 57 is made from silicone or neoprene material with shore hardness in the range of 40-50A and may sustain pressures of up to 25ata. Optional radiopaque band markers 503 and 504 may be located at the proximal and distal end of the stent to allow visualization of the
15 extremities of the stent under fluoroscopic guidance. The proximal end 54 of the stent 52 may include a flexible outside ring with flap 507 that may be "tucked" within the carrier during the delivery of the stent.

In one embodiment, in which stricture of biliary duct is being treated, the inner cavity 501 of the stent is filled via port 57 and valve assembly 56 by a contrast media
20 solution to a prescribed pressure to achieve an outside diameter of the stent greater by 1-2mm than the diameter of the biliary duct.

In one embodiment, the carrier 51 comprises a combination of at least two movable concentric tubes. As shown in Figure 5c, in one embodiment, a first tube 509 forms a drainage lumen 520 and an inflation lumen 521. In another embodiment shown
25 in Figure 5d, the first tube 509 (not shown for clarity) houses a drainage tube 531 and an inflation tube 532. The second tube 515 (shown in Figure 5d but not in Figure 5c) is a movable member that houses the first tube and is movable over the stent in an expanded form.

The second tube 515 may be made of Pebax, PE, PTFE or other similar
30 extruded polymeric material in the range of 60-70D hardness with outside diameter in the range of 5 to 8 inches and inside diameter of 4.5 to 7.5mm. The proximal end of the second tube 515 may have a short perforated section 540 to allow the tube second tube to ride over the expandable stent. A proximal end of the second tube 531 may be

connected to connector **538**, which may be connected to a rotating hemostatic valve connector **539**.

In one embodiment, the drainage lumen **520** or drainage tube **531** is designed to accommodate a guidewire. In one embodiment, the drainage lumen **520** or drainage tube **531** has an internal diameter of 0.042" - 0.045" and an outer diameter of 0.048"-0.052".

Prior to the delivery of the stent, the drainage tube **531** is positioned within lumen **55** of the stent. In one embodiment, the drainage tube **531** is designed to act as a guidewire lumen and a fluid discharge channel which will be left in the patient once the expandable stent is placed within the passage to be treated and other parts of the carrier are removed. Inflation lumen **521** or inflation tube **532** communicate through the port **57** and valve assembly **56** with an internal cavity **501** of the stent.

A proximal end of the drainage tube **531** may be connected to a connector **535**. In one embodiment, the connector **535** has a tapered cavity **536**, which allows the introduction of a Teflon coated guidewire with outside diameter of 0.035" to 0.038".

The carrier may optionally include an outer tube **550** designed as a movable sheath to be able to ride over the second tube **515** and seal it tightly over the proximal end **54** of the expandable stent **52**. The outer tube **550** may be made of Pebax, PE, PTFE or other similar polymeric extruded material and may have, for example, an inside diameter in the range of 5.5 to 7.5 mm and outside diameter in the range of 6 to 8 mm.

In another embodiment illustrated in Figures 6a-6c, a tubular net-like structure **63** is connected to the outside surface of the stent **62**. The net-like structure may be a braided net made of thin filament of PTE. For example, 0.006" to 0.008" diameter fiber could be used. This net-like structure may connect to a multitude of "barb" elements **65**. The net-like structure **63** may also be fused with or connected to an outside surface of the expandable stent **62**.

The diameter of the net-like structure **63** is designed in such a way that it "hugs" an outside surface of the stent **62** and it could follow its contour after its deflation as well as during its inflation.

The "barb" elements **65** are made of stainless steel or an equivalent material and facilitate engagement of the expandable stent to the inner wall of the bodily passage during deployment. The sharp edge **67** of "barb" elements **65** is positioned toward the inner wall of the passage. After the deployment of the stent, the "barb" elements **65**

assure the positioning and the engagement of the expandable stent within the passage while the internal pressure of the expandable stent provides sufficient radial force for the barbs to be engaged within the passage.

In one embodiment, barb elements 65 are connected to the net 63 according to
5 Figure 6c. The through channel 69, located at the center of barb element 65, is designed to be engaged into the crossing point between the crossing filaments of PE fiber. The notch 601 will allow the placement of the barb element 65 over the two PE filaments and once that is accomplished the notch 601 can be crimped to lock the PE filaments into the barb element permanently.

10 The net-like structure 63 may also be made of a self-expanding metallic stent made of stainless steel, elgiloy or Ni-Ti wires having barb elements such as 65 connected to the outside surface of the expandable structure. In one embodiment, this expandable structure (either the PE braided net or metallic stent) is connected or crimped to the outside diameter of the expandable stent and since this connection is
15 intact, when the expandable biliary stent is deflated, the net structure or the metallic stent will also be forced to “deflate” and consequently disengage the barbs 65 from the internal wall of the bodily passage.

In another aspect, the present invention provides a method of expanding a bodily passage in a patient and draining a fluid therefrom. The method comprises: (a)
20 providing a stent assembly of the present invention; (b) inserting a guidewire into the bodily passage through the drainage lumen of the carrier; (c) advancing the assembly along the guidewire until the assembly reaches a desired location; (d) expanding the stent; and (e) draining the fluid through drainage lumen of the carrier. In one embodiment, the method further comprises a step of retrieving the stent percutaneously.
25 The retrieved stent may be replaced with a new stent, such that the new stent, when expanded, has a size that is larger than the size of the retrieved stent.

In one embodiment, the stent is permanently affixed to the carrier and the method further comprises steps of deflating the stent, removing the assembly over the guidewire, inserting a new assembly over the guidewire, and expanding a new stent of
30 the new assembly. In another embodiment, the stent is detachable from the carrier and the method further comprising a step of disengaging the carrier from the stent after the stent is inflated and removing the carrier over the guidewire. In case of a treatment of a biliary stricture, the stent assembly of the present invention may be inserted into a biliary duct using conventional techniques such as Percutaneous Transhepatic

Cholangiography (PTC) or Endoscopic Retrograde Cholangio-pancreatography (ERCP).

Example 1

Clinical Application Of The Biliary Stent¹

5 Patient is placed on spine in a decubitus position. The skin is prepared with betadine and the area of interest which is the upper abdomen lower torso on the right side is exposed and surrounded by sterile towels. 1% lidocane local anesthesia is injected in the 10th inter-costal space at the mid axillary line on the right side. A 15cm long flexible 22 gauge needle with an external diameter of 0.8mm and 30 degree
10 cutting bevel is used for puncture towards the 11th vertebral body. The needle is advanced under direct fluoroscopic control in a parallel fashion to the X-ray table through the liver in the 10th inter-costal space toward the body of the 12th vertebrae until the tip of the needle reaches the midline at this level under fluoroscopy

The stylet of the needle is then removed, and a 10mm syringe filled with diluted
15 contrast with normal saline (50%) is attached to a clear flexible tubing which is connected to the needle hub. Under fluoroscopic observation, contrast medium is slowly injected with a syringe as the needle is slowly withdrawn from its initial position in the liver. Once a biliary radical is identified, the needle is held in place, bile is aspirated to confirm the position of the needle into the biliary system, then the tubing is
20 disconnected frond the needle.

A 0.018" guidewire with a stiff body and a flexible tip is passed through the 22 gauge needle towards the narrow area of the biliary system. A catheter (4 French, which allow the passage of 0.035 inch guide wire) is introduced over the soft guide wire to dilate the track of the guide-wire from the skin to the liver. A stiff steerable
25 guide wire (0.035 inch) with a flexible tip is introduced into the canula sheath and advanced toward the stenotic area of the biliary system. The guide wire is steered to go through the stricture into the distal common bile duct or across the bilio-enteric anastomosis.

The canula is withdrawn leaving the guide wire in place across the biliary
30 stricture. Referring to Figure 7a, the biliary stent assembly 10 of the present invention is then introduced over the guide wire 70 towards the stenotic area and its position is

confirmed under fluoroscopy by the extendable stent **12** filled with a contrast solution as well as X-ray markers present on each side of the balloon area (not shown).

Referring to Figure 7b, when the location of the stent is confirmed under fluoroscopy, the stent **12** is deployed to stabilize the stent in place and to begin
5 dilatation of a stricture **75**. After deployment, optional barb elements **61** assure the positioning and the engagement of the stent **12**. Referring to Figure 8a, the drainage lumen **17** of the catheter **11** is connected to a bile bag **81**. The guidewire is removed and guidewire lumen **18** is capped. The inflation lumen **19** is connected to an inflation device (not shown). The catheter **11** is then sutured to the skin using monofilament
10 suture **83**. The inflation device is activated and provides a progressive dilatation of one or of a plurality of successive balloons over 24 - 48 hours with diluted contrast.

The size of dilatation of the stricture is verified under fluoroscopy in 24-48 hours, and once the appropriate size is reached the balloon is left in place for up to 7 days then deflated progressively. Once the deflation is completed, the size of stricture is
15 reassessed. If residual stricture persists, additional dilatation is performed by adding contrast solution as shown in Figure 8b. Once the appropriate size is reached the catheter **11** is withdrawn.

The foregoing is meant to illustrate, but not to limit, the scope of the invention. Indeed, those of ordinary skill in the art can readily envision and produce further
20 embodiments, based on the teachings herein, without undue experimentation.

What is Claimed is:

1. A stent assembly for expanding a bodily passage in a patient and draining a fluid therefrom, the assembly comprising:

at least one expandable stent having a first and a second end; and

an elongated carrier for delivery or retrieval of the stent, the carrier having a distal end and a proximal end, wherein the stent is circumferentially attached to the distal end of the carrier,

the carrier defining at least two concentric lumens therethrough, a drainage lumen in fluid communication with the bodily passage and an inflation lumen in fluid communication with the expandable stent.

2. The assembly of claim 1, wherein the drainage lumen is sized to accommodate a removable guidewire.

3. The assembly of claim 1, wherein the carrier further comprises a separate guidewire lumen sized to accommodate a guidewire.

4. The assembly of claim 1, wherein the inflation lumen communicates with an internal cavity of the stent through inflation holes located within an orthogonal projection of the stent onto the inflation lumen of the carrier.

5. The assembly of claim 1, wherein the drainage lumen communicates with the bodily passage through a plurality of drainage holes connecting an outer surface of the carrier with the drainage lumen.

6. The assembly of claim 1, wherein the carrier is a catheter with an outer diameter from 8 to 18 French.

7. The assembly of claim 1, wherein the carrier comprises a plurality of drainage lumens.

8. The assembly of claim 1, wherein the carrier is made from a polymeric biocompatible material with hardness in the range of 80A to 50D.

9. The assembly of claim 1, wherein the stent is made from a resilient polymeric material.

10. The assembly of claim 1, wherein an outer diameter of the stent when expanded is larger than an internal diameter of the bodily passage to be treated.

11. The assembly of claim 1, wherein the passage is selected from a group consisting of biliary duct, kidney duct, sinus pathway, intracranial passages and voids, esophagus, urinary tract, gastrointestinal (GI) tract, and the tracheo-bronchial tree.

12. The assembly of claim 11, wherein the stent assembly is used for treatment of a biliary stricture and drainage of biliary tract.

13. The assembly of claim 12, wherein an outer diameter of the stent is from 4 to 12mm when expanded.

14. The assembly of claim 12, wherein a length of the stent is from 20 to 100 mm when expanded.

15. The assembly of claim 11, wherein the stent assembly is used intracranially, wherein an outer diameter of the stent is from 3 to 5 French when expanded and the carrier is a catheter with an outer diameter from 2 to 3 French.

16. The assembly of claim 1, wherein an outer diameter of the stent when expanded is larger than an internal diameter of the bodily passage to be treated by from 1 to 2 mm.

17. The assembly of claim 1, wherein the assembly further comprises a connector attached to the proximal end of the carrier, the connector having a first side arm in a communication with the drainage lumen and a second side arm in a communication with the inflation lumen.

18. The assembly of claim 17, wherein the first side arm is further connected to a fluid collection container.

19. The assembly of claim 17, wherein the second side arm is further removably connected to an inflation device for inflation or deflation of the stent via a valve connector or a three-way stopcock.

20. The assembly of claim 19, wherein the valve connector allows injection of a solution into the expandable stent while preventing retrograde flow of the solution from the stent.

21. The assembly of claim 17, wherein the carrier further comprises a separate guidewire lumen sized to accommodate a guidewire and the connector further comprises a third side arm in a communication with the guidewire lumen of the carrier.

22. The assembly of claim 1, wherein the stent forms a spiral about the carrier.

23. The assembly of claim 22, wherein the stent is fused or glued to an outer surface of the carrier at multiple points of their junction.

24. The assembly of claim 1, wherein a plurality of expandable stents is circumferentially attached to the distal end of the carrier.

25. The assembly of claim 24, wherein the plurality of the stents are fused with or glued to the carrier.
26. The assembly of claim 1, wherein the stent is permanently affixed to the carrier.
27. The assembly of claim 1, wherein the stent is detachable from the catheter.
28. The assembly of claim 27, wherein the carrier comprises a combination of at least two movable concentric tubes, wherein a first tube forms a drainage lumen and an inflation lumen and a second tube is a movable member that houses the first tube and is movable over the stent in an expanded form.
29. The assembly of claim 28, wherein the drainage lumen is sized to accommodate a guidewire during insertion of the assembly into the bodily passage.
30. The assembly of claim 28, wherein the drainage lumen is structured to remain connected to the stent and act as a fluid discharge channel when other parts of the carrier are removed.
31. The assembly of claim 28, wherein the second tube has a perforated section to allow the tube to move over the expanded stent.
32. The assembly of claim 28, wherein the carrier further comprises a third concentric tube capable of moving over the second tube to seal the second tube over the expanded stent.
33. The assembly of claim 27, wherein the stent further comprises a valve assembly for inflation or deflation of the stent, the valve assembly is in a fluid communication with an internal cavity of the stent.
34. The assembly of claim 33, wherein the valve assembly allows injection of a solution into the cavity of the stent while preventing retrograde flow from the stent when the carrier is disengaged from the stent.
35. The assembly of claim 1, wherein the stent further comprises a cylindrical net-like structure.
36. The assembly of claim 35, wherein the net-like structure is connected to a plurality of barb elements located on its outer surface.
37. The assembly of claim 35, wherein the net-like structure is fused or connected to an outer surface of the stent.
38. A method of expanding a bodily passage in a patient and draining a fluid therefrom, the method comprising:

- (a) providing a stent assembly comprising:
- at least one first expandable stent having a first and a second end; and
 - an elongated carrier for delivery or retrieval of the stent, the carrier having a distal end and a proximal end, wherein the stent is circumferentially attached to the distal end of the carrier, the carrier defining at least two concentric lumens therethrough, a drainage lumen in fluid communication with the bodily passage for drainage of the fluid and an inflation lumen in fluid communication with the expandable stent;
- (b) inserting a guidewire into the bodily passage through the drainage lumen of the carrier;
- (c) advancing the assembly along the guidewire until the assembly reaches a desired location;
- (d) expanding the stent; and
- (e) draining the fluid through drainage lumen of the carrier.

39. The method of claim 38, wherein the carrier further comprises a separate guidewire lumen and wherein step (b) is carried out by inserting the guidewire into the bodily passage through the guidewire lumen.

40. The method of claim 38 further comprising a step of retrieving the stent percutaneously.

41. The method of claim 40 further comprising steps of replacing the retrieved stent with a new stent, wherein the new stent, when expanded, has a size that is larger than the size of the retrieved stent.

42. The method of claim 41, further comprises steps of sequentially replacing stents, wherein each subsequent stent has a size, when expanded, that is larger than a size of a previous stent.

43. The method of claim 40, wherein the guidewire has a proximal end, which remains accessible from an outside of the body, and wherein the guidewire remains in the passage after expansion of the stent.

44. The method of claim 43, wherein the stent is permanently affixed to the carrier, the method further comprising steps of deflating the stent, removing the assembly over the guidewire, inserting a new assembly over the guidewire, and expanding a new stent of the new assembly.

45. The method of claim 43, wherein the stent is detachable from the carrier, the method further comprising a step of disengaging the carrier from the stent after the stent is inflated and removing the carrier over the guidewire.

46. The method of claim 45, further comprising steps of moving the carrier over the guidewire into the passage; attaching the carrier to the stent; deflating the stent; removing the carrier with the deflated balloon over the guidewire; and using the carrier to deliver a new stent over the guidewire.

47. The method of claim 38, wherein the stent is continuously expanded until it reaches a desirable size.

48. The method of claim 38, wherein the stent is incrementally expanded until it reaches a desirable size.

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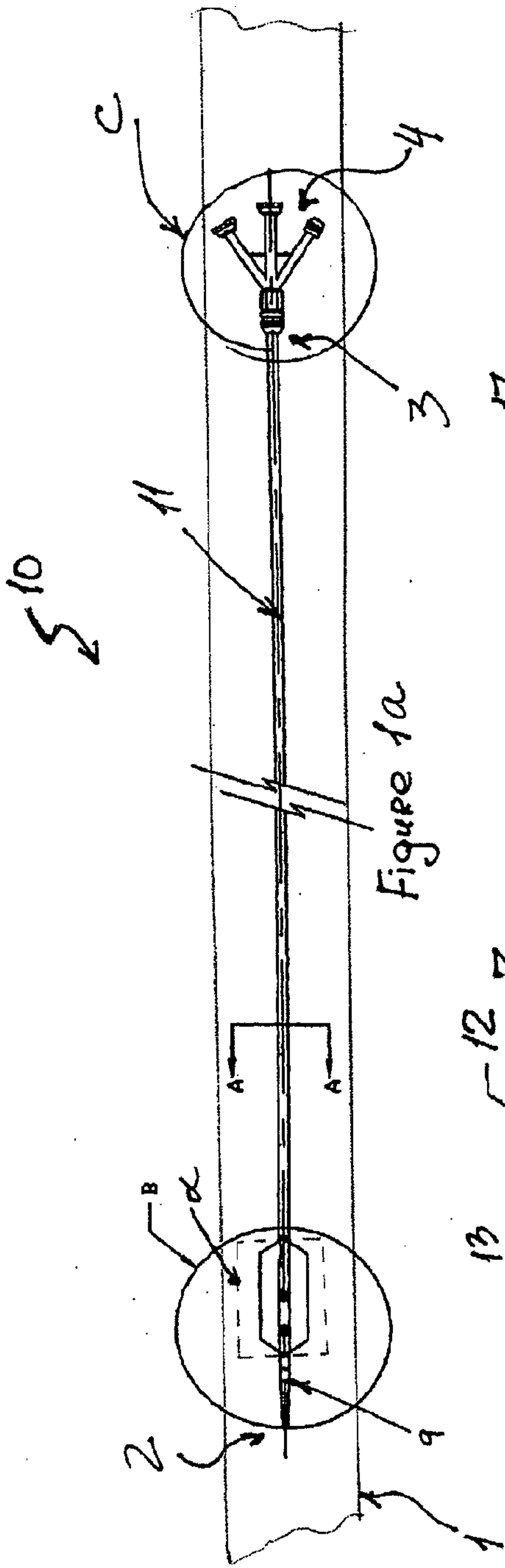


Figure 1a

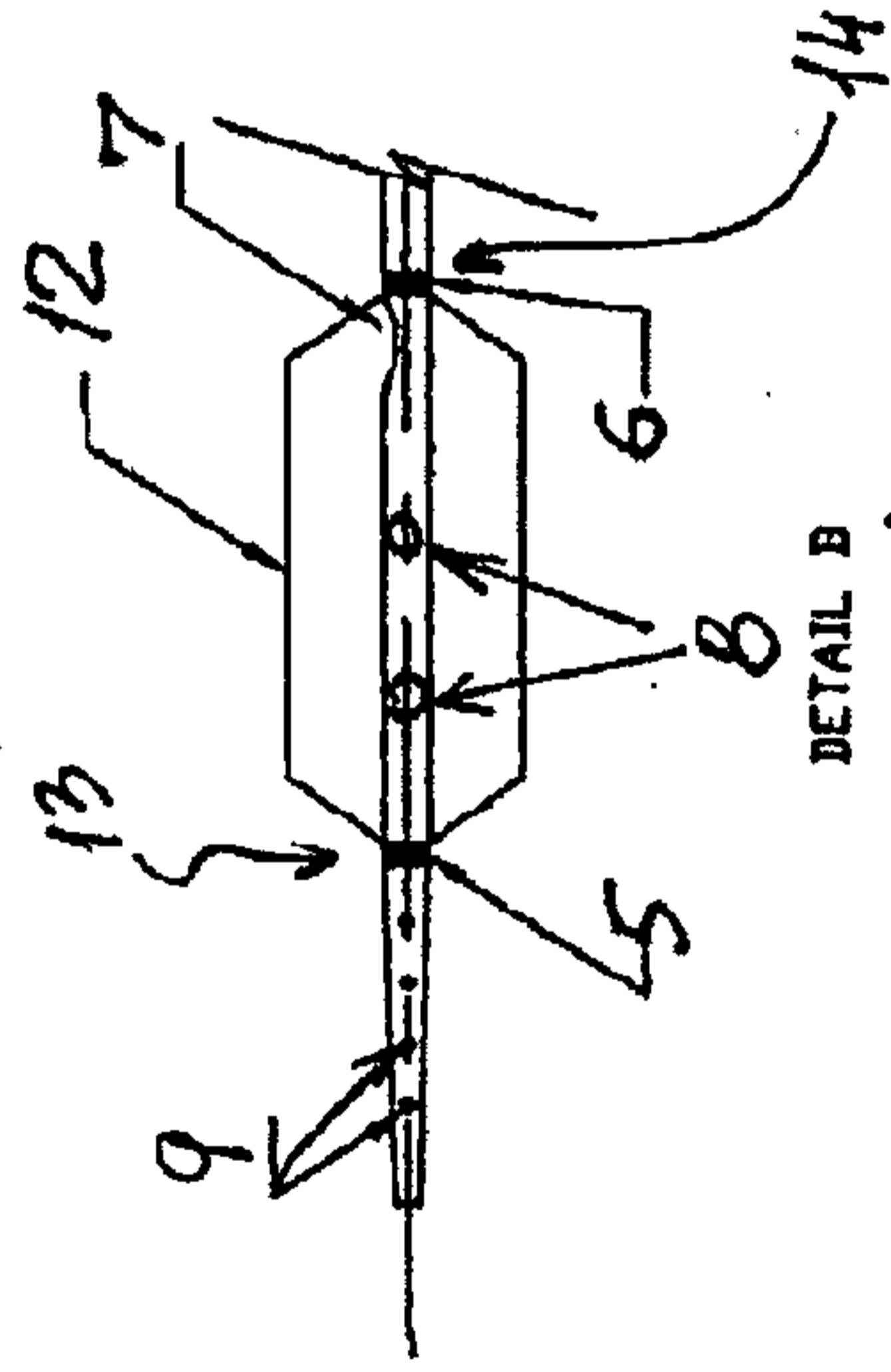


Figure 1b

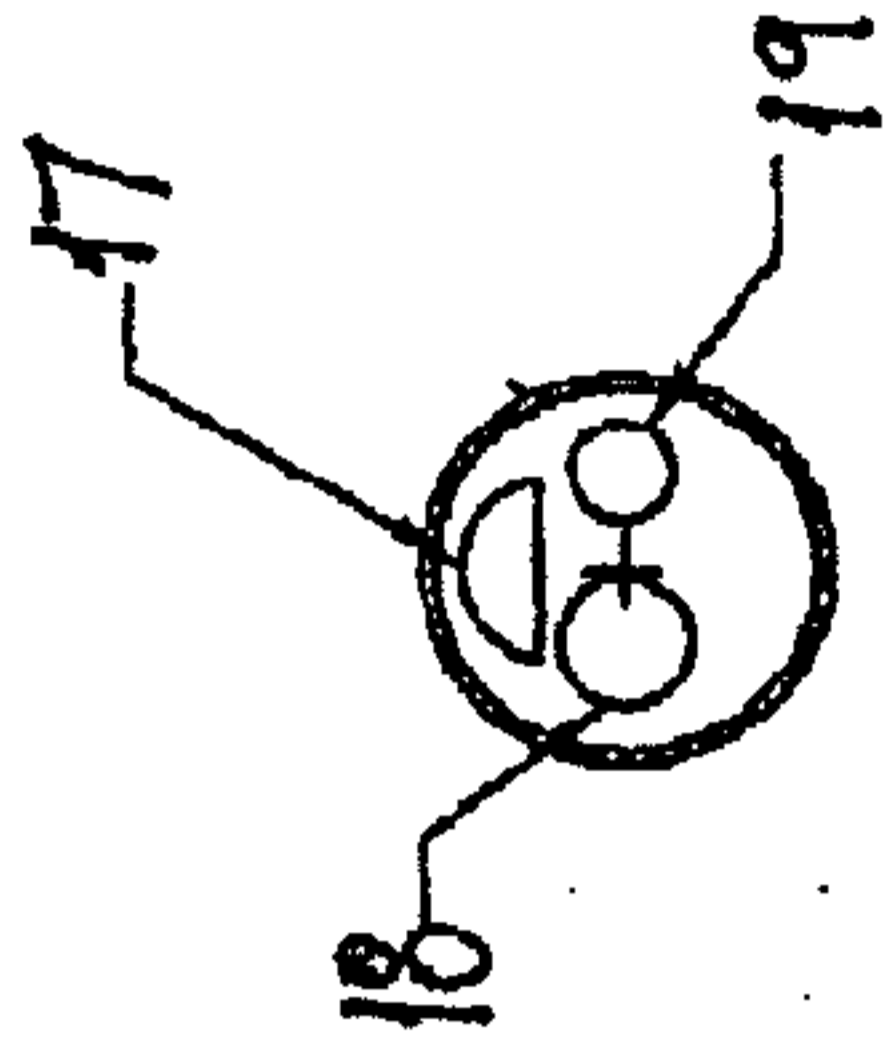


Figure 1c

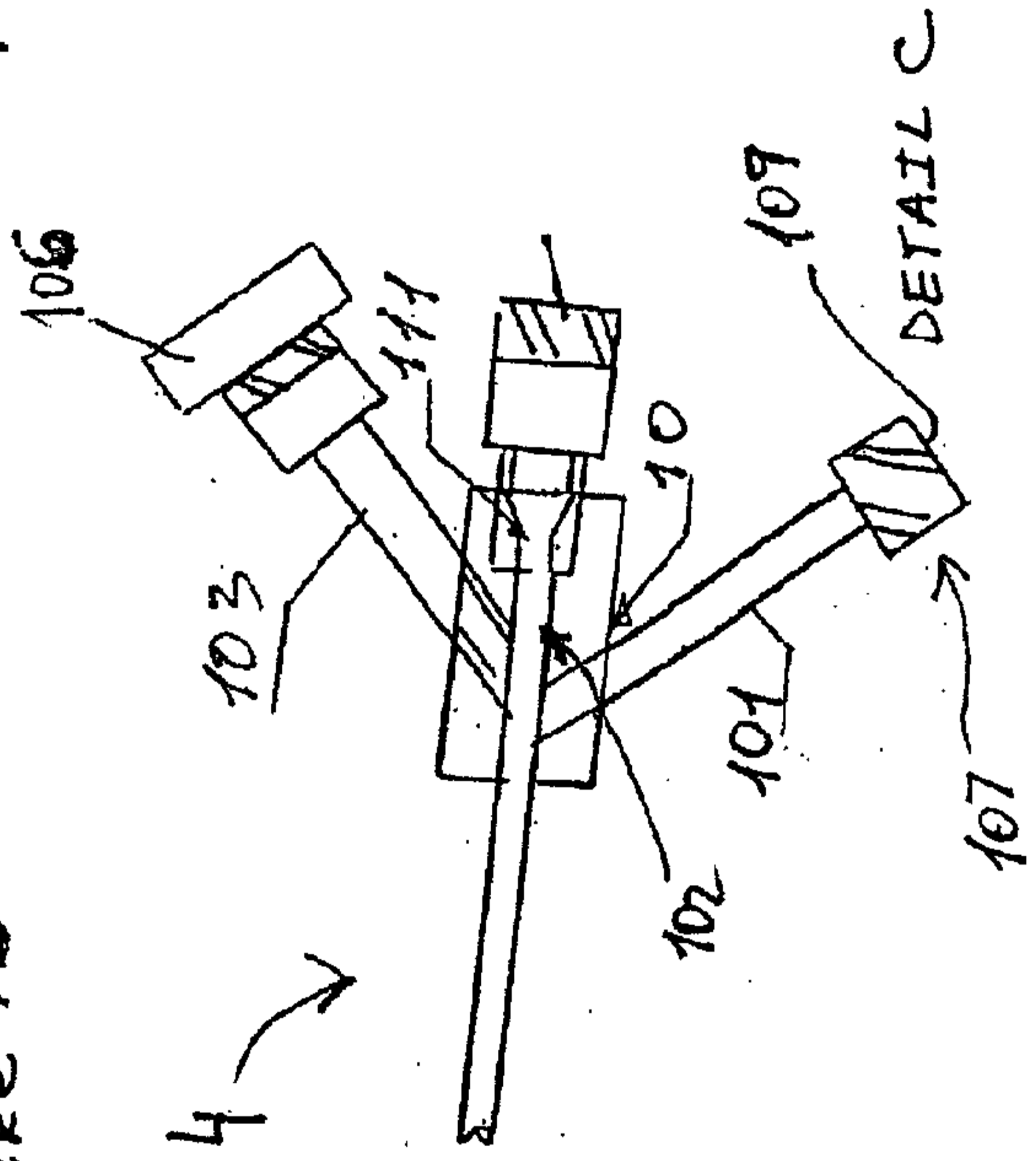
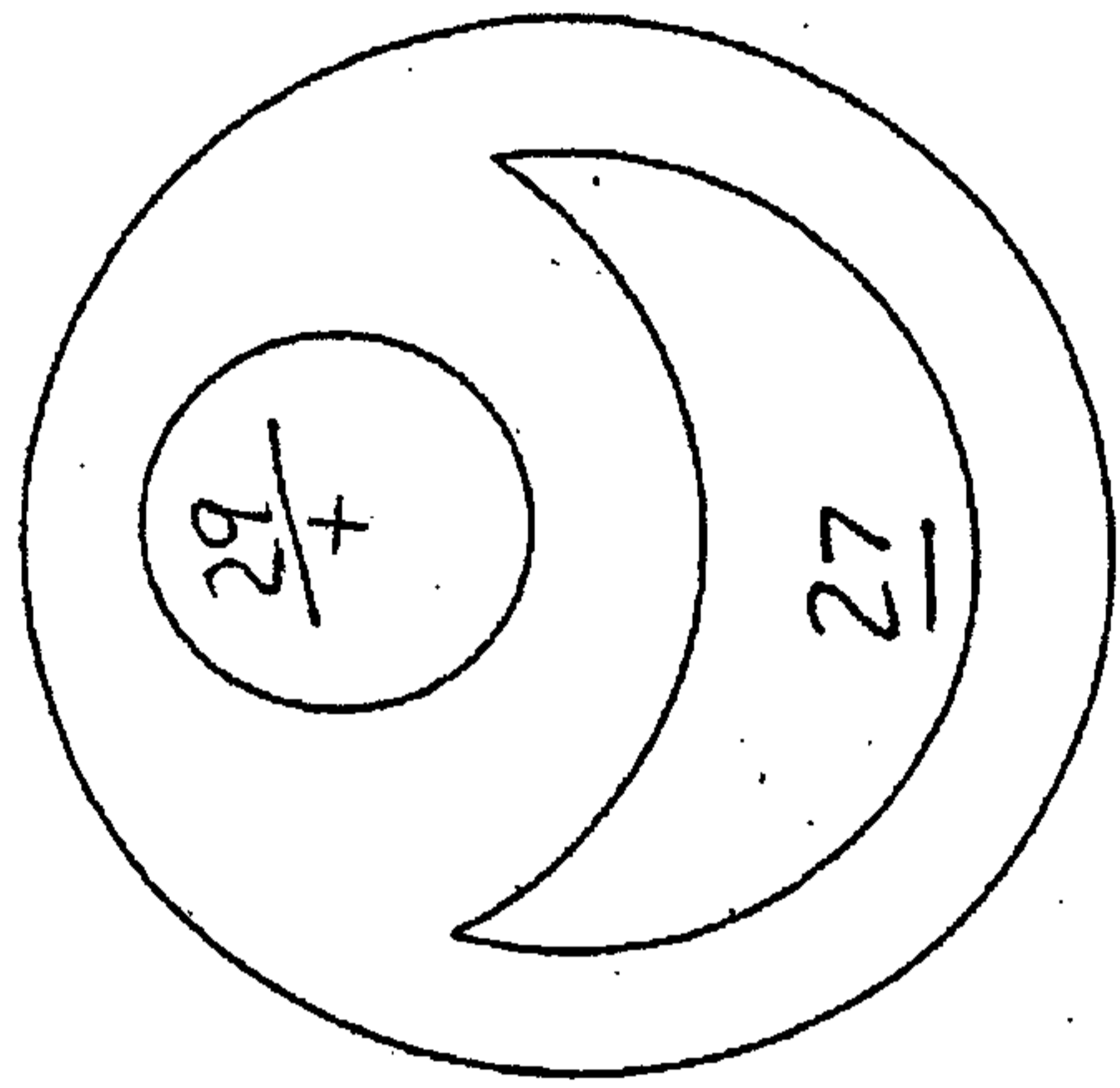
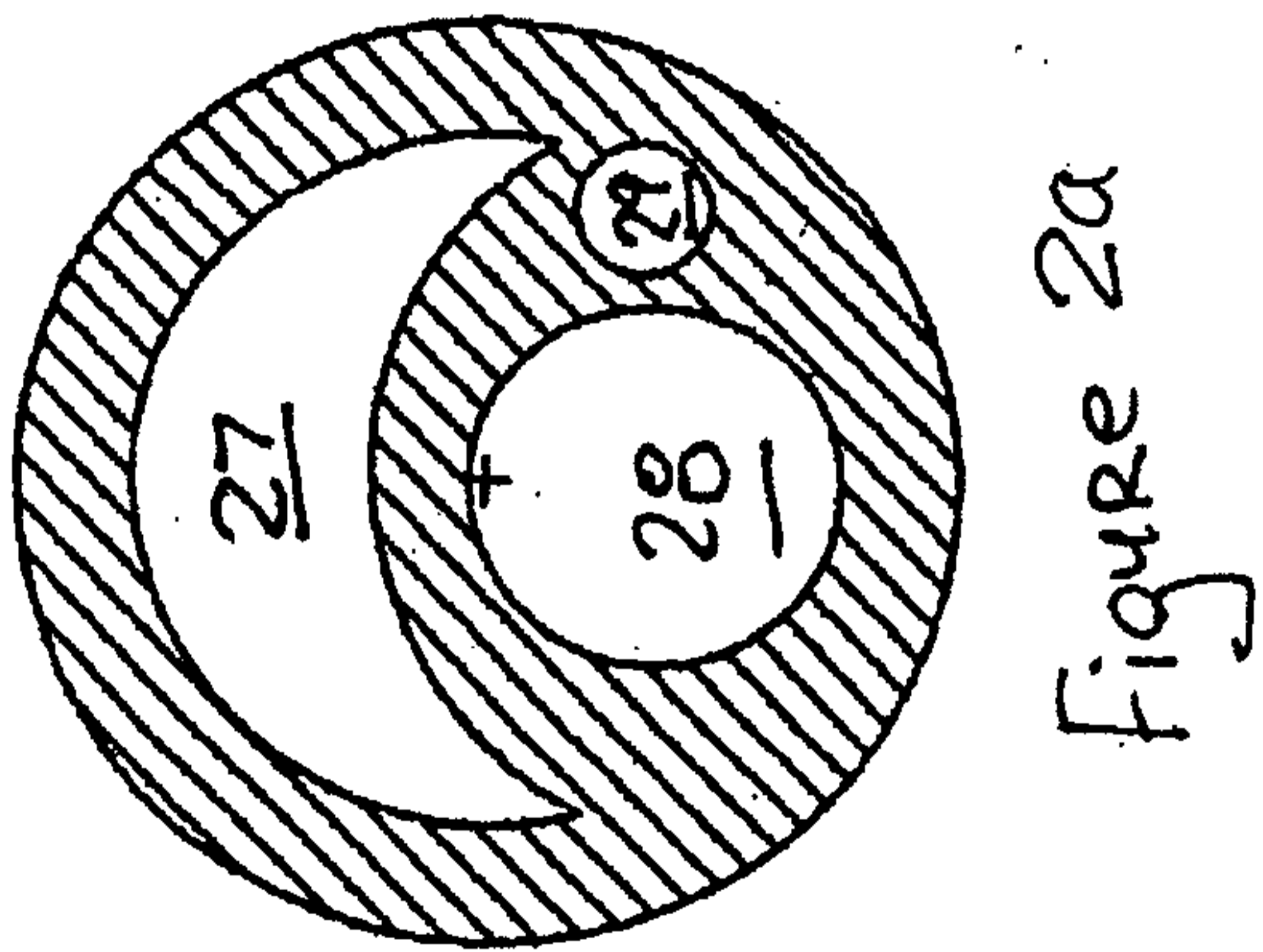
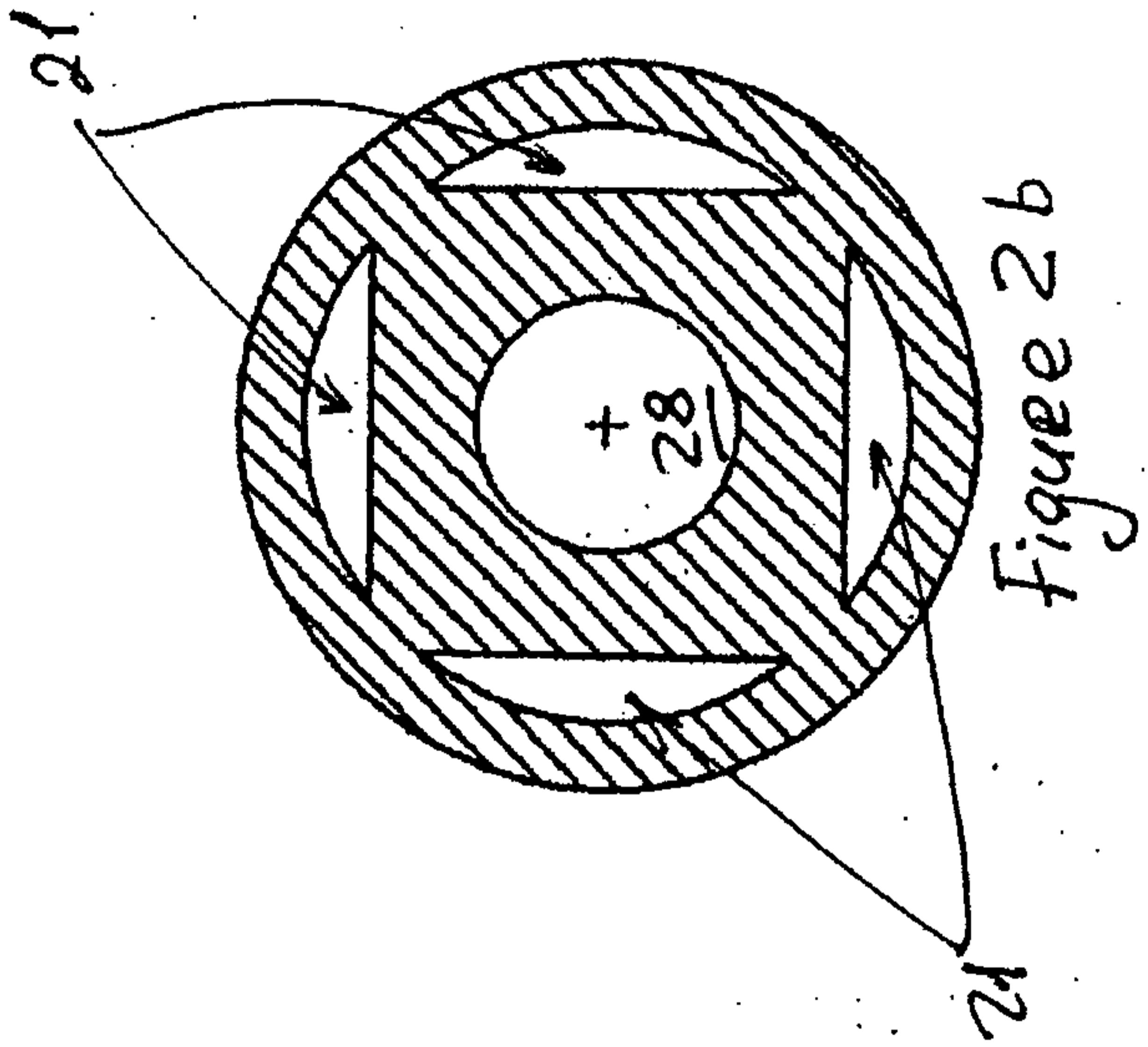
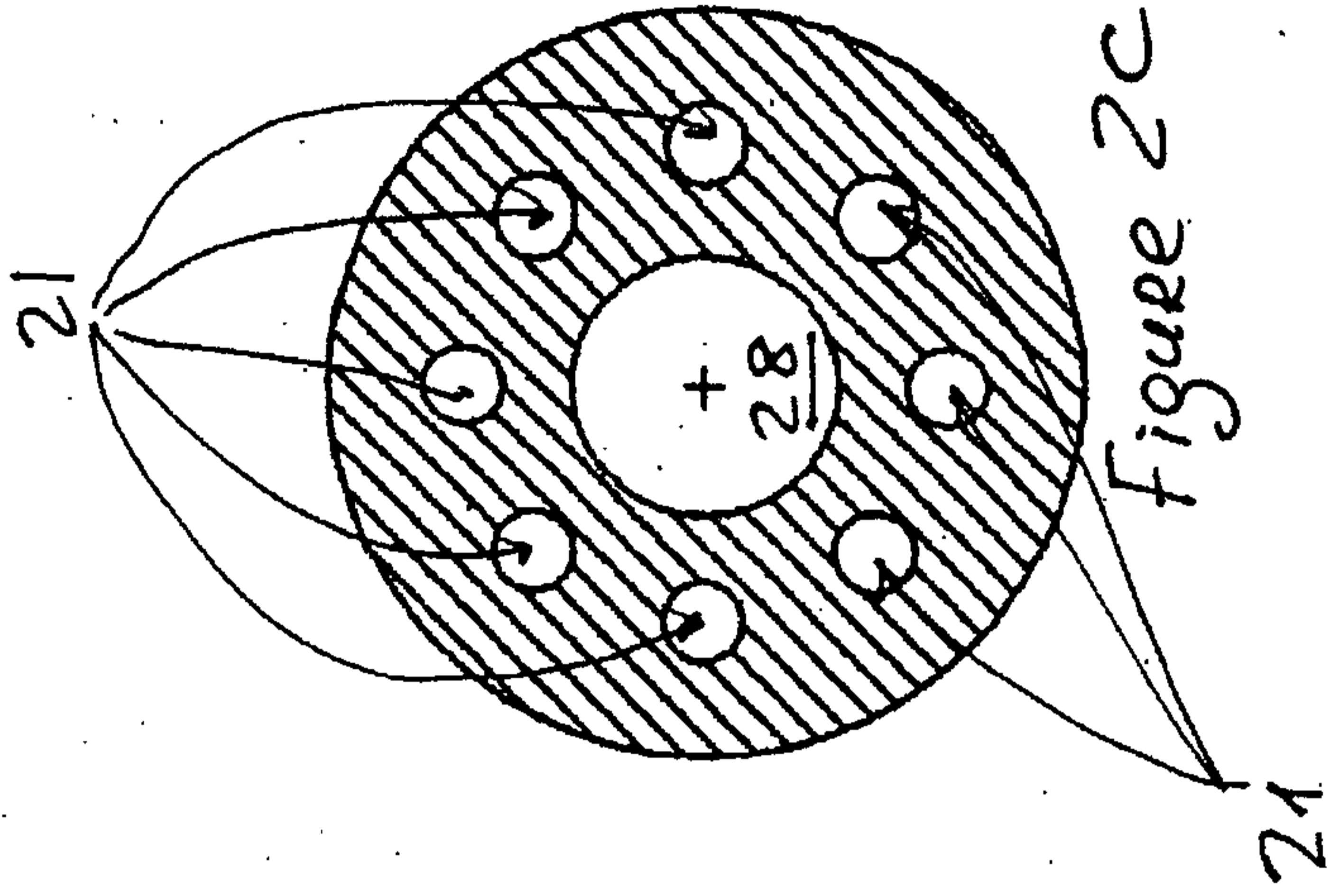
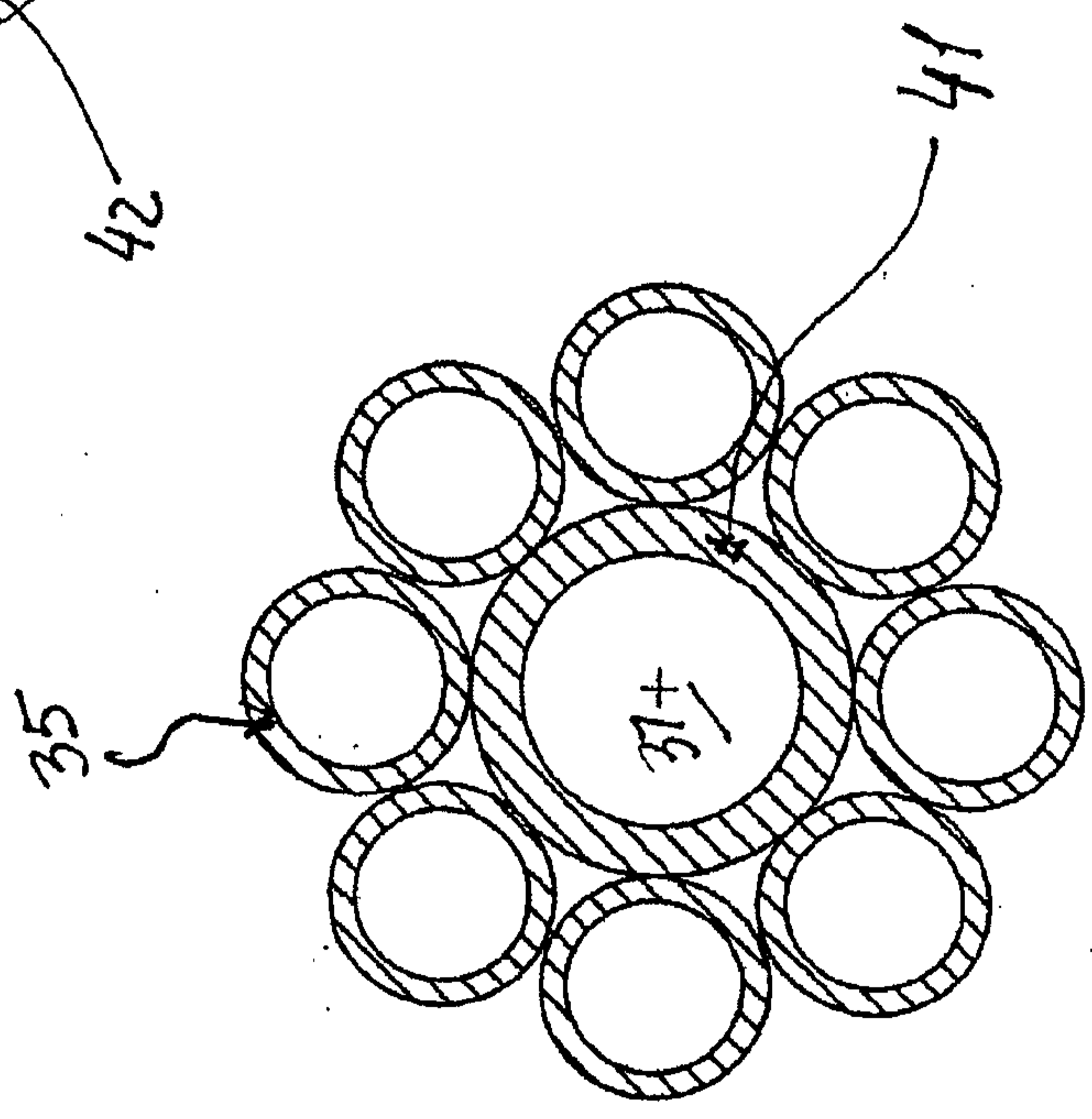
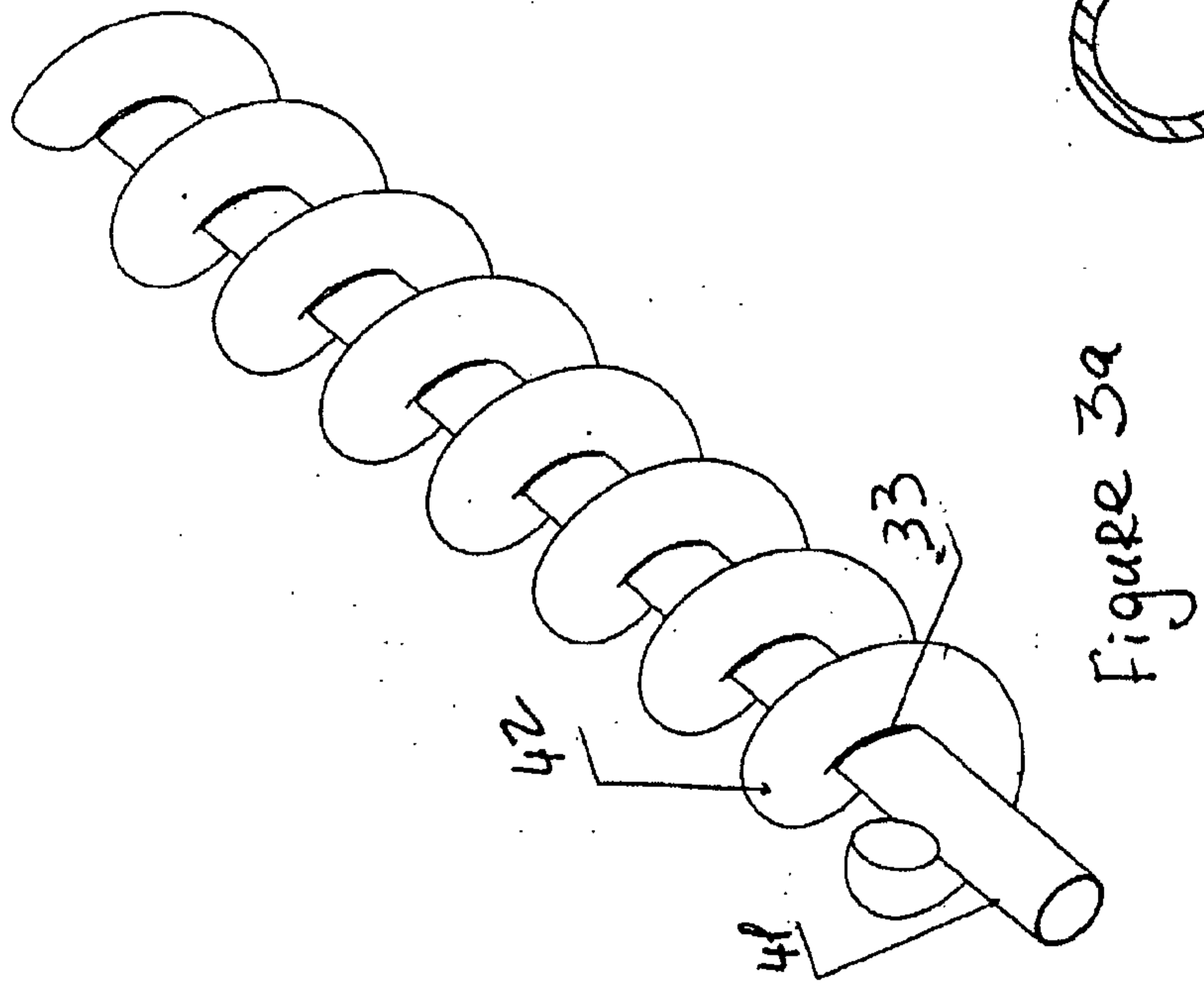
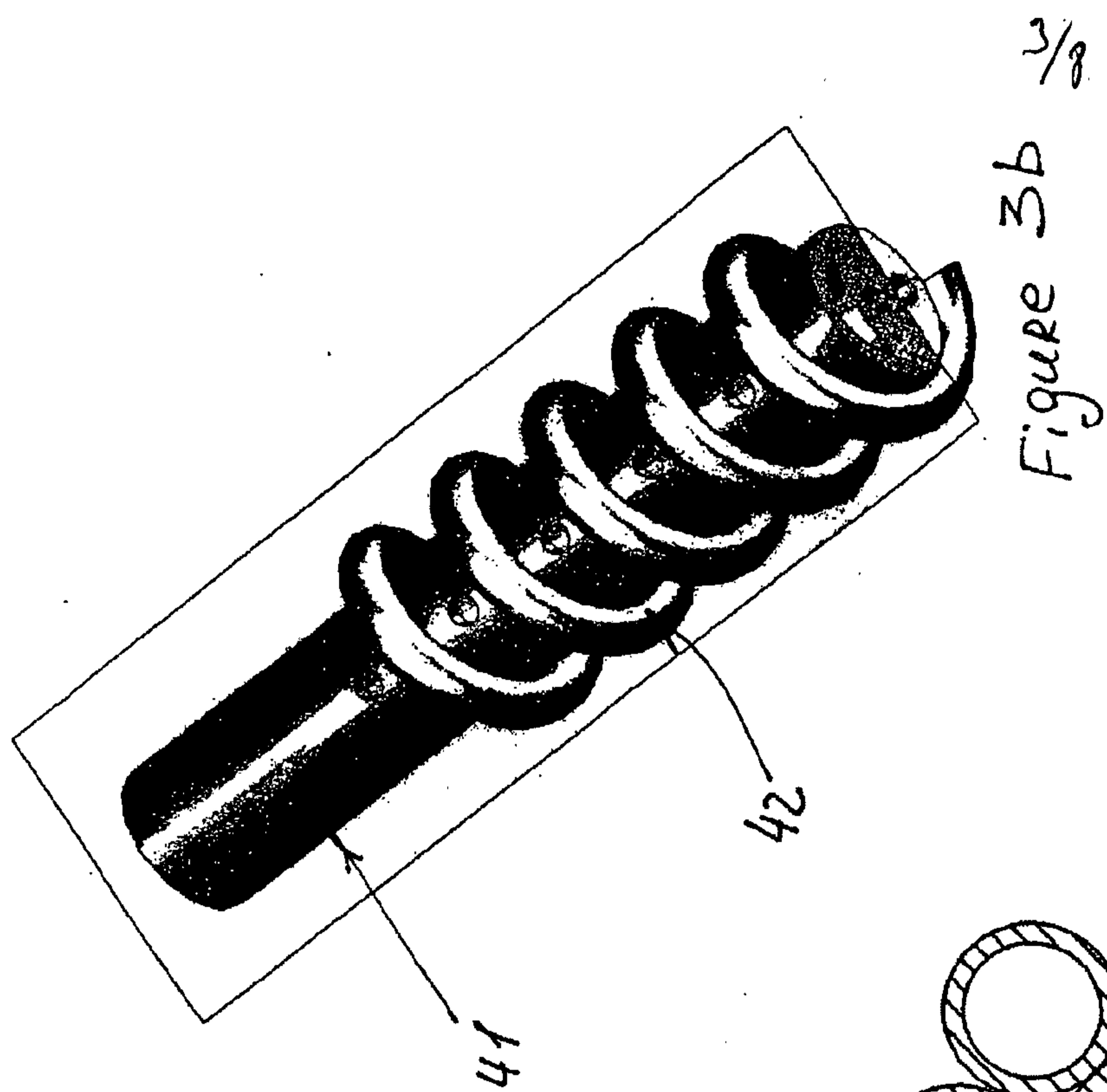


FIGURE 1d

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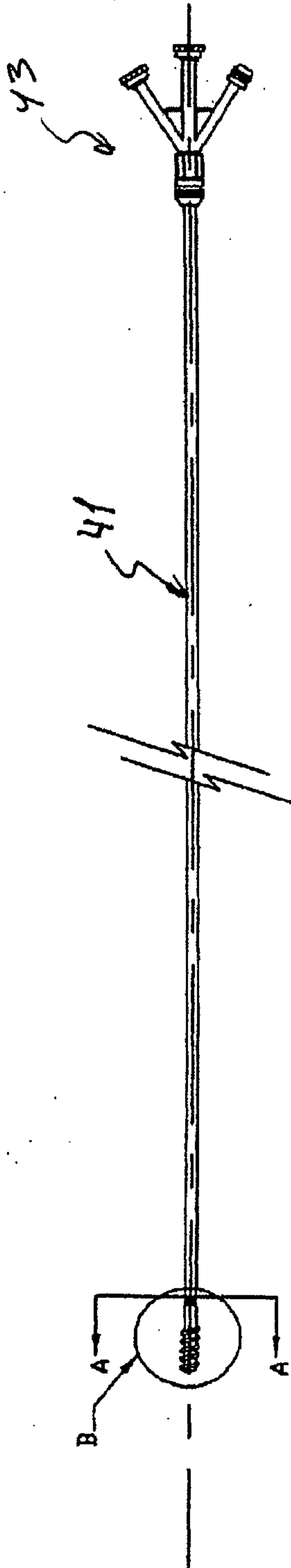
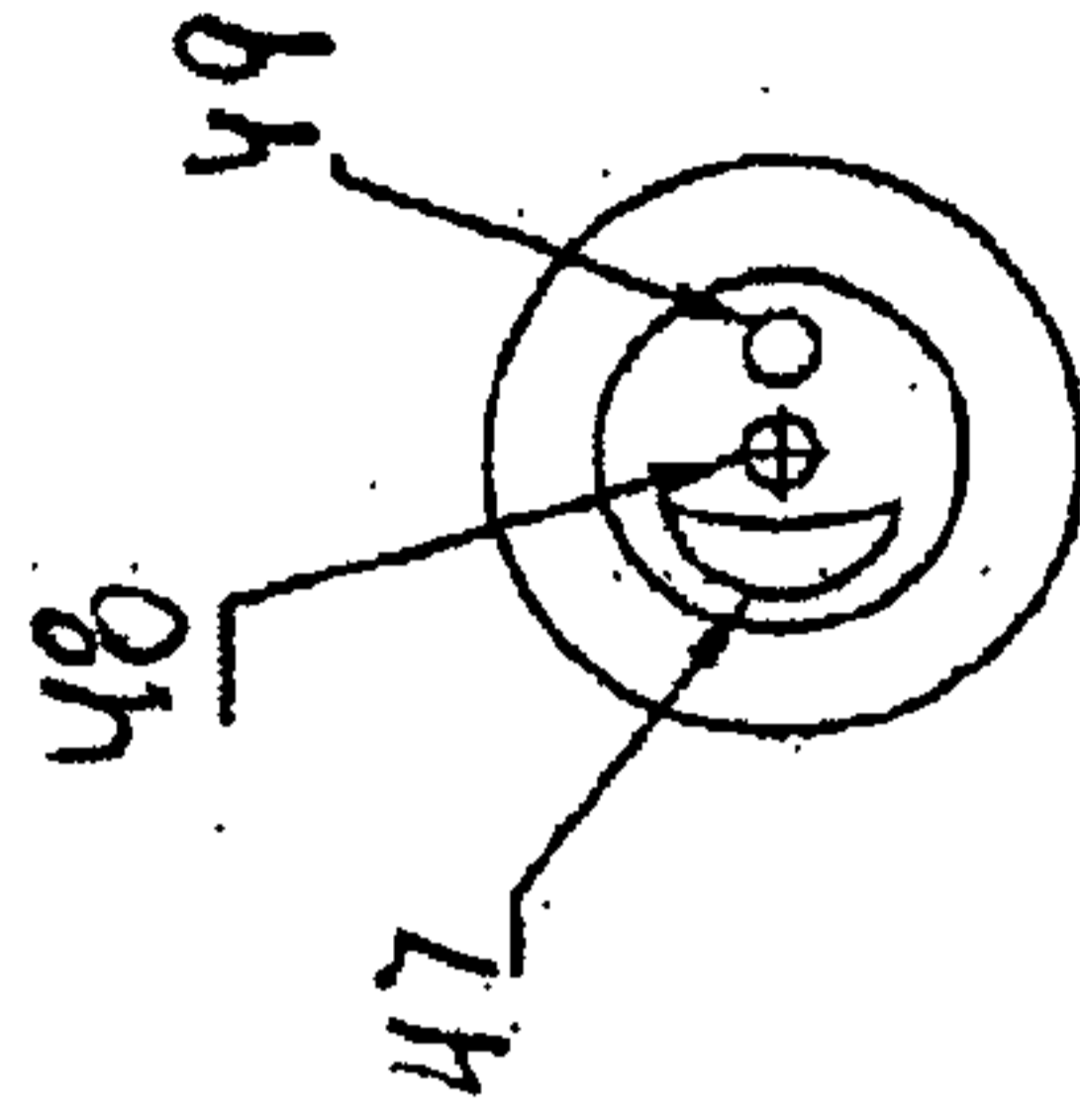
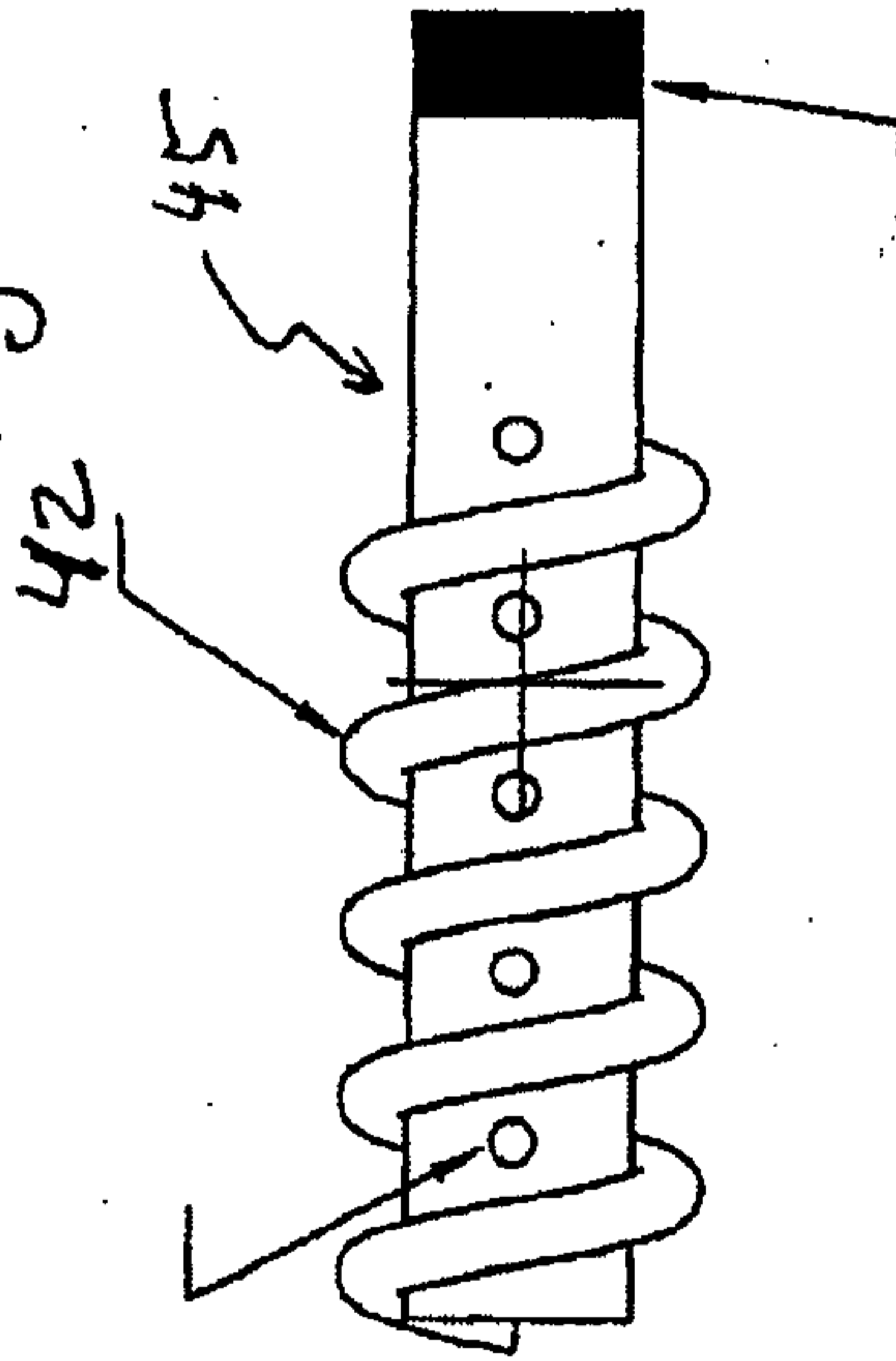


Figure 4a



DETAIL A-A

Figure 4c



DETAIL B

Figure 4b

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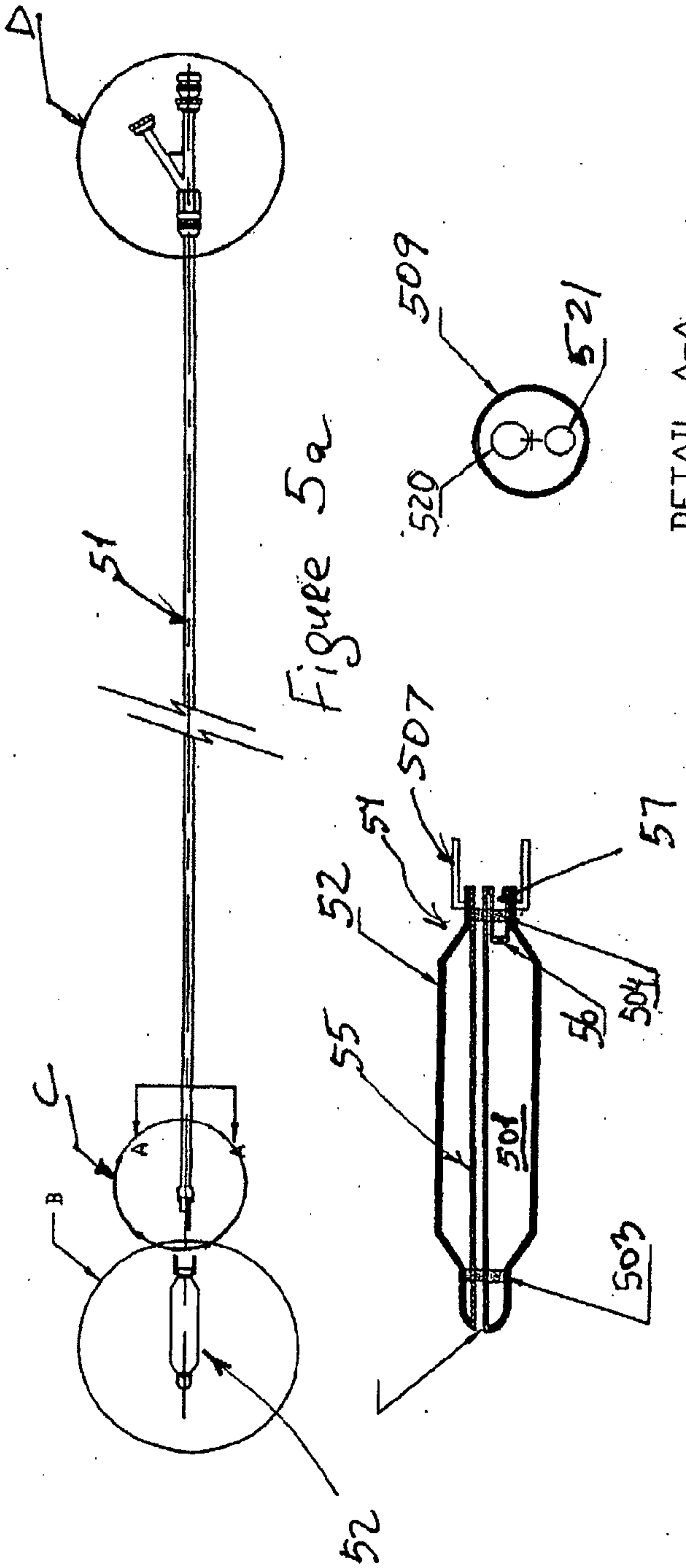


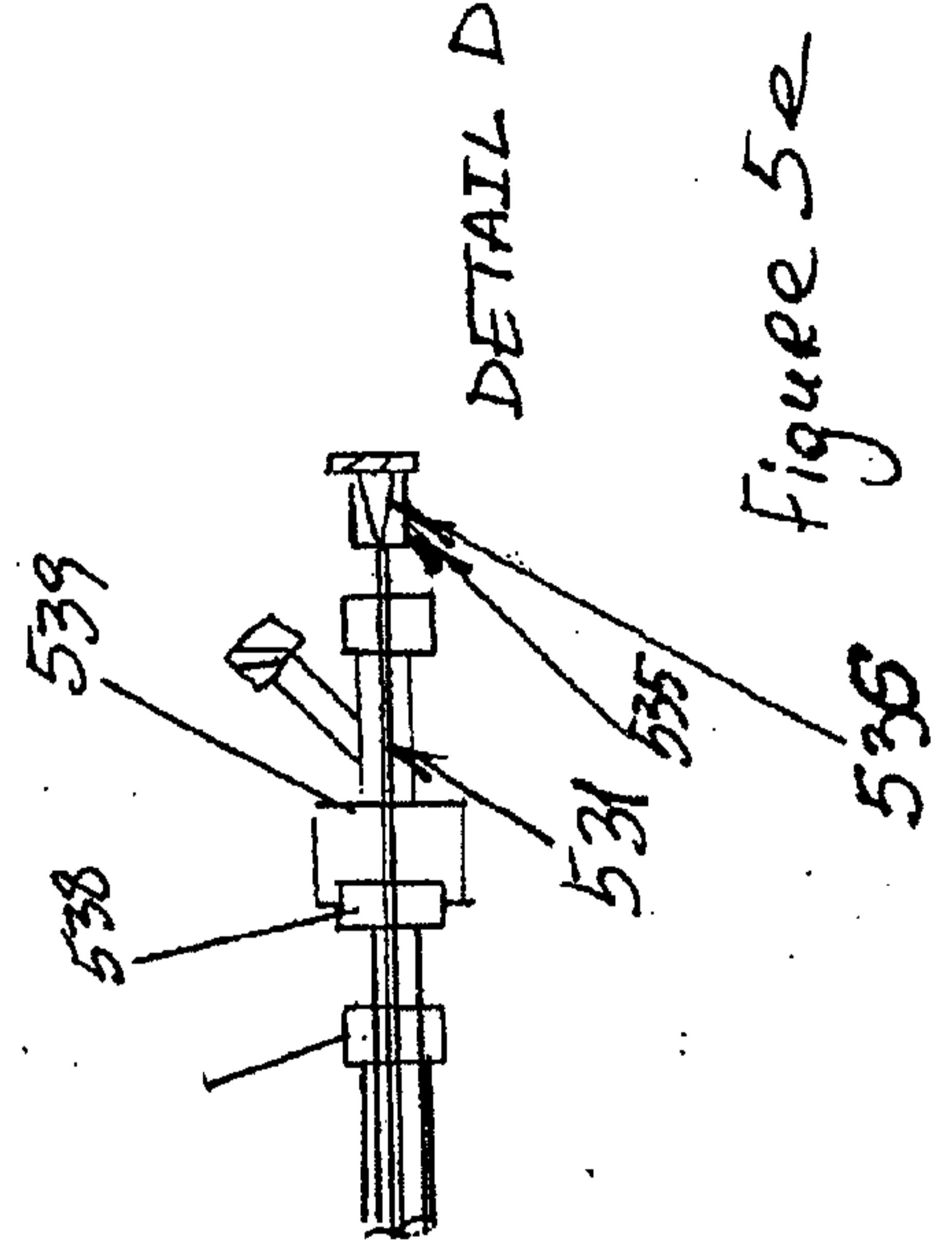
Figure 5a

DETAIL B

Figure 5b

DETAIL A-A

Figure 5c



DETAIL C

Figure 5d

DETAIL D

Figure 5e

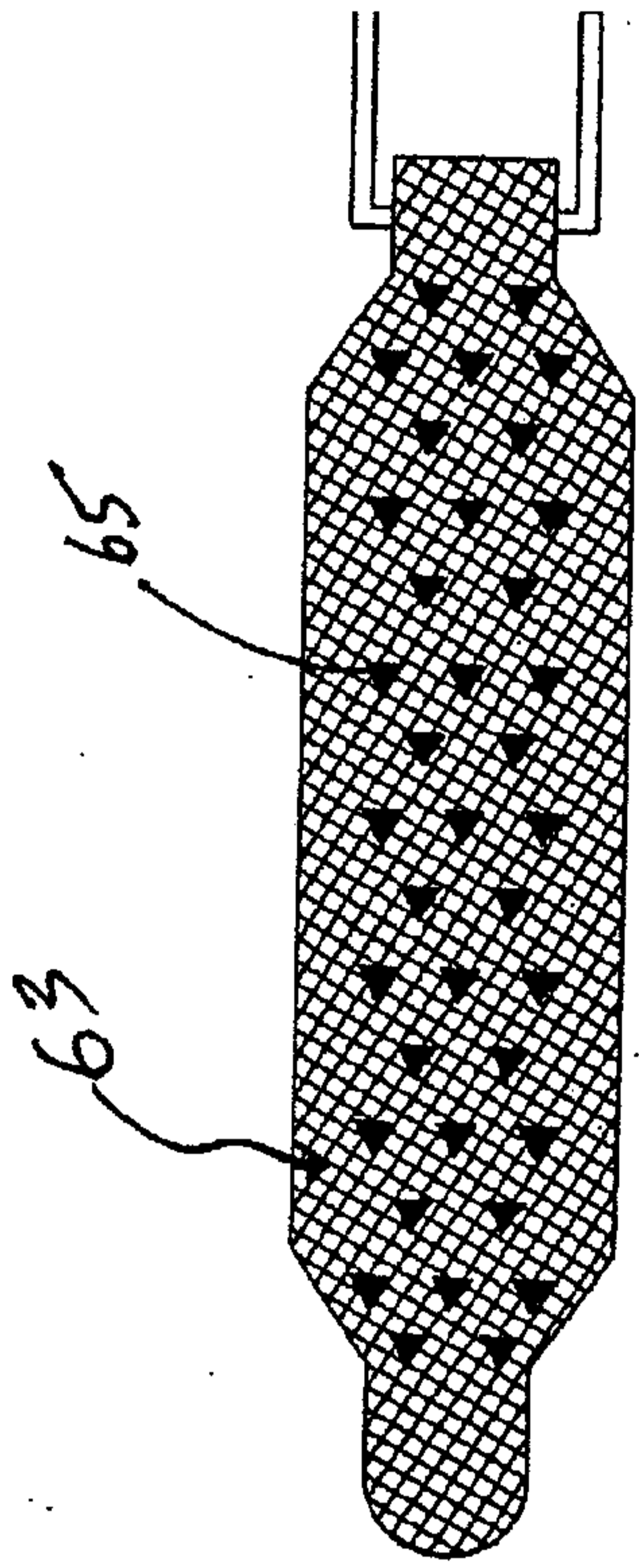


Figure 6b

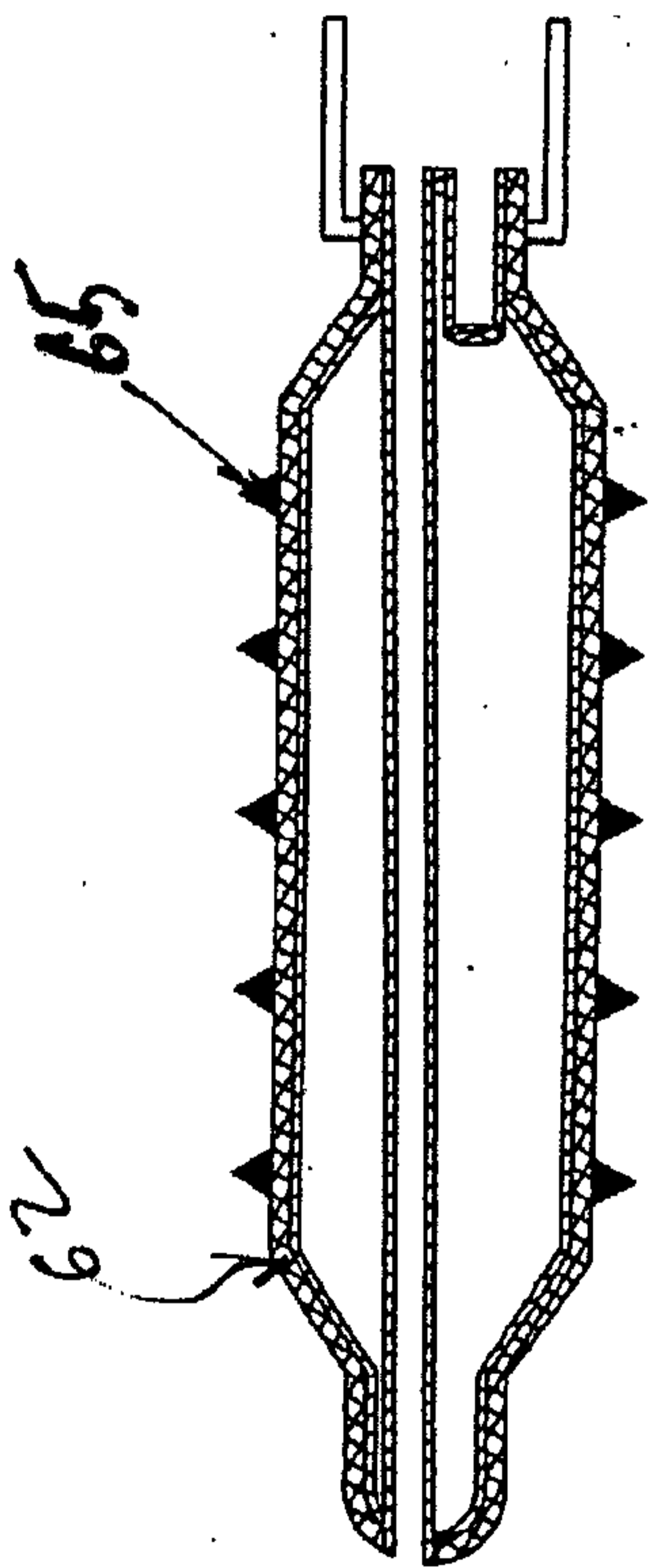


Figure 6a

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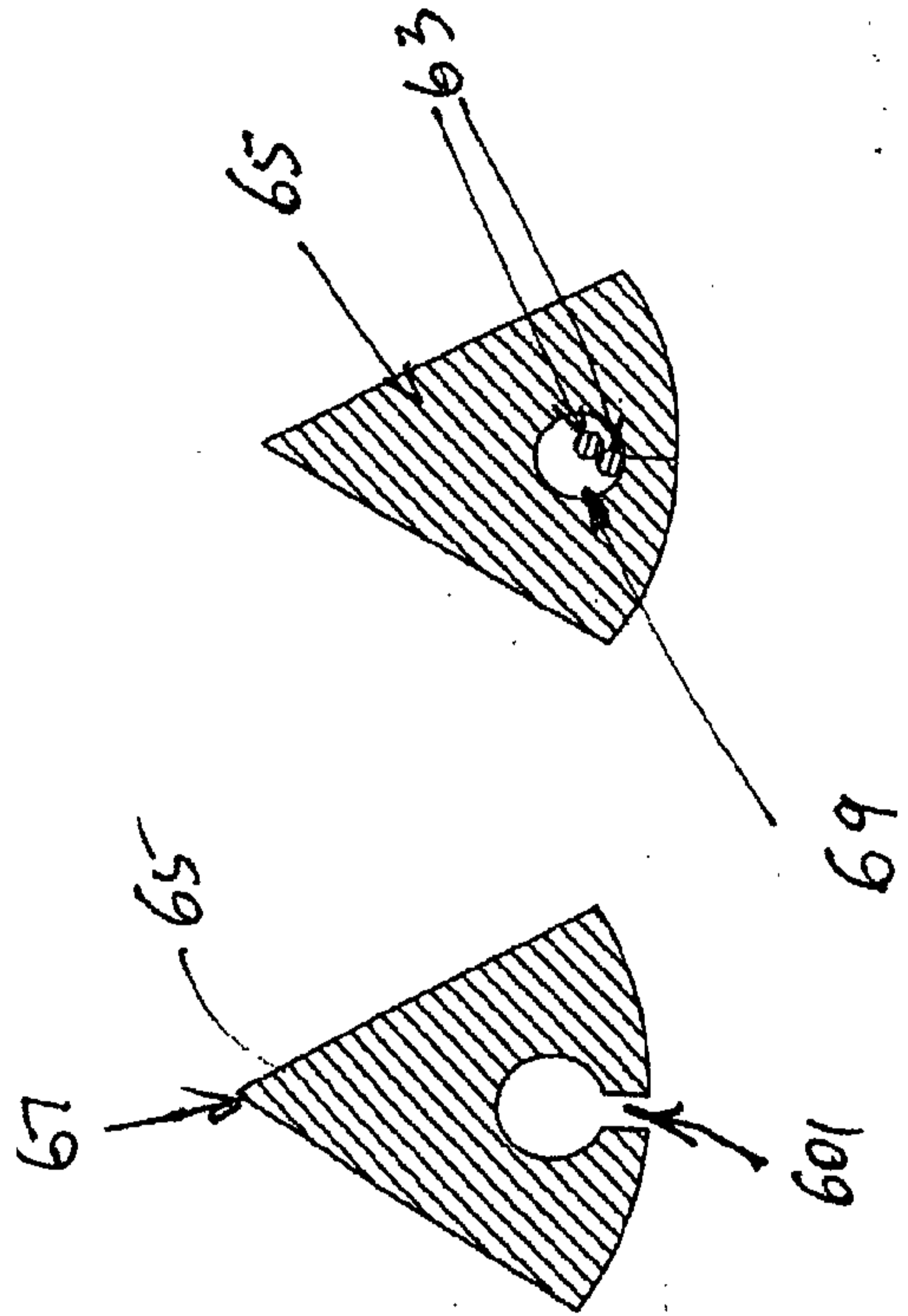


FIGURE 6c

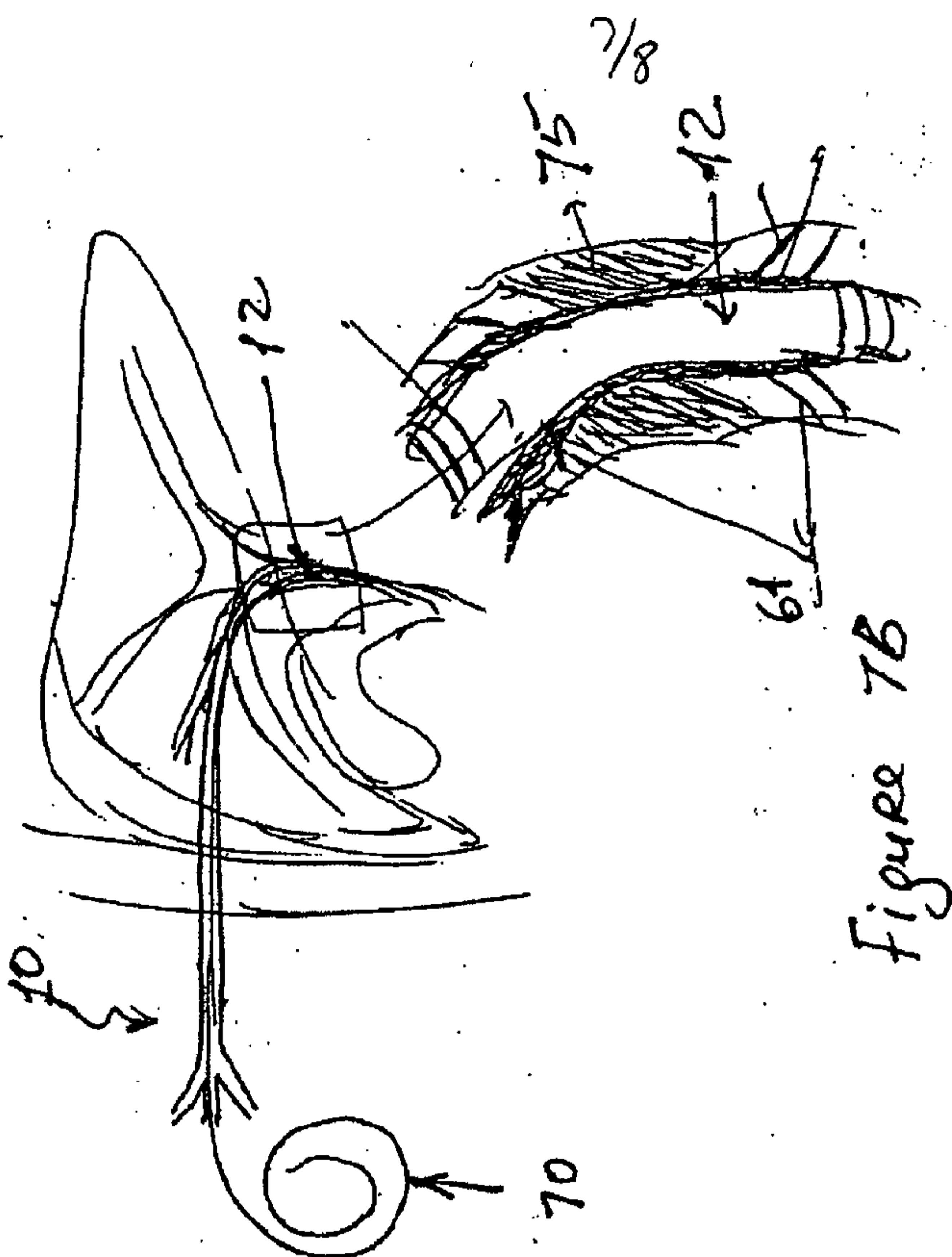


Figure 7B

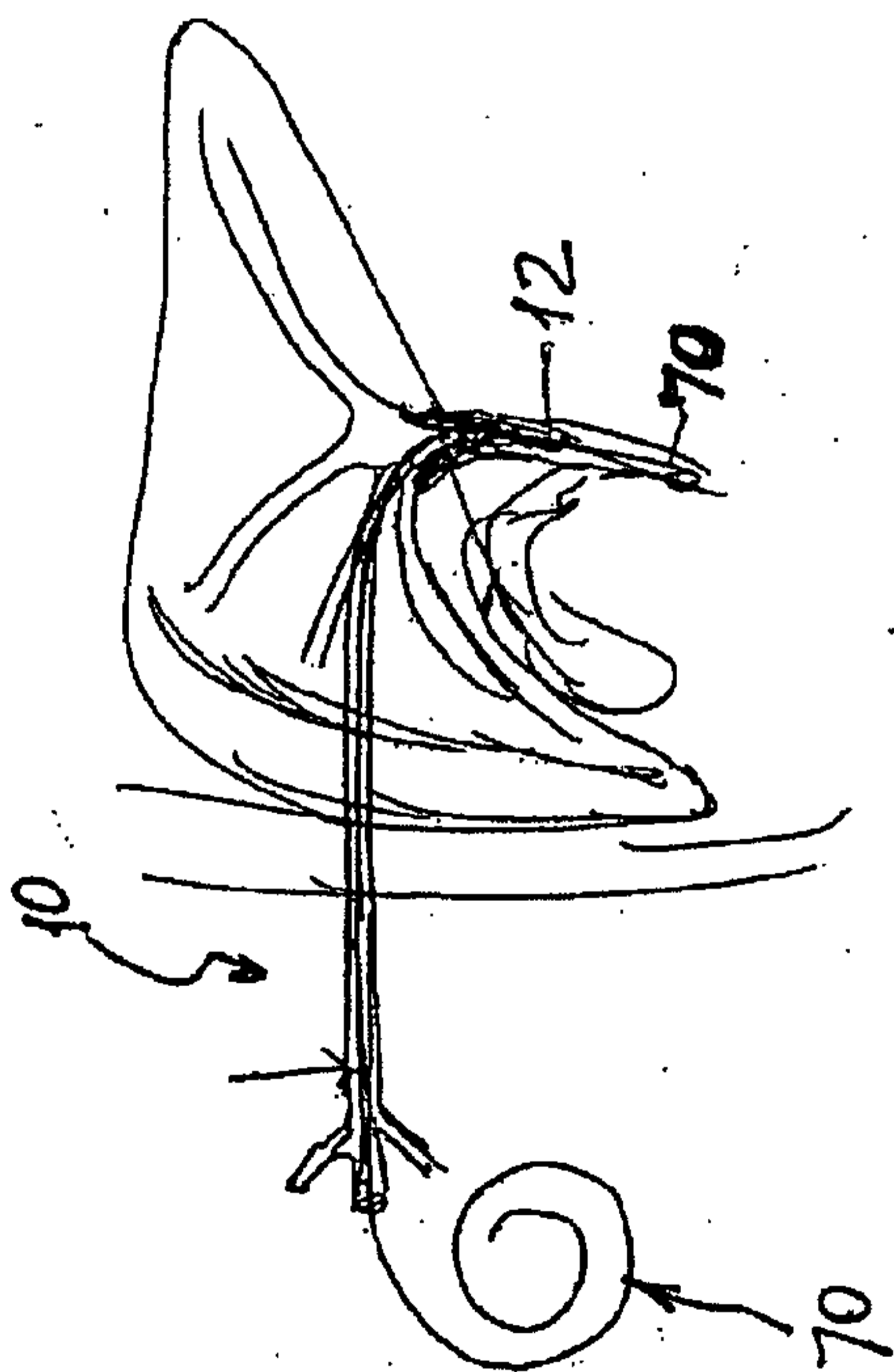


Figure 7a

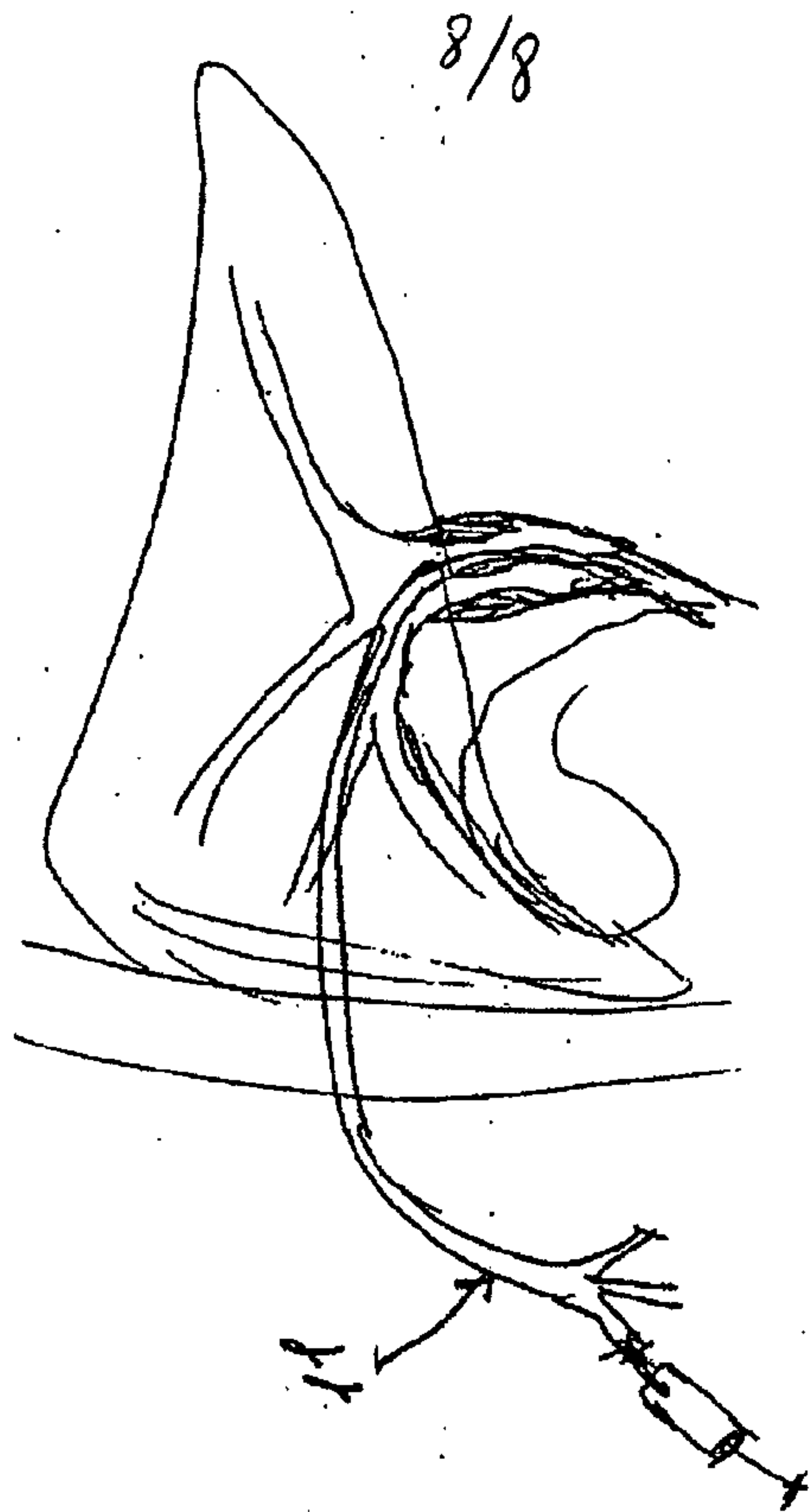


Figure 8B

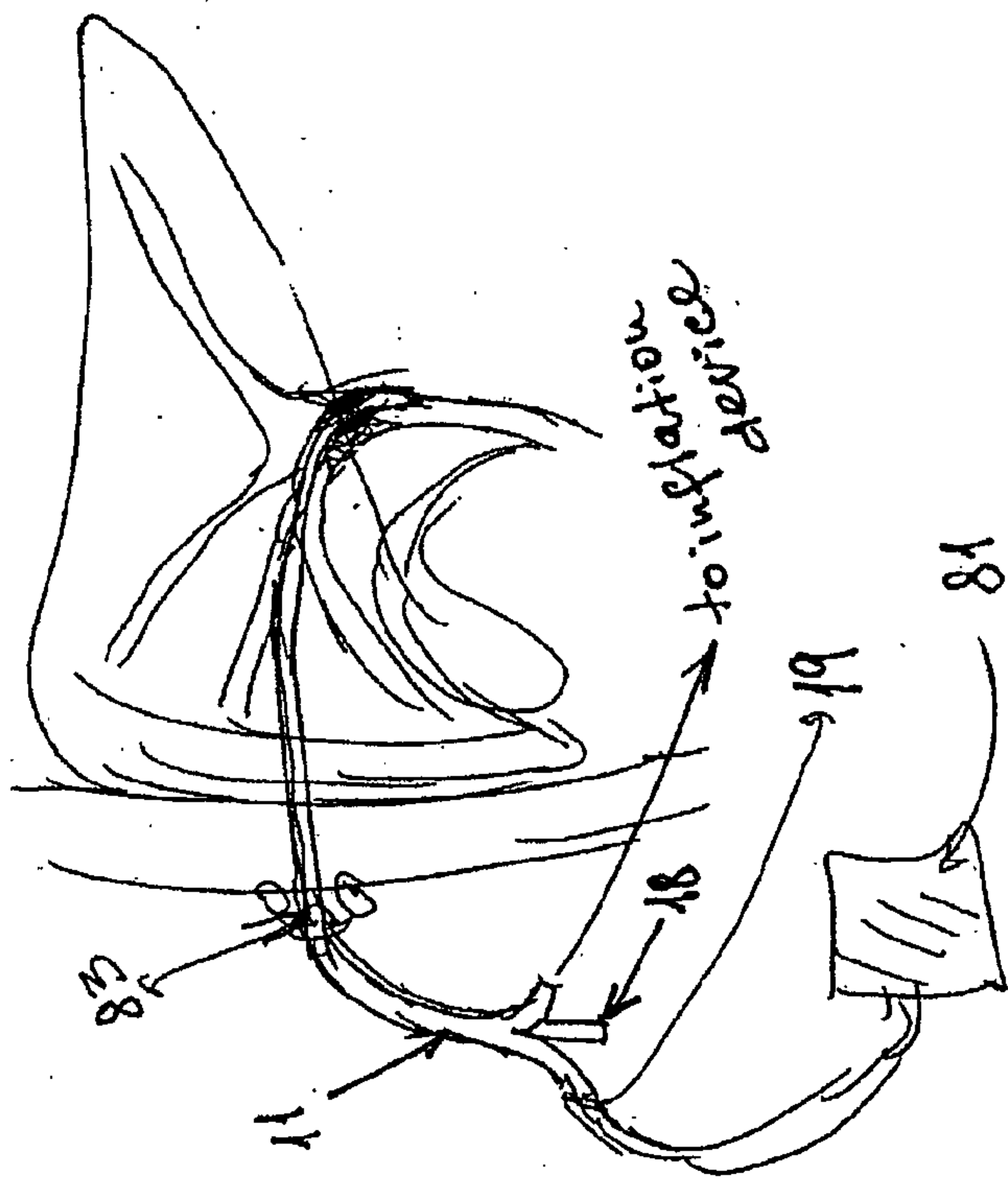


Figure 8a

