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(54) ONE-WAY VALVE SYSTEM

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No. OF CLAIMS 2

ABSTRACT OF THE DISCLOSURE

A needle assembly for facilitating the collection of a blood sample from a patient into an evacuated collection container while alleviating the danger of flow of fluid from the collection container into the patient during and after collection of the blood sample. The assembly includes a housing, a forward penetrating end for insertion into the patient, a rearward end for coupling with an evacuated collection container, a continuous passageway therethrough, and a resilient elastomeric valve member on the assembly normally in position to close the passageway between the patient and the rearward end and adapted to be responsive to a predetermined decrease in pressure in the rearward end to deform and automatically open the passageway when an evactuated container is coupled with the rearward end. Thereafter, the valve is responsive to a predetermined

This invention relates to a needle assembly for facilitating the collection of a blood sample from a patient.

In the blood sampling field, there are several well known systems. One of the more commonly used systems is the collection of blood from a vein through a needle assembly into an evacuated container. The evacuated container provides the pressure differential necessary to facilitate flow and collection of the blood through the needle assembly into the container. The basic system and apparatus for collecting blood in this manner is disclosed in U.S. Patent No. 2,689,564 to Kleiner.

Improvements have been made in recent years to the basic evacuated container system for blood sampling such as by the provision of a valve on the assembly to automatically open and close the flow path through the assembly as evacuated containers are coupled in succession with the assembly. In this manner a multiplicity of samples can be collected in a multiplicity of containers with only one venipuncture required. Needle assemblies with automatic valves are shown and described in U.S. Patent No. 3,469,572 to Nehring and U.S. Patent No. 3,494,352 to Russo et al.

Frequently the evacuated containers contain chemical materials, useful in the clinical laboratory tests to be conducted after mixing with the patient's blood. However, these chemical materials may be harmful to a patient if any were to flow from the evacuated container into the patient's blood system. For example, some evacuated containers are partially filled with protein culture medium, and the possibility exists that if any of this protein material were carried back into the patient, such foreign protein might cause anaphylactic shock. Therefore, it would be extremely desirable to utilize a system for blood sampling which employs evacuated containers in a

manner such as in the systems described above and which would alleviate the danger of back flow of fluid into the patient during and after the fluid sampling process.

Attempts have been made to solve the problem resultant from the danger of back flow in the blood collecting environment. For example, U.S. Patent No. 3,557,778 to Hughes discloses the use of a ball valve housed in a cage within a needle assembly which is responsive to a difference in pressure in one direction. However, positive sealing with the Hughes type structure is extremely difficult if not impossible. The needle assembly must be held at a particular angle in order to get the ball to return subject to gravity to its initial closed position. A time delay often occurs before gravity takes affect or in order to overcome friction between the ball and other parts of the assembly before it automatically returns to its seated position. Furthermore, the valve assembly is quite complicated in structure and costly to manufacture. This is particularly true in view of the fact that it is necessary to get a positive seal between the ball and the seat structure. It is particularly important in the medical field that the seal be positive so that in no instance would there be a back flow of fluid into the patient. Construction of the outer surface of the ball and the seating surface has to be closely controlled which greatly adds to the manufacturing cost and cost of the product. Therefore, it would be extremely advantageous in the art to provide a one-way valve which positively prevents back flow of fluid into the patient and which can be economically and efficiently manufactured.

It should be kept in mind that one-way valve structures which employ a spring loading to hold the valve in the normally closed or seated position requires a substantial threshold value of pressure differential before the valve will

open at all. Therefore, it is necessary that an extremely high vacuum pressure be employed to get the valve to open at all and as soon as the vacuum of the evacuated container begins to lessen and the pressure tends to equalize, the spring will often prematiurely return the valve to its seated position. Consequently, it is of great advantage to have a one-way valve which is responsive to a change in pressure and which does not require a substantial force to cause it to open and one which is sensitive to small pressure differentials in order to insure that an evacuated container is filled to the desired degree before the valve closes. This is particularly true in the blood testing field where various evacuated tubes require a carefully predetermined volume of blood fill in relation to the chemical material already in the evacuated tube so that a predetermined ratio of blood to chemical mixture is present. This assures that ultimate testing is accurate and precise.

With the above thoughts in mind particularly in regard to closely controlled filling requirements and the cost factor involved when considering quantity production of evacuated tubes and needles, any increase in threshold value of pressure differential required to open or close the valve directly increases the inaccuracy of the blood fill. Therefore, valve types requiring as near zero threshold differential pressure to open and close, while at the same time being normally closed, would be extremely valuable and important to the art under consideration.

With the above background in mind, it is among the primary objectives of the present invention to provide a needle assembly for use with an evacuated container in collecting blood samples wherein a one-way valve means is provided on the needle assembly to prevent the possibility of back flow of chemical materials from the evacuated container into the patient.

The valve is designed of a resilient elastomeric self-sealing material to automatically deform and open and permit flow into the evacuated container when the system is utilized under a low pressure differential and to automatically return to the normal closed position preventing flow to and from the forward end of the needle assembly when subjected to flow pressure from the rear end of the assembly to which the evacuated container is connected or exhaustion of the vacuum in an evacuated container utilized in a sampling collection operation.

Thus, a needle assembly is provided for facilitating the collection of a blood sample from a patient into an evacuated collection container while alleviating the danger of flow of fluid from the collection container into the patient during and after collection of the blood sample. The assembly includes a housing with a forward penetrating end including a cannula extending from the housing for penetration into the blood vessel of the patient. The assembly also includes a rearward end extending from the housing and including a cannula and being adapted to be coupled in fluid communication with the interior of an evacuated collection container. Portions of the assembly form a passageway for directing blood from the vein to the collection container when the forward end is in the blood vessel and the rearward end is in the container. Finally, an elastomeric resilient valve member is part of the assembly [illegible]

position to close the passageway between the blood vessel and the rearward end of the assembly and adapted to be responsive to decrease in pressure in the rearward end to deform and automatically open the passageway when the evacuated container is coupled with the rearward end of the assembly. Thereafter, the valve is

Other features which may be included in accordance with the invention will be described hereinafter and referred to in the appended claims.

With the above objectives in mind, reference is had to the attached drawings which show, by way of example, embodiments of the invention and in which:

Fig. 1 (on Sheet 1 of the drawings) is a partially sectional side elevation view of the needle assembly of the invention shown incapsuled in a sealed container;

Fig. 2 (Sheet 1) is a side elevation view of the needle assembly of the invention shown in operable position in combination with a holder, an evacuated container, and a needle shield;

Fig. 3 (Sheet 1) is a fragmentary sectional elevation view thereof with the needle shield removed and the assembly in fluid communication with a blood vessel immediately prior to collection of a sample;

Fig. 4 (Sheet 2) is an enlarged fragmentary view of the valve portion of the needle assembly as shown in Fig. 3;

Fig. 5 (Sheet 3) is a fragmentary sectional view of the needle assembly in operable position with the valve portion open and blood being collected in an evacuated container;

Fig. 6 (Sheet 2) is an enlarged fragmentary view of the valve portion of the needle assembly of Fig. 5 with arrows showing the blood flowing through the needle assembly;

Fig. 7 (Sheet 3) is an enlarged sectional view of the needle assembly of the invention in operable position in the vein of the patient subsequent to collection of a sample in an evacuated container after the valve portion has reclosed;

Fig. 8 (Sheet 2) is an enlarged fragmentary view of the valve portion of the needle assembly of Fig. 7 with the valve having reclosed upon completion of collection of a sample;

Fig. 9 (Sheet 4) is a fragmentary side elevation sectional view of an alternate embodiment of a needle assembly of the invention with the assembly being positioned in the vein of a patient and the valve portion being closed just prior to collection of a blood sample;

Fig. 10 (Sheet 5) is an enlarged fragmentary sectional view of the valve portion of the needle assembly of Fig. 9 prior to collection of a sample with the needle positioned in the vein;

Fig. 11 (Sheet 4) is a fragmentary sectional elevation view of the needle assembly of the invention showing the valve in the open position permitting blood to flow from the needle assembly into a collection container;

Fig. 12 (Sheet 5) is an enlarged fragmentary view of the valve portion of the needle assembly of Fig. 11 with arrows showing the flow of blood through the assembly with the valve in the open position;

Fig. 13 (Sheet 2) is a fragmentary enlarged sectional view of the valve portion of Fig. 12 taken along the plane of line 13-13 of Fig. 12;

Fig. 14 (Sheet 5) is a fragmentary sectional elevation view of the alternate embodiment of the needle assembly of the invention showing the valve in the reclosed position after a blood sample has been taken;

Fig. 15 (Sheet 5) is an enlarged fragmentary view of the valve portion of the needle assembly of Fig. 14 showing the valve in the reclosed position;

Fig. 16 (Sheet 6) is a fragmentary sectional elevation view of a second alternate embodiment of the needle assembly of the invention with the needle being positioned within the vein just prior to taking of a blood sample;

Fig. 17 (Sheet 7) is an enlarged fragmentary view

of the valve portion of the needle assembly of Fig. 16 showing the valve in the normally closed position;

Fig. 18 (Sheet 6) is a fragmentary sectional elevation view of the needle assembly of Fig. 16 showing the valve in the open position during collection of a blood sample within an evacuated container;

Fig. 19 (Sheet 7) is an enlarged fragmentary view of the valve portion of the needle assembly of Fig. 18 with arrows showing the direction of flow of blood through the needle assembly during collection;

Fig. 20 (Sheet 7) is a fragmentary sectional elevation view of the needle assembly of Fig. 16 showing the valve portion in the reclosed position after a blood sample has been collected;

Fig. 21 (Sheet 7) is an enlarged fragmentary view of the valve portion of the needle assembly of Fig. 20 showing the valve in the reclosed position after a blood sample has been collected;

Fig. 22 (Sheet 8) is a fragmentary sectional elevation view of a third alternate embodiment of the needle assembly of the invention showing the needle positioned within the vein immediately prior to taking of a blood sample with the valve in a closed position;

Fig. 23 (Sheet 9) is an enlarged fragmentary view of the valve portion of the needle assembly of Fig. 22 with the valve in the normally closed position;

Fig. 24 (Sheet 8) is a fragmentary sectional elevation view of the needle assembly of Fig. 22 showing the valve portion in the open position to permit blood flow through the needle assembly during collection of a blood sample;

Fig. 25 (Sheet 9) is an enlarged fragmentary view of the valve assembly of the needle assembly of Fig. 24 with

arrows showing the path of blood through the needle assembly with the valve in the open position;

Fig. 26 (Sheet 9) is a fragmentary sectional elevation view of the needle assembly of Fig. 22 showing the valve in the reclosed position after a blood sample has been collected; and

Fig. 27 (Sheet 9) is an enlarged fragmentary view of the valve portion of the needle assembly of Fig. 26 with the valve in the reclosed position after a blood sample has been collected.

As shown in Figs. 1, 2 and 3 in particular, needle assembly 20 includes a housing 21 on the forward end of which is mounted a forward venipuncture cannula 22 and on the rear end of which is mounted a second cannula 23.

Housing 21 includes a forward end portion 24 having a passageway 25 therethrough. Mounted in passageway 25 is the rear end portion of venipuncture cannula 22. The cannula is held in position in a convenient manner such as by epoxy 26 as shown.

Forward portion 24 of housing 21 has a tapered frusto conical rear mating end 27 with a hollow interior. The rear end portion of cannula 22 extends rearwardly from passageway 25 into the hollow interior of tapered frusto conical portion 27. The forward end of cannula 22 extends from the forward tip of housing 21 and has a beveled tip 28 for insertion into the vein of a patient. The rear end of cannula 22 has a blunt tip 29 and the end portion adjacent blunt tip which extends from passageway 25 has an elastomeric cap or valve member 30 mounted thereon.

Valve member 30 has a closed rear end and has its open forward end in sealing engagement with cannula 22. Between the rear end of valve 30 and blunt tip 29 of cannula 22, valve 30 has a hollow center 31 in communication with the

passageway through cannula 22. Valve 30 is of a self-sealing elastomeric material and contains one or more slits 32 where hollow portion 31 is located. Valve 30 is of a lesser inner diameter than the outer diameter of cannula 22 so that when the sleeve or valve 30 is positioned on cannula 22 it is expanded at the location of contact so as to provide sealing interengagement between the cannula and valve sleeve.

Housing 21 is of a two-part construction with the tapered outer surface of forward portion 24 which forms frusto conical portion 27 in frictional engagement with a tapered inner surface of a rear end 33 of the housing. Rear end 33 includes the hollow cylindrical portion 34 with a tapered inner surface in interengagement with forward end 24 and a rear cylindrical neck 35 having a passageway 36 therethrough. The outer surface 37 of neck 35 is threaded for interengagement with a holder as will be discussed in detail below. As shown, when forward portion 24 and rear portion 33 of housing 21 are interengaged, a chamber 38 is formed therein. Access to chamber 38 is gained through the hollow cannula 22 mounted in passageway 25 or through the hollow cannula 23 which is mounted in passageway 36. Cannula 23 is mounted in a conventional manner such as by epoxy 39. The forward tip of cannula 23 is located intermediate the ends of passageway 36 and the rear tip of cannula 23 extends beyond neck 35 and has a pointed end 40 for penetration into an evacuated container as will be discussed in detail below. As shown, cap or valve 30 is housed within chamber 38 in housing 21.

In reference to Fig. 1, it can be seen how needle assembly 20 is packaged for shipment and storage in a sealed aseptic fashion prior to use. The package is in the form of a hollow capsule 41 of rigid material such as a rigid plastic in a two-part assembly. The forward part 42 covers the forward part

of needle assembly 20 and terminates intermediate the ends of housing 33. The rear part 43 covers the rear end of the needle assembly and terminates below the lower end of housing 21. Both the forward part 42 and the rear part 43 of capsule 41 have a closed end distal from one another and an open end proximal to one another for frictional interengagement to form capsule 41 with the needle assembly contained therein. At the point of joinder of portions 42 and 43 of capsule 41 an outer cylindrical mating surface is formed on which is mounted a tamper-proof band 144. As long as band 144 is not disturbed and remains intact, the capsule 41 is unbroken and the assembly 20 contained therein remains in aseptic condition. The rigid nature of capsule 41 alleviates the danger of damage to the assembly during shipment, storage and handling prior to use. Assembly 20 is of a disposable nature so that, if desired, once capsule 41 is opened and assembly 20 is utilized it may be discarded.

In use, tamper-proof band 144 is broken and capsule 41 is opened by removing rear portion 43 from forward portion 42 and from its surrounding relationship with the rear end of assembly 20. Forward portion 42 of capsule 41 is retained in position covering venipuncture cannula 22 to alleviate the danger of contamination thereof during the preliminary preparation procedures prior to use. Removal of rear end 43 of capsule 41 exposes cannula 23 and neck 35 so that a holder 44 may be extended over cannula 23 and into threaded interengagement with threaded surface 37 of housing 33. In this position as shown in Fig. 2 cannula 23 is located within holder 44.

An evacuated container 45 is then partially inserted within holder 44 to the rear of tip 40 of cannula 23. The evacuated container is of a conventional type having a tubular body 46 terminated in an open end which is capped and sealed by a punctureable self-sealing stopped 47. The assembly is then

in condition for the actual blood sampling operation and forward portion or shield portion 42 of capsule 41 can then be removed from frictional interengagement with housing 21 thereby exposing cannula 22. As shown in Fig. 3, tip 28 of cannula 22 is then inserted into vein 48 of a patient. Since valve 30 is closing the rear blunt end 29 of cannula 22, no blood can travel beyond hollow chamber 31 within valve 30 under the influence of venous pressure alone.

Evacuated container 45 is then extended forward until tip 40 of cannula 23 punctures through stopper 47 thereby providing communication between the interior of evacuated tube 45 and central chamber 38 of housing 21. Thereafter, the pressure differential interiorly and exteriorly of valve 30 caused by the vacuum within container 45 automatically opens slits 32 and permits blood to flow from the vein through cannula 22 through slits 32 through chamber 38 and then through cannula 23 into container 45. Flow will continue as long as the pressure differential exists. Therefore, once the vacuum is exhausted within container 45 valve 30 will automatically return to its normal configuration with slits 32 returning to the sealed position thereby shutting off the blood flow adjacent to blunt end 29 of cannula 22. Similarly, should a back pressure build up during the filling operation, the pressure differential will be disturbed and the increased pressure exteriorly of valve 30 will cause slits 32 to be closed and eliminate any danger of fluid flow into valve 30 and consequently into cannula 22 and

the patient. As discussed above, this is particularly useful in instances where harmful materials to be used in later chemical

taking of a blood sample while alleviating the danger of blood flow or other fluid flow back through the needle into the patient.

Figs. 3 and 4 show the venipuncture having been made in the vein 48 of a patient. With valve 30 in the closed position, no blood flow due to venous pressure can occur beyond valve 30 in the assembly. The evacuated tube 45 is shown in position for engagement with the rear tip of the needle assembly. Thereafter, in Figs. 5 and 6 the evacuated tube 45 has been coupled with assembly 20 so that tip 40 of cannula 23 is within the evacuated tube 46. The vacuum causes a pressure differential and reduces the pressure in chamber 38 so that slits 32 open in valve 30 permitting blood to pass through needle assembly 20 into evacuated tube 46 for collection. During this procedure, should any back flow or increased pressure occur to the rear of valve 30 this force will cause slits 32 to return to their relaxed position sealing valve 30 and preventing flow in either direction within the assembly.

When the vacuum has been exhausted in tube 46, the pressure will equalize on both sides of valve 30 and valve 30 will return to its normal relaxed position with slits 32 sealing the passageway through assembly 20. No flow can then occur between tip 28 and tip 40 of the cannulas of assembly 20. The evacuated container 45 can then be removed from the needle assembly as shown in Figs. 7 and 8 and processed as desired. Subsequent evacuated containers can then be coupled with assembly 20 in a similar manner for the collection of further samples.

An alternate embodiment of the needle assembly 20a is depicted in Figs. 9-15 of the drawings. Like parts are identified by the same reference numerals as were used in the previously discussed embodiment with the subscript "a" being applied thereto. Needle assembly 20a includes a housing 21a

comprising two interengaging members, a forward end 27a and a rear end 33a. Mounted in the passageway 25a of forward end 27a is a cannula 22a. In turn, a cannula 23a is mounted in the passageway through rear end 33a. Rear end 33a has a threaded outer surface 37a for interengagement with a holder 44a. The rear end of holder 44a is open to receive evacuated containers 45a in sequence with each container including a tube 46a and a stopper 47a. The interengagement between forward portion 27a and rear portion 33a forms an interior chamber 38a (see Fig. 13). The rear tip 29a of cannula 22a extends into chamber 38a and engages with the central portion of a thin elastomeric disc 30a in sealing interengagement. The outer circumferential portions of disc 30a are stressed into a dome shape with a flattened edge and are held in normal fixed position by a series of castellations 50 extending into chamber 38a from rear portion 33a. A sequence of spaced castellations 50 are positioned circumferentially about chamber 38a. As shown, there are four castellations 50, however, the number of castellations is a matter of choice.

A plurality of grooves 51 are radially positioned on forward portion 27a and are open to chamber 38a to form additional points of sealing with disc 30a when the elastomeric disc is in the normally closed position.

In operation, the function of the needle assembly is identical to that of the previous embodiment. The sequence of operational steps is shown in Figs. 9-15. In Figs. 9 and 10, disc 30a is in the normally closed or sealed position preventing fluid flow between the vein 48 and the evacuated container 45a. Thereafter, as shown in Figs. 11 and 12 when evacuated container 45a is fully coupled with cannula 23a the vacuum in the container will cause a pressure differential between the opposite sides of elastomeric disc 30a. The disc will then be deformed so as to be unseated from its sealing engagement with tip 29a of the cannula

and from interengagement with the grooves 51. Additionally, the portions of disc 30a between each pair of adjacent castellations 50 will be deformed so as to provide a series of passageways to permit blood to flow from cannula 22a through chamber 38a, through cannula 23a into the evacuated collection container 45a.

Thereafter, when the pressure differential is reduced or a pressure build up increases in chamber 38a to the rear of disc 30a, the disc which acts as a valve member will reseat on tip 29a and with grooves 51 and at its extreme portions between the castellations and forward portion 27a to prohibit any flow from the rear of disc 30a into cannula 22a. In this manner, the danger of back flow into the patient is prevented. As shown in Figs. 14 and 15 when the vacuum in container 45a is dissipated, disc 30a will reseat and seal off the passageway through assembly 20a thereby prohibiting flow in either direction through the entire length of assembly 20a. Tip 28a can remain in the vein if it is desired to take other samples in a sequence of separate tubes or can be removed if the sampling procedure is completed

A further embodiment is disclosed in Figs. 16-21. Like parts are identified by the same reference numerals as were used in the previously two discussed embodiments with the subscript "b" being applied thereto. Once again the sequence of operations is identical to that described in connection with the previous two embodiments and the difference lies in the type of valve member employed. In this embodiment, the rear tip 29b of cannula 22b is sealed by a convenient means such as epoxy 52. The cannula is provided with a side opening 53 adjacent to tip 29b and located in chamber 38b. A thin walled elastomeric sleeve 54 is mounted on the rear end portion of cannula 22b and is held in position by means of epoxy 52. Sleeve 54 is mounted with an interference fit so that it forms a sealing

engagement with the outer walls of cannula 22b. In the normal position it forms a valve closure for side opening 53 thereby preventing passage of fluid from the vein through assembly 20b and out the rear tip 40b.

When the evacuated container 45b is fully coupled with assembly 20b, the vacuum therein will cause a pressure differential which deforms elastomeric sleeve 54 as shown in Figs. 18 and 19 so that blood will flow out of side opening 53 between the inner surface of deformed sleeve 54 and the outer surface of cannula 22b into chamber 38b. From there the blood flows through cannula 23b into the evacuated container 45b. As discussed in relation to the previous embodiment, if a back pressure builds up or the vacuum is exhausted in the evacuated container 45b, the pressure differential will be eliminated and sleeve 54 will return to the relaxed position in sealing engagement with cannula 22b preventing fluid flow into or out of side opening 53 of cannula 22b. In this manner, fluid flow in either direction through needle assembly 20b is stopped. Thereafter, as shown in Figs. 20 and 21, the evacuated tube can be removed if desired and replaced by successive tubes without the necessity of removing tip 28b from vein 48 of the patient.

A third alternative embodiment is shown in Figs. 22-27. Once again, like parts are given the same reference numerals as similar parts in the previously discussed embodiments with each numeral being given the subscript "c". The operational steps are the same as discussed above in connection with the other embodiments and the peripheral difference in structure resides in the valve member being employed. Additionally, it should be noted that in this particular embodiment a single cannula is employed rather than two separate cannulas, however, the cannula is crimped intermediate its ends at 55 so as to in effect form two separate operational cannulas 22c and 23c forward and rearward respectively of crimp 55. Crimp 55

is located in chamber 38c of assembly 20c. Shortly above crimp 55 in chamber 38c, cannula portion 22c has a side opening 56 for communication between the interior of cannula 22c and chamber 38c. Similarly, adjacent to crimp 55 rear cannula portion 23c has a side opening 57 for communication between the interior of cannula 23c and chamber 38c. An elastomeric sleeve 58 surrounds a portion of cannula 22c within chamber 38c and normally closes opening 56 therein. Elastomeric sleeve 58 is in an interference fit with the outer surface of cannula 22c so that an effective seal is normally accomplished. Figs. 22 and 23 of the drawings show the normally closed position so that blood cannot flow through the entire length of assembly 20c even after a venipuncture has been accomplished. Thereafter, as shown in Figs. 24 and 25, when an evacuated container 45c is fully coupled with assembly 20c, a pressure differential will be created on opposite sides of closure sleeve 58 so that a sleeve will be deformed as shown to expose opening 56 to chamber 38c. Blood flow will then proceed from vein 48 through cannula 22c, out of opening 56 through chamber 38c into opening 57 and through cannula 23c into tube 45c. This flow will continue as in the previous embodiments until the pressure differential is relieved. The relief will occur either by exhaustion of the vacuum within container 45c or by a back flow pressure. In either case, sleeve 58 will return to its relaxed normal configuration in tight frictional engagement with cannula 22c and closing off opening 56. Once again, this prevents flow between the ends of assembly 20c and alleviates the danger of back flow from the rear of the assembly to the patient. Additionally, as in the previously discussed embodiments and depicted in Figs. 26 and 27 the evacuated tube may be removed as desired and replaced by additional tubes without the necessity of additional venipunctures. The process may be repeated as many

times as needed to achieve the desired number of collected samples in separate containers 45c.

The elastomeric material of the valve member of the above discussed embodiments permits close control over the opening and closing of the valve. The valve is responsive to deform when subjected to a low threshold of differential pressure. This enables the valve to be extremely accurate in controlling the flow into an evacuated container when a predetermined amount of fluid such as blood is to be collected. As discussed above, this is extremely advantageous in the blood sampling field.

Naturally, although four specific embodiments are depicted and described above, there are many other embodiments which fall within the scope of the invention as described and claimed. Thus, the above discussed objectives, among others, are effectively attained.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A needle assembly for facilitating the collection of a blood sample from a patient into an evacuated collection container while preventing flow of fluid from the collection container into the patient during and after collection of the blood sample comprising:

a housing having a forward end with an opening therein and a rear end with an opening therein with both openings extending into a central chamber in the housing;

a first double ended substantially rigid cannula having a passage therethrough mounted in fixed position in the opening in the forward end of the housing with the forward end of the cannula being pointed for venipuncture and the rear end of the cannula in the chamber of the housing;

a second double ended substantially rigid cannula having a passage therethrough mounted in fixed position in the opening in the rear end of the housing with the passage opening in the forward end of the second cannula in fluid communication with the chamber in the housing through the opening in the rear end of the housing and the rear end of the second cannula being pointed for insertion into the evacuated collection container thereby providing a continuous passage from the forward end of the first cannula to the rear end of the second cannula;

a resilient cylindrically shaped cap of elastomeric self-sealing material having an open end and a closed end;

the opening in the open end extending a substantial distance throughout the length of the cap and being of normally

the cap being mounted on the rear end of the first cannula in the chamber with the portion of the cap on the cannula in expanded condition so as to fit thereon in tight sealing engagement therewith; and

at least one slit in the cap aligned with the opening therein and spaced from the portion of the cap mounted on the first cannula with the slit being normally closed; so as to close the passageway through the assembly and being responsive to a reduction in fluid pressure at the rearward end of the second cannula to resiliently deform independent of any force other than the reduction in fluid pressure and independent of orientation of the assembly so as to automatically open the passageway through the assembly, and thereafter be responsive to a predetermined increase in fluid pressure at the rearward end of the second cannula to automatically return to the closed position independent of any other force than the increase in fluid pressure and independent of orientation of the assembly.

2. The invention in accordance with Claim 1, wherein the rear end of the housing has a threaded outer surface portion for interengagement with the holder for an evacuated collection container.

Fig. 1

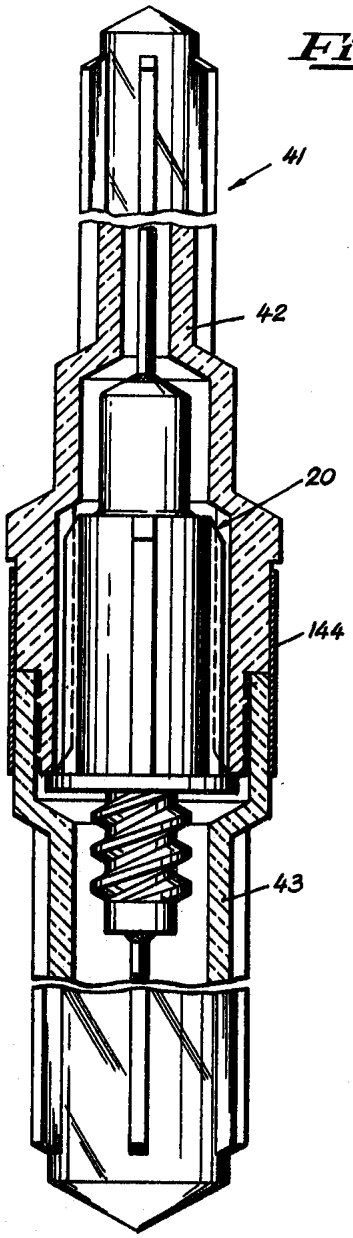

Fig. 2

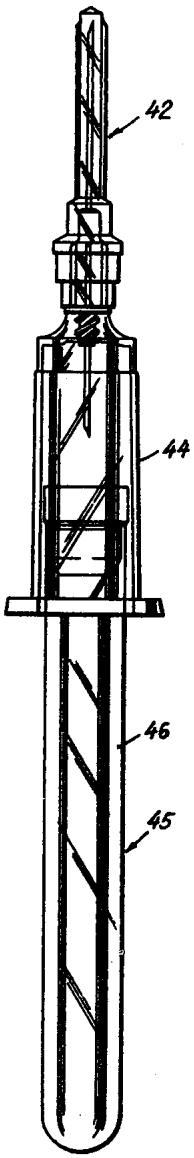

Fig. 3

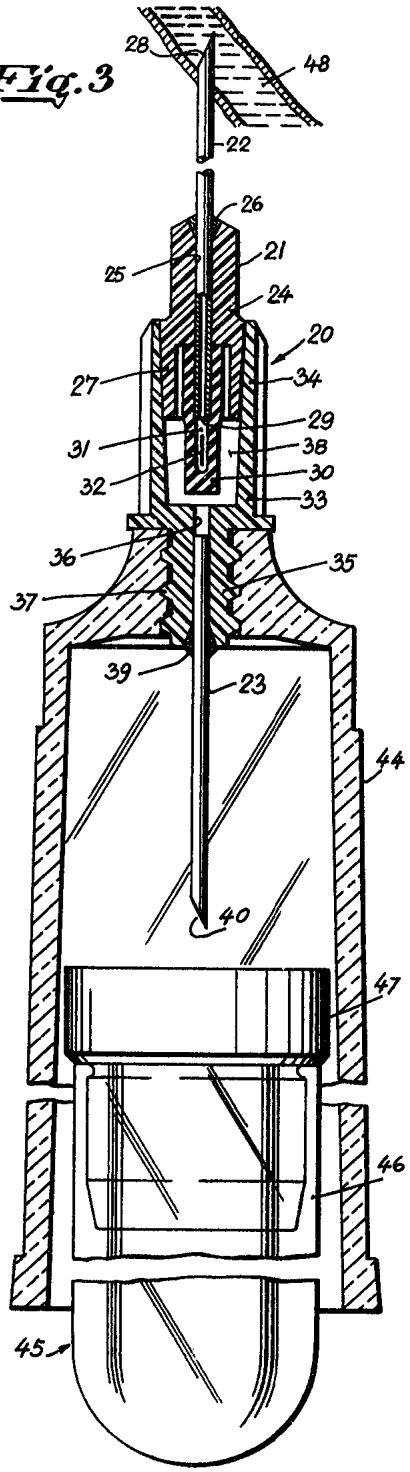

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Fig. 4

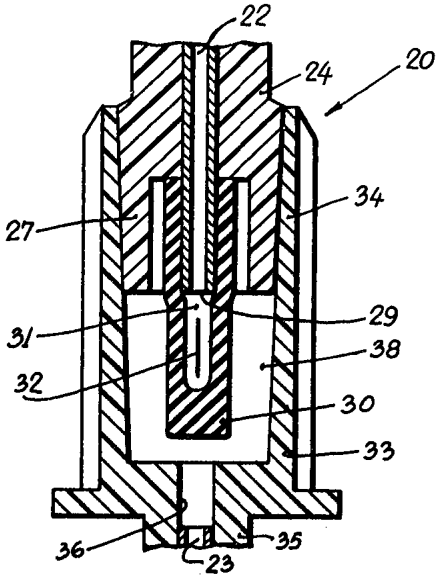

Fig. 8

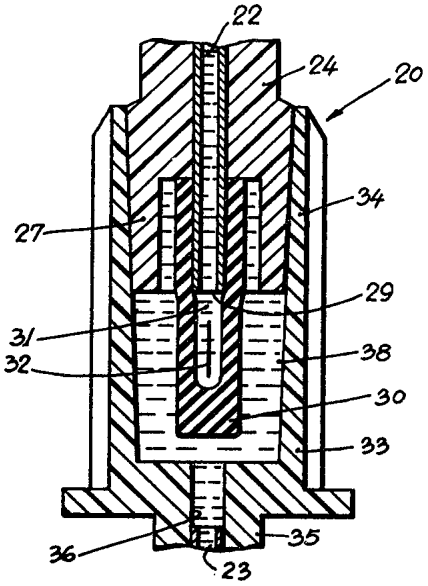

Fig. 6

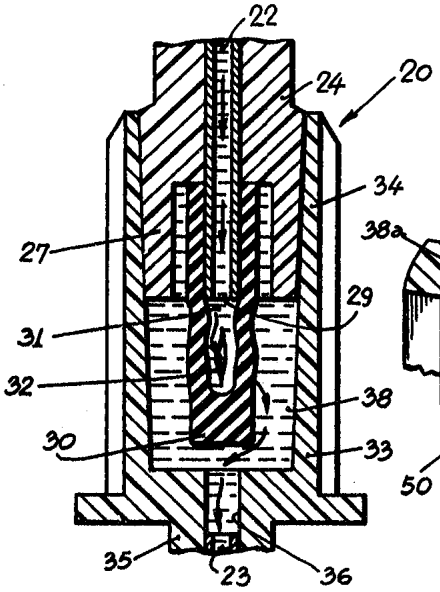

Fig. 13

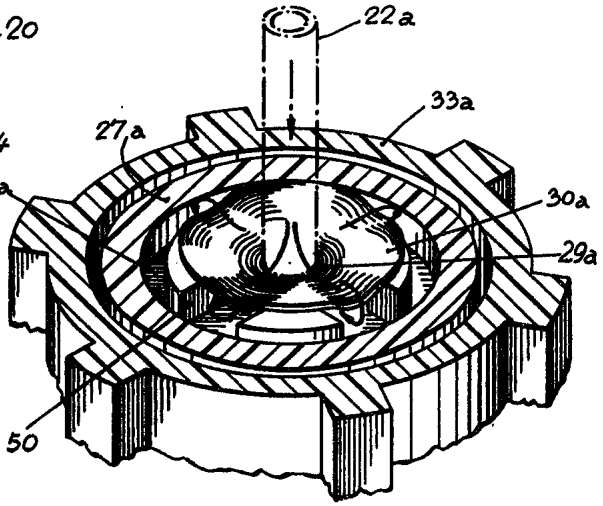

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Fig. 5

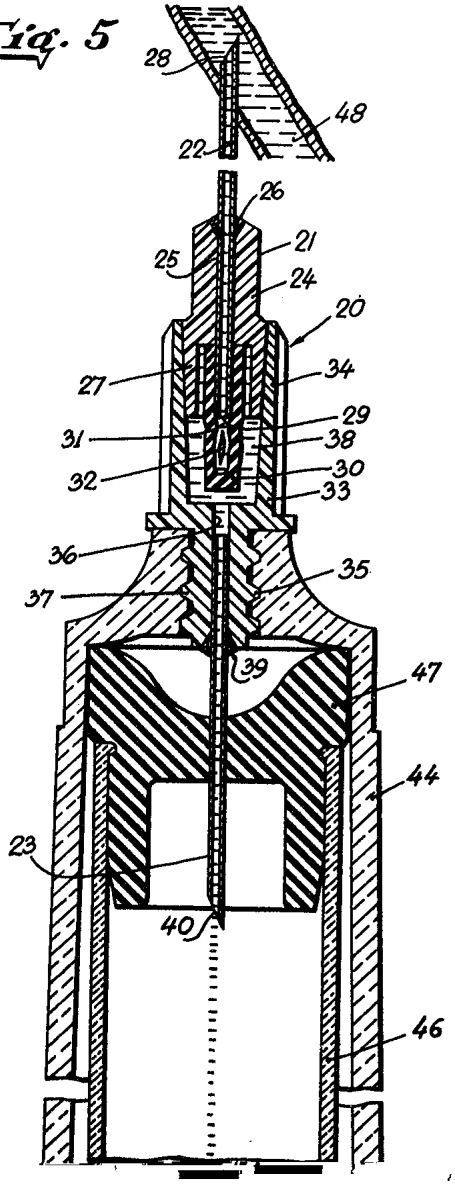
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Fig. 7

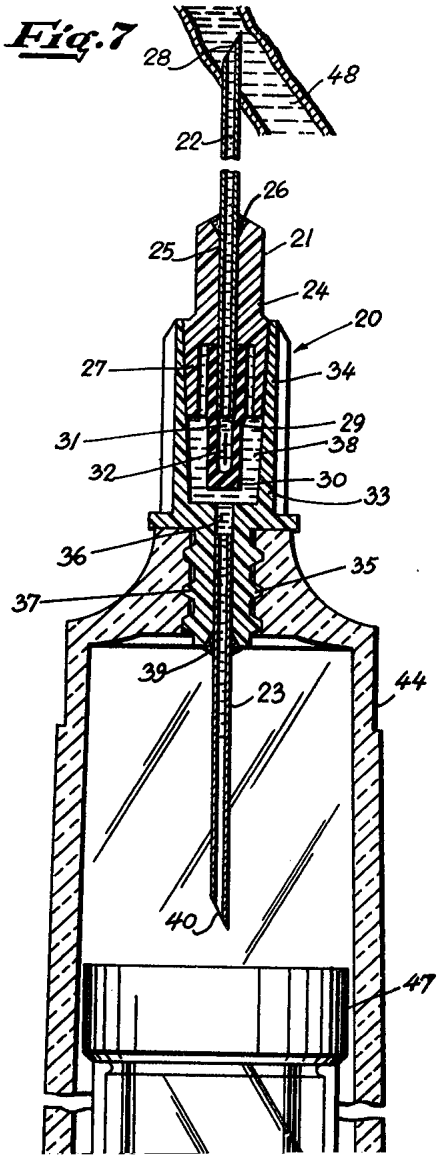
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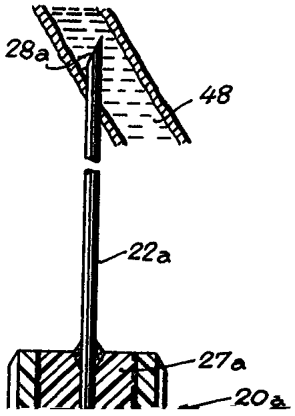
Fig. 9



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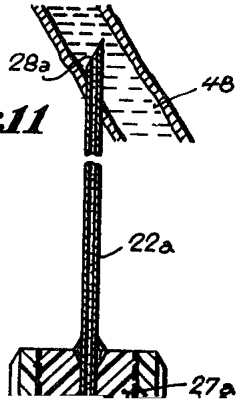

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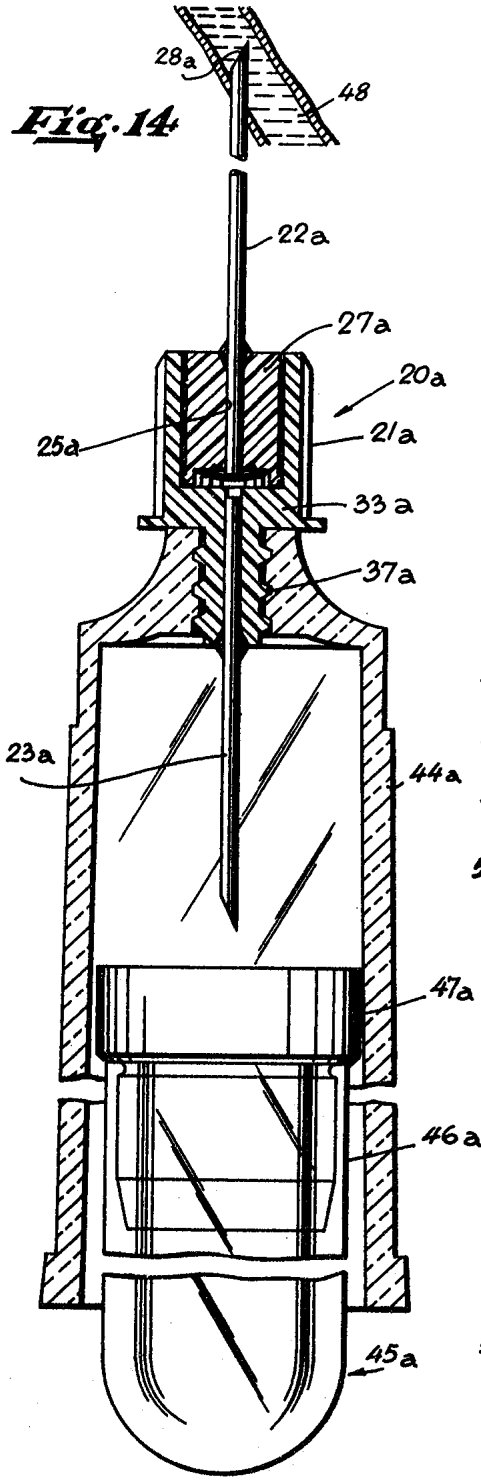

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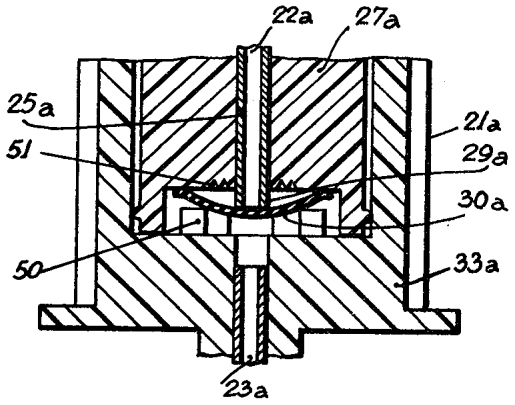

Fig. 12

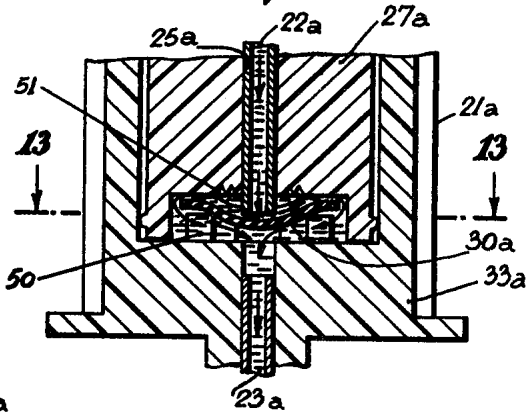

Fig. 15

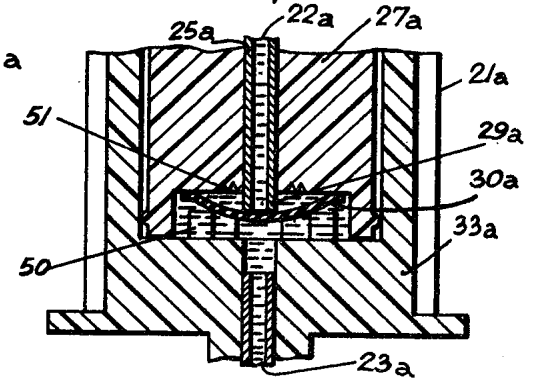

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Fig. 16

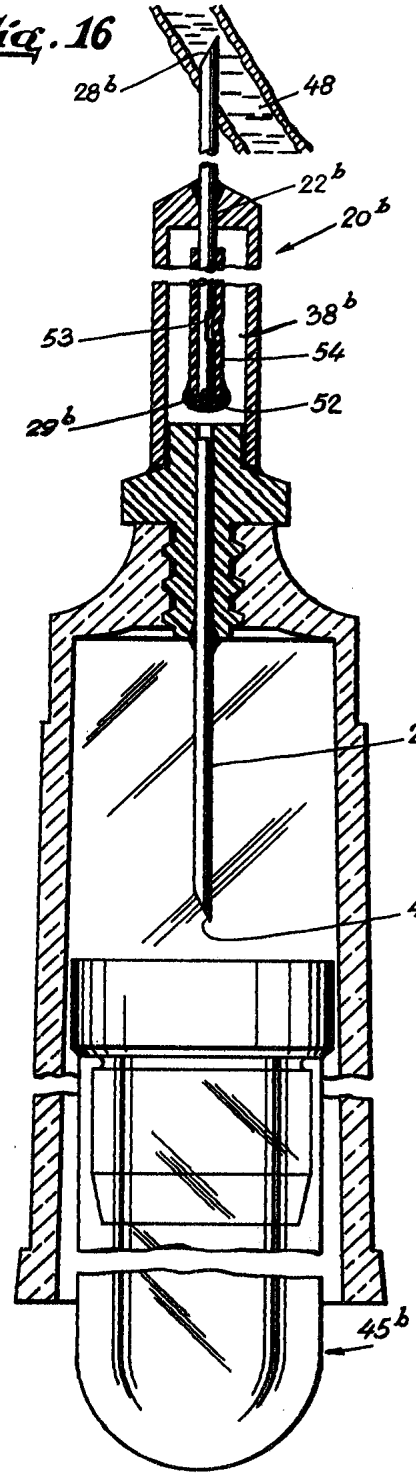

Fig. 18

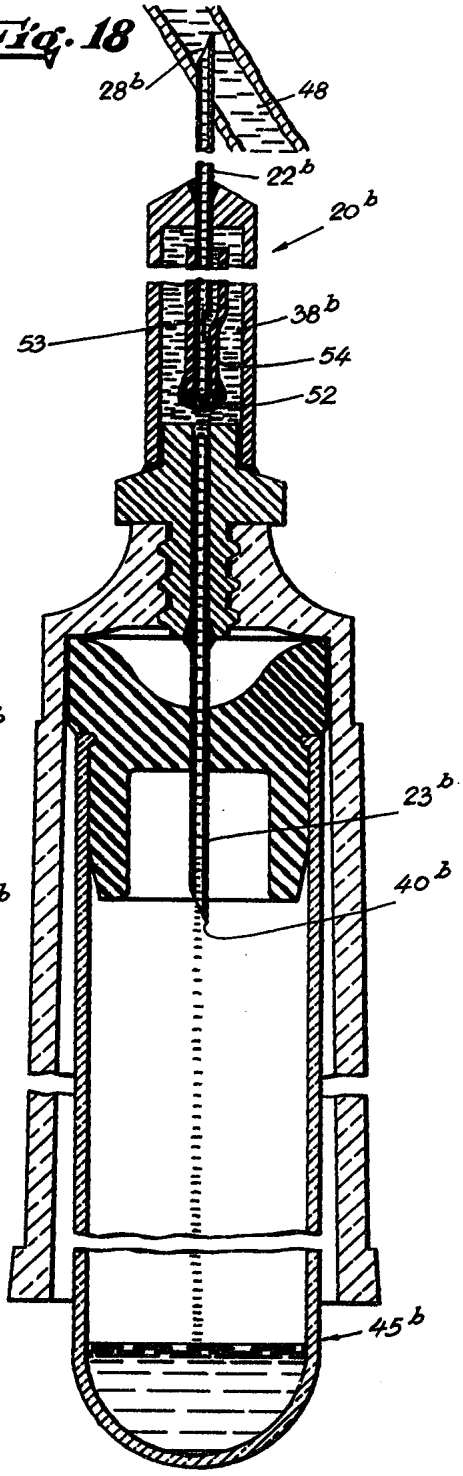

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Fig. 20

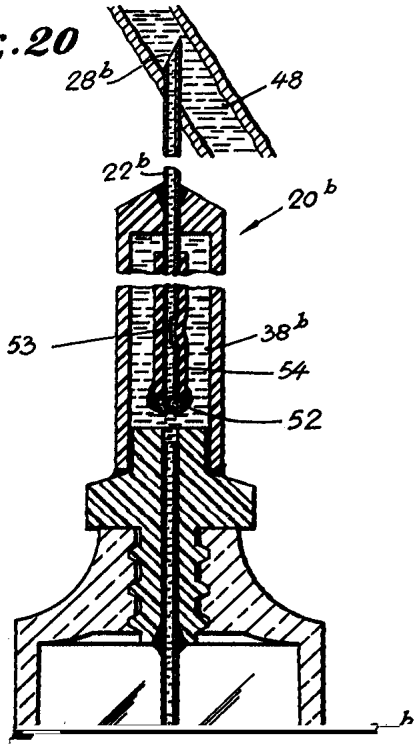


Fig. 17

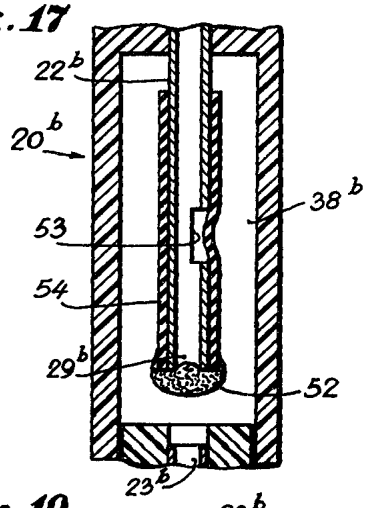
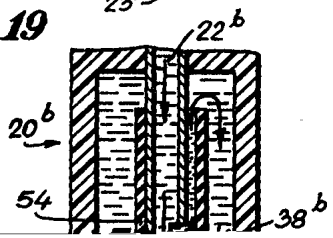


Fig. 19



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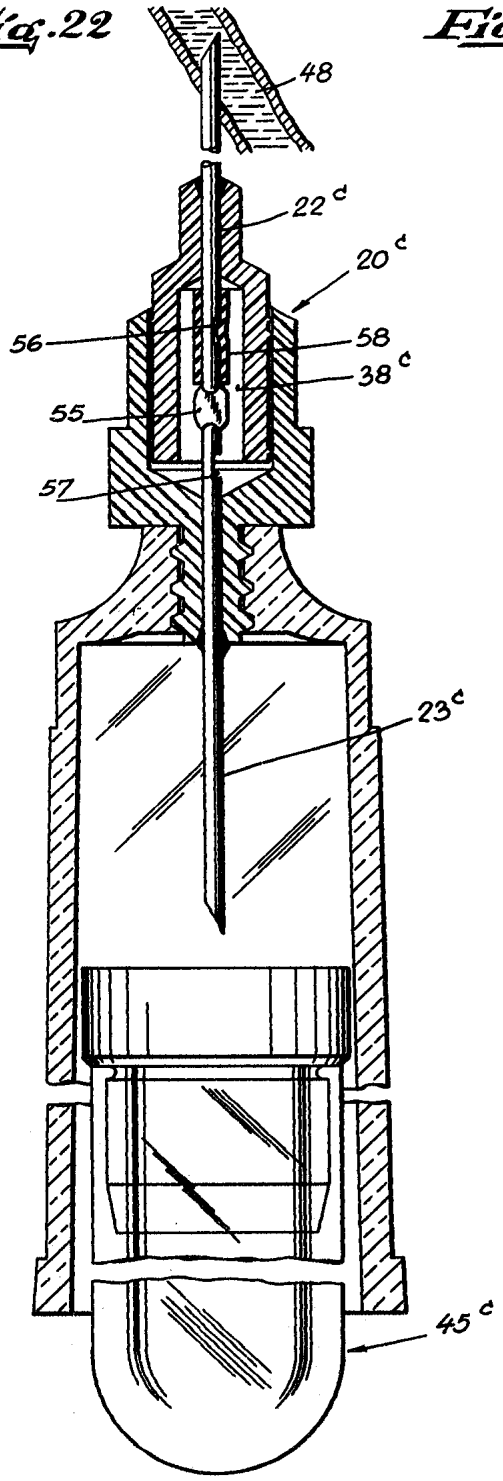

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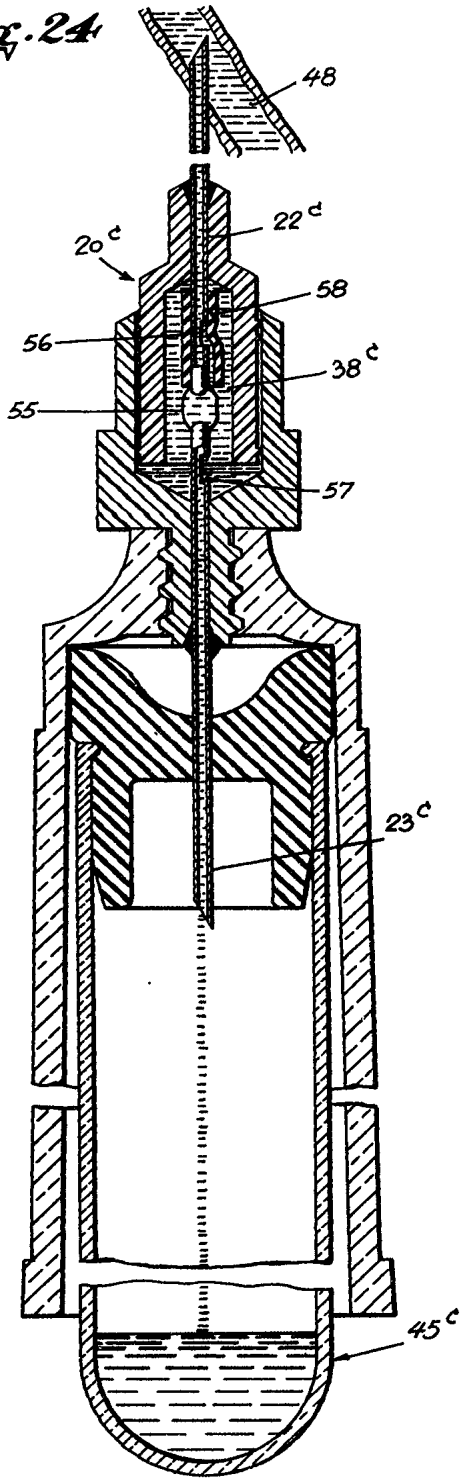

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Fig. 26

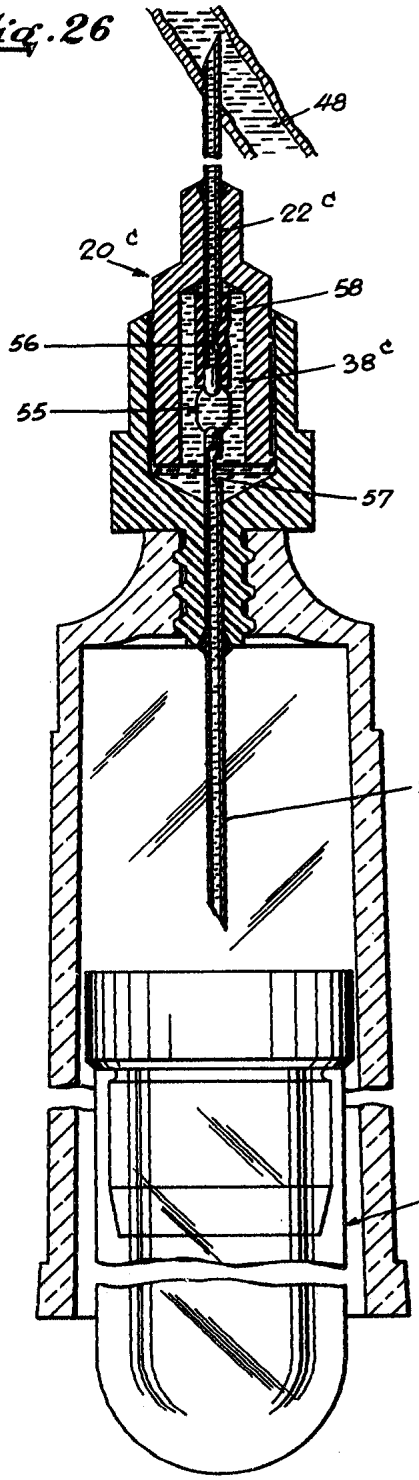


Fig. 23

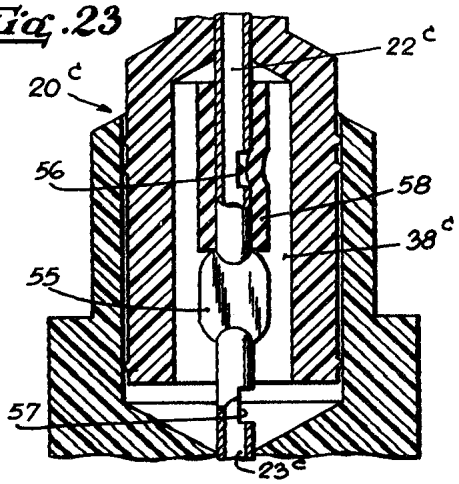


Fig. 25

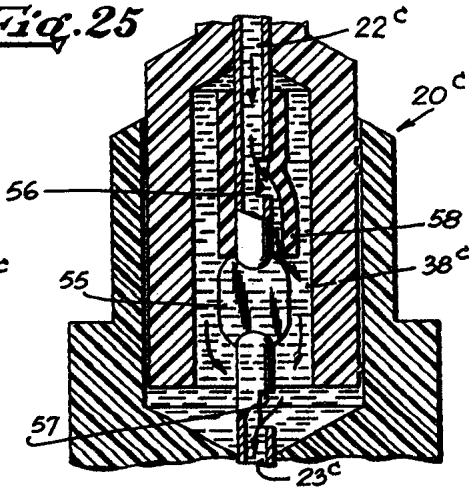
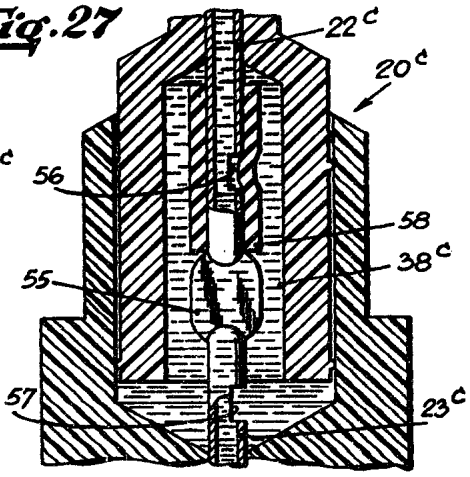


Fig. 27



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