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[54] SAFETY NEEDLE SYSTEM ASSURING HAZARD-FREE HANDLING AFTER NEEDLE CONTAMINATION

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[73] Assignee: MBO Laboratories, Inc., Carlisle, Mass.

[\*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: 09/345,949

[22] Filed: Jul. 1, 1999

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[64] Patent No.: 5,755,699
Issued: May 26, 1998
Appl. No.: 08/745,803
Filed: Nov. 8, 1996

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U.S. Applications:

[63] Continuation of application No. 08/398,772, Mar. 6, 1995, abandoned, which is a continuation of application No. 07/972,013, Nov. 6, 1992, Pat. No. 5,395,347, which is a continuation-in-part of application No. 07/610,583, Nov. 8, 1990, Pat. No. 5,176,655, and a continuation-in-part of application No. PCT/US91/08063, Nov. 6, 1991.

[51] Int. Cl.7 ..... A61M 5/32
[52] U.S. Cl. .... 604/198; 604/192; 604/110
[58] Field of Search ..... 604/110, 162, 604/167, 187, 192, 195, 197, 198, 203; 600/578, 579

Primary Examiner—Wynn Wood Coggins
Assistant Examiner—A. T. Nguyen
Attorney, Agent, or Firm—Low and Low

[57] ABSTRACT

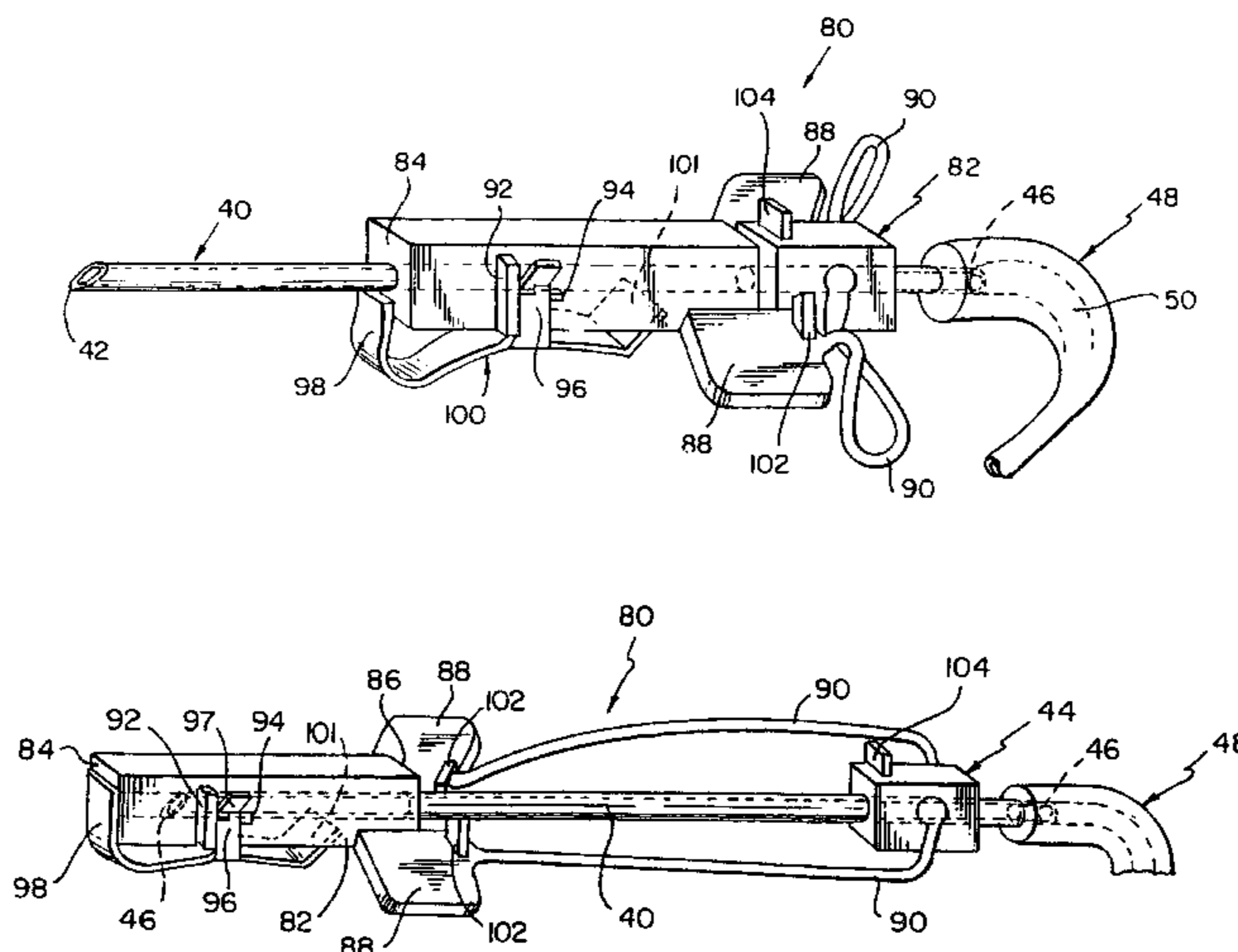
A safety needle and blood collection and sampling system precluding needstick injury by contaminated needles wherein a used needle is captured immediately within its carrier upon retraction of the needle flush with the carrier. Blood sampling is effected without reverse flow through the system and without reuse or exposure of a contaminated needle. Simplified means of assembling the needle are also set forth to minimize cost with maximum reliability notwithstanding a minimum of components.

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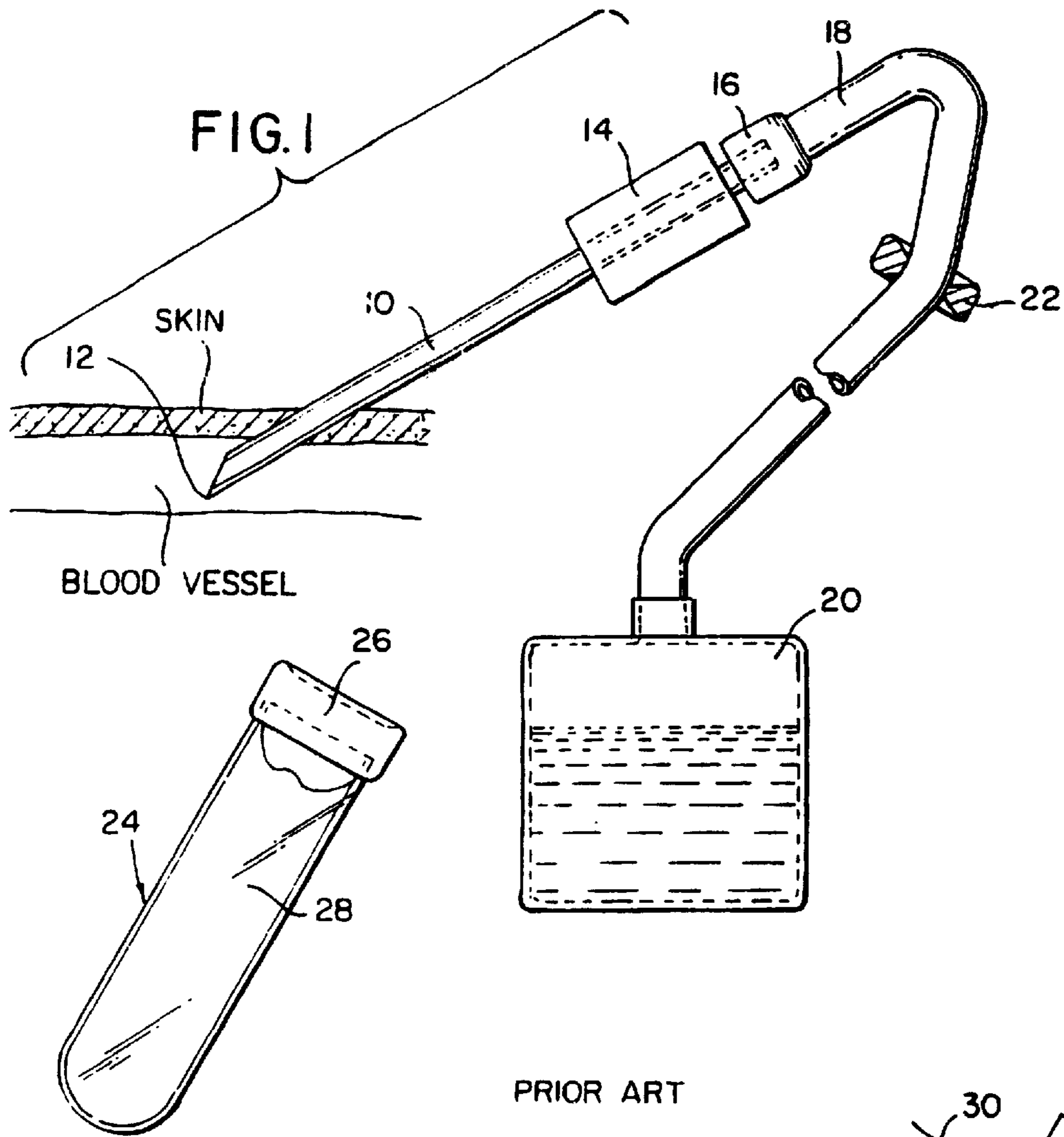
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36 Claims, 8 Drawing Sheets

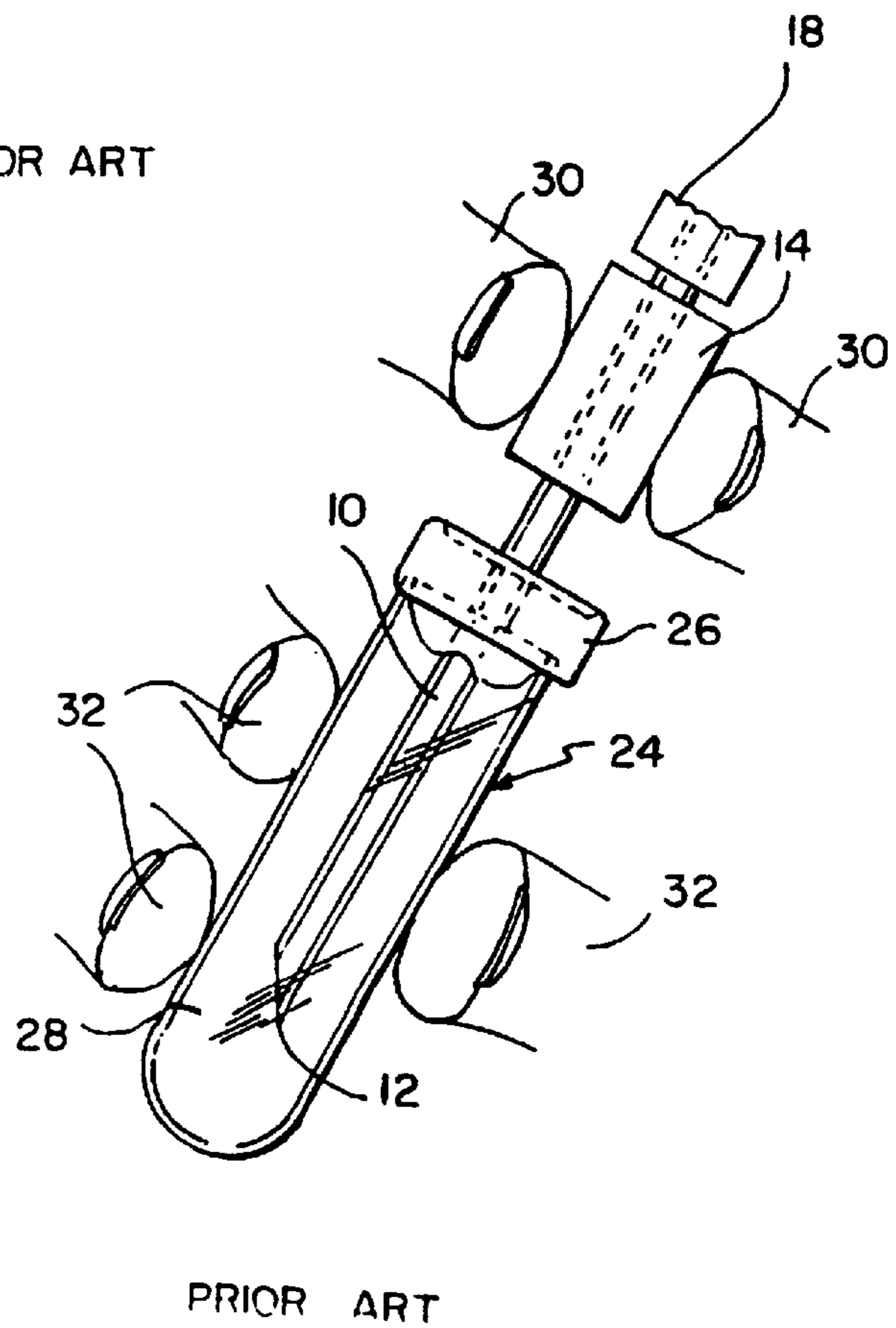


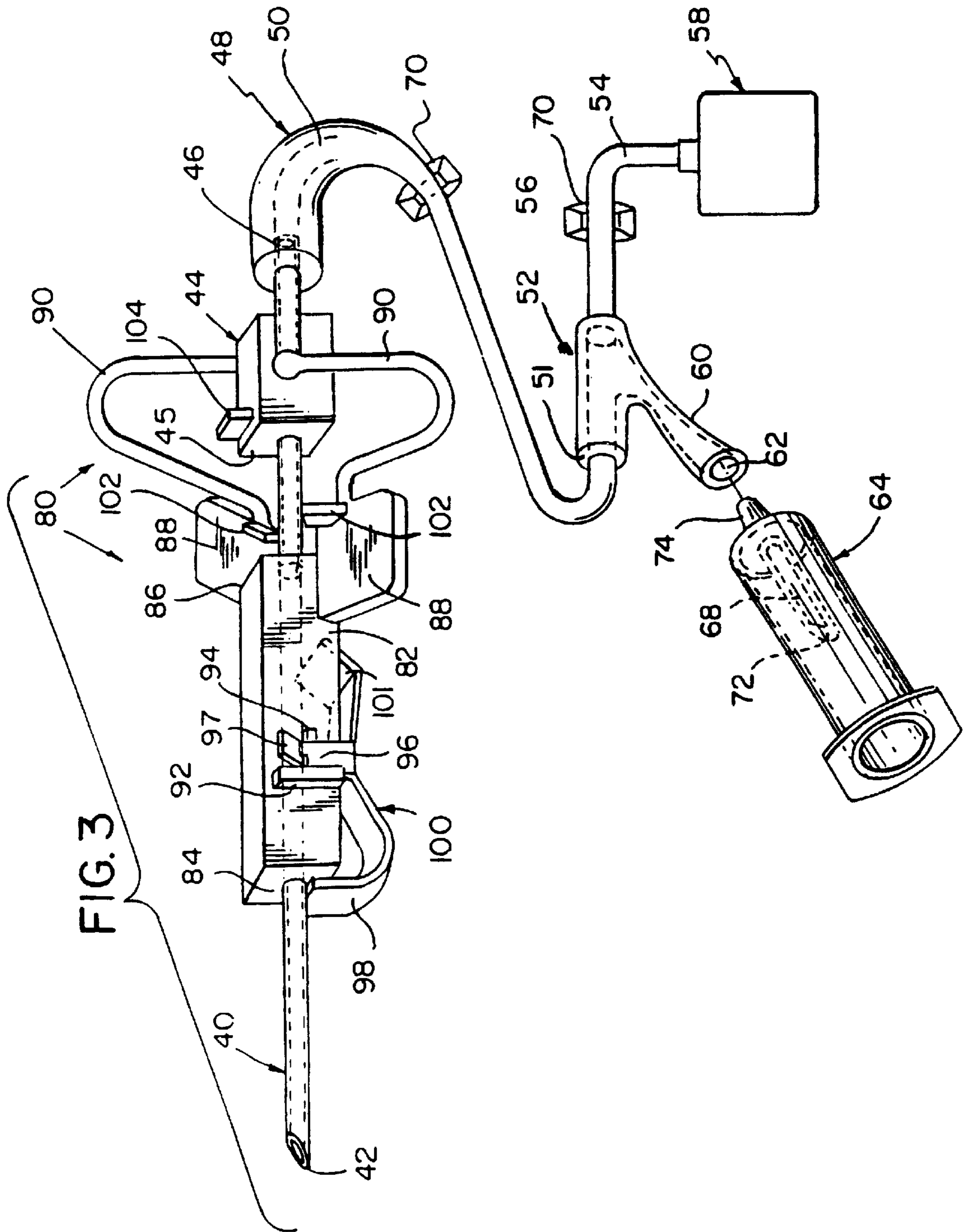
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**FIG. 2**





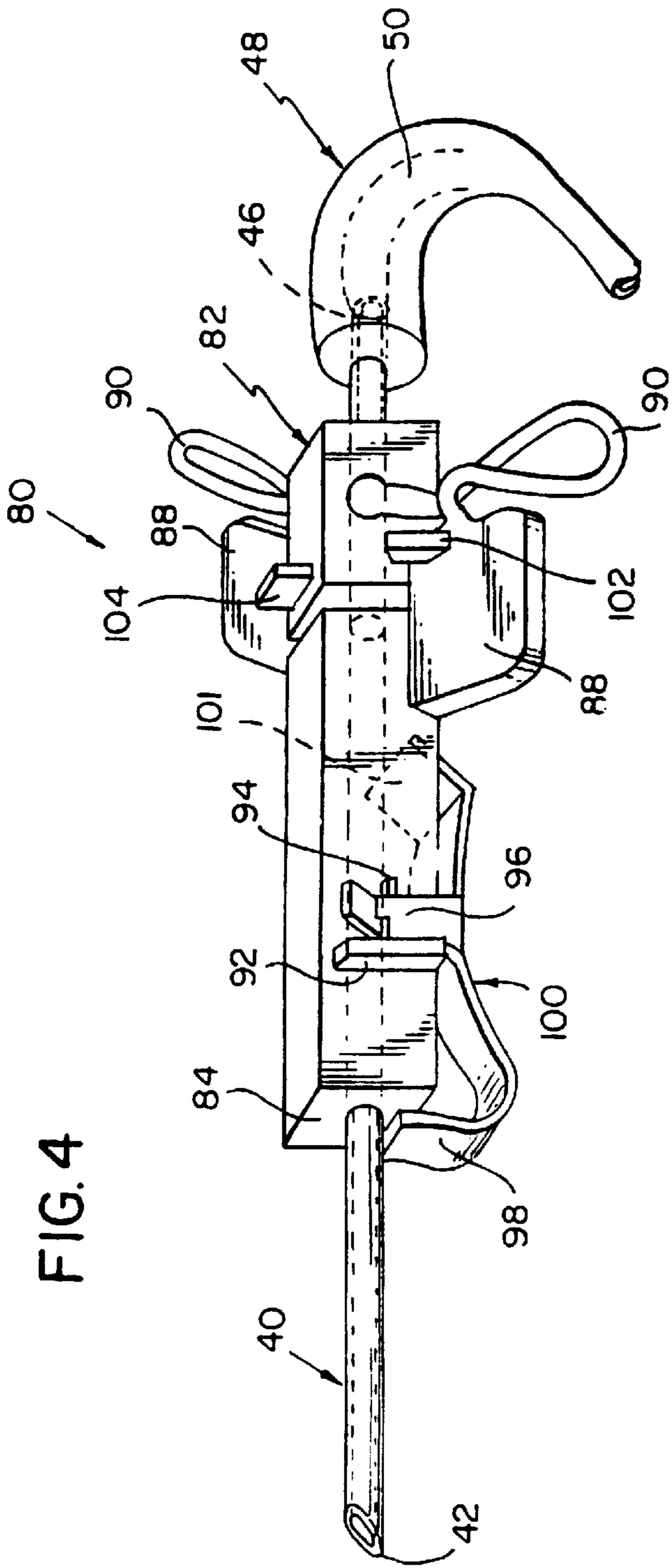


FIG. 4

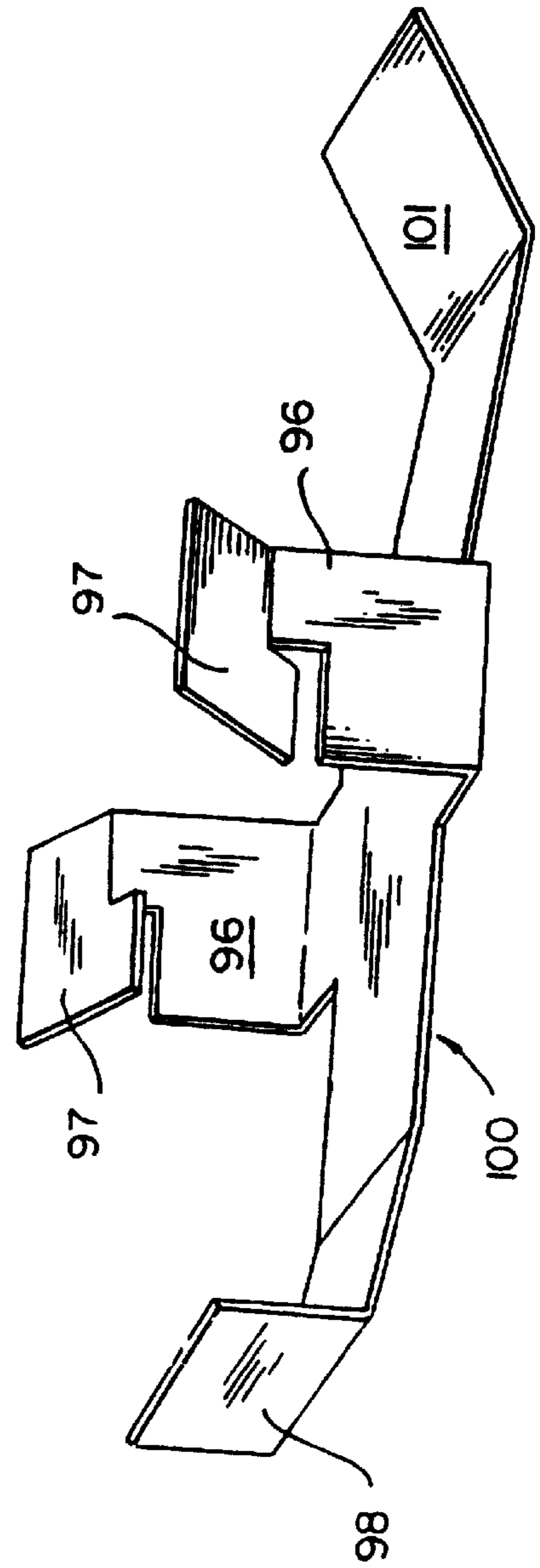


FIG. 7

FIG. 5

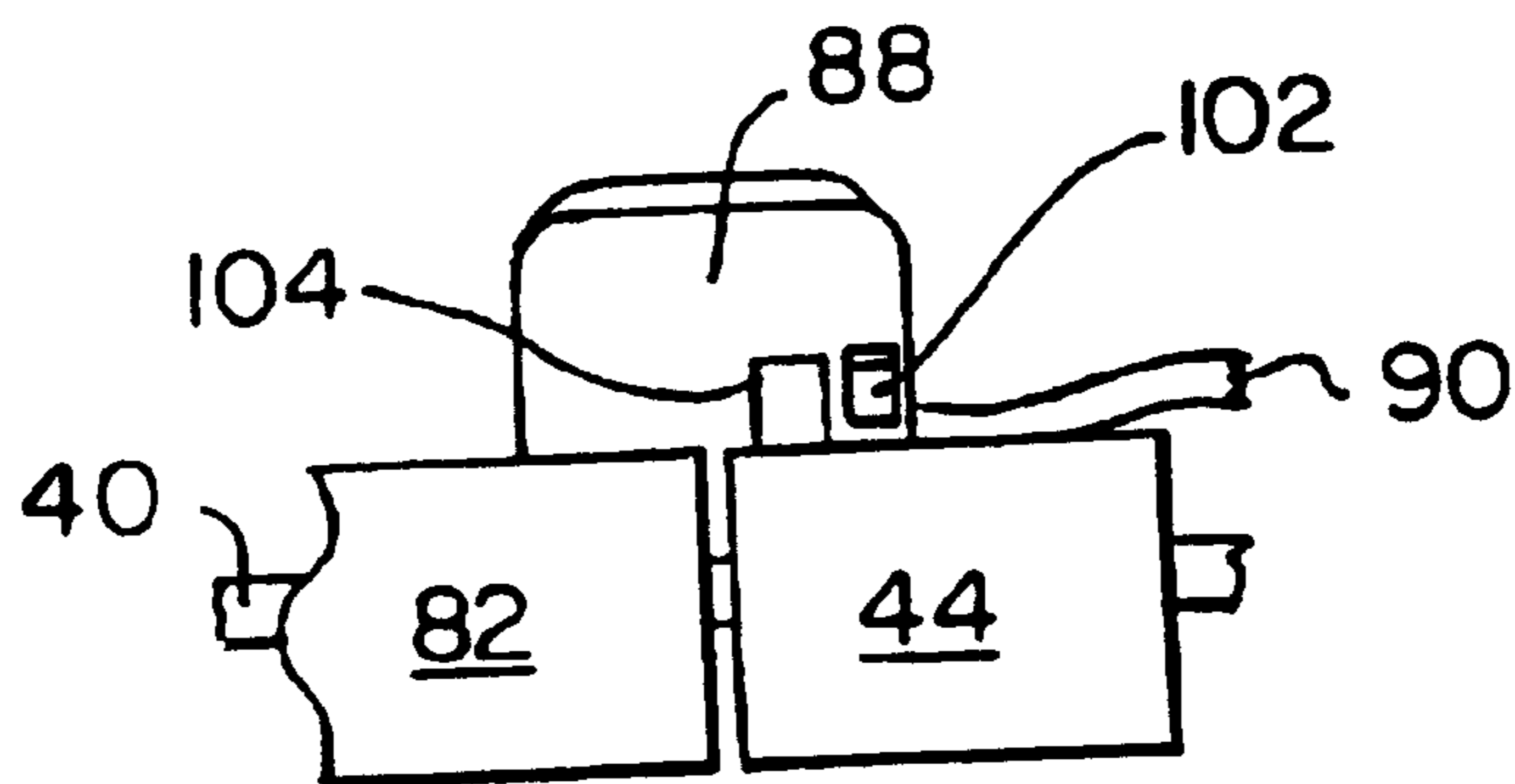
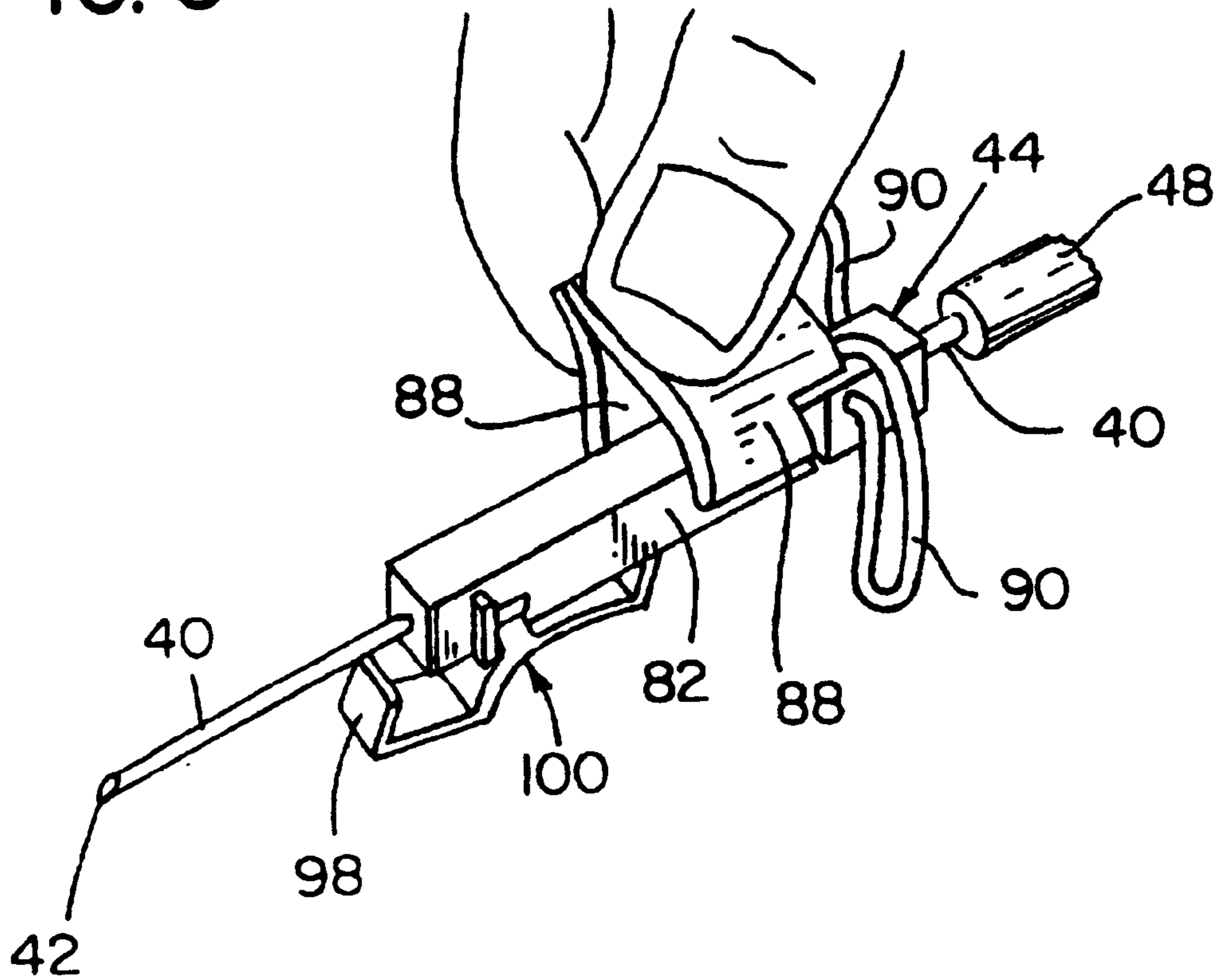


FIG. 5A

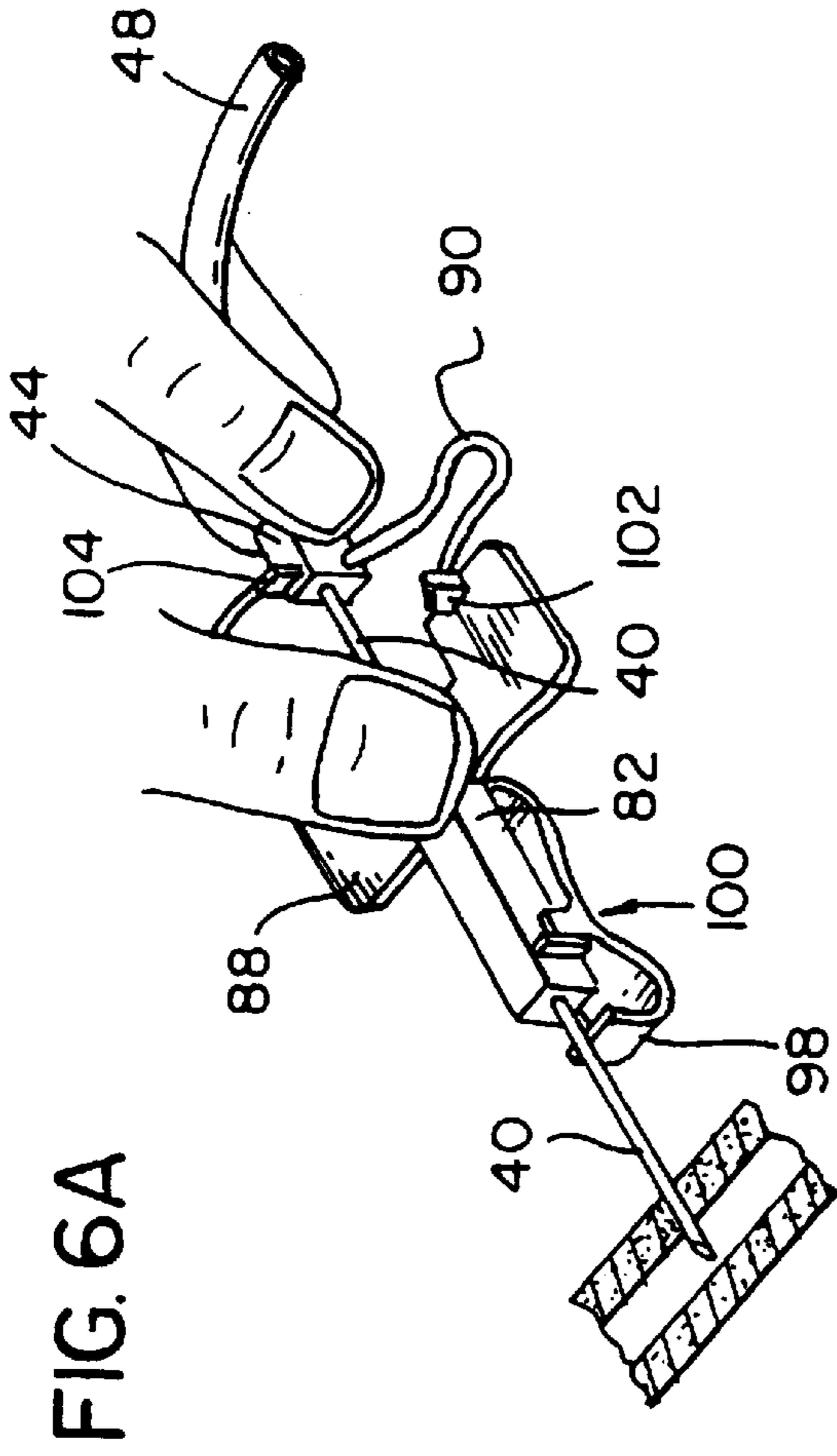


FIG. 6A

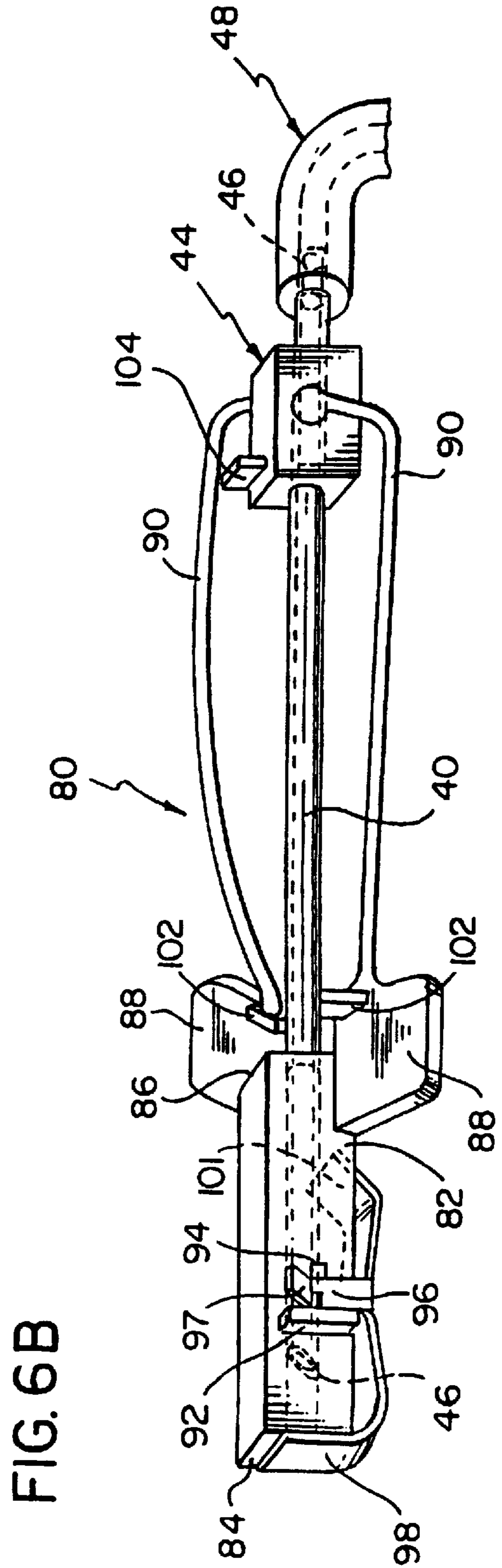


FIG. 6B





FIG. 9A

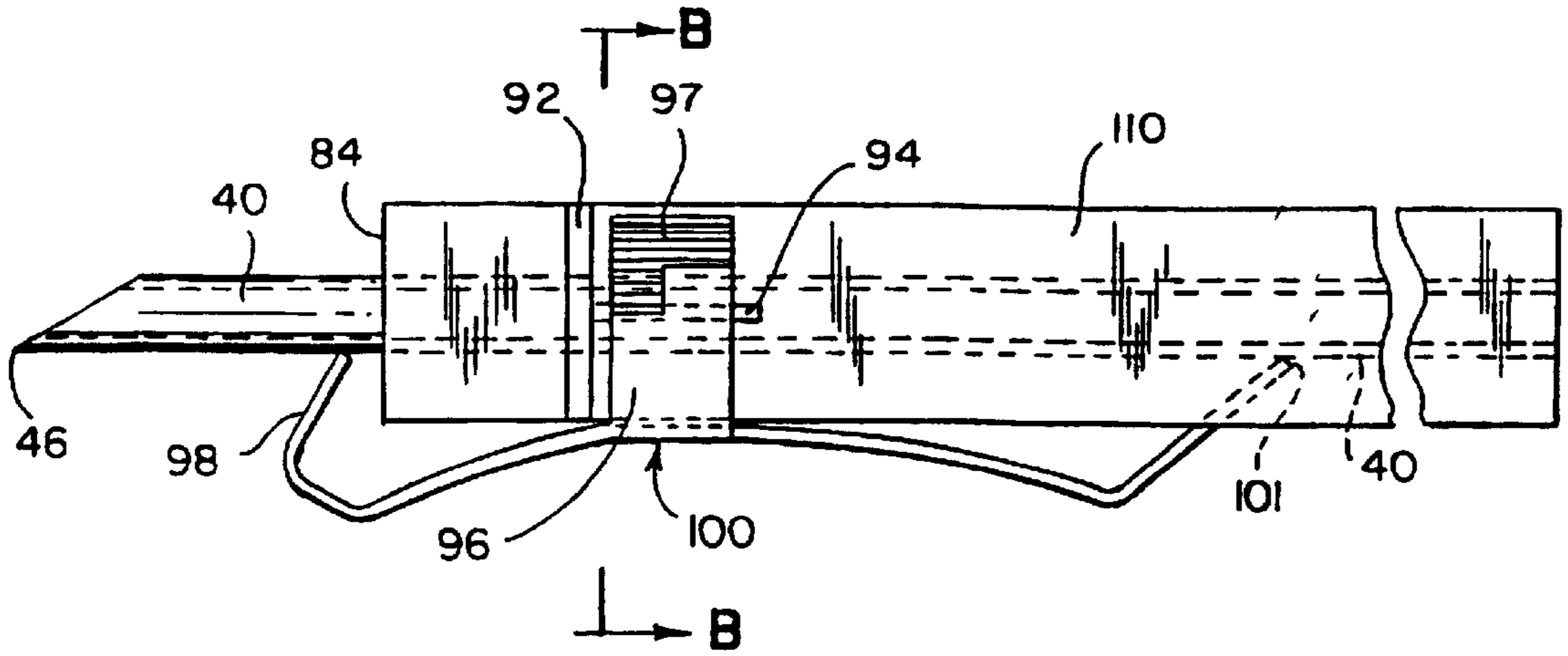


FIG. 9B

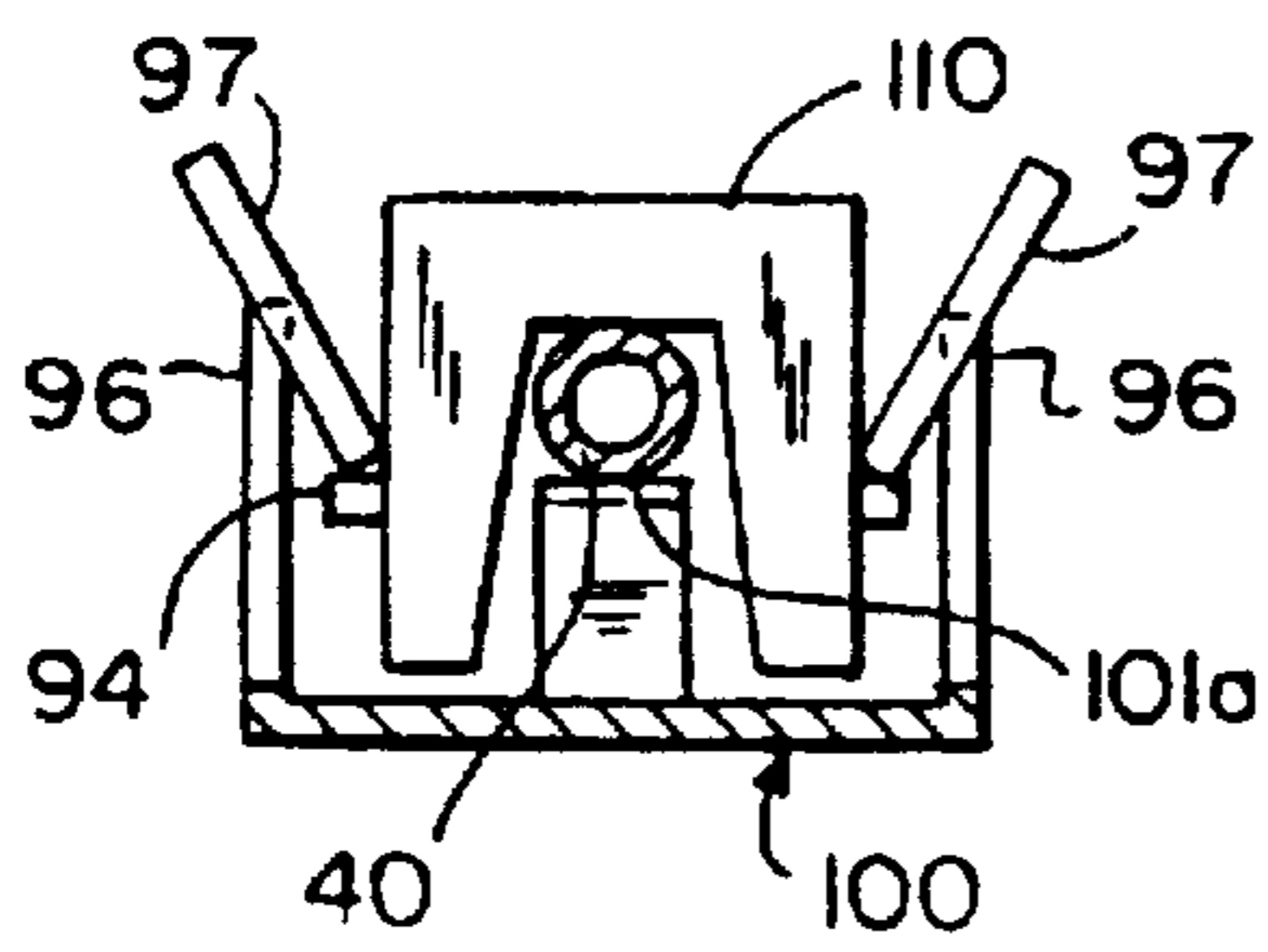


FIG. 9C

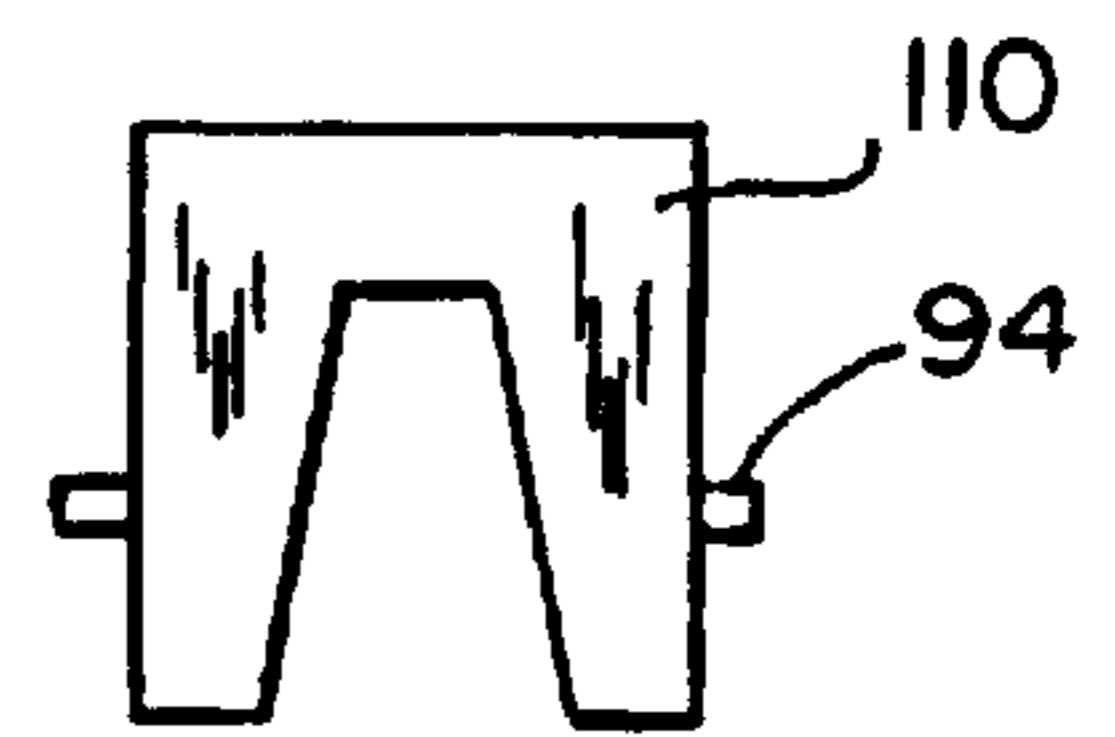
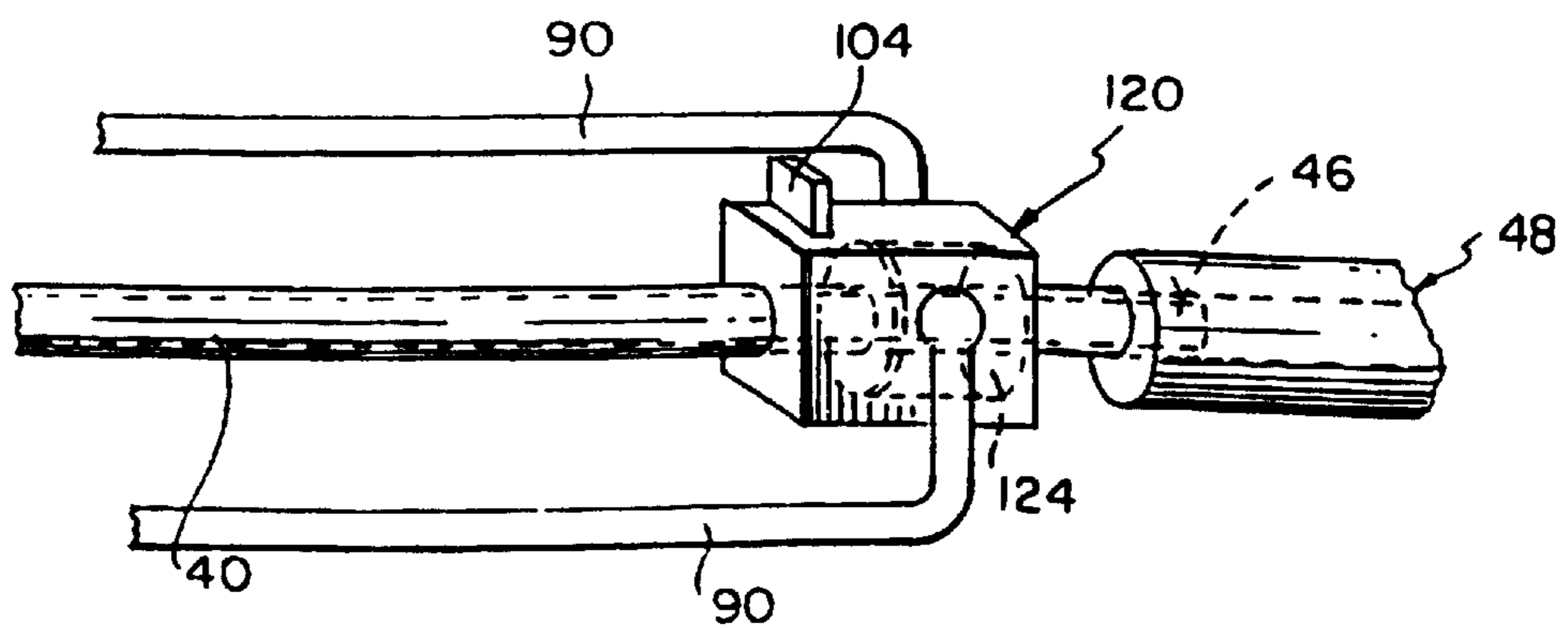
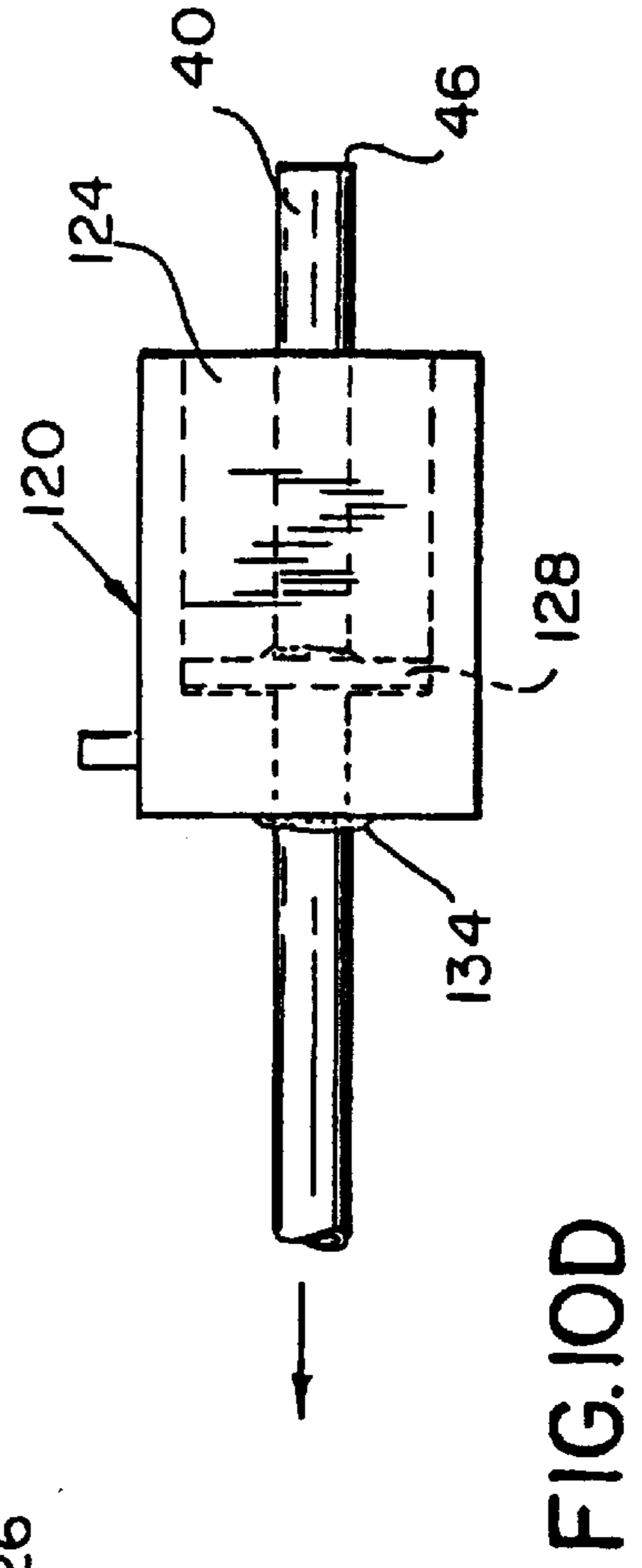
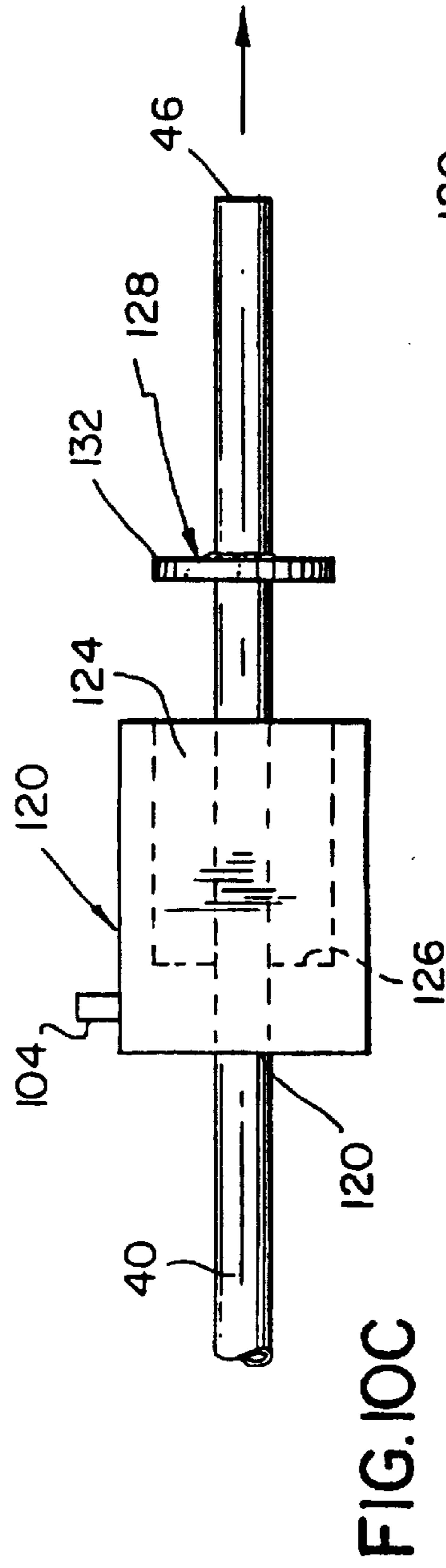
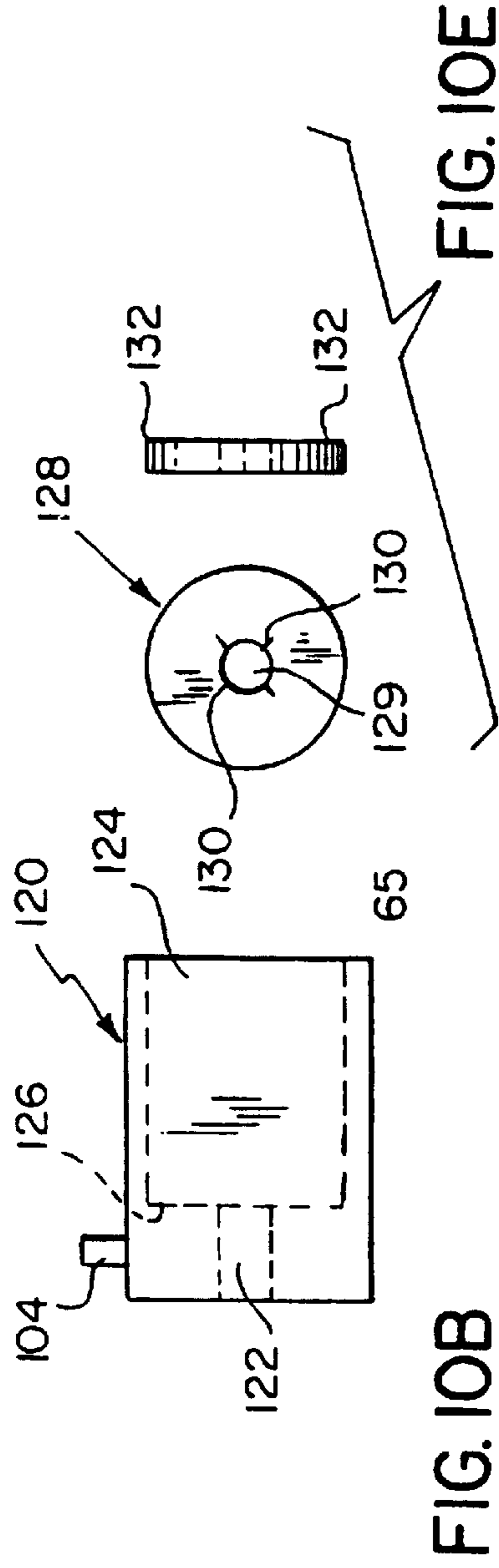


FIG. 10A





**SAFETY NEEDLE SYSTEM ASSURING  
HAZARD-FREE HANDLING AFTER NEEDLE  
CONTAMINATION**

**Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.**

CROSS-REFERENCE TO RELATED  
APPLICATIONS

This is a continuation of Ser. No. 08/398,772 filed Mar. 6, 1995 now abandoned which is a continuation of application Ser. No. 07/972,013, filed Nov. 6, 1992, now U.S. Pat. No. 5,395,347 which is a continuation-in-part of our application Ser. No. 07/610,583 filed Nov. 8, 1990, now U.S. Pat. No. 5,176,655 and is also a continuation-in-part of our pending application PCT/US91/08063 filed Nov. 6, 1991 under the Patent Cooperation Treaty.

BACKGROUND OF THE INVENTION

At high-volume medical facilities as blood bank centers, hospitals, and the like, blood is drawn from human donors in large quantities for processing and storage. In connection therewith, small volume specimens of the blood are withdrawn from the blood collection apparatus for necessary analysis. Blood withdrawal from humans exposes the medical worker to the risk of accidental needlestick injuries preparatory to connection of blood collection equipment to the donor in the unavoidable handling of used, unshielded, blood-contaminated needles.

In current practice, blood banking services, such as the American Red Cross among others, obtain, process, and store whole blood and blood components for a variety of medical uses such as transfusions and the like. Before any such blood can be used, however, all collected blood is analyzed to characterize its immune properties or so-called "blood type". Equally or more importantly, all blood must also be pre-tested for the presence of communicable disease pathogens, such as the hepatitis virus and the human immunodeficiency virus (HIV). As is well known, HIV is the causative agent of the uniformly fatal AIDS disease in humans, and thereby mandates the safest possible environment when handling human blood.

Blood collection as now commonly practiced utilizes a system including (1) a straight metal needle whose pointed end is inserted into a human donor to access a blood vessel wherein the needle usually includes a gripping portion bonded thereto to facilitate manual manipulation; (2) a length of flexible tubing in fluid communication at one end with the non-pointed proximal end of the needle; and, (3) one or more blood storage bags connected to the other end of the tubing. Additionally, helpful agents such as citrate-phosphate dextrose (CPD) are commonly included as anti-clotting additives within the collection system to prevent coagulation of the blood and permit it to remain in fluid condition.

Accordingly, traditional blood bag collection apparatus is thus a closed, sterile system in which the blood flows from the donor's blood vessel through the tubular metal needle, through the flexible tubing and into the blood storage bag, and in the use thereof for actual blood collection does not present a significant hazard to medical personnel.

As indicated, however, it is necessary to take a small sample of collected blood for analysis to insure the integrity and quality of the bag quantity. Customarily, to obtain the

test sample, the medical or health care worker initially shuts off tubing flow as by a clamp, and then grips the needle with one hand by the enlarged grasping component thereof, removing the needle from the donor. Thereafter, the exposed needle tip, which is now blood-contaminated, is inserted through a rubber stopper or seal into a sample collection test tube, and the clamp is released to permit drawing of a sample of the collected blood reversely through the needle and into the test tube usually held in the other hand.

The open manipulation of the contaminated needle between withdrawal and sample securement presents unwanted hazards to personnel in the possibility of accidental needlestick injury.

Thus, the physical movement of the contaminated needle with one hand toward and in close proximity to the other hand holding the sample collector, there is a significant probability of self-inflicted injury. In effecting the sampling, the needle point may misalign with the rubber seal and puncture the worker's hand. Additionally, upon withdrawal of the inserted needle from the sample vial the frictional resistance of the rubber stopper retarding needle withdrawal suddenly ceases as the needle pulls clear, and there is an involuntary tendency and reflex for the worker's hand holding the needle to recoil back toward the hand holding the test tube.

The actual rates and likelihood of needlestick injuries with such conventional blood collecting equipment have been well documented in a report appearing in the publication TRANSFUSIONS. Vol. 29, No. 8, October, 1989, pages 693-695, entitled "Needlestick Injuries in Blood Collection Staff—A Retrospective Analysis". Attempts to improve the present practice by using a guard mechanism to reduce the chances of accidentally puncturing the healthcare worker's fingers, especially those grasping the sample tube, have reduced but failed to eliminate the rates of such injuries. In one typical Red Cross blood collection center, for example, there are about 10 to 12 needlestick injuries annually out of a total staff of 165 individuals who are in fact using such a prior art guard device.

There is, therefore, a substantial and real need for means to eliminate the needlestick hazard and its actual threat to the health of medical workers in blood collection operations.

Concomitant to the foregoing, ease of fabrication, simplicity of assembly, and reliability of function are prime requisites of devices and equipment in the healthcare arts. To this end, the present invention embraces improved and reliable needle-carrying and manipulating elements, and modes of fabrication and assembly thereof.

SUMMARY OF THE INVENTION

The present invention addresses this problem confronting the healthcare industry and is designed specifically to eliminate needlestick injuries of the type described in connection with blood collection.

To this end, there is provided a new and improved system which (1) shields the blood-contaminated needle simultaneously with its withdrawal from the donor, and (2) uses a separate shielded needle in a blood sample tube holder for the safe drawing of blood samples, whereby the probability of an exposed contaminated point being in any injury-causing proximity to a medical worker is virtually nil, whereby the threat to or even the fear of HIV or other disease by the worker is eliminated.

To this end, a unique and mechanically simple but reliable snap-on needle enclosing guard is provided on a specialized needle device disclosed herein, which is similar in some

respects to the needle safety device as set forth in our  
aforenoted application Ser. No. 07/610,583 now U.S. Pat.  
No. 5,176,655. Thereby, upon withdrawal of the needle from  
the blood donor, the needle is immediately retracted within  
the guard and a shield positively blocks the contaminated  
needle point and access thereto. Two different forms of the  
needle assembly are provided and which have differing  
fabrication and use advantages.

Obviously, such protection precludes use of the same  
needle for the aforementioned separate sampling purposes.  
The invention, therefore, further embraces means to effect  
the necessary sampling without the use of a contaminated  
needle and without concomitant needlestick exposure of the  
worker.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood in reference to the  
accompanying drawings in which:

FIG. 1 is a diagrammatic illustration of prior art presently  
practiced blood collection technique and equipment;

FIG. 2 is an illustration of prior art sample collection in  
a test tube;

FIG. 3 is an overall perspective view of the blood col-  
lection system of the invention;

FIG. 4 is similar to FIG. 3 showing the apparatus with  
advance of the needle for insertion into the donor;

FIG. 5 is an illustration of the gripping means of the  
apparatus for needle insertion;

FIG. 5A is a fragmentary side elevation of the device as  
seen in FIG. 5;

FIG. 6A is an illustration of the system at commencement  
of needle withdrawal from the donor;

FIG. 6B illustrates full withdrawal of the needle and  
enclosure thereof with in the guard and protection of the  
needle point by the shield;

FIG. 7 is a perspective view of the shield spring member;

FIG. 8A is a view of the end of the guard with the needle  
extended therefrom but with the shield removed for clarity;

FIG. 8B is an enlarged side elevation similar to FIG. 8A  
but with the shield in initial position;

FIG. 8C is a view taken on the line C—C of FIG. 8B;

FIG. 8D is a fragmentary view similar to FIG. 8B but with  
the needle retracted and shielded;

FIG. 9A is a view similar to FIG. 8B illustrating a  
modified needle carrier and guard;

FIG. 9B is a view taken on the line C—C of FIG. 9A;

FIG. 9C is a section view similar to FIG. 9B but with the  
shield and needle removed;

FIG. 10A is a view similar to FIG. 6B but showing a  
modified form of gripping portion for the needle.

FIG. 10B is a side view of the modified gripping member,  
internal portions being shown in phantom;

FIG. 10C is a parital assembly view of a needle and its  
securing disc with the modified gripping member;

FIG. 10D is an assembled view of the parts of FIG. 10C;  
and,

FIG. 10E are front and side views of the needle securing  
disc.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, there is generally indicated in  
FIGS. 1 and 2 a typical widely used blood collection and

blood banking system which in use presents the aforemen-  
tioned safety and needlestick hazards. Thus, a hollow metal  
cannula needle 10 having a tapered point 12 has a finger-  
grippable enlarged annulus 14 secured to a proximal needle  
portion to facilitate handling and maneuvering of the needle  
in the collection and sampling process.

The donor's skin is punctured by the point 12 and the  
same is the positioned in a blood vessel. The proximal end  
16 of the needle is bonded, clamped, or otherwise secured in  
known manner to flexible tubing 18, the opposite end of  
which communicates with a blood collection bag 20,  
whereby the needle, tubing, and bag form a closed passage-  
way for the flow of blood. Clamp means 22 of known form  
is provided along tubing 18 to regulate or shut off blood flow  
as may be required from time to time during collection or  
thereafter.

There is also provided a standard blood specimen tube 24  
having a usual rubber seal stopper 26. Such sealed tubes are  
conventionally provided on manufacture with a partial  
vacuum in its internal chamber 28 to facilitate the drawing  
of blood thereinto. Such specimen tubes 24 are routinely  
used for taking small volume blood samples for analysis  
from donor blood obtained for blood bank processing and  
storage purposes.

The current practice of obtaining the blood samples  
entails a procedure which is in fact hazardous to health care  
workers. After the desired quantity of blood is collected  
from the donor into bag 20, clamp 22 is used to shut off flow.  
The fingers 30 of one hand of the worker grasp enlarged  
collar 14 and remove needle 10 from the donor and move the  
now-contaminated needle point 12 through space to aim and  
position the point 12 to puncture stopper seal 26 of the  
specimen tube 24, the latter being held by fingers 32 of the  
other hand of the worker, as seen in FIG. 2. The clamp 22  
is released, and a small quantity of blood is drawn in reverse  
flow from the tubing 18 into the partially evacuated chamber  
28 in specimen tube 24.

Apart from other real possibilities of mishandling the  
contaminated needle tip 12 during donor withdrawal and  
holding the same openly as the specimen tube is manually  
positioned, it is principally the manipulation of needle 10 for  
alignment and entry into specimen test tube 24 that consti-  
tutes a significant danger of accidental needlestick injury to  
the health care worker. In necessarily moving a blood-  
contaminated needle in one hand directly toward the other  
hand holding the tube, and with sufficient moving force to  
penetrate the stopper 26, the danger of self-inflicted injury  
increases substantially. Thus, the needle point 12 may miss  
the small-diameter stopper entirely and puncture the fingers  
32. Alternatively, the needle point may be improperly posi-  
tioned at an angle, on the stopper 26 and with stopper-  
puncturing force applied the needle may slip laterally from  
the stopper and puncture the worker's hand. These possi-  
bilities are entirely apart from other imperfections of the  
worker as relatively poor eyesight, nervousness, and the  
like.

Additionally, as earlier noted, there exists the threat of  
injury in retracting the needle from the vial stopper 26 from  
a recoil-like motion immediately after the needle 10 is  
pulled out of stopper 26 and the previously existing fric-  
tional resistance of the rubber to needle withdrawal suddenly  
ceases. As the blood-contaminated needle then starts to "fly"  
rearwardly on leaving the stopper, there is a frequent  
immediate reflex by the worker to stop the rearward motion  
and abruptly move the needle again toward the fingers 32  
holding the specimen tube with risk of scratching these  
fingers with the needle.

The se difficulties are obviated by the apparatus and system of FIGS. 3-9. Thus, therein, the blood-contaminated needle is shielded simultaneously with its withdrawal from the donor whereby no inadvertent puncture can occur, and a separate shielded needle in a blood sample tube holder is used for safe drawing of the blood sample.

One form of the invention is seen in FIG. 3 wherein needle cannula 40, somewhat similarly to needle 10 in FIG. 1, includes the usual needle point 42 and further includes a special gripping portion or base member 44 bonded there-around near the needle proximal end 46, which latter is secured in usual manner to the flexible blood collection tubing 48 having its internal flow passage 50. Tubing 48 terminates into one branch end 51 of a Y-connector 52 of well-known form, while a length of tubing 54 extends from the other end 56 of the Y-fitting 52 to communicate with blood bag 58. Well-known flow control adjustable clamps 70, 70 are provided along the length of tubing 48 and 54.

The Y-fitting includes a second branch 60 providing a sampling port 62 communicating with the tubing 48. The port 62 is a conventional medical industry fitting, commonly known as a Luer female fitting. The port 62 is adapted to cooperate with a standard blood collection tube holder 64 having a standard multiple sample blood collection needle 68 with a rubber sleeve 72 associated with a male Luer fitting 74, which latter forms a dripless collection with female port 62. Prior to sample collection into tube holder 64, the fitting 74 is inserted into the port 62 to prevent drippage until the collection tube is inserted into holder 64 in known manner to open access to needle 68.

The safety and guard assembly 80 in FIGS. 3 and 4 carrying needle 40 in overall respects is in accordance with that disclosed and claimed in U.S. Pat. No. 5,176,655. The same includes a needle shielding or guide body 82 having an opening shown as a bore extending from port means in its front surface or distal end 84 to proximal end 86 within which needle 40 is slidably received. While the body 82 is shown for illustrative purposes as being of square or rectangular cross-section, the particular configuration may vary within the limits of the required structure and function thereof. Similarly, the assembly may readily be fabricated as by molding from plastic, such as polyethylene, polyvinyl chloride, or the like.

The rear portion of front guide 82 may be provided with laterally extending flexible winglike members 88, and flexible restraints or tethers 90 extending from wings 88 interconnect the guide 82 and the base section 44 which is bonded to needle 40. In the absence of wings 88, the tethers 90 may be connected directly to the body 82. The wings 88 also include respective upstanding lugs 102, 102 outwardly from the guide body 82 for cooperation in use with an upstanding lug 104 on base section 44, as described further hereinafter.

Preferably, needle guide body 82 is provided on either side thereof with a series of laterally extending projections or lug members 92 and 94 for cooperative abutment with gripping legs 96 of a specially configured leaf spring 100. Obviously, the spring legs 96 could cooperate with other forms of abutments than flange-like projections, as recesses in the guide body 82, for example.

The spring 100 forms an essential element of the safety needle assembly. Thus, as shown in FIG. 3, the spring includes an inturned imperforate blocking flange 98 at its forward end, which rests upon and is biased transversely against needle 40 when the needle is extended for use as shown. As seen in FIG. 3, the needle 40 is so positioned

relative to the imperforate flange 98 that the flange 98 bears against the needle on the side area thereof corresponding to the maximum length of the needle at the pointed tip 42 of the conventionally tapered or bevelled needle. The proximal end 101 of spring 100 is also angled and stressed against the guide body 82, the spring being maintained in position by the inwardly angled portions 97 of legs 96 bearing against projections 94.

Uniquely, the one-piece spring 100 facilitates assembly of the unit, as the gripping legs 97 thereof readily snap past the body projections 94, and positively hold the spring on the body with no chance or accidental removal. The assembly is thus a one-step process minimizing cost with no sacrifice of safety or reliability. As above noted, the projections 94 may be replaced by molded indentations in the body 82 with equally effective results. The forward or vertical projections 92 preclude any likelihood that the spring could slide forwardly on the body to expose excessively the needle, while the safety flange obviously precludes rearward movement of the spring.

Accordingly, the needle assembly 80 comprises the needle 40, the body 82 slidably carrying the needle, the flexible tethers 90, the rearmost base section 44 bonded to the needle, and the spring 100.

In use, and as set forth in applicants, U.S. Pat. No. 5,176,655, during preparation for needle insertion through the skin of the blood donor, the assembly 80 is as shown in FIG. 4 with the wings 88 initially flexed sufficiently downwardly to permit base section 44 to closely approach or abut the forward needle guide body 82 from the former position of FIG. 3. Thereupon, the wings 88 are flexed upwardly and gripped as seen in FIG. 5. In so doing, the wing lugs 102 are repositioned to be disposed immediately rearwardly of the base member lug 104 as best seen in FIG. 5a. Thereupon, with forward movement by the fingers gripping wings 88, base member will move forwardly therewith to insert the needle point into the donor.

While the foregoing is a positive and unitary handling of the assembly 80 during needle insertion, under particular conditions with a donor or patient, the medical technician may leave the wings down and separately manipulate the base member 44 and the needle carried thereby to insert the needle without concomitant interlocked or interengaged lugs 102, 104.

As similarly taught in U.S. Pat. No. 5,176,655 safe needle withdrawal from the donor's (or patient's) blood vessel is effected by holding the needle shielding body 82 stationary adjacent the needle skin entry point and with wings 88 relaxed to remove lugs 102 outwardly from behind lug 104. Thereupon, as shown in FIG. 6A, the base section 44 (or the tubing 48 thereat) is pulled in a proximal direction while needle guide body 82 is stationary thereby causing needle 40 to slide rearwardly in the proximal direction through the guideway therefor in body 82.

Thus, with the construction described, immediately as the needlepoint 42 passes rearwardly of the distal end of spring 100, the spring relaxes and snaps the angled face 98 thereof transversely of the guide body forward face 84 and securely encloses the needlepoint within guide body 82 as seen in FIG. 6D. It should be borne in mind that as compared to the drawing illustrations, the actual device of the invention is quite small and the needlepoint is absolutely without capability of exposure and contact with medical or donor personnel once retracted and blocked, whereby needlestick injury is positively prevented in a simple and effective manner.

More particularly, and this is an outstanding safety feature of the invention, with the blocking flange face **98** immediately adjacent the forward surface of the body at **84**, as soon as the needle passes behind the flange **98**, the spring snaps the flange forward surface over the **84** of the body into needle-blocking position and positively precludes reemergence of the contaminated needle point from the body **82** and thus needlestick injury is absolutely avoided. While the needle may be withdrawn further into the body **82**, such extra movement is unnecessary as the safety spring acts on and over the end face **84** of the body at the immediate point of potential emergence of the contaminated needle. The fully withdrawn and safety-shielded needle is shown in FIG. 6B, for example.

This contrasts with other attempts to reduce injury wherein the needle must be withdrawn at least a minimum predetermined distance beyond the exit from the tubular body. With such equipment, a visual perusal indicates that the needle is not exposed, and therefore may be considered to be safe. In fact, if the needle is not retracted sufficiently inwardly from the exit aperture, it is still able to be accidentally projected to cause hazard and is not securely in a safe position immediately upon its retraction inside the carrying body, with no further retraction being required. Such devices are known in the prior art.

A modified body **110** for receiving the needle is shown in FIGS. 9A–C in lieu of the body **82**. The same is not provided with a tubular bore as in FIG. 3, but with an open-sided U- or V-configuration, as well seen in FIG. 9B. In so doing, the spring **100** has a modified rear tang **101a** dimensioned to fit within the body **110** and bear against the needle **40** therein. Along with the forward safety shield **98** of the spring, the needle is held firmly in the body, and upon snap operation of shield **98** as heretofore, the needle is made safe being blocked at its proximal end, gripped at **101a**, and overlaid by the body generally of the spring, whereby access cannot be had to the needle point. In other respects the elements of the assembly **80** are essentially the same. It will be evident that the U-shaped body facilitates ready assembly of the needle system.

FIGS. 10A–10E illustrate a modified form of gripping member and a simplified assembly technique for associating the needle **40** therewith. Thus, the modified gripping element **120** is similar to that at **44** in FIG. 3 in being of polymeric material and generally of cylindrical or polygonal external configuration and includes a similar upstanding wing-engaging flange **104**. Internally thereof, however, instead of a simple through bore as in FIG. 3 for receiving and bonding as by cement to the needle **40**, only a short needle-diameter bore portion **122** is provided in the distal end thereof, the member **120** being countersunk therebehind to an enlarged diameter chamber **124** having an internal front wall **126**.

Cooperating therewith is needle-gripping and securing disc **128** having a diameter substantially that of chamber **124**, and having a hole or aperture **129** therethrough bounded by short radial cuts **130**. Hole **129** is of a diameter slightly less than that of the needle **40** whereby the cuts **130** permit slight flexing of the disc as the needle is inserted therethrough in a snug mechanical interference fit.

Additionally, disc **128**, which is preferably fabricated from thin flexible metal, is provided at its periphery with a plurality of rearwardly directed barbs or tangs **132**. Accordingly, the disc is assembled with gripping member **120** by axially advancing the disc into chamber **124** against front wall **126**, and is locked therein by the presence of the

barbs **132** whereby the disc cannot be removed and the needle is securely positioned. Further, a liquid bonding agent is applied about the needle at **134** (FIG. 10D) at its exit from member **120**, thereby sealing the needle to the base gripping member **120**.

In this manner the needle is reliably secured to the member **120** both by the mechanical-interaction of the disc **128** with base **120** and also by the bonding material **134**.

Accordingly, in summary, it will be seen that in use with cannula **40** inserted into the patient, blood is collected into bag **58** as desired, and then the clamp **70** is shut and the needle **68** opened onto a collection tube for desired sampling without removal of the needle **40** from the patient. As many samples may be taken as desired with manipulation of the ramps **70**, **70** prior to retraction and immediate safetying of the needle **40** without reuse thereof or hazard therefrom. The healthcare worker at no time has to manipulate an unshielded blood-contaminated needle whether collecting blood or taking samples for analysis.

The assembly of the present invention lends itself to ready fabrication, as is evident from the foregoing. Thus, the body **82**, gripping portion **44**, tethers **90** and wings **88** if used may be simultaneously molded, as by injection molding, of polymeric material, as polyvinyl chloride. The unit assembly may then have the needle **40** appropriately positioned in the body **82** and the gripping portion **44** for bonding of the distal needle portion to member **44**. If the modified U-body **110** of FIG. 9 is employed, the needle need not necessarily be propositioned therein, but all elements other than member **44** can be flexed to one side while the needle is fixed to **44**. In either case, thereafter the spring **100** is snap-fitted onto the body, and the assembly is complete and ready to use. The same advantages in assembly accrue with the needle securement technique of FIGS. 10 A–D, as above discussed.

While we have disclosed our invention in preferred embodiments, it is evident that the concepts and techniques thereof may be employed in differing arrangements, such as indwelling needles, tubing, biological fluid reservoir, drainage systems for pleural fluid drainage, and the like, within the scope of the invention as defined in the appended claims.

What we claim is:

1. A safety needle system comprising:

- a needle having a proximal portion and a distal portion terminating in a pointed end,
- a needle-carrying body having means for receiving the needle for sliding movement therein and, said body having a front surface having port means through which the needle distal portion is initially extended for use outwardly of said front surface, and retracted rearwardly after use in a direction through said port means into said body with said needle pointed end no longer extending through said body front surface, and, movable safety means cooperatively associated with said needle and fixedly mounted on said body against axial movement with respect thereto and for blocking immediately and positively reemergence of said needle distal portion through said body front surface upon retraction of the pointed end of said needle in said rearward direction through said port means to a position no longer extending through said body front surface, thereby retaining said needle pointed end within said body with no portion thereof extending or projecting outwardly from said body through said front surface, said safety means including

- (1) imperforate blocking flange means disposed exteriorly of said body adjacent said body front surface, and,

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(2) spring means for bodily moving said flange means in a needle-blocking direction transversely of said body into adjacent and overlying relation to said port means on said body front surface upon retraction of said needle into said body,

whereby a used needle cannot have its pointed end or adjacent distal portion re-exposed for hazard and injury after initial retraction thereof into said body.

2. The safety needle system of claim 1 wherein said flange means is in spring-urged lateral engagement with said needle distal portion when said needle is in initial extended relation through said port means.

3. The safety needle system of claim 1 further including means for limiting bodily movement of said blocking flange means by said spring means in said needle blocking direction to at all times maintain said flange means in said adjacent and overlying blocking relation to said port means on said body front surface when said needle is retracted.

4. The safety needle system of claim 3 wherein said spring means is disposed on one side of said body front surface, and wherein said flange means has no portion thereof extending beyond said body front surface on any other side thereof, thereby to preclude any possible movement of said flange means in a direction unblocking said port means against the force of said spring means.

5. The safety needle system of claim 4 wherein said blocking flange means overlying said body front surface when the needle is retracted terminates in an edge spaced inwardly from all sides of said body front surface.

6. The safety needle system of claim 4 wherein said spring means is disposed entirely exteriorly of said body in exposed, relation thereby to facilitate assembly and inspection thereof to insure proper operation.

7. The safety needle system of claim 4 wherein said spring means is a leaf spring fixedly secured to said body and wherein said blocking flange means thereof is a short, integral, and substantially planar portion of said leaf spring.

8. The safety needle system of claim 7 wherein said blocking flange means merges into an intermediate leaf spring portion disposed on one side of said body, said intermediate spring portion being disposed in spaced stressed relationship to said body when said blocking flange means is in lateral engagement with said needle initially extending through said port means.

9. The safety needle system of claim 8 wherein said leaf spring includes gripping flange means latchingly engaged with said body to securely mount said spring thereon.

10. The safety needle system of claim 9 wherein said gripping flange means include spring legs extending along opposite sides of said body, and said body has lug members respectively engaged with said spring legs.

11. The safety needle system of claim 10 wherein said body lug members include a pair of stop lugs adjacent said spring legs and between said legs and said front surface, thereby to preclude any forward movement of said legs and said leaf spring which would cause said blocking flange to become spaced forwardly of said body front surface.

12. A safety needle system comprising:

a needle having a proximal end and a distal portion terminating in a pointed end,

a needle-carrying body having a bore for receiving the needle for sliding movement therein and, said body having a front surface having a port through which the needle distal portion is initially extended for use outwardly of said front surface, and retracted rearwardly after use in a direction through said port into said body with said needle pointed end no longer extending through said body front surface, and,

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a movable safety flange cooperatively associated with said needle and said body for blocking immediately and positively reemergence of said needle distal portion through said body front surface upon retraction of the pointed end of said needle in said rearward direction through said port to a position no longer extending through said body front surface, thereby retaining said needle pointed end within said body with no portion thereof extending or projecting outwardly from said body through said front surface,

said safety flange including

(1) an imperforate blocking portion disposed exteriorly of said body adjacent said body front surface,

(2) a spring for bodily moving said blocking portion in a needle-blocking direction transversely of said body and into adjacent and overlying relation to said port on said body front surface upon retraction of said needle into said body, and,

(3) a mount for said spring fixedly secured to said body to preclude axial movement of said spring,

whereby a used needle cannot have its pointed end or adjacent distal portion re-exposed for hazard and injury after initial retraction thereof into said body.

13. A method of immediately and positively precluding needlestick injury from a contaminated needle comprising the steps of:

providing an elongated needle having a pointed end,

providing a body slidably receiving the needle and having a front surface through which the needle extends for use and is retracted into the body after use,

providing a spring having an imperforate blocking flange portion, and,

affixing said spring to the body so as to preclude axial movement of said spring and to dispose the flange portion in adjacent relation to the body front surface and in spring-urged relation against the needle extending from the body when the needle is in use,

whereby when the needle is retracted after use to bring its pointed end flush with the body front surface, the imperforate blocking flange is spring urged over the body front surface past the needle point thereby to block any reemergence of the needle from the body.

14. A safety needle system comprising:

a needle having a proximal portion and a distal portion terminating in a pointed end,

a needle-shielding body having means for receiving the needle for sliding movement therein and, said body having a forward surface having a port through which the needle distal portion is initially extended for use outwardly of said forward surface, and retracted rearwardly after use through said port into said body with said needle pointed end no longer extending through said body forward surface, and,

a movable safety device cooperatively associated with said needle and fixedly mounted on said body against axial movement with respect thereto and for blocking immediately and positively substantial reemergence of said needle distal portion through said body forward surface upon retraction of the pointed end of said needle in said rearward direction toward and then past said safety device and through said port to a position no longer extending through said body forward surface, thereby retaining said needle pointed end within said body with no portion thereof extending or projecting outwardly from said body through said forward surface and past said safety device,

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said safety device including

(1) an imperforate blocking flange disposed exteriorly of said body forward surface, and,

(2) a spring for bodily moving said flange in a needle-blocking direction transversely of said body into adjacent and overlying relation to said port on said body forward surface upon retraction of said needle past and behind said flange and toward and into said body,

whereby a used needle cannot have its pointed end or adjacent distal portion re-exposed through said port past said flange for hazard and injury after initial retraction of said needle past said flange and toward said body.

**15.** The safety needle system of claim **14** wherein said blocking flange is spring urged to bear against the needle prior to retraction of the needle.

**16.** The safety needle system of claim **15** wherein the needle pointed end is transversely tapered to a distal point, and wherein said blocking flange bears against said needle on the same side area thereof as the needle distal point.

**17.** A safety needle system comprising:

a needle having a proximal portion and a distal portion terminating in a pointed end adjacent a bevelled end of the needle,

a needle-shielding body having means for receiving the needle for sliding movement therein and, said body having a forward surface having a port through which the needle distal portion is initially extended for use outwardly of said forward surface, and retracted rearwardly after use through said port into said body with said needle pointed end no longer extending through said body forward surface, and,

a movable safety device cooperatively associated with said needle and fixedly mounted on said body against axial movement with respect thereto and for blocking immediately and positively substantial reemergence of said needle distal portion through said body forward surface upon retraction of the pointed end of said needle in said rearward direction toward and then past said safety device and through said port to a position no longer extending through said body forward surface, thereby retaining said needle pointed end within said body with no portion thereof extending or projecting outwardly from said body through said forward surface and past said safety device,

said safety device including

(1) a blocking flange disposed exteriorly of said body forward surface and having an edge thereof engaging said needle when said needle extends forwardly from said body, and,

(2) a spring for bodily moving said flange in a needle-blocking direction transversely of said body into adjacent and overlying relation to said port on said body forward surface upon retraction of said needle past and behind said flange and into said body, wherein said flange has no portion thereof having an aperture or is otherwise relieved such that any portion of the said needle would be able to extend therethrough,

whereby a used needle cannot have its pointed end or adjacent distal portion re-exposed through said port and past said flange for hazard and injury after initial retraction of said needle behind said flange and toward said body.

**18.** A safety needle system comprising:

a needle having a proximal portion and a distal portion terminating in a pointed end,

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a needle-shielding body having a bore for receiving the needle for sliding movement therein,

said body having a forward surface provided with a port through which (a) the needle distal portion is initially extended for use outwardly of said forward surface, and (b) the needle is retracted rearwardly after use into said body with said needle pointed end no longer extending substantially through said body [a movable safety] *forward surface in a position for use*, and,

a movable safety member cooperatively associated with said needle and said body for blocking immediately and positively reemergence of said needle distal portion through said body forward surface upon retraction of the pointed end of said needle in said rearward direction past said safety member and toward said port, thereby retaining said needle pointed end within said body with no portion thereof extending or projecting outwardly for use from said body through said forward surface thereof and past said safety member,

said safety member including

(1) an imperforate blocking portion disposed exteriorly of said body adjacent said body forward surface,

(2) a spring for bodily moving said blocking portion in a needle-blocking direction transversely of said body and into adjacent and overlying relation to said port on said body forward surface upon retraction of said needle into said body, and,

(3) means for fixedly securing said safety member to said body to preclude axial movement of said safety member on said body,

whereby a used needle cannot have its pointed end or adjacent distal portion re-exposed for hazard and injury after initial retraction thereof past said safety member toward said body.

**19.** A method of immediately and positively precluding needlestick injury from a contaminated needle comprising the steps of:

providing an elongated needle having a pointed end, providing a body slidably receiving the needle and having a forward surface through which the needle extends from the body for use and is retracted toward and into the body after use,

providing a spring having an imperforate blocking flange, and,

affixing said spring to the body so as to preclude axial movement of said spring with respect to the body and to dispose the flange in adjacent relation to the body forward surface and in spring-urged relation to bear against the needle extending from the body when the needle is in use,

whereby when the needle is retracted after use to bring its pointed end into immediate proximity to the body forward surface, the imperforate blocking flange is spring urged over the body forward surface past the needle pointed end thereby to block any reemergence of the needle from the body and past the flange to present a needlestick hazard.

**20.** The method of claim **19** including the further step of providing the flange with peripheral dimensions relative to the body forward surface such that after the flange is spring urged to blocking position, no free edge of the flange is exposed laterally outwardly of the body forward surface to preclude any lateral or rearward movement of the flange by engagement with any free edge thereof.

**21.** A safety needle system comprising:

a needle having a proximal portion and a distal portion terminating in a pointed end,



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a needle-shielding body having a configuration for receiving the needle for axial movement therein and, said body having a forwardly-facing surface having a port through which the needle distal portion is initially extended relative to said body for use outwardly of said forwardly-facing surface, and retracted relative to said body after use through said port into said body with said needle pointed end no longer extending through said body forwardly-facing surface, and,

a movable safety device cooperatively associated with said needle and fixedly mounted on said body against axial movement with respect thereto and for blocking immediately and positively reemergence of said needle distal portion through said port at said body forwardly-facing surface subsequent to relative retraction of the pointed end of said needle toward and then past said safety device and through said port to a position no longer extending through said body forwardly-facing surface, thereby retaining said needle pointed end within said body with no portion thereof extending or projecting outwardly from said body through said port and past said forwardly-facing surface and past said safety device,

said safety device including

- (1) an imperforate blocking flange disposed exteriorly of said body forwardly-facing surface and,
- (2) a spring for bodily moving said flange in a needle-blocking direction transversely of said body into adjacent and overlying relation to said port on said body forwardly-facing surface upon relative movement of said needle distal portion and point past and behind said flange and toward said body,

whereby a used needle cannot have its pointed end or adjacent distal portion re-exposed through said port past said flange for hazard and injury after initial relative movement of said needle past said flange and toward said body.

22. The safety needle system of claim 21 wherein said blocking flange is spring urged to bear against the needle prior to relative movement of the needle toward said body.

23. The safety needle system of claim 22 wherein the needle pointed end is transversely tapered to a distal point, and wherein said blocking flange bears against said needle on the same side area thereof as the needle distal point.

24. A safety needle system comprising:

a needle having a proximal portion and a distal portion terminating in a pointed end adjacent a bevelled end of the needle,

a needle-shielding body having a configuration for receiving the needle for axial movement therein and, said body having a forwardly-facing surface having a port through which the needle distal portion is initially extended relative to said body for use outwardly of said forwardly-facing surface, and retracted relative to said body after use through said port toward said body with said needle pointed end no longer extending through said body forwardly-facing surface, and,

a movable safety device cooperatively associated with said needle and fixedly mounted on said body against axial movement with respect thereto and for blocking immediately and positively reemergence of said needle distal portion through and past said safety device at said body forwardly-facing surface subsequent to relative retraction of the pointed end of said needle with respect to said body toward and then past said safety device and through said port to a position no longer

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extending through said body forwardly-facing surface, thereby retaining said needle pointed end with no portion thereof extending or projecting outwardly from said body through said forwardly-facing surface and past said safety device,

said safety device including

- (1) a blocking flange disposed exteriorly of said body forwardly-facing surface and having an edge thereof engaging said needle when said needle extends forwardly from said body, and
- (2) a spring for bodily moving said flange in a needle-blocking direction transversely of said body into adjacent and overlying relation to said port on said body forwardly-facing surface upon relative movement of said needle distal portion and point past and behind said flange and toward said body, wherein said flange has no portion thereof having an aperture or is otherwise relieved such that any portion of the said needle would be able to extend therethrough,

whereby a used needle cannot have its pointed end or adjacent distal portion re-exposed through said port and past said flange for hazard and injury after initial movement of said needle behind said flange and toward said body.

25. A safety needle system comprising:

a needle having a proximal portion and a distal portion terminating in a pointed end, a needle-shielding body having a bore for receiving the needle for axial movement therein,

said body having a forwardly-facing surface provided with a port through which (a) the needle distal portion is initially extended relative to said body for use outwardly of said forwardly-facing surface, and (b) the needle is retracted relative to said body after use into said body with said needle pointed end no longer extending through said body forwardly-facing surface in a position for use, and,

a movable safety member cooperatively associated with said needle and said body for blocking immediately and positively reemergence of said needle distal portion through said body forwardly-facing surface and past said safety member subsequent to relative retraction of the pointed end of said needle with respect to said body past said safety member and toward said port, thereby retaining said needle pointed end within said body with no portion thereof extending or projecting outwardly for use from said body through said forwardly-facing surface and also past said safety member,

said safety member including

- (1) an imperforate blocking portion disposed exteriorly of said body adjacent said forwardly-facing surface,
- (2) a spring for bodily moving said blocking portion in a needle-blocking direction transversely of said body and into adjacent and overlying relation to said port on said body forwardly-facing surface upon relative movement of said needle toward said body, and,
- (3) a connection for fixedly securing said safety member to said body to preclude axial movement of said safety member on said body,

whereby a used needle cannot have its pointed end or adjacent distal portion re-exposed for hazard and injury after initial movement thereof past said safety member toward said body.

26. The safety needle system of claim 21 wherein said blocking flange has peripheral dimensions relative to the body forwardly-facing surface such that after said flange is

spring urged to blocking position, no free edge of the flange is exposed laterally outwardly of the body forwardly-facing surface, thereby to preclude any lateral or rearward movement of the flange by engagement with any free edge thereof.

27. A method of immediately and positively precluding needlestick injury from a contaminated needle comprising the steps of:

providing an elongated needle having a pointed end,  
 providing a body slidably receiving the needle and having a forwardly-facing surface through which the needle extends from the body for use and is relatively moved toward and into the body after use,

providing a spring having an imperforate blocking flange, and

affixing said spring to the body so as to preclude axial movement of said spring with respect to the body and to dispose the flange in adjacent relation to the body forwardly-facing surface and in spring urged relation to bear against the needle extending from the body when the needle is in use,

whereby when the needle is relatively moved after use to bring its pointed end into proximity to the body forward surface, the imperforate flange is spring urged over the body forwardly-facing surface past the needle pointed end thereby to block any reemergence of the needle from the body and past the flange to present a needlestick hazard.

28. The method of claim 27 including the further step of providing the flange with peripheral dimensions relative to the body forwardly-facing surface such that after the flange is spring urged to blocking position, no free edge of the flange is exposed laterally outwardly of the body forwardly-facing surface, thereby to preclude any lateral or rearward movement of the flange by engagement with any free edge thereof.

29. A safety needle system comprising:

a needle having a proximal portion and a distal portion terminating in a pointed end,

a needle-shielding body having a configuration for receiving the needle for axial movement therein and,

said body having a portion including a forwardly-facing surface having a port through which the needle distal portion is initially extended relative to said body for use outwardly of said forwardly-facing surface, and retracted relative to said body after use through said port into said body with said needle pointed end no longer extending through said body forwardly-facing surface, and,

a movable safety device cooperatively associated with said needle and fixedly mounted on said body portion against axial movement with respect thereto and for blocking immediately and positively reemergence of said needle distal portion through said port at said body portion forwardly-facing surface subsequent to relative retraction of the pointed end of said needle toward and then past said safety device and through said port to a position no longer extending through said body portion forwardly-facing surface, thereby retaining said needle pointed end within said body with no portion thereof extending or projecting outwardly from said body portion through said port and past said safety device, said safety device including

(1) an imperforate blocking flange disposed exteriorly of said body forwardly-facing surface, said flange having a terminal edge along one peripheral side

thereof engaging said needle when said needle is in position for use, and,

(2) a spring for bodily moving said flange in a needle-blocking direction transversely of said, body into adjacent and overlying relation to said port on said body forwardly-facing surface upon relative movement of said needle distal portion and point past and behind said flange and toward said body,

whereby a used needle cannot have its pointed end or adjacent distal portion re-exposed through said port past said flange for hazard and injury after initial relative movement of said needle past said flange and toward said body.

30. The safety needle system of claim 29 wherein said blocking flange terminal edge is spring urged to bear against the needle prior to relative movement of the needle toward said body.

31. The safety needle system of claim 29 wherein the needle pointed end is transversely tapered to a distal point, and wherein said blocking flange terminal edge bears against said needle on the same side area thereof as the needle distal point.

32. A safety needle system comprising:

a needle having an axis, a proximal portion, and a distal portion terminating in a pointed end,

a needle pointed end shielding body configured to receive the needle and to enable relative axial slidable movement of said body and said needle,

said needle and said body being movable relative to one another between a first position and a second position, said needle and said body in said first position thereof having said distal portion of said needle and said pointed end thereof extending forwardly of said body for use outwardly of said body and in said second position thereof having said needle pointed end in said body,

a movable safety device cooperatively associated with said needle and mounted on said body for blocking emergence of said needle pointed end forwardly of said body subsequent to relative movement of said needle and said body into said second position,

said safety device including (1) an imperforate blocking flange disposed forwardly of said needle pointed end when said needle and said body lie in said second position, and (2) a spring for moving said flange in a needle blocking direction transversely of said body into a position blocking emergence of said needle pointed end forwardly of said body.

33. A needle system according to claim 32 wherein flange is positioned relative to said needle to prevent relative movement of said needle and said body from said second position into said first position.

34. A needle system according to claim 32 wherein said body includes a bore for receiving said needle generally coaxially within said bore, said flange intersecting the axis of said needle and the axis of said bore upon movement thereof into said needle pointed end blocking position.

35. A needle system according to claim 32 including a base member for fixedly mounting a proximal portion of said needle, said body and said base member being spaced respective, axially discrete distances from one another when said needle and said body lie in said first and second positions thereof.

36. A needle system according to claim 35 including a tether interconnecting said body and said base member.