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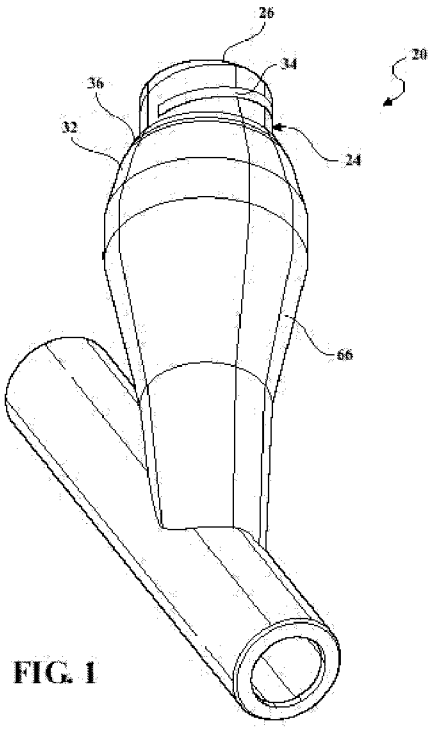

FIG. 1

(57) Abstract: A medical valve assembly including a rigid external housing and a valve stem of a resilient material. The valve stem includes a passageway for conveying a fluid which has an hourglass shape to create a venturi effect when cleaning the valve stem to improve the efficiency of the cleaning process. The passageway also includes no sharp edges, thus reducing the risk of fluid getting trapped inside the passageway when the medical valve assembly is not in use. Even further, when a needleless syringe is removed from the valve stem, the valve stem expands to an uncompressed state with its top end being generally flush with an end of the housing to present a swabable surface for cleaning purposes.

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MEDICAL VALVE ASSEMBLY

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of provisional application Serial Number 61/392,063 filed October 12, 2010 and of provisional Serial Number 61/474,925, filed April 13, 2011.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The invention relates to a medical valve assembly for receiving a fluid from a needleless syringe.

2. Description of the Prior Art

[0003] Needleless syringes are used in the medical field to deliver fluids to a patient without the risk of an accidental needle poke on either the patient or the person treating the patient. Needleless syringes generally include a luer for delivering the fluid to a medical valve and threads for threadedly engaging the medical valve. Various medical valves have been developed to engage the needleless syringes and deliver the fluid to an IV line of a patient. One such medical valve is shown in US Patent No. 6,651,956, issued to Pavel T. Miller on November 25, 2003 (hereinafter referred to as "Miller '956"). The Miller '956 valve includes a housing; a receiver; and a valve stem presenting passageway and a stem slit for opening to receive the luer of the needleless syringe. The valve stem has an outer wall including a notch, which creates a gap between the internal wall of the housing and the outer wall of the valve stem. In operation, the luer of the needleless syringe is inserted into the stem slit of the valve stem and the valve stem buckles outwardly into the gap at the notch to provide room for the luer to penetrate into the passageway of the valve stem. This buckling movement of the valve stem changes the volume of the passageway and requires wasted space to allow for the valve stem to buckle outwardly.

[0004] When connected to an indwelling catheter, such medical valves provide a direct pathway for the infusion of fluids and medications into the vascular system of the patient. However this open pathway can also lead to the serious patient complications, if left unattended. It is a common practice to infuse fluids and medications by hanging a saline bag on an IV pole and permitting the gravity flow of

fluid into the patient through an IV tube connected to the medical valve. If the attending staff are not vigilant, air can also enter the patient after all fluid has been infused. The resulting air embolism can cause significant patient morbidity or death. This can be prevented by placing a one way valve, or a check valve, between the needle free adapter and the IV tubing; however, this solution may be costly, a suitable check valve may not be available, and the additional connections and disconnections can be a source of contamination. Furthermore, check valves generally prevent the aspiration of blood for sampling to assess the patient's condition, thus requiring a separate valve for this process.

[0005] There remains a continuing need for improved medical valves for receiving needleless syringes.

SUMMARY OF THE INVENTION

[0006] According to one aspect of the invention, the medical valve assembly includes a housing, a receiver, and a valve stem. The valve stem presents a passageway for the flow of fluid and is of a resilient material, such as silicone, for resiliently deforming when the luer of a needleless syringe is inserted into the valve stem through the stem slit. The passageway of the valve stem has an hourglass shape for bulging inwardly in response to compression of the valve stem. Because of the hourglass shape, the volume of the passageway is decreased as compared to a valve stem having straight inner walls which could lead to a reduced risk of infection from fluids remaining in the passageway when the medical valve assembly is not in use. This reduction of the inner diameter of the fluid pathway creates a venturi effect when fluid is infused rapidly, such as during flushing of the valve. This venturi effect results in a more effective and efficient cleaning of the interior surfaces of the fluid pathway, thereby ensuring that blood is completely removed. This efficient design permits a minimal amount of saline flush to achieve the desired result without the use of heparin, which is contraindicated in neonates and immune surpressed patients. In other words, the medical valve assembly is more safe and sanitary than the medical valve assemblies of the prior art.

[0007] According to another aspect of the invention, the valve stem defines a point of reduced wall thickness, or a point of weakness, for deforming and collapsing a portion of the valve stem inwardly and downwardly into the housing at the point of weakness. The volume of the passageway of the valve stem remains relatively

constant when this portion of the valve stem buckles and subsequently returns to its resting space after the luer of the needleless syringe is removed. This has the effect of reducing aspiration of the fluid when the luer of the needleless syringe is removed from the valve stem.

[0008] The medical valve assembly permits infusion of fluids as well as aspiration of blood samples. In addition, the medical valve is designed to prevent the inadvertent aspiration of air into the patient by stopping the fluid meniscus before it reaches the needleless syringe. Thus, the mechanism improves patient safety and reduces staff stress, thus permitting the staff to attend to more urgent matters.

[0009] According to yet another aspect of the invention, the medical valve assembly includes a bi-directional disc valve, which provides a safety mechanism to prevent exsanguination in the event of failure of the valve stem. The disc valve is never exposed to the perforation in the valve stem and responds only to differential pressure. The disc valve may additionally be calibrated to permit flow of fluid from the patient only in response to a higher pressure than those generated in the vascular system.

[0010] According to a further aspect of the invention, the medical valve assembly is smaller and more comfortable for the patient than the prior art medical valve assemblies because the valve stem collapses inwardly and downwardly at the point of weakness rather than buckling outwardly. This eliminates the need for a gap between the inner wall of the housing and the outer wall of the valve stem.

[0011] According to an additional aspect of the invention, all of the internal surfaces of the inner stem wall of the valve stem are smooth and rounded, i.e. there are no internal ribs or sharp corners. This reduces the chance that blood coagulates or other particulates will get trapped inside of the valve stem upon disconnection of the needleless syringe, thereby contaminating the valve stem.

[0012] According to yet another aspect of the invention, the valve stem presents a first stem end flush with a first housing end to seal the valve stem to the housing. The first stem end can be quickly and easily wiped clean between uses of the medical valve assembly.

[0013] According to another aspect of the invention, the housing of the medical valve has a housing exterior wall presenting threads for engaging the needleless syringe. The housing exterior wall defines a shoulder to present a stopping point for the needleless syringe. In other words, the needleless syringe can only be

threaded onto the housing up to the shoulder. The shoulder prevents the luer from being inserted too far into the housing and also prevents the needleless syringe from being overtightened onto the housing, which can crack the rigid housing. This feature is also designed to limit the penetration of the luer into the passageway (lumen) of the valve stem, thereby displacing less volume than other designs. The reduced displaced volume reduces both negative pressure and negative displacement of fluid when the needleless syringe is disconnected.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Other advantages of the present invention will be readily appreciated, as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

[0015] Figure 1 is a perspective view of a first exemplary embodiment of the medical valve assembly;

[0016] Figure 2 is a perspective and exploded view of the first exemplary embodiment of the medical valve assembly;

[0017] Figure 3 is a perspective view of the valve stem;

[0018] Figure 4 is a cross-sectional view of the valve stem taken along line 4-4 of Figure 3;

[0019] Figure 5 is an enlarged view of the first stem end of Figure 4;

[0020] Figures 6a-6e are cross-sectional views of the valve first embodiment of the invention and showing the luer being inserted into the housing;

[0021] Figure 7 is a top view of the first exemplary embodiment wherein the valve stem includes a linear stem slit;

[0022] Figure 8a is a top view of the first exemplary embodiment and showing exemplary circles in dashed lines for shaping an alternate stem slit;

[0023] Figure 8b is a top view of the first exemplary embodiment and wherein the valve stem has a reverse-S shape;

[0024] Figure 9a is a top view of the first exemplary embodiment and showing exemplary circles different than the circles of Figure 8a for shaping a different alternate stem slit;

[0025] Figure 9b is a top view of the first exemplary embodiment and wherein the valve stem has a reverse-S shape different than the stem slit of Figure 8b;

[0026] Figure 10 is a perspective and exploded view of the second exemplary embodiment of the medical valve assembly;

[0027] Figure 11a is a perspective view of an exemplary disc valve; and

[0028] Figure 11b is a cross-sectional view of the exemplary disc valve taken along line B-B of Figure 11a.

DETAILED DESCRIPTION OF THE ENABLING EMBODIMENTS

[0029] Referring to the Figures, wherein like numerals indicate corresponding parts throughout the several views, a first exemplary embodiment of a medical valve assembly **20** for receiving a fluid from a needleless device is generally shown in Figure 1. The needleless device is hereinafter referred to as a needleless syringe **22**, though it should be appreciated that the needleless device could be any desirable device for injecting and/or ejecting a fluid.

[0030] The first exemplary medical valve assembly **20** includes a rigid external housing **24**, generally indicated, extending along an axis **A** from an open first housing end **26** to an open second housing end **28**. Preferably, the housing **24** is made of a polymeric material, but it should be appreciated that the housing **24** can be made of any rigid material. The housing **24** defines a housing inner wall **30** and a housing exterior wall **32**, which defines threads **34** adjacent to the first housing end **26** for threadedly engaging the needleless syringe **22**. The housing exterior wall **32** further defines a shoulder **36**, which defines a stopping point for the needleless syringe **22** or other similar device used in IV infusion. As will be discussed in greater detail below, when the needleless syringe **22** is threaded by a predetermined distance onto the threads **34** of the housing **24**, the needleless syringe **22** will abut the shoulder **36** to prevent further threading. This protects the medical valve assembly **20** by preventing the luer **38** of the needleless syringe **22** from being inserted too far into the medical valve assembly **20** and by preventing the needleless syringe **22** from being over tightened onto the housing **24**, which could crack the rigid housing **24**.

[0031] The first exemplary medical valve assembly **20** also includes a valve stem **40**, which is generally indicated in Figure 1 and generally shown in Figure 3. As shown in Figures 6a-e, the valve stem **40** is disposed in the housing **24** and extends along the axis **A** between the first and second housing ends **26, 28**. The valve stem **40** receives the luer **38** of the needleless syringe **22** and prevents the fluid from flowing out of the housing **24** upon removal of the male luer **38**. To accomplish this,

the valve stem **40** has an outer stem wall that engages and is sealed to the housing inner wall **30** and an inner stem wall **42** presenting a passageway **44** for conveying the fluid through the valve stem **40**. The valve stem **40** is preferably made of a resilient material for resiliently deforming when the male luer **38** of the needleless syringe **22** is inserted into the valve stem **40** and for returning to a relaxed, or uncompressed, position when the male luer **38** has been removed from the valve stem **40**. The valve stem **40** is preferably made of a silicone material having a durometer in the range of 25 to 65. The silicone material is also preferably lubricated to reduce friction forces between the valve stem **40** and the housing **24**. Among other options, the silicone can be prelubricated, the lubrication could be added during the injection molding process of forming the valve stem **40**, or the silicone could be sprayed on the outside of the valve stem **40** after the valve stem **40** has been formed.

[0032] The valve stem **40** has a first stem end **46** extending radially inwardly form the housing inner wall **30** to close the first housing end **26**. When the valve stem **40** is in an uncompressed state, the first stem end **46** is flush with the first housing end **26** to provide a swabable surface for cleaning the valve stem **40** between uses. The first stem end **46** further presents a stem slit **48** which is normally closed and opens to receive the male luer **38** of the needleless syringe **22**, as will be discussed in further detail below. The stem slit **48** subsequently recloses when the luer **38** is withdrawn from the passageway **44** to prevent the entry of contaminates or the exit of the fluid from the valve stem **40**. The stem slit **48** can be either cut straight across and through the first stem end **46**, as shown in Figure 7, or it could alternatively may have a reverse S-shape, the later of which is shown in Figures 8b and 9b. The purpose of the reverse-S shaped stem slit **148, 248** is to relieve stresses created at either end of the slit created by the clockwise rotation of the needleless syringe **22** from threading it onto the external housing **24** A reduction of mechanical stress at the endpoints of the stem slit **48, 148, 248** reduces the potential of tearing of the silicone, thereby prolonging the life of the valve stem **40** and increasing the number of times the medical valve assembly **20** may be used without compromising the integrity of the valve stem **40**.

[0033] The valve stem **40** further defines a first stem portion **50** adjacent the first housing end **26**, a second stem portion **52**, and a third stem portion **54** adjacent the second housing end **28**. As best shown in Figures 4 and 5, at the intersection of the first stem end **46** and the first stem portion **50**, there is a fillet **56** which serves to strengthen the junction to resist torsional and axial stress. Additionally, all of the edges

of the inner stem wall **42** of the valve stem **40** are rounded and smooth, i.e. there are no ribs or sharp corners. This reduces the chance that blood coagulates or other particulates, which could contaminate the valve stem **40**, will get trapped inside of the passageway **44**.

[0034] The first stem portion **50** has a generally cylindrical shape and extends axially along the housing inner wall **30** from the first stem end **46** to the second stem portion **52**. As best shown in Figure 4, the inner stem wall **42** is radiused inwardly from a point **58A** on the inner stem wall **42** of the first stem portion **50** to a point **58B** on the inner stem wall **42** of the third stem portion **54**. The radius of the inner stem wall **42** of the second stem portion **52** bulges out into passageway **44** for conveying the fluid through the valve stem **40** to give the passageway **44** an hourglass shape. Because of the hourglass shape, the volume of the passageway **44** is decreased as compared to a valve stem **40** having straight inner walls, which could lead to a reduced risk of infection from fluids remaining in the passageway **44** when the medical valve assembly **20** is not in use.

[0035] The second stem portion **52** extends between the first and third stem portions **50, 54**, and the outer stem wall of the second stem portion **52** slopes outwardly present a larger wall thickness in the second stem portion **52** relative to the first stem portion **50**. The larger wall thickness of the second stem portion **52** urges the first stem portion **50** toward the first housing end **26** when the luer **38** is withdrawn from the valve stem **40**. Likewise, the stem wall slopes outwardly in the third stem portion **54** to present a larger wall thickness for urging the second stem portion **52** to its uncompressed location when the luer **38** is withdrawn from the valve stem **40**.

[0036] The valve stem **40** defines a point of reduced wall thickness in the valve stem **40**, or a point of weakness **60**, at the intersection of the interior wall of the first and second stem portions **50, 52**. As discussed in further detail below, the first stem portion **50** deforms and buckles inwardly and downwardly at the point of weakness **60** in response to the luer **38** being inserted into the stem slit **48** of the first stem end **46**.

[0037] In the exemplary valve stem **40**, the outer stem wall in the third stem portion **54** defines a lip **62** and an open area **64**. As shown in Figures 6a-e, when the needleless syringe **22** is threaded onto the threads **34** of the external housing **24** wall, the valve stem **40** deforms by a predetermined distance before the stem slit **48** opens to allow the insertion of the luer **38** into the passageway **44**. The open area **64**

functions to reduce the friction between the valve stem **40** and the inner housing **24** wall during the deformation of the valve stem **40**. As the valve stem **40** compresses and deforms, the lip **62** is guided along the housing inner wall **30** of the housing **24**.

[0038] The collapsing of the first stem portion **50** of valve stem **40** inwardly and downwardly at the point of weakness **60** and then the subsequent urging of the valve stem **40** back toward the first housing end **26** upon the removal of the needleless syringe **22** reduces the likelihood that any of the fluid will get trapped around the valve stem **40**, thereby contaminating the valve stem **40**. The opening of the stem slit **48** in the first stem end **46** provides a pathway for fluid exchange between the passageway **44** of the valve stem **40** and the needleless syringe **22**. The outside edges of the first stem end **46** act as a seal about the luer **38** to prevent the escape of fluid about the valve stem **40**. Additionally, the volume of the passageway **44** of the valve stem **40** changes very little when the valve stem **40** collapses downwardly at the point of weakness **60**. There is a risk that the fluid will aspirate when the internal chamber expands in the prior art medical valve assemblies, but that risk is minimized with the exemplary medical valve assembly **20**.

[0039] The shoulder **36** (discussed above) is specifically positioned for allowing the luer **38** of the needleless syringe **22** to penetrate the stem slit **48** while minimizing entry of the luer **38** into the passageway **44**. In other words, the shoulder **36** is designed to limit the axial travel of the luer **38**. As such, the negative displacement which occurs upon removal of the luer **38** during detachment is limited.

[0040] The medical valve assembly **20** further includes a receiver **66, 166** mechanically engaging the second housing end **28** of the housing **24** for receiving the fluid delivered to the passageway **44** by the needleless syringe **22**. The receiver **66** of the exemplary embodiment of Figures 1 and 2 is a Y-connector for conveying the fluid from the passageway **44** into a tube, whereas the receiver **166** of Figures 6a-e is a hose connector for mating with and delivering the fluid into an IV line or any other hose. The receiver **66, 166** is preferably ultrasonically welded to the housing **24**, but any other method of connecting the receiver **66, 166** to the housing **24** may be used. As shown in Figure 6, the valve stem **40** is compressed and captured between the housing **24** and the receiver **66, 166** to form a tight seal and prevent the fluid from leaking out of the medical valve assembly **20** where the housing **24** and receiver **66, 166** meet. As best shown in Figure 4, the valve stem **40** contains a positioning recess **68** which mates

with a positioning ridge **70** on the receiver **66, 166**, thus capturing the valve stem **40** between the housing **24** and receiver **66, 166**.

[0041] As shown in Figure 10, the second exemplary medical valve assembly **20** includes a valve disc **72**, generally indicated, disposed at the second housing end **28** of the housing **24** for restricting the flow of the fluid therethrough and out of the housing **24**. The valve disc **72** presents an upstream side **76** facing the first housing end **26** and a downstream side **74** facing the receiver **66, 166**. The valve disc **72** further defines a circumferential raised rib **78** extending from the upstream side **76** of the valve disc **72**, and a disc slit **80** for allowing the fluid to flow through the valve disc **72** in response to the pressure of the fluid being greater on one side of the valve disc **72** than on the other side of the valve disc **72**. In other words, pressure in the fluid opens and closes the disc slit **80** to allow the fluid to flow therethrough. As shown in Figures 11a-b, the upstream side **76** of the valve disc **72** defines a dimple **82** at the disc slit **80** for reducing the pressure difference required to convey the fluid from the upstream side **76** of the valve disc **72** through the valve disc **72** relative to the pressure difference required to convey the fluid from the downstream side **74** of the disc through the disc. In other words, the dimple **82** allows fluid to flow more easily through the disc slit **80** in one direction relative to the other direction. When valve disc **72** is combined with valve stem **40**, as illustrated in Figure 10, the negative pressure created by the detachment of a luer **38** is insufficient to cause fluid flow to pass through disc slit **80** from the downstream side **74** to the upstream side **76**, thereby eliminating displacement of fluid on the downstream side **74** of valve disc **72**. In other words the combination of disc and valve stem **40** creates a near zero displacement valve. In a further embodiment, the elastic characteristics of valve disc **72** can be modified such that the valve disc **72** will be drawn toward external housing **24** upon withdrawal of the luer **38** without opening disc slit **80**. Immediately upon withdrawal of the luer **38**, the valve disc **72** will snap back to its resting position, forcing a positive displacement of fluid downstream from the downstream side **74** of disc valve and out the passageway **44** of the luer **38**.

[0042] The valve disc **72** could also include a positioning ridge for mating with the positioning recess **68** of the valve stem **40** to seal the valve stem **40** and the valve disc **72** together. Even further, the valve disc **72** can be easily inserted into an existing valve assembly for controlling the flow of the fluid through the valve assembly.

[0043] While the invention has been described with reference to an exemplary embodiment, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted for elements thereof without departing from the scope of the invention. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from the essential scope thereof. Therefore, it is intended that the invention not be limited to the particular embodiment disclosed as the best mode contemplated for carrying out this invention, but that the invention will include all embodiments falling within the scope of the appended claims.

CLAIMS

What is claimed is:

1. A medical valve assembly for receiving a luer of a needleless syringe comprising:

an rigid external housing extending along an axis from an open first housing end to an open second housing end;

a valve stem disposed in said housing and extending from a first stem end defining a slit to a second stem end;

said valve stem presenting a passageway extending from said slit to said second stem end for conveying a fluid therebetween;

said valve stem being of a resilient material for compressing in response to pressure from the luer and wherein said slit on said first stem end opens to receive said luer in response to said valve stem being compressed by a predetermined distance; and

wherein said passageway of said valve stem has an hourglass shape for bulging inwardly in response to compression of said valve stem.

2. The medical valve assembly as set forth in claim 1 wherein said external housing presents an exterior wall presenting threads for threadedly engaging the needleless syringe.

3. The medical valve assembly as set forth in claim 2 wherein said exterior wall further presents a shoulder for limiting the axial travel of the luer into said passageway of said valve stem.

4. The medical valve assembly as set forth in claim 1 wherein said first stem end of said valve stem is generally flush with said open first housing end when said valve stem is uncompressed.

5. The medical valve assembly as set forth in claim 1 wherein said slit has a reverse-S shape.

6. The medical valve assembly as set forth in claim 5 wherein said slit bisects the center of said first stem end.

7. The medical valve assembly as set forth in claim 1 wherein said valve stem further includes a first stem portion having a generally cylindrical shape and wherein said first stem portion deforms inwardly and downwardly in response to pressure from the luer to open said slit.

8. The medical valve assembly as set forth in claim 7 wherein said valve stem further includes second stem portion and a third stem portion presenting an open area for reducing friction between said third stem portion and said valve stem during compression of said valve stem.

9. The medical valve assembly as set forth in claim 8 wherein said valve stem includes an inner stem wall which defines said passageway and wherein said inner stem wall is radiused inwardly from a point in the first stem portion to a point in said third stem portion to define said hourglass shape.

10. The medical valve assembly as set forth in claim 9 wherein all of the edges of said inner stem wall are rounded.

11. The medical valve assembly as set forth in claim 8 wherein said second stem portion has a larger wall thickness than said first and third stem portions for expanding said valve in response to said luer being withdrawn.

12. The medical valve assembly as set forth in claim 1 wherein said valve stem is of a material having a durometer in the range of 25 to 65.

13. The medical valve assembly as set forth in claim 12 wherein said valve stem is of silicone.

14. The medical valve assembly as set forth in claim 13 wherein said silicone of said valve stem is pre-lubricated for reducing friction between said valve stem and said external housing.

15. The medical valve assembly as set forth in claim 1 further including a receiver engaging said second housing end of said external housing for receiving the fluid from said passageway.

16. The medical valve assembly as set forth in claim 15 wherein said receiver is ultrasonically welded to said external housing.

17. The medical valve assembly as set forth in claim 15 wherein said second stem end of said valve stem presents a positioning recess and wherein said receiver presents a positioning ridge for mating with said positioning recess to capture said valve stem between said external housing and said receiver.

18. The medical valve assembly as set forth in claim 1 further including a disc valve disposed at said second housing end for restricting the flow of fluid therethrough and out of said passageway.

19. The medical valve assembly as set forth in claim 18 wherein said disc valve includes a raised rib presenting a disc slit for allowing the fluid to flow through said disc valve in response to the pressure of the fluid being greater on one side of said disc valve than on the other side of said disc valve.

20. The medical valve assembly as set forth in claim 18 further including a receiver engaging said second housing end of said external housing for receiving the fluid from said passageway and wherein said disc valve is disposed between said valve stem and said receiver.

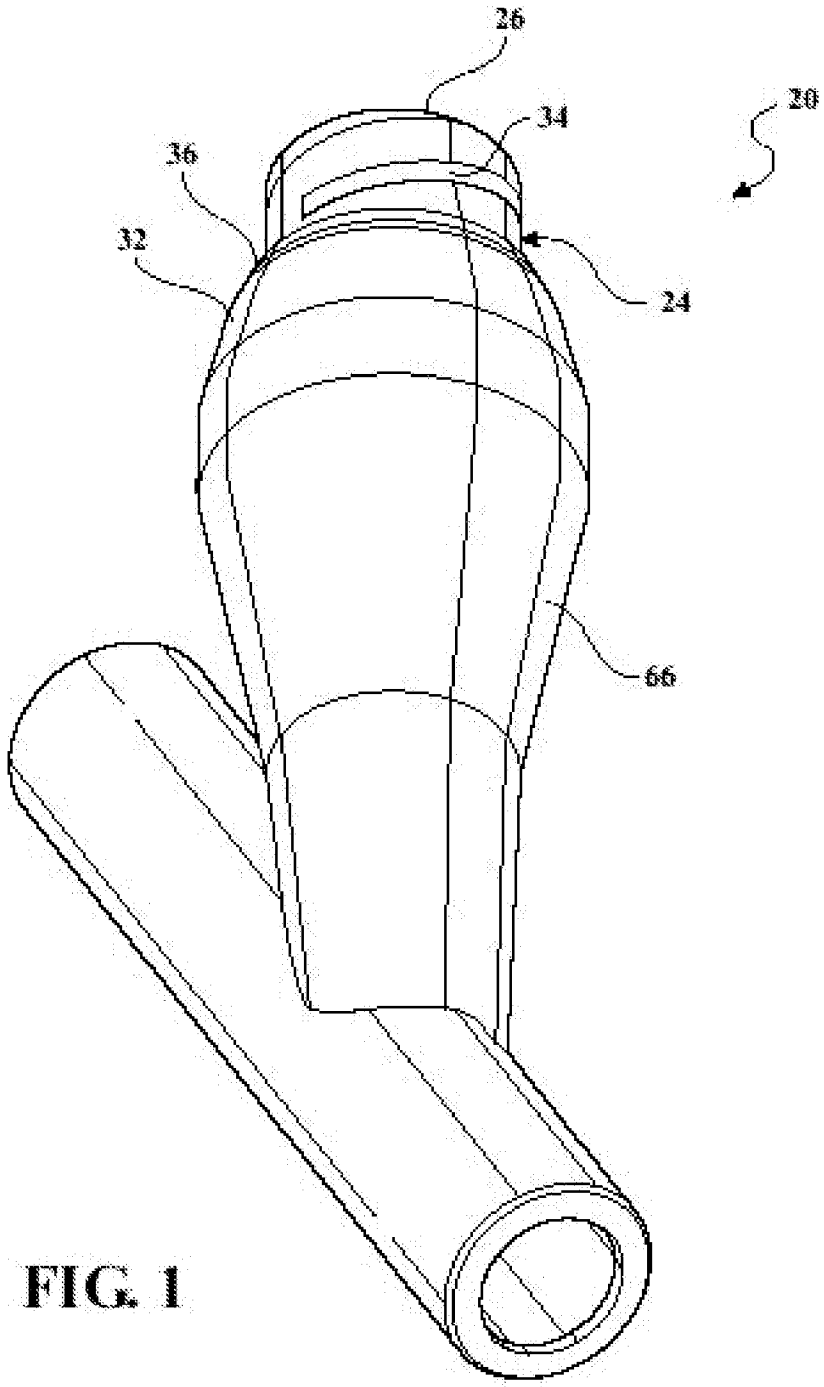

FIG. 1

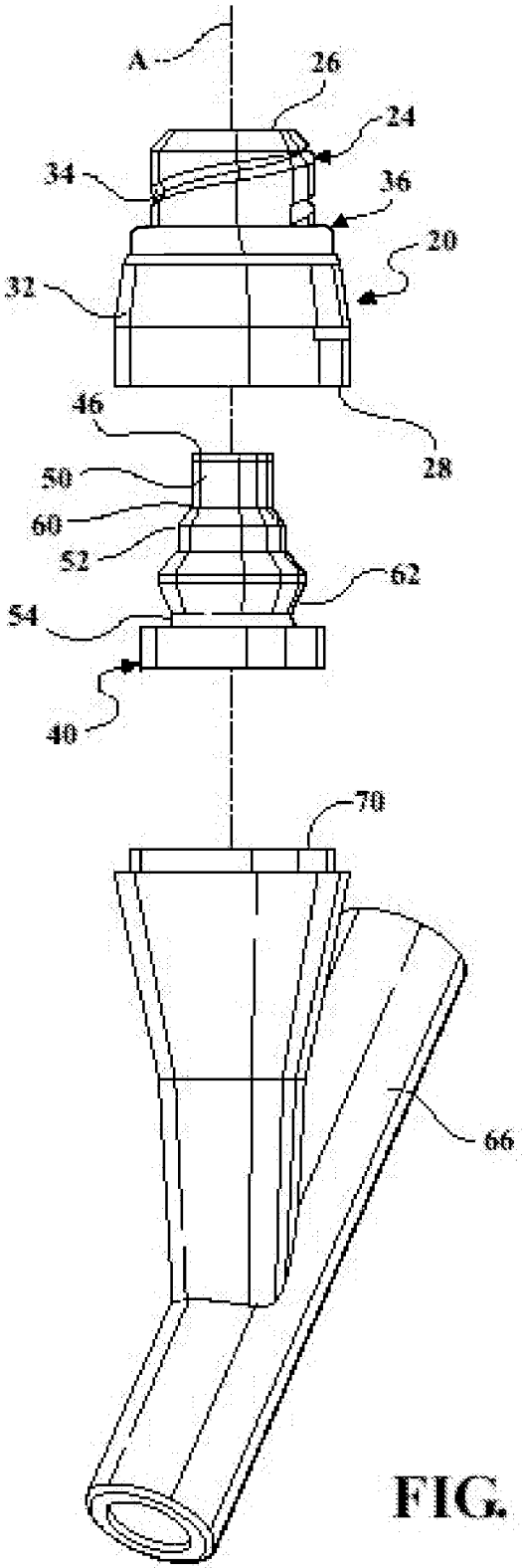
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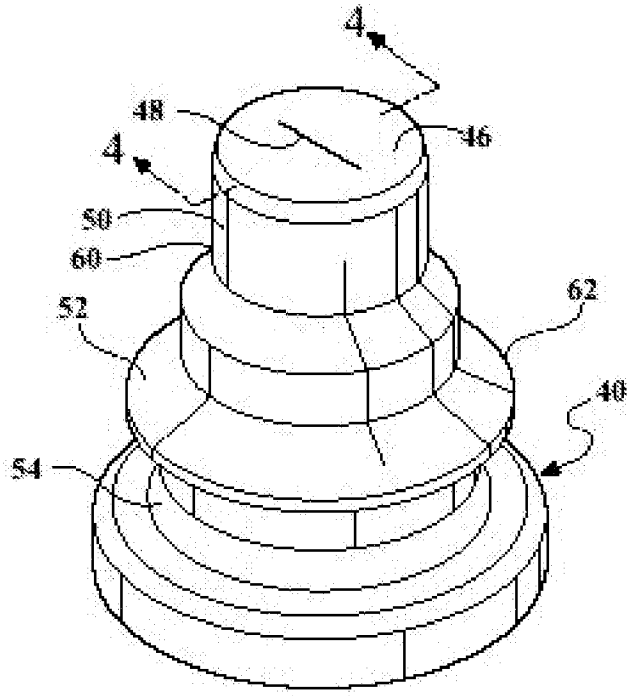
FIG. 2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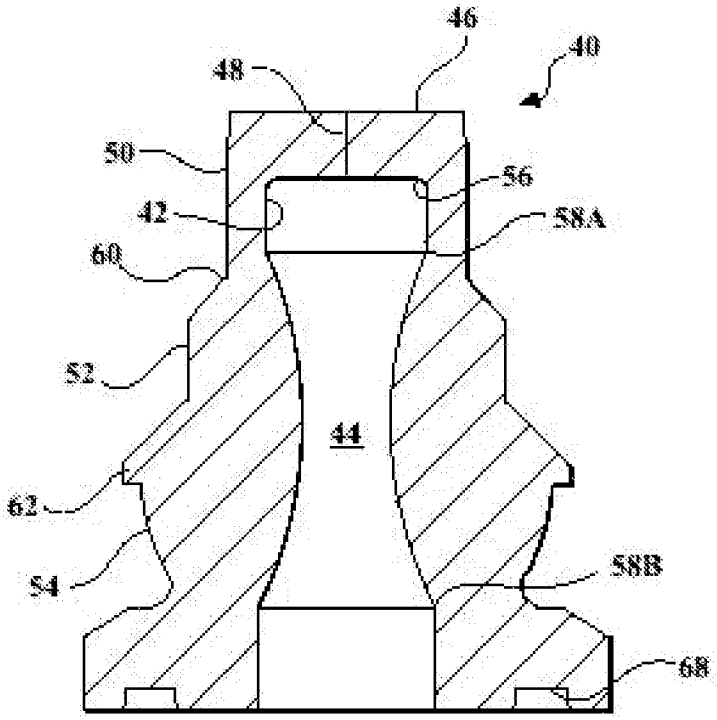
54

FIG. 3


46
40
48
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56
42
58A
60
52
44
62
54
58B
68

FIG. 4

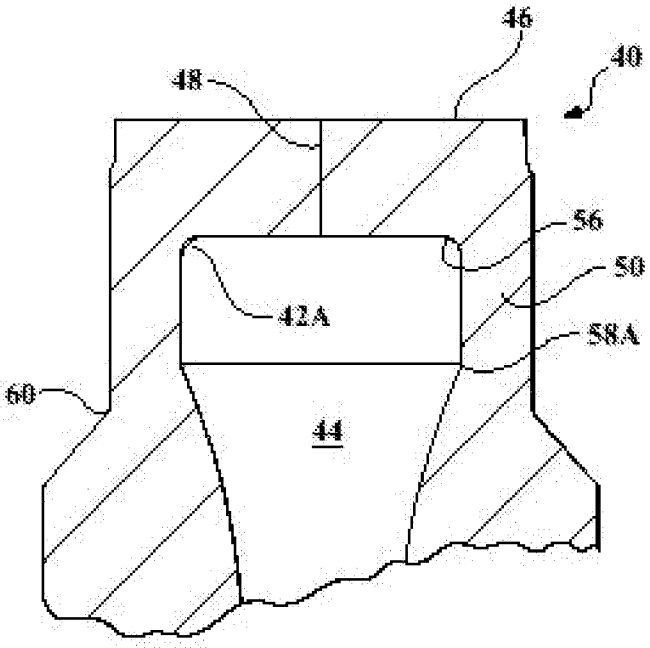
46
40
48
56
50
42A
58A
60
44

FIG. 5

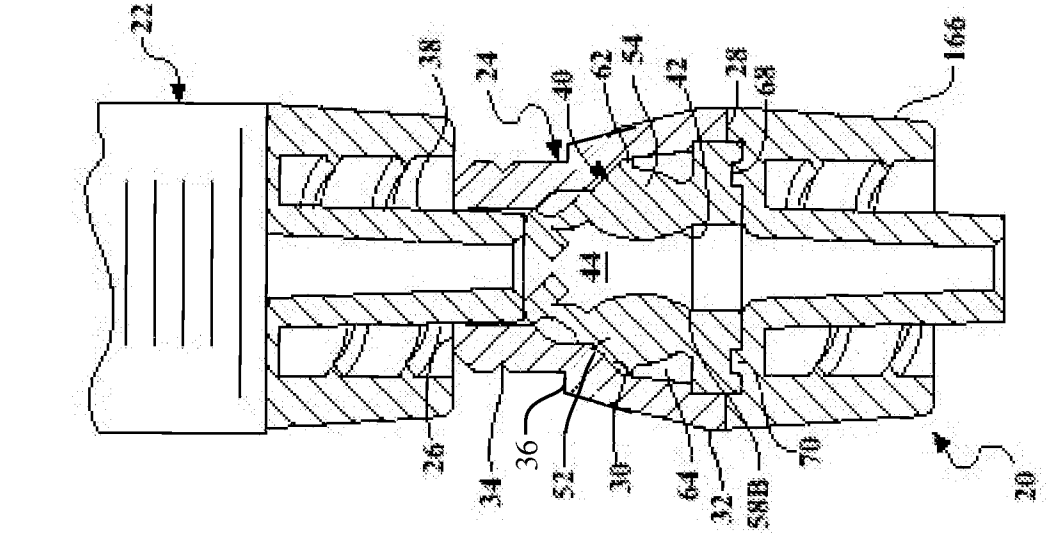

FIG. 6C

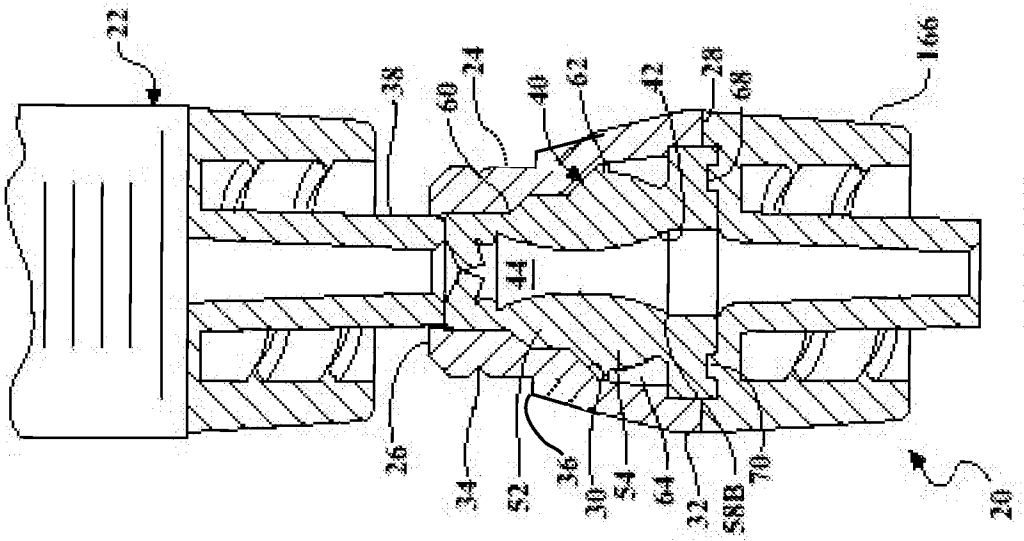

FIG. 6B

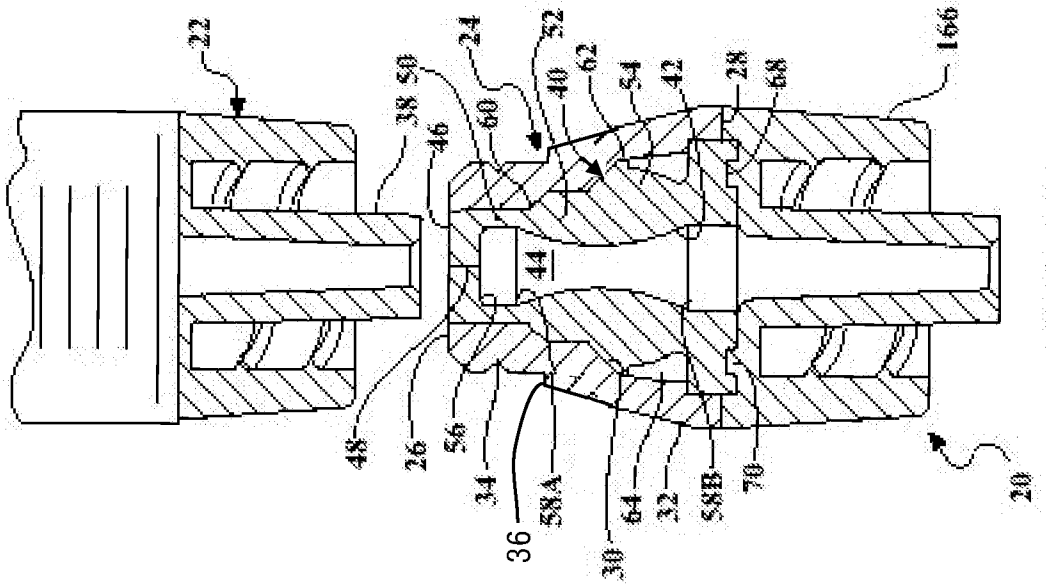

FIG. 6A

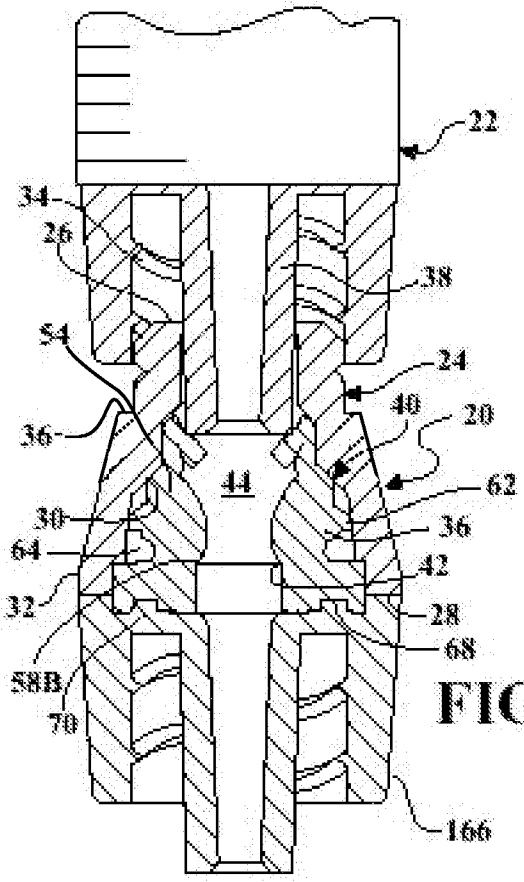

FIG. 6D

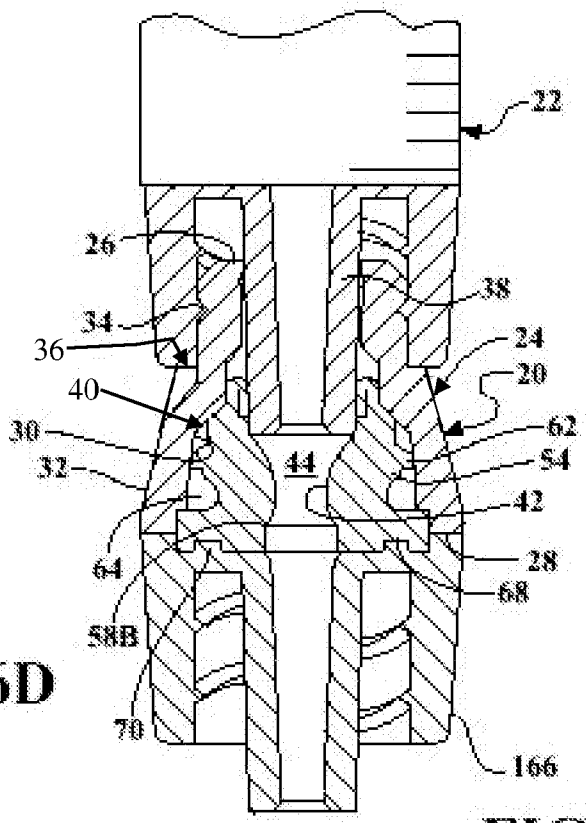

FIG. 6E

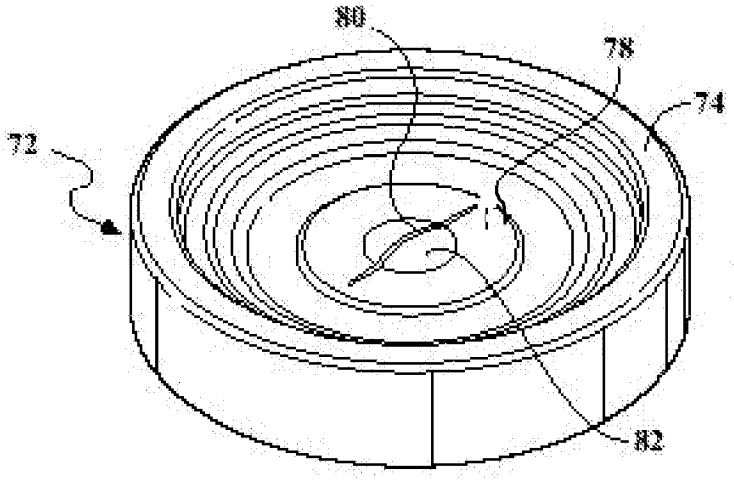

FIG. 11A

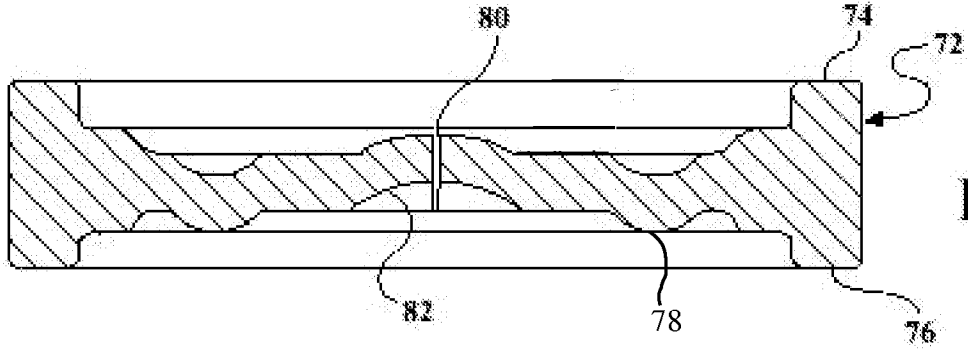

FIG. 11B

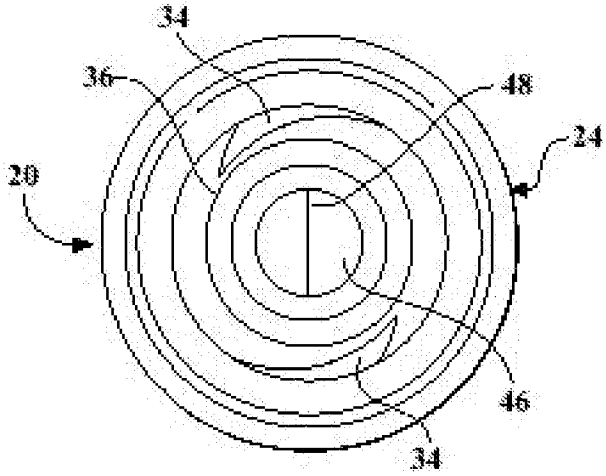

FIG. 7

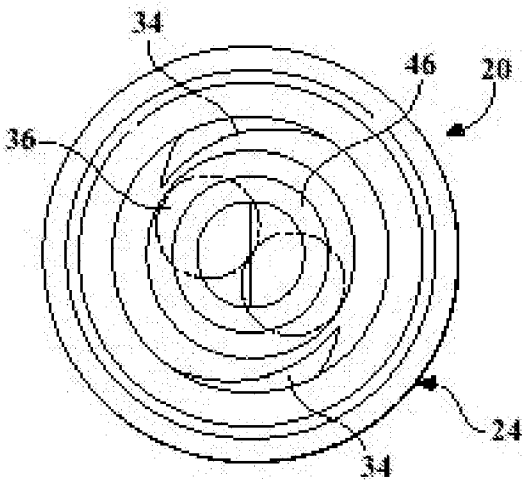

FIG. 8A

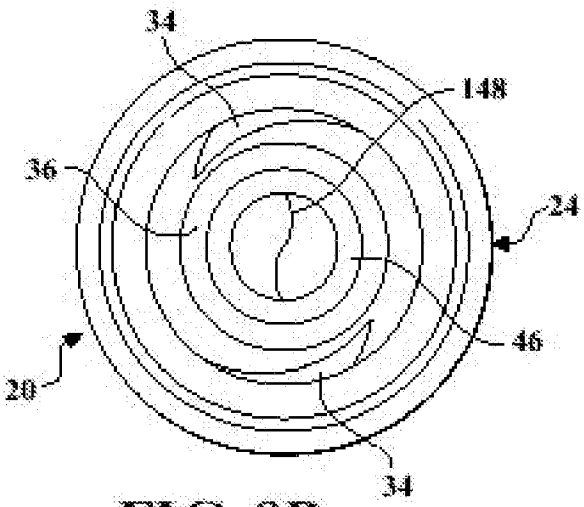

FIG. 8B

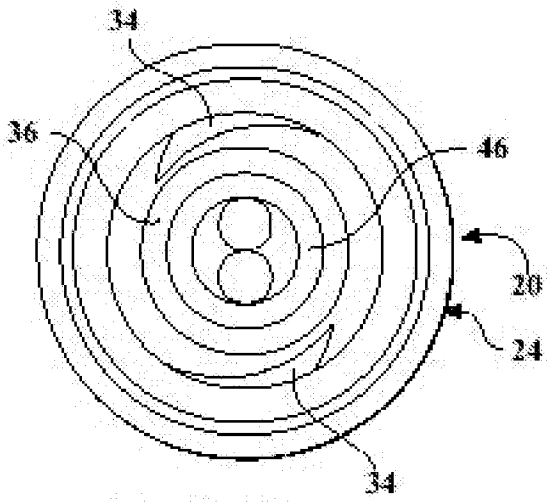

FIG. 9A

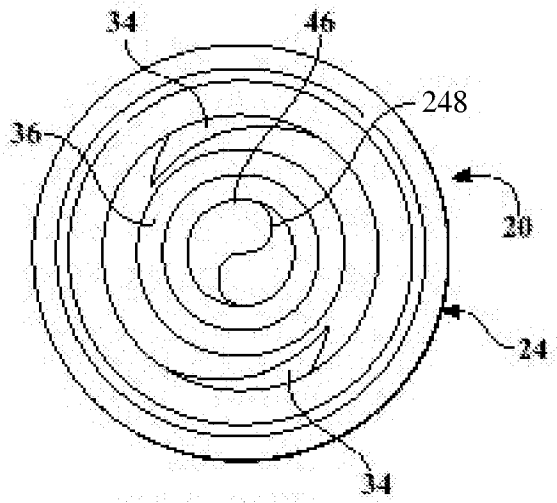

FIG. 9B

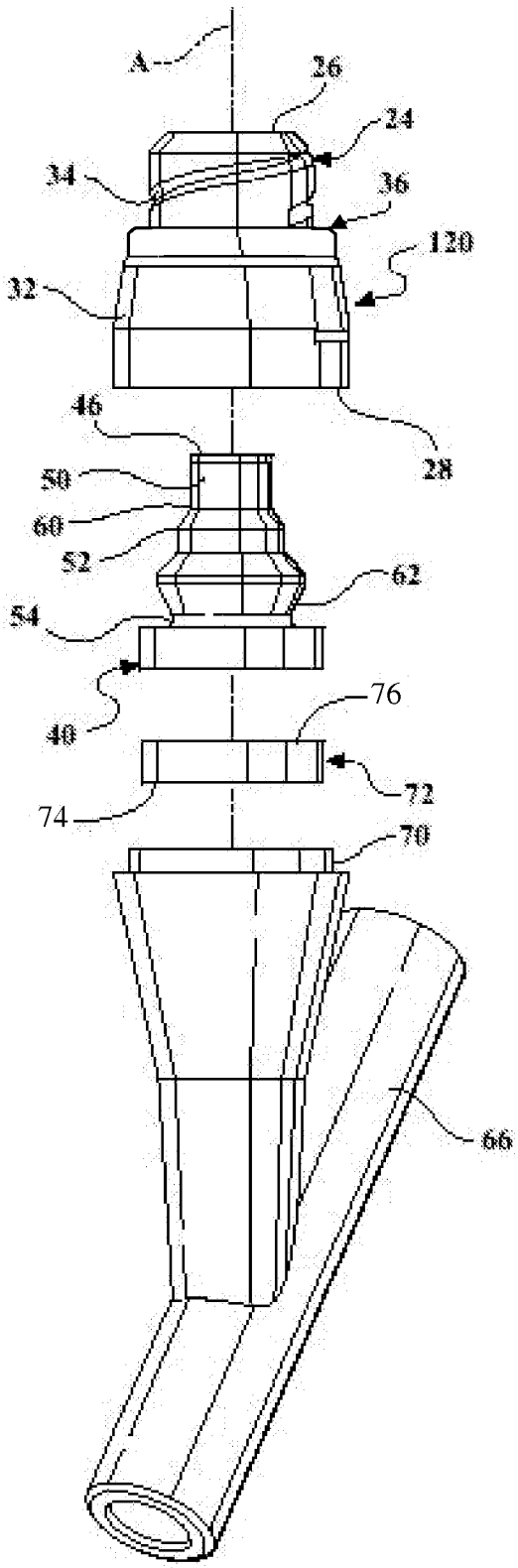

FIG. 10