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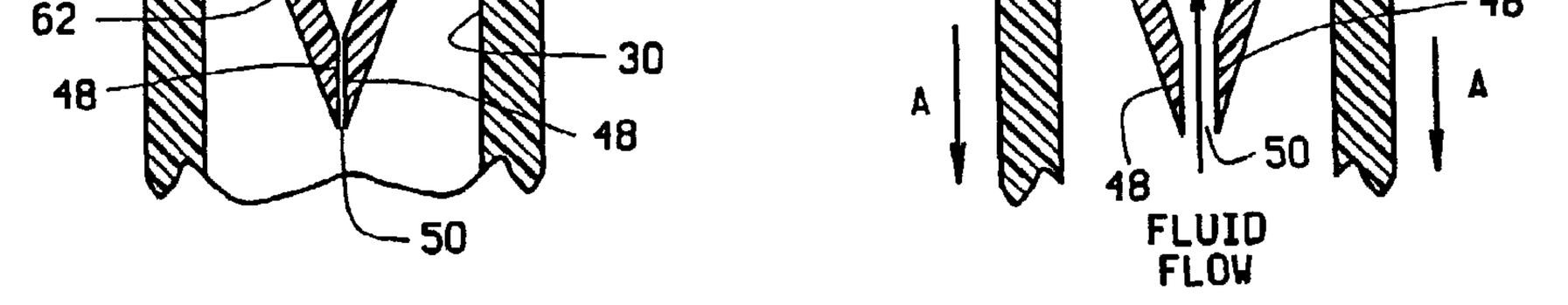

(57) Abrégé/Abstract:
The present invention relates to an anti-free-flow valve (16) to prevent fluid free-flow through a tube assembly (14) having a lumen (30). The valve device (16) comprises a body (44) disposed inside the lumen (30) having a cylindrical portion (56) formed adjacent a tapered portion (60), the cylindrical portion (56) includes an opening (52) and the tapered portion (60) has a pair of beveled surfaces (62) with ends (48) that form a slit (50) therebetween. The slit (50) communicates with the opening (52) through a passage (64) formed through the body (44) of the valve device (16). When the tube assembly (14) is in a relaxed condition, the ends (48) of the beveled surfaces (62) confront one another and place the slit (50) in the closed position which prevents fluid flow through the passage (64) of the body (44) and through the valve device (16). When a tensile force (A) is applied along the tube assembly (14) in an area adjacent the valve device (16), the inner diameter of the lumen (30) decreases which elongates the body (44) and urges the ends (48) of the beveled surfaces (62) away from one another and places the slit (50) in the open position which permits fluid flow through the passage (64) and out the body (44) of the valve device (16).

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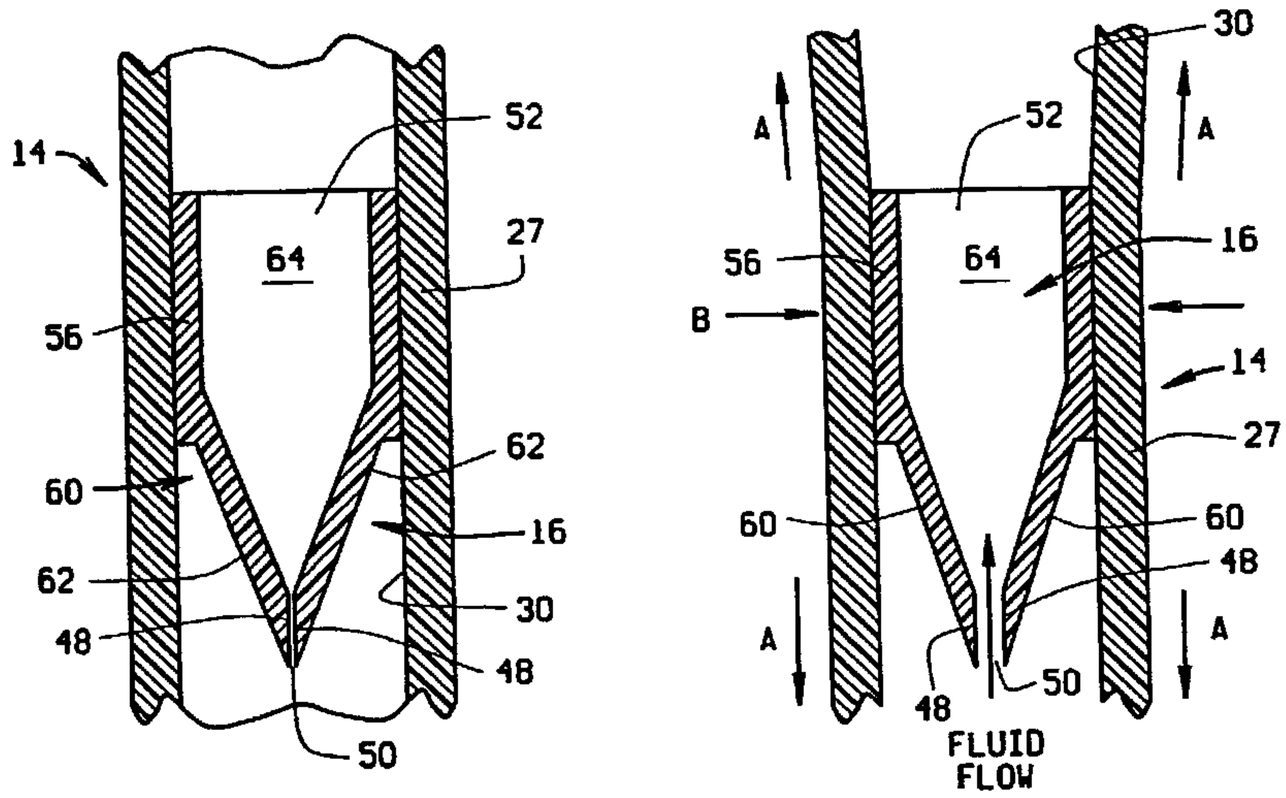

(57) Abstract: The present invention relates to an anti-free-flow valve (16) to prevent fluid free-flow through a tube assembly (14) having a lumen (30). The valve device (16) comprises a body (44) disposed inside the lumen (30) having a cylindrical portion (56) formed adjacent a tapered portion (60), the cylindrical portion (56) includes an opening (52) and the tapered portion (60) has a pair of beveled surfaces (62) with ends (48) that form a slit (50) therebetween. The slit (50) communicates with the opening (52) through a passage (64) formed through the body (44) of the valve device (16). When the tube assembly (14) is in a relaxed condition, the ends (48) of the beveled surfaces (62) confront one another and place the slit (50) in the closed position which prevents fluid flow through the passage (64) of the body (44) and through the valve device (16). When a tensile force (A) is applied along the tube assembly (14) in an area adjacent the valve device (16), the inner diameter of the lumen (30) decreases which elongates the body (44) and urges the ends (48) of the beveled surfaces (62) away from one another and places the slit (50) in the open position which permits fluid flow through the passage (64) and out the body (44) of the valve device (16).

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TUBE DEPENDENT ANTI-FREE-FLOW VALVE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a device for preventing fluid free flow in a fluid administration system, and more particularly to an anti-free flow valve device disposed within a lumen of a tube assembly. More specifically, the present invention relates to a tube diameter dependent anti-free-flow valve device that prevents fluid free flow when the tube assembly is in a relaxed condition, while permitting uninhibited fluid flow when the tube assembly is in a stretched condition.

2. Prior Art

Administering fluid containing medicine or nutrition to a patient is generally well-known in the art. Typically, fluid is supplied to a patient by a tube assembly which provides a fluid pathway between a fluid source and a patient. The fluid is supplied to the patient through the tube assembly by either an enteral connection which accesses a visceral organ (gastrointestinal feeding) of a patient or through a parenteral connection which accesses a non-visceral organ (intravenous feeding).

Fluid flow rate through the tube assembly may be manually controlled by a mechanical clip which is designed to progressively occlude the tube assembly and selectively impede fluid flow induced by the force of gravity. One such mechanical clip which operates to occlude a portion of the tube assembly is a conventional roller clamp that has a hollow body with opposed outlets and a pair of angled slots formed opposite of one another transverse to the outlets. The clip further includes a wheel having an axle which is coupled to the body through the slots. A portion of the tube assembly is then inserted through both the outlets and the wheel axially advanced along the slots to pinch a portion of the tube against the body which progressively occludes the tube assembly. Although the mechanical clip operates to provide a cost-efficient method for controlling fluid flow rate, the clip must be manually

actuated by the user. Further, the wheel of the mechanical clip can be inadvertently bumped or jostled out of position resulting in an inappropriate flow rate.

In order to better enhance fluid flow rate control in a fluid administration system, calibrated pumps have been utilized. One such calibrated pump is a peristaltic pump connected in-line along a portion of the tube assembly between the fluid source and the patient. The peristaltic pump advances the fluid through the tube assembly by progressively occluding successive portions of the tube assembly and urging each occluded portion forward. When a peristaltic pump is utilized to control the fluid flow rate, mechanical clips are typically not employed or are disengaged to prevent the clip from interfering with the operation of the pump.

Although peristaltic pumps have substantially advanced the art, further improvements are required. For example, once the tube assembly is disengaged from the pump fluid flow rate through the tube assembly becomes unrestrained as fluid is drawn through the tube assembly due to the force of gravity. This situation is known as fluid free flow and may present an undesirable, or even life-threatening situation, if left undetected because of the risk of overfeeding or overmedicating a patient.

In order to overcome the above-noted drawbacks to fluid administration systems utilizing pumps, several devices have been suggested which operate to automatically occlude a portion of the tube assembly and prevent fluid free flow when the tube assembly becomes disengaged from the pump while also permitting uninhibited fluid flow when the tube assembly is properly engaged to the pump. For instance, a variety of automatic occluders have been suggested to improve the art such as those disclosed in U.S. Patent No. 4,689,043 to Bisha entitled “IV Tube Activator” which describes a clamp for use with a peristaltic pump. The clamp includes a V-shaped channel which is spring biased into a closed position where the narrow portion of the V-shaped channel is sized to substantially crimp, or occlude, a portion of the tube assembly and prevent fluid free flow therethrough. The clamp is placed in an open position by a handle which overlays the pump and depresses the springs such that the tube assembly is positioned within the wider portion of the V-shaped channel to permit unrestricted flow through the tube assembly when the

pump is operating. When the handle is released, the V-shaped portion will automatically slide into the closed position and prevent fluid free flow by occluding a portion of the tube assembly.

Another automatic occluder is disclosed in U.S. Patent No. 5,704,582 to Winterer, et al. entitled "Pinched Clipped Occluder for Infusion Sets" which describes a clip that is positioned between a housing and a cover of a pump. The clip has a plunger biased by a spring towards a portion of the tube assembly so that the lumen of the tube assembly becomes occluded by the plunger. Fluid flow through the tube assembly may only be established when the plunger is biased away from the lumen of the tube assembly which occurs when the cover is properly coupled with the housing. However, once the cover becomes disengaged from the housing, the plunger is automatically biased into the closed position by the spring to prevent fluid free flow.

Although both of the aforementioned automatic occluders have advanced the art, both devices are mechanically complex and prone to mechanical failure. In addition, the mechanical complexity of these devices also results in occluders which are expensive to manufacture. Accordingly, there is a need in the art for a simple valve device that is capable of preventing fluid free flow when the tube assembly is disengaged from the pump, while permitting uninhibited fluid free flow when the tube assembly is disengaged from the pump.

OBJECTS AND SUMMARY OF THE INVENTION

In brief summary, the present invention overcomes and substantially alleviates the deficiencies present in the art by providing a valve device for preventing fluid free-flow in a fluid administration system. The valve device of the present invention is disposed within the lumen of a tube assembly for preventing fluid free flow when the tube assembly is disengaged from the pump, while permitting uninhibited fluid flow when the tube assembly is engaged with the pump.

Preferably, the pump of the fluid administration system used in conjunction with the present invention includes a rotor for advancing fluid through the tube assembly and a pair of recesses positioned adjacent the rotor for retaining portions

of the tube assembly to the housing of the pump during operation of the system. The tube assembly comprises three interconnected tube segments each having a distal and proximal ends for providing a fluid pathway between the fluid source and a patient. The fluid source is connected to the distal end of the first tube segment, while the proximal end thereof is connected to the distal end of the second tube segment by a drip chamber having an abutment surface. The proximal end of the second tube segment is interconnected to the distal end of the third tube segment by a coupling having an external flange. Finally, the proximal end of the third tube segment is attached to a patient through either an enteral or parenteral connection.

The tube assembly is engaged with the pump by threading a portion of the assembly around the rotor with the abutment surface of the drip chamber and external flange of the coupling engaged within the first and second recesses, respectively, of the pump. Preferably, the second tube segment as it is engaged around the rotor has a length which permits the abutment surface and the external flange to be properly captured by the first and second recesses and place the second tube segment in a stretched condition. Each of the tube segments has a lumen formed therethrough to allow the passage of fluid through the tube assembly. Alternatively, the valve device may be used with a tube assembly not having a drip chamber or coupling.

Preferably, the valve device of the present invention is disposed within the lumen of one of the tube segments to prevent fluid free-flow when the tube assembly is disengaged from the pump. The valve device comprises a body having a generally cylindrical portion formed adjacent a tapered portion. The cylindrical portion of the valve device includes an outlet and both the cylindrical portion and the outlet are generally circular in configuration. The tapered portion includes opposite beveled surfaces having ends with the beveled surfaces being bounded by a pair of side walls. Preferably, the beveled surfaces are planar in shape, while the side walls have a generally rounded configuration. The tapered portion also includes a slit formed between the ends of the beveled surfaces and a passage which interconnects the outlet and the slit of the valve device such that any fluid that enters through the slit can pass along the passage and exit from the outlet. Preferably, the

valve device is disposed within the lumen of the second tube segment adjacent the coupling with the slit or proximal end of the valve device facing the proximal end of the second tube segment and the outlet directed towards the distal end thereof. The cylindrical portion of the valve device is sized and shaped to sealingly engage against the inner circumference of the lumen and prevent fluid flow around the valve device at all times.

When the second tube segment is in a relaxed condition or disengaged from the pump, the slit is placed in the closed position by the ends of the beveled surfaces confronting one another and occluding the lumen of the second tube segment. However, once a tensile force is applied along the second tube segment by stretching it, the second tube segment assumes a stretched condition which urges the ends of the beveled surfaces away from one another as the inner diameter of the lumen is decreased and elongates the body of the valve device. This action places the slit in the open position, thereby allowing fluid to pass through the lumen of the second tube segment. Once the applied tensile force is released by disengaging the tube assembly from the rotor, the inner diameter of the lumen increases and the body of the valve device returns to the relaxed condition. The expansion of the lumen when the tube assembly is in the relaxed condition permits the ends of the beveled surfaces to come together again and return the slit to the closed position. Alternatively, the slit may be placed in the open position by manually pinching the body of the valve device transverse to the slit which also causes the ends of the beveled surfaces to be urged away from one another as the inner diameter of the lumen is decreased.

In operation, the valve device of the present invention prevents fluid free flow whenever the tube assembly is disengaged from the pump while permitting uninhibited fluid flow when the tube assembly is engaged around the rotor of the pump, or the valve device is manually actuated by the user. The valve device is placed within the lumen of the tube assembly during manufacture. To utilize the valve device, the user first connects the first tube segment of the tube assembly with the fluid source and allows fluid to flow to the point where the valve device is located within the tube assembly. The user then primes the tube assembly in order to

evacuate air from the remaining portions of the tube assembly and initiate fluid flow therethrough. Preferably, the tube assembly may be manually primed by stretching a portion of the tube assembly surrounding the valve device which urges the ends of the beveled surfaces away from one another as the body of the valve device elongates and opens the slit to fluid flow through the lumen of the tube assembly. Air is then forced out through the remaining portions of the tube assembly.

To regulate and urge the fluid through the tube assembly, the tube assembly is connected to the pump. Specifically, the abutment surface of drip chamber is engaged within the first recess of the pump and the second tube segment is stretched around the rotor. The external flange is then inserted into the second recess of the pump to retain the second tube segment in a stretched condition. Due to the tensile force applied to the second tube segment, the inner diameter of the lumen is decreased such that the lumen confronts and urges the pair of side walls together which urges the ends of the beveled surfaces away from one another to place the slit in the open position. Once in the open position, fluid flow is established through the lumen of the second tube segment. However, if the tube assembly becomes disengaged from the pump, the tensile force exerted upon the second tube segment will be released which automatically results in expansion of the inner diameter of the lumen so that the ends of the beveled surfaces confront one another and close the slit to fluid flow.

Accordingly, the primary object of the present invention is to provide a valve device which prevents fluid free-flow.

Another object of the present invention is to provide a valve device that prevents fluid free flow when the tube assembly is disengaged from the pump, while permitting uninhibited flow when the tube assembly is engaged to the pump.

Still another object of the present invention is to provide a valve device which may be automatically or manually actuated.

Yet another object of the present invention is to provide a valve device that is disposed within the lumen of the tube assembly.

A further object of the present invention is to provide a valve device which reduces manufacturing costs.

These and other objects of the present invention are realized in the preferred embodiment of the present invention, described by way of example and not by way of limitation, which provides for a valve device for use in a fluid administration system to prevent fluid free-flow.

Additional objects, advantages and novel features of the invention will be set forth in the description which follows, and will become apparent to those skilled in the art upon examination of the following more detailed description and drawings in which like elements of the invention are similarly numbered throughout.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a partial fragmentary perspective view of a fluid administration system having a pump and a tubing assembly coupled thereto with a valve device disposed within the lumen of the tubing assembly according to the present invention;

FIG. **2** is a front elevational view of the tube assembly and fluid source according to the present invention;

FIG. **3** is a front view of the valve device disposed within the lumen of the second tube segment with the slit in the closed position according to the present invention;

FIG. **4** is a perspective view of the valve device according to the present invention;

FIG. **5** is a side elevational view of the valve device according to the present invention;

FIG. **6** is a cross-sectional view of the valve device taken along line **6-6** of FIG. **3** according to the present invention;

FIG. **7** is a rear elevational view of the valve device according to the present invention;

FIG. **8** is a front view of the valve device disposed within the lumen of the second tube segment with the slit in the open position according to the present invention;

FIG. **9** is a cross-sectional view of the valve device taken along line **9-9** of FIG. **8** according to the present invention;

FIG. **10** is a partial cross-sectional view of the valve device showing slots adapted to retain an insert according to the present invention;

FIG. **11** is a perspective view of the preferred embodiment of an insert having a thin oval body according to the present invention;

FIG. **12** is a perspective view of an alternative embodiment of the insert having an elongated rectangular body according to the present invention;

FIG. **13** is a perspective view of the valve device with the alternative embodiment of the insert of FIG. **12** shown in partial phantom; and

FIG. **14** is a perspective view of another alternative embodiment of the insert having an elongated oval body according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings, the preferred embodiment of the valve device of the present invention is illustrated and generally indicated as **16** in FIG. **1**. The valve device **16** is used in a fluid administration system **10** which comprises a tube assembly **14** engaged with a pump **12** and a fluid source **40** (FIG. **2**). For ease of reference, proximal shall refer to the end of the valve device **16** or tube assembly **14** farthest from fluid source **40**, while distal shall refer to the end of device **16** or assembly **14** closest to fluid source **40**.

Pump **12** is preferably a rotary peristaltic pump as shown in FIG. **1**. Of course one skilled in the art can best appreciate that a variety of other pumps such as a linear peristaltic pump, may be utilized without departing from the novel aspects of the present invention. Specifically, pump **12** includes a rotor **18** and a control panel **20** located adjacent rotor **18** which permits a user to monitor and adjust the rotation rate of rotor **18** for controlling fluid flow rate by pump **12**. A first recess **22** and a second recess **24** are formed above rotor **18** for engaging portions of tube assembly **14** which will be discussed in greater detail below.

Referring to FIG. **2**, tube assembly **14** includes a first tube segment **26**, a second tube segment **27**, and a third tube segment **28** which are in communication with one another. Each of the first, second and third tube segments **26**, **27**, and **28** have respective distal and proximal ends **31**, **32**. Connected to distal end **31** of first

tube segment **26** is fluid source **40** for providing fluid to a patient while the proximal end **32** thereof is attached to a drip chamber **33**. As further shown, drip chamber **33** has an abutment surface **34** which interconnects proximal end **32** of first tube segment **26** with distal end **31** of second tube segment **27**. The proximal end **32** of second tube segment **27** is then interconnected to distal end **31** of third tube segment **28** by a coupling **36** having an external flange **38**. Finally, third tube segment **28** terminates at a proximal end **32** which is attached to an enteral or parenteral connection (not shown) made with the patient for delivery of fluid.

As illustrated in FIG. **1**, drip chamber **33** and coupling **36** are sized and shaped to be captured within first recess **22** and second recess **24**, respectively. Preferably, the length of second tube segment **22** permits drip chamber **33** and coupling **36** to be properly captured within first recess **22** and second recess **24**, respectively, while also stretching second tube segment **27** as it is engaged around rotor **18**. Accordingly, the amount of tensile force A (FIG. **9**) applied along second tube segment **27** as it is engaged around rotor **18** may be varied by altering the length of tube segment **27**. With reference to FIG. **6**, each tube segment **26**, **27** and **28** of tube assembly **14** includes a lumen **30** formed therethrough by which fluid may pass from fluid source **40**.

Referring to FIG. **4**, valve device **16** comprises a hollow flexible body **44** having a tapered portion **60**. With further reference to FIGS. **3** and **5**, tapered portion **60** includes opposing beveled surfaces **62** bounded by a pair of side walls **63** with surfaces **62** having ends **48** which define a slit **50**. Body **44** further includes a proximal end **46**, as shown in FIG. **7**, which forms an outlet **52** in communication with a passage **64** such that fluid which enters slit **50** may pass along passage **64** and out outlet **52**. As further shown in FIG. **4**, the intersection between tapered portion **60** and cylindrical portion **56** defines a shoulder **54**. However, in the alternative cylindrical portion **56** may simply taper gradually into tapered portion **60** without departing from the scope of the present invention.

As shown in FIGS. **6** and **9**, valve device **16** is preferably disposed within lumen **30** of second tube segment **27** adjacent coupling **36** (FIG. **2**) with slit **50** facing the direction of fluid flow while outlet **52** is oriented toward proximal end **32** of

third tube segment **28** (FIG. **2**). The cylindrical portion **56** is sized and shaped to sealingly engage against the inner surface of lumen **30** and prevent fluid flow around valve device **16**. When second tube segment is in a relaxed condition, the ends **48** of opposing beveled surfaces **62** substantially confront one another such that slit **50** is maintained in a closed position, thereby preventing fluid flow through passage **64** of hollow body **44**. Referring to FIGS. **8** and **9**, fluid flow may be established through valve device **16** by applying tensile force A along second tube segment **27** by engaging a portion of tube segment **27** around rotor **18**. When engaging second tube segment **27** around rotor **18**, tube segment **27** is placed in a stretched condition as tensile force A is applied therealong. As further shown, tensile force A also causes a transverse force B to be applied to cylindrical portion **56** which decreases the inner diameter of the lumen **30** as a result of second tube segment **27** being placed in the stretched condition. In the stretched condition body **44** becomes elongated which urges the ends **48** of opposing beveled surfaces **62** away from one another and opens slit **50** to permit fluid flow therethrough. Referring to FIG. **6**, once second tube segment **27** is disengaged from rotor **18**, tensile force A and transverse force B cease and tube segment **27** is returned to the relaxed condition. In the relaxed condition, ends **48** of opposing beveled surfaces **62** confront one another, thereby placing slit **50** in the closed position and prevent fluid free flow.

One skilled in the art can appreciate that the decrease in the inner diameter of lumen **30** is directly proportional to the tensile force applied to second tube segment **27**. Accordingly, the amount second tube segment **27** is stretched due to the tensile force applied thereto may be modified by changing the length of second tube segment **27**. Alternatively, the amount that the inner diameter of lumen **30** is decreased may be accomplished by pre-stressing body **44** of valve device **16** in a direction approximately transverse to slit **50**, thereby biasing body **44** into a generally oval shaped configuration. Preferably, valve device **16** may be pre-stressed by placing an oval-shaped insert **66**, as shown in FIG. **11**, into passage **64** of body **44**. The preferred embodiment of insert **66** comprises a thin oval body **68** defining apertures **70** for allowing fluid flow therethrough. In addition, insert **66** also includes tabs **72** which are sized and shaped to be received within a respective slots **65**

formed along the inner surface of passage **64**, as illustrated in FIG. **10**, for facilitating retention of insert **66** within valve device **16**. It is contemplated that insert **66** may have one or more tabs **72** or one or more apertures **70**.

One skilled in the art can appreciate that a variety of other methods may be utilized to pre-stress valve device **16** into an oval shaped configuration such that the major diameter of insert **66** is transverse to the slit **50**. For example, the present invention also contemplates a variety of alternative embodiments of insert **66**. As illustrated in FIGS. **12** and **13**, one alternative embodiment is insert **166** which is shown having a generally rectangular-shaped body **74** which biases body **44** into a generally oval shaped configuration when inserted through opening **52** and retained within passage **64** by opposing tabs **172** which securely engage slots **65** formed along the inner surface of passage **64**.

In another alternative embodiment shown in FIG. **14**, insert **266** has an elongated oval body **276** with no tabs required to retain insert **266** inside valve device **16**. Insert **266** is inserted through opening **52** and substantially fills passage **64** such that body **44** takes a generally oval shaped configuration.

In operation, the user of the present invention connects the distal end **31** of first tube segment **26** with fluid source **40** and permits fluid flow through lumen **30** until the fluid reaches the point where valve device **16** is disposed within tube assembly **14**. With tube assembly **14** in a relaxed condition and disengaged from pump **12**, valve device **16** prevents fluid free flow into third tube segment **28**. Preferably, air is cleared from third tube segment **28** when the user primes tube assembly **14** by applying a tensile force A along the area of the tube assembly **114** adjacent valve device **16** to place second tube segment **27** in the stretched condition and open slit **50** to fluid flow. Applying tensile force A causes second tube segment **27** to stretch which in turn exerts a transverse force B against body **44** that decreases the inner diameter of lumen **30**. The decrease in the inner diameter of lumen **30** elongates body **44** and urges the ends **48** of opposing beveled surfaces **62** away from one another, thereby placing slit **50** in the open position and allow fluid flow therethrough. Alternatively, the user can manually prime the tube assembly **14** by pinching body **44** of valve device **16** in a direction transverse to slit **50**. By

pinching valve device **16** in this manner, the ends **48** of the beveled surfaces **62** are urged away form one another which opens slit **50** such that fluid flow may be established through lumen **30**. Once all the air is cleared from tube assembly **14**, the proximal end **32** of third tube segment **28** may be connected to an enteral or parenteral connection on the patient.

To regulate and urge the fluid through tube assembly **14**, a pump **12** is connected in-line along tube assembly **14**. Specifically, abutment surface **34** of drip chamber **33** is engaged with first recess **22** and second tube segment **27** is stretched by the user around rotor **18**. The external flange **38** of coupling **36** is then engaged within second recess **24** in order to retain second tube segment **27** in the stretched condition. Due to the tensile force applied along second tube segment **27**, the inner diameter of lumen **30** is decreased such that the inner surface of lumen **30** confronts and elongates body **44**. When body **44** becomes elongated, the ends **48** of beveled surfaces **62** are urged away from one another and slit **50** is placed in the open position, thereby permitting fluid flow through passage **64** and out outlet **52**. However, if tube assembly **14** becomes disengaged from pump **12**, the tensile force exerted along second tube segment **27** will be released which automatically results in expansion of the inner diameter of lumen **30** so that the ends **48** of opposing beveled surfaces **62** confront one another and place slit **50** in the closed position which prevents fluid flow through body **44**.

It should be understood from the foregoing that, while particular embodiments of the invention have been illustrated and described, various modifications can be made thereto without departing from the spirit and scope of the present invention. Therefore, it is not intended that the invention be limited by the specification; instead, the scope of the present invention is intended to be limited only by the appended claims.

CLAIMS

~~I~~We Claim:

1. CANCELLED.

2. The valve (16) according to claim 11, wherein an inner diameter of the lumen (30) decreases when the tube assembly (14) is in said stretched condition which elongates said body (44).

3. The valve (16) according to claim 11, wherein said body (44) elongates when the tube assembly (14) is in said stretched condition.

4. The valve (16) according to claim 11, wherein said body (44) is made of a flexible material.

5. The valve (16) according to claim 11, wherein said valve (16) further comprises an insert (66) inserted within said passage (64).

AMENDED SHEET

6. The valve (16) according to claim **5**, wherein said insert (66) comprises:

a body (68) having at least one aperture (70) formed therethrough and at least one tab (72) extending from said body (68).

7. The valve (16) according to claim **6**, wherein said valve (16) further comprises at least one slot (65) formed along said passage (64) which is sized and shaped to receive said tab (72) for retaining said insert (66) inside said passage (64).

8. The valve (16) according to claim **6**, wherein said body (68) has a generally thin oval shape.

9. The valve (16) according to claim **6**, wherein said body (166) has a generally elongate square shape.

10. The valve (16) according to claim **6**, wherein said body (276) has a generally elongated oval shape.

11. (Amended) A tube assembly (14) for use with a fluid administration system (10) connected between a patient and a fluid source (40) characterized in that:

at least one elastic tube segment (26, 27, 28) having a lumen (30) therethrough; and

a valve (16) disposed within said lumen (30) and sealing said lumen (30) to fluid flow therethrough, said valve (16) having a body (44) including a cylindrical portion (561) having an opening (52) and a tapered portion (60) formed adjacent said cylindrical portion (56), said tapered portion (60) having a slit (50), and a passage (64) formed between said opening (52) and said slit (50).

wherein when said at least one elastic tube segment (26, 27, 28) is in a relaxed condition, said slit (50) is placed in a closed position which prevents fluid free flow through said passage (64) and when said at least one elastic tube segment (26, 27, 28) is in a stretched condition said slit (50) is placed is placed in an open position which permits fluid flow through said passage (64).

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12. The tube assembly (14) according to claim 11, wherein said at least one tube segment (26, 27, 28) comprises:

a first tube segment (26);

a second tube segment (27) connected to said first tube segment (26); and

a third tube segment (28) connected to said second tube segment (27)

13. The tube assembly (14) comprising:

a drip chamber (33) interconnected between said first tube segment (26) and said second tube segment (27); and

a coupling (36) interconnected between said second tube segment (27) and said third tube segment (28).

14. The tube assembly (14) according to claim 11, wherein the valve (16) is formed from an elastically deformable material.

15. The tube assembly (14) according to claim 11, wherein said body (44) elongates when said at least one tube segment (26, 27, 28) is in said stretched condition.

16. The tube assembly (14) according to claim 11, wherein said an inner diameter of said lumen (30) decreases when said at least one tube segment (26, 27, 28) is in said stretched condition.

17. The tube assembly (14) according to claim 11, wherein said tapered portion (60) further comprises opposing beveled surfaces (62) with ends (48) which form said slit (50).

18. The tube assembly (14) according to claim 11, wherein said valve (16) further comprises an insert (66) fitted within said passage (64).

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19. The tube assembly (14) according to claim 18, wherein said insert (66) comprises:

a body (68, 166, 276) having at least one opening (52) formed therethrough and at least one tab (72) extending from said body (68, 166, 276).

20. The tube assembly (14) according to claim 19, wherein said valve (16) further comprises at least one slot (65) formed along said passage (64) which is sized and shaped to receive said tab (72) and retain said insert (66) inside said passage (64).

21. The tube (14) assembly according to claim 19, wherein said body (68) has a generally thin oval shape.

22. The tube (14) assembly according to claim 19, wherein said body (166) has a generally elongated square shape.

23. The tube assembly (14) according to claim 19, wherein said body (276) has a generally elongated oval shape.

24. (Amended) A method for preventing fluid free-flow in a fluid administration system (10) which is connected to a fluid source (40) and the fluid administration (10) system including a pump (12) and a tube assembly (14) having two ends and a lumen (30) formed therethrough, the fluid administration system (10) further including a valve (16) disposed within the lumen (30), the valve (16) comprising a body (44), the body (44) including a cylindrical portion (56) with an opening (52) formed at one end and a tapered portion (60) formed adjacent another end of the cylindrical portion (56), the tapered portion (60) including opposing beveled surfaces (62) with ends (48) that define a slit (50) between the ends (48), the method comprising the steps of:

(a) attaching one end of the tube assembly (14) to a fluid source (40); and

(b) attaching the tube assembly (14) to the pump (12) such that the tube assembly (14) stretches and elongates the body (44) of the valve (16); to

permit fluid flow therethrough while disconnecting the tube assembly (14) from pump (12) closes body (44) to fluid flow

(c) attaching the other end of the tube assembly (14);

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25. The method according to claim **24**, wherein when the body (44) elongates said slit (50) is placed in an open position which permits fluid flow through said passage (64) of the body (44).

26. The method according to claim **24**, wherein when one end of the tube assembly (14) is attached to the fluid source (40), the slit (50) is placed in a closed position which prevents fluid free flow through the passage (64) of the body (44).

27. The method according to claim **25**, wherein when the slit (50) is in the closed position, the ends (48) of the opposing beveled surfaces (62) confront one another and prevent fluid flow through the passage (64) of the body (44).

28. The method according to claim 24, wherein attaching the tube assembly (14) to the pump (12) causes fluid to flow through the body (44) of the valve (16).

Empfangszeit 24.Apr. 0:24

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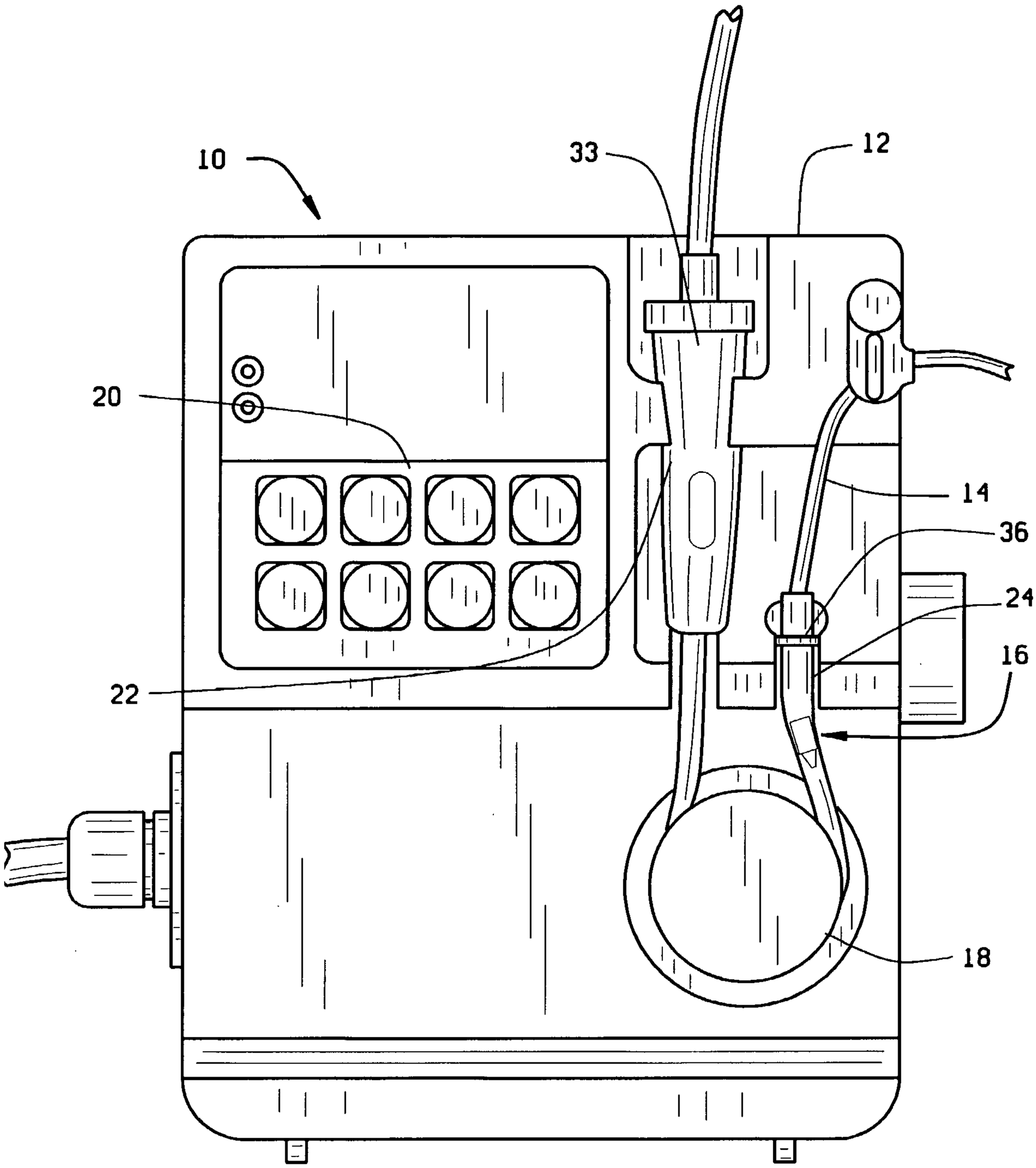


FIG. 1

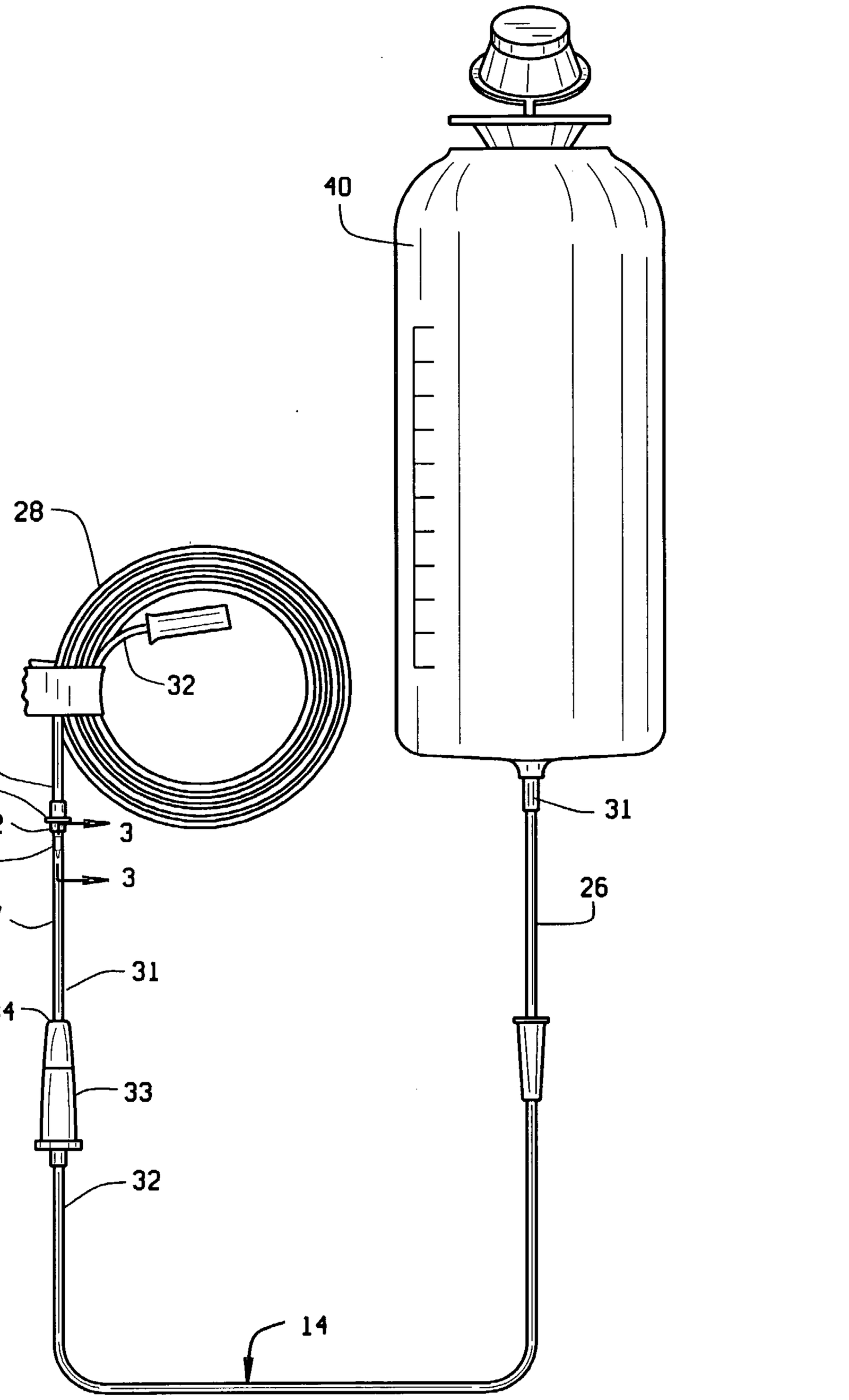


FIG. 2

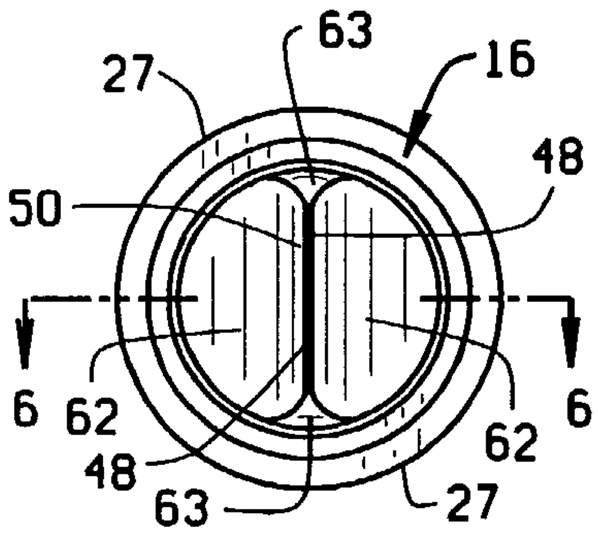


FIG. 3

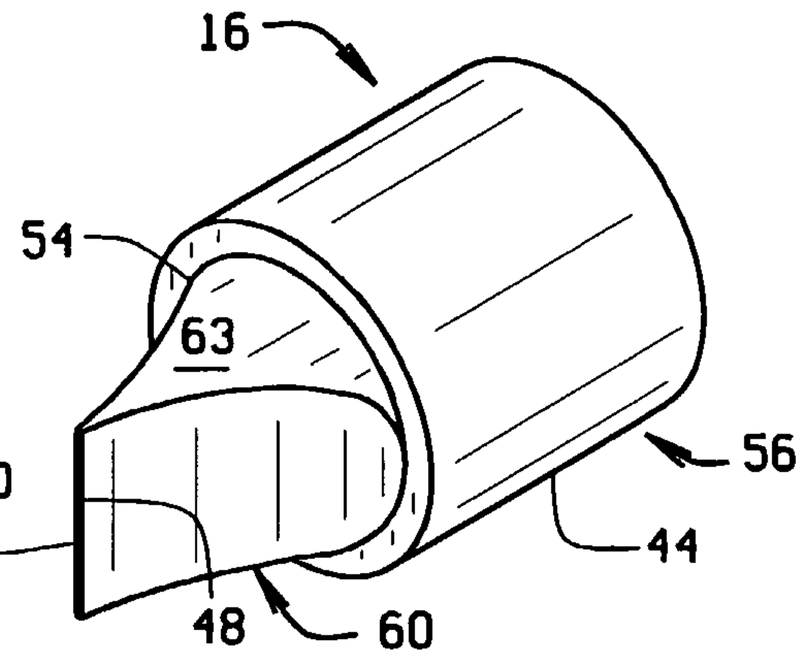


FIG. 4

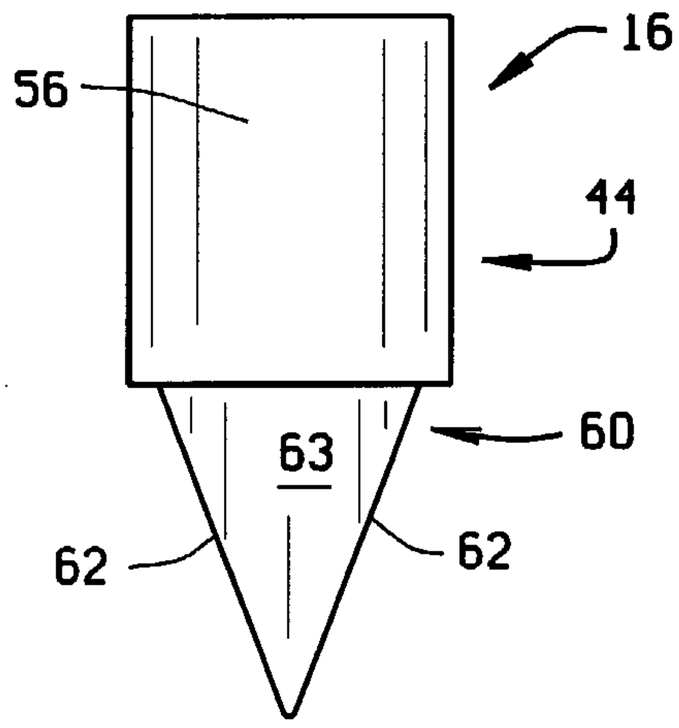


FIG. 5

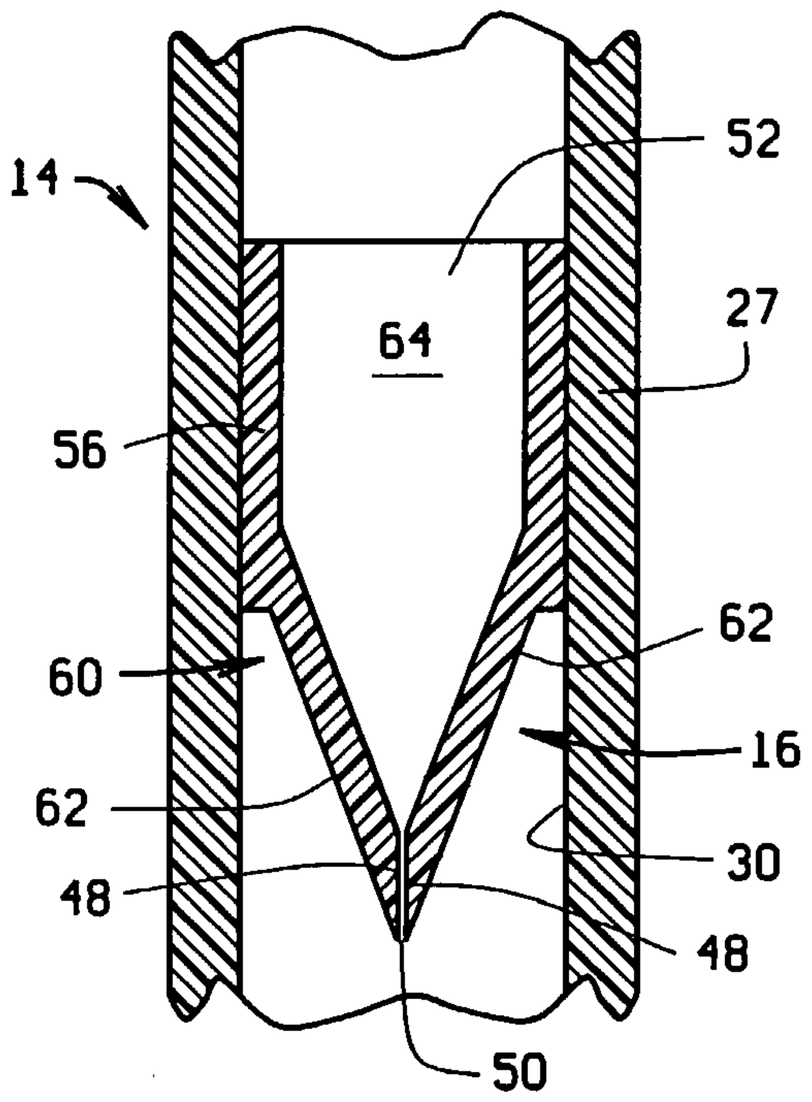


FIG. 6

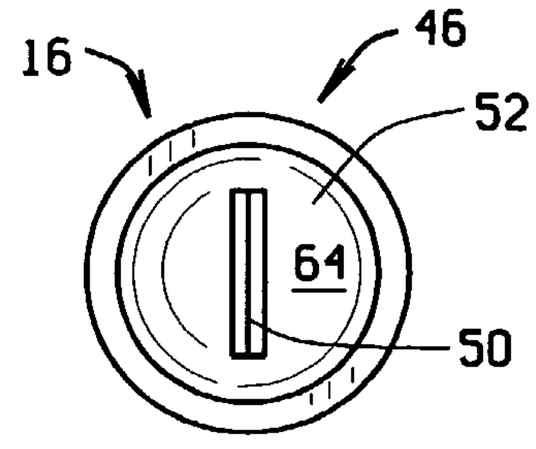


FIG. 7

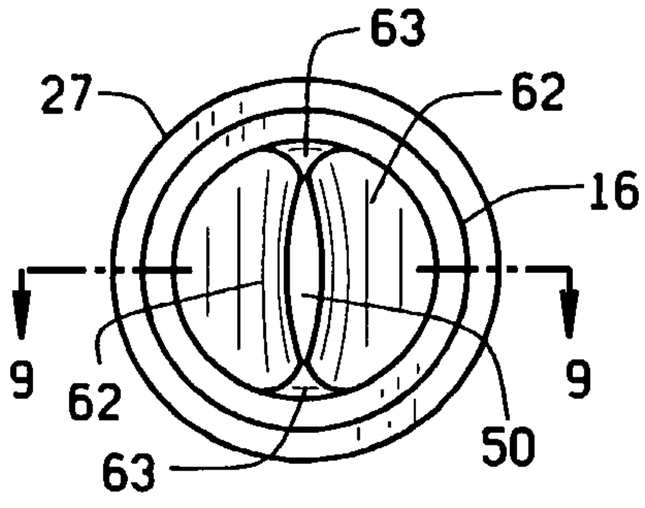


FIG. 8

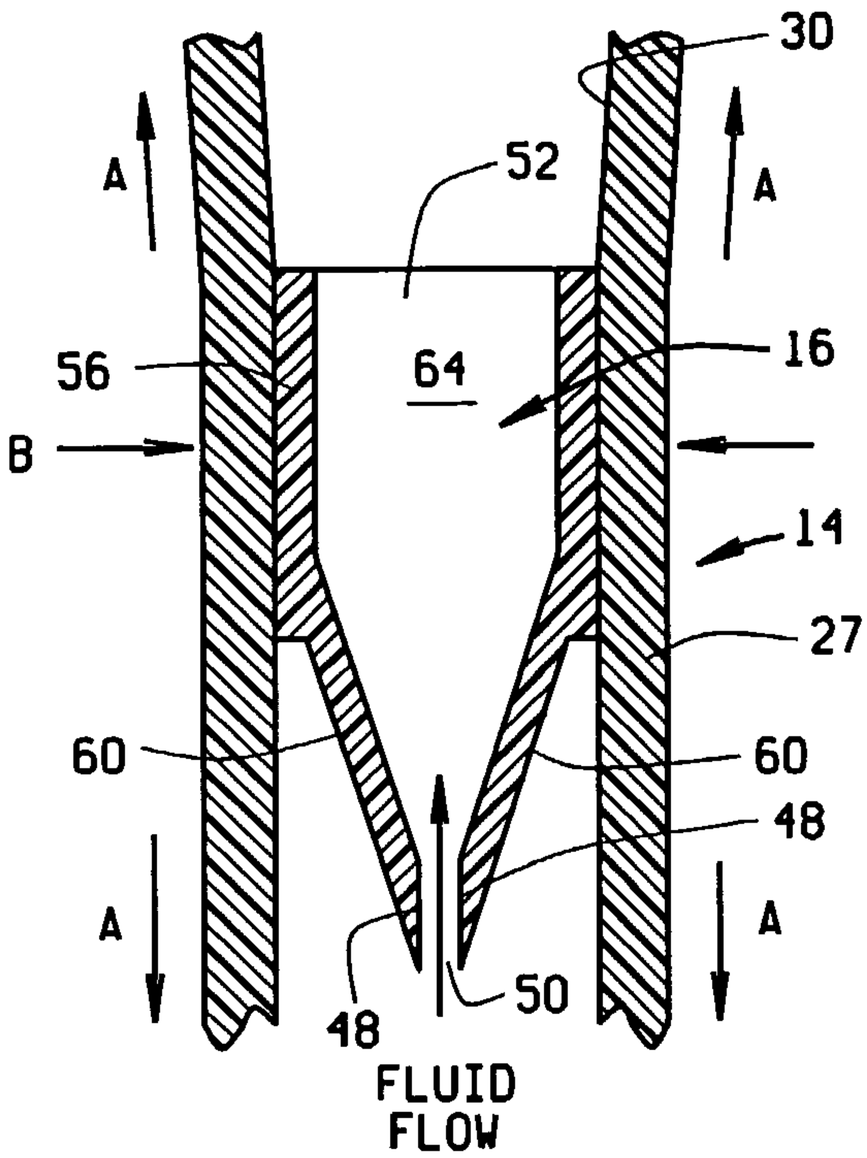


FIG. 9

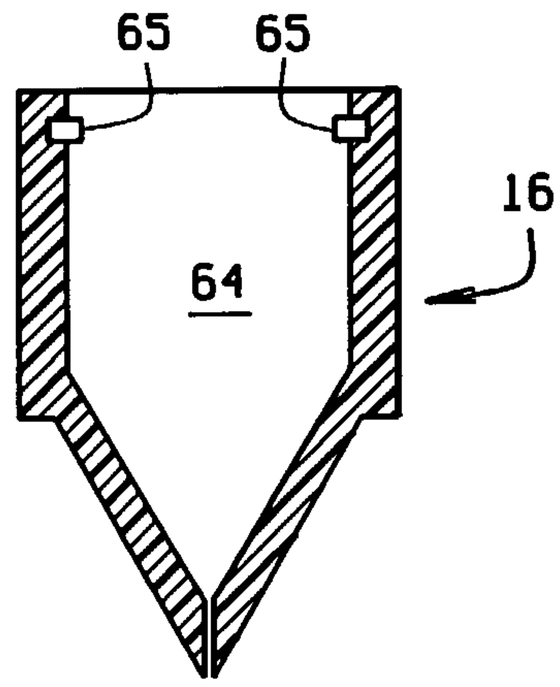


FIG. 10

FIG. 12

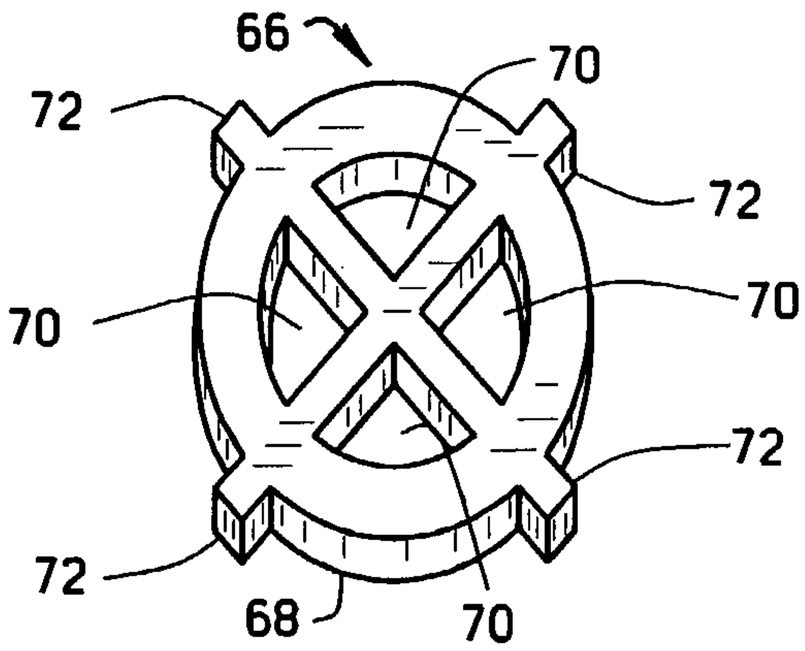


FIG. 11

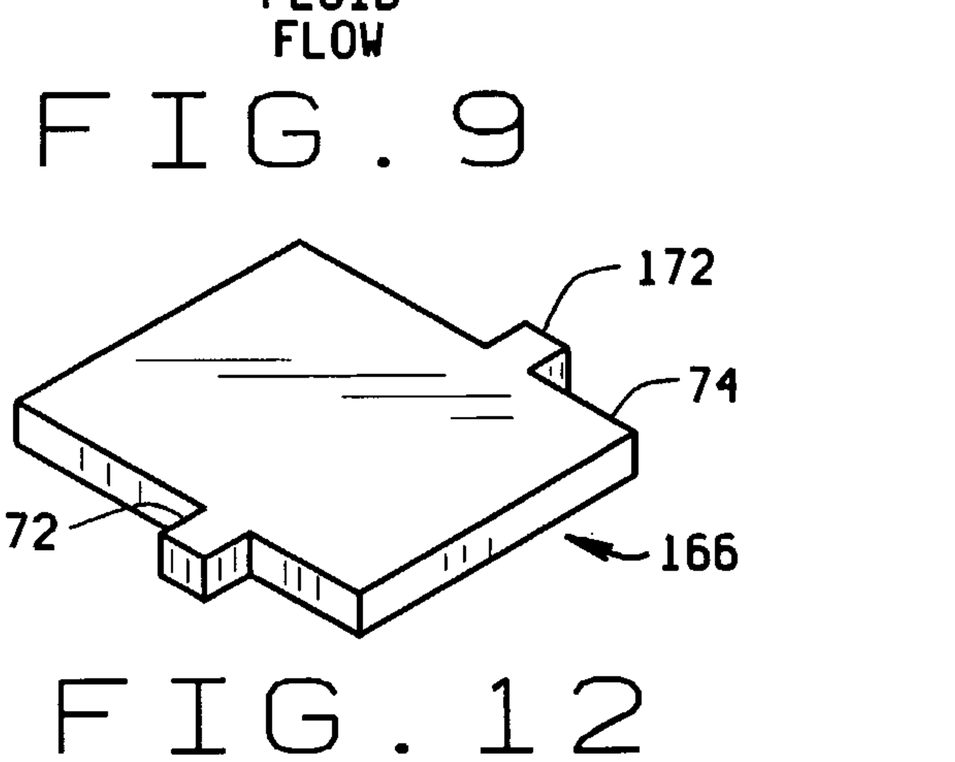


FIG. 13

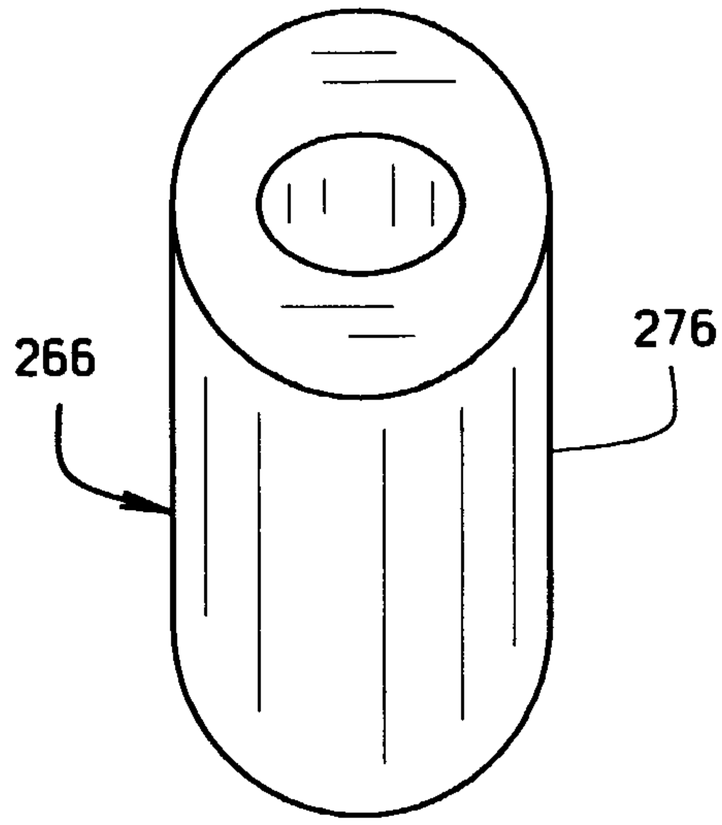
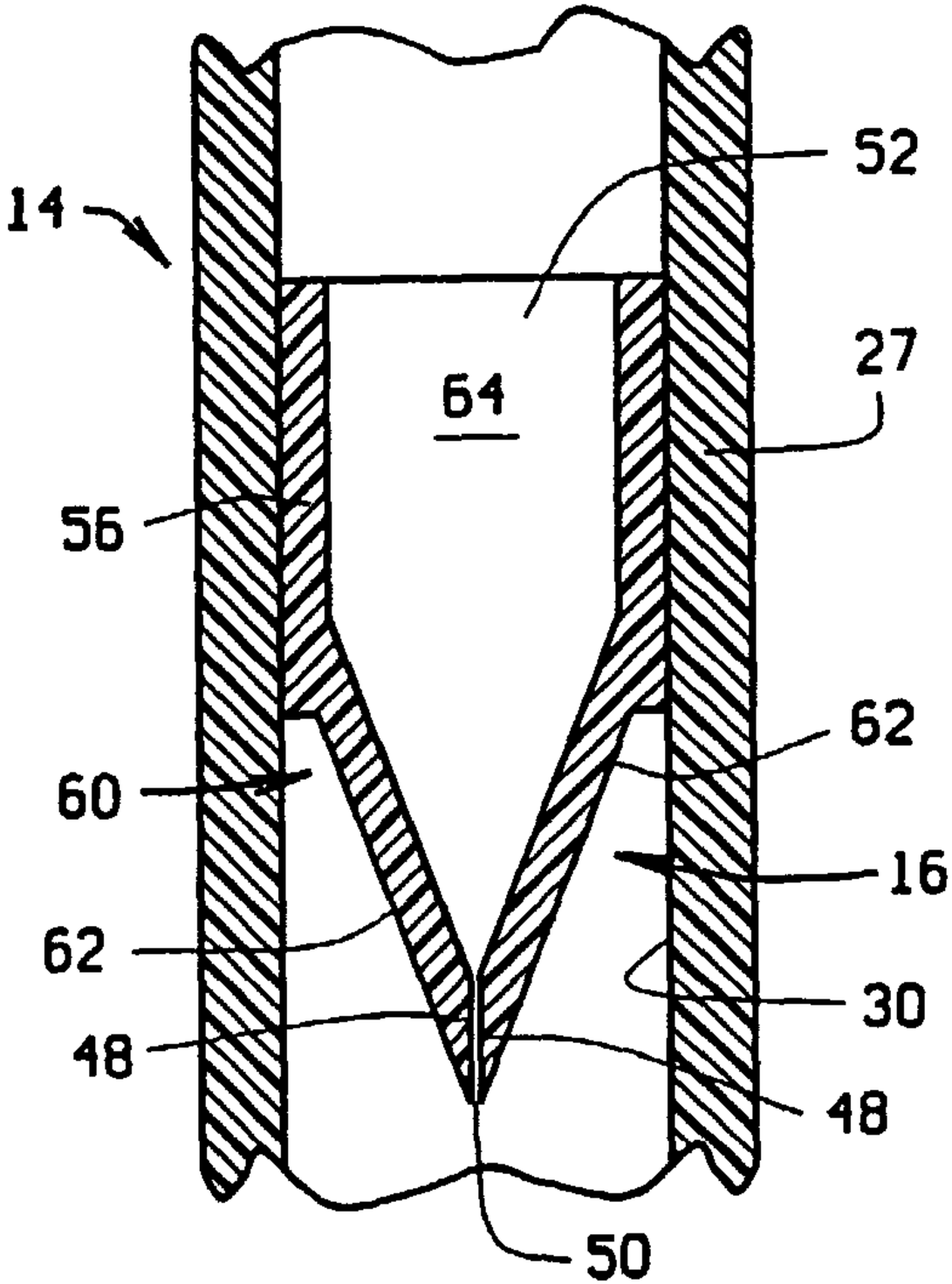


FIG. 14


14
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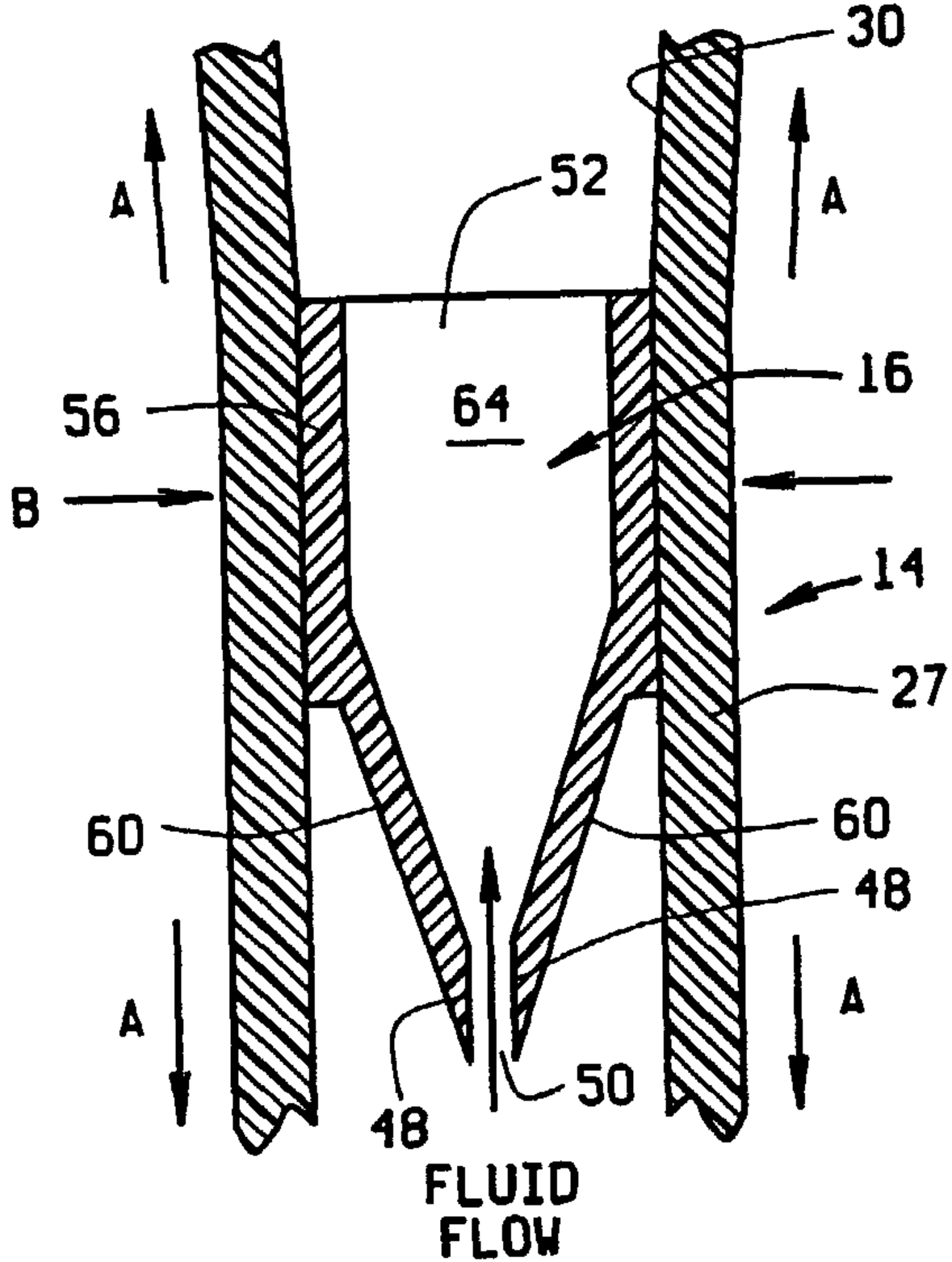
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FLOW