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(54) Title: CATHETER

(57) Abstract: A catheter including a tube (12) with a coupling assembly (30) at one end. The coupling assembly (30) has an interior volume within which a ball (24) is captured between a seat (22) and a retainer (26). When fluid flows through the catheter in a first directed the fluid flows around the ball (24) and exits through a port (20). When fluid starts to back-flow in a second direction the ball (24) seals against the seat (22) preventing flow in the second direction.

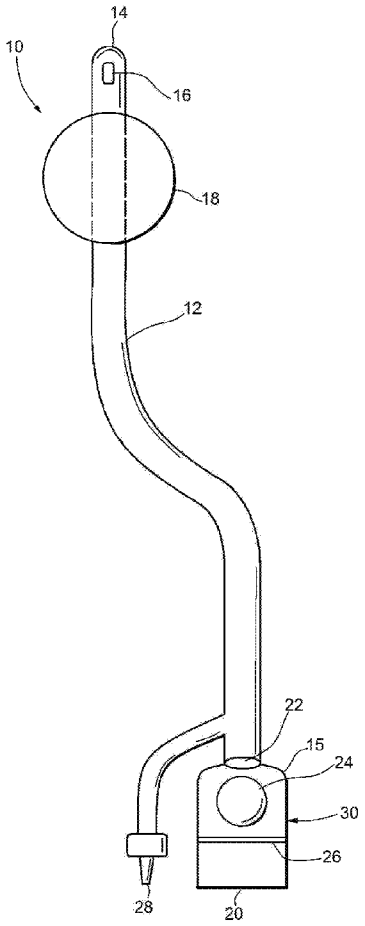

FIG.1

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— *with information concerning request for restoration of the right of priority in respect of one or more priority claims; the decision of the receiving Office regarding the request for restoration is pending and will be published separately once available (Rules 26bis.3 and 48.2(j))*

I. TITLE: *"CATHETER"*

II. FIELD OF THE INVENTION

The present invention relates to medical catheters, and more particularly, to valve and catheter device.

III. OTHER RELATED APPLICATIONS

The present application relates to U.S. Patent Application No. 14/799,883 filed on 15 July 2015 titled "Catheter", which is hereby incorporated by reference.

IV. DESCRIPTION OF RELATED ART

Foley catheters have been used for years in medical treatments for draining fluids from the body. Often "Foleys" are used for bladder draining. A Foley is generally a flexible tube that is inserted through the urethra and into the bladder. A small balloon near the end of the catheter is inflated to prevent the catheter from coming out of the bladder. An aperture is at the end of the catheter and allows fluid in the bladder to escape and be captured outside of the body. To remove the Foley catheter the balloon is deflated and the catheter is gently pulled out through the urethra.

A problem has been observed when fluid that had been previously drained from the body through the catheter back flows returning to the body. This has a propensity to cause urinary tract infections (UTI) and other conditions related to this unsanitary condition.

A problem arises when using available valves to limit the back flow of the discharged fluid. Since those patients using a catheter often have medical complications there is an increased likelihood of passing small solids or semi-solids through the catheter. For example, blood clots, mineral stones or mucous can be discharged. A failing of the prior art catheter valves prevents these other-than-liquids (OTL) from passing through the valve. The valve then can clog completely and prevent any or all flow through the catheter. Obviously, this can cause leakage, pain and risks infection.

Another problem has been observed in the prior art in that one way (check) valves used for medical purposes require a significant amount of back pressure to activate and prevent the fluid flow from returning in the wrong direction. A Foley catheter typically operates at very low pressure because it is essentially an open system at atmospheric pressure. Therefore when there is no fluid draining there is a likelihood of slow flow reversal that risks infection and other potential medical complications that must be avoided.

Several designs for catheters have been designed in the past. None of them, however, includes among other features a one way valve that is able to allow other than liquids to pass while preventing backflow at ultra-low pressure differentials.

Other patents describing the closest subject matter provide for a number of more or less complicated features that fail to solve the problem in an efficient and economical way. None of these patents suggest the novel features of the present invention.

V. SUMMARY OF THE INVENTION

It is one of the main objects of the present invention to provide a catheter with improved hygiene by limiting backflow returning into the human body.

It is another object of this invention to provide a catheter valve that permits small solids, gels and colloids to pass through the valve in the proper direction.

It is still another object of the present invention to provide a catheter with a check valve that prevents flow reversal with very little backflow pressure

It is yet another object of this invention to provide such a device that is inexpensive to manufacture and maintain while retaining its effectiveness.

Further objects of the invention will be brought out in the following part of the specification, wherein detailed description is for the purpose of fully disclosing the invention without placing limitations thereon.

VI. BRIEF DESCRIPTION OF THE DRAWINGS

With the above and other related objects in view, the invention consists in the details of construction and combination of parts as will be more fully understood from the following description, when read in conjunction with the accompanying drawings in which:

Figure 1 shows an elevation cross section view of a catheter.

Figure 2 shows an elevation cross section of a catheter.

Figure 3 shows an elevation cross section of a valve in an open mode.

Figure 4 shows an elevation cross section of a valve in a closed mode.

Figure 5 shows a perspective cross section of a catheter valve.

Figure 6 shows a top plan view of a catheter valve.

Figure 7 shows a bottom plan view of a catheter valve.

VII. DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings at figure 1, where the present invention is generally referred to with numeral **10**, it can be observed that it basically includes a tube **12**, a tip **14**, a body **15**, an aperture **16**, a balloon **18**, a port **20**, a seat **22**, a ball **24**, a retainer **26**, a balloon port **28** and a coupling assembly **30**.

Figure 1 shows a catheter with a version of the present back flow preventer valve. The tip **14** leads when inserting the tube **12** of the catheter into the body. When the tip **14** enters the bladder (or other body part to be drained) then the balloon **18** is inflated. Figure 1 shows the balloon **18** inflated but it would be fully deflated to allow the insertion of the catheter though the urethra.

The balloon port **28** on the lower end of the catheter attaches to an air pump, for example a syringe, to add or remove air through to the balloon **18**. The tube **12** has separate channels for fluid draining and air delivered to the balloon **18**.

During normal use when inserted into the body the aperture **16** near the tip **14** of the tube **12** takes in fluid. The tube **12** conducts this fluid to the port **20** where the fluid is drained, often through tubing and into a collection bag, neither of which are shown in the drawings, and are well known in the art.

Looking now at figures 2 through 7 in combination where a version of a back flow reducing valve is shown in more acute detail. The ball **24** is the primary moving part of the device. The ball **24** is captured inside the coupling assembly **30** between the seat **22** on the upstream side and the retainer **26** on the downstream side.

In a preferred version of the device the ball **24** has a diameter d2 that is larger than the diameter d1 of the seat **22**. Both the seat **22** and the ball **24** are constructed of materials that effectively prevent fluid flow when the ball **24** is against the seat **22**. Typically plastics would be effective and can be delivered sterile in a hermetically sealed package.

In a version of the device the ball **24** may be constructed of a material that is less dense than the fluid expected to be discharged. In this sense the ball **24** would float as the coupling assembly **30** fills with that fluid. In other versions the ball may preferably be denser and thus sink. This can be used in a situation where the coupling assembly **30** is inverted or used in various orientations.

In another version of the device the ball **24** is neutrally buoyant by having the same density as the fluid being discharged. In this case the orientation of the seat **22** being above or below the ball **24** would perform similarly. This configuration may be preferred when the orientation of the coupling assembly **30** is continually in motion or inverted and reverted during in vitro use.

The retainer **26** is provided to keep the ball **24** inside the coupling assembly **30** yet allow movement of the ball **24** as needed to allow OTL (i.e. clots, stones, etc…) as they pass the ball **24** on the way out through the port **20** where they are collected in a fluid bag or otherwise drained away from the body.

In the version of the device shown in figure 5 it is evident that the retainer **26** is a piece that spans the width of the body **15**. The retainer can be cylindrical or other shapes and may or may not span the entirety of the body **15**. For example, nubs or other protrusions on the interior of the body **15** can act as a retainer if the ball **24** is not able to exit the port **20** and fluid with OTL is always able to exit the port **20** around the side of the ball **24** and past the retainer **26**.

It is important that the diameter d3 of the body **15** be greater than diameter d2 of the ball **24** so that fluid and fluid containing OTL can pass around the ball **24** and out the port **20**. The retainer **26** prevents the ball **24**

from exiting the coupling assembly **30** along with the drained fluids and OTL.

The ball **24** is generally not connected to other parts of the device except when up against the seat **22**. The ball **24** can freely move about the interior of the coupling assembly **30** between the seat **22** and the retainer **26**. As fluid and OTL pass through the coupling assembly **30** the ball **24** may be nudged aside so that larger OTL can pass freely around the ball **24** and exit through the port.

During normal drainage of the catheter the fluid is flowing in the direction indicated by the arrows in figure 3. The fluid passes through the tube **12** (truncated in figures 2-5) past the seat **22** where the fluid exits through the port **20**. The ball **24** is shown pushed against the retainer **26** so that the fluid can freely flow with minimal resistance around the ball **24** and out through the port **20**. The flow direction of the fluid prevents the ball **24** from contacting the seat **22** alone or in combination with the density of the ball **24**.

Figure 4 shows the ball **24** against the seat **22** preventing virtually any backflow from entering into the tube **12**. If there is even a slight pressure differential between above seat **22** and below the retainer **26** then the ball **24** can flow towards the lower pressure side. In the case of normal flow through the tube **12** towards the port **20**, the ball **24** flows against the

retainer **26** and the fluid is provided wide berth to pass the ball **24** and exit the catheter through the port **20**.

Conversely by example, if the collection bag is compressed or moves out of position then pressure at the port **20** can exceed the pressure inside the tube **12**. In a catheter not including the present catheter design this would tend to push fluid in the wrong direction through the port **20** and into the tube **12** and ultimately back into the patient and potentially causing a hazard to the patient.

However, with the present design this reversal of flow, even minute volumes and very low pressure will cause the ball **24** to quickly seal against the seat **22** and prevent any further flow. There may be a very small amount of fluid that could pass the ball **24** in a backflow condition during the time the flow reverses and when the ball **24** contacts the seat. However, the amount is so small it would not be able to reach the aperture **16** and gain contact to the patient.

Figure 6 shows the coupling assembly **30** from the port **20** end. The retainer **26** is shown to fully span the interior volume of the coupling assembly **30** however it need not fully span as long the ball **24** remains completely captured between the seat **22** and the retainer **26**. The ball **24** is shown to be loose inside the coupling assembly **30** so that liquid and OTL can pass through the device.

Figure 7 shows the top side of the coupling assembly **30** with the tube **12** removed. The ball **24** is shown sealing the coupling assembly **30** pressed against the seal thereby blocking any fluids from back-flowing into the patient.

An important version of the invention can be fairly described as a catheter comprised of a tube and a coupling assembly. The coupling assembly on a first end is connected to an end of the tube generally a liquid-tight seal. The coupling assembly on a second end includes a port that can further be connected to tubing (not shown in the drawings) to carry the transported fluid to, for example, a collection bag. The coupling assembly has an interior volume bounded on a first end by a seat and on a second end by a retainer. There may be some material on either side of the seat and retainer but the primary function of the valve system in the coupling assembly is bounded by the seat and retainer. The seat has a first diameter selected to interface with the ball to form a seal when backflow is present. The interior volume includes a ball captured between the seat and the retainer but the ball remains freely moveable inside the interior volume of the coupling assembly and can move with the flow of fluid to seal and unseal fluid flow. The ball has a second diameter adapted to seal against the seat and not be able to pass through the retainer. The interior volume between the seat and retainer has a third diameter so the ball has freedom of movement subject to the flow of fluid. The first diameter is less than the second diameter so the ball can't pass through the seat. The second diameter is less than the third diameter so the ball can move inside the

interior volume. The ball freely moves in the interior volume between the seat and retainer responsive to the flow of fluid through the device and the commensurate pressures therein. When a fluid flows in first direction through the coupling assembly the ball does not contact the seat and fluids can flow from the first end of the coupling assembly past the ball and to the port and drains out of the device, possibly into a collection bag (not shown in the drawings). When the fluid flows or starts to flow in a second direction (essentially back flow towards the patient and away from the collection bag end of the system) though the coupling assembly the ball flows into contact with the seat creating a watertight seal between the ball and seat and substantially preventing further flow in the second direction. The seat is in contact with the ball completely so that fluid is not permitted to backflow.

In a version of the device the density of the ball is the same as the fluid so that gravity cannot effectively interact on the ball relative the fluid so that the device can function in any orientation. In other version of the device the ball may be denser or less dense affecting the ability of the ball to float or sink inside the interior volume which can have the effect of biasing the ball in a particular position. In some cases this differing density configuration can be effective when the entire coupling assembly is oriented in a stable position to take advantage of the balls propensity to either sink or float.

In a version of the device the difference between the second diameter and third diameter is sufficient to allow the passage of other-than-liquids around the ball when fluid flows in the first direction. This can allow clots, stones and other OTLs to pass the ball on the way out of the device. Essentially the ball is moveable so that OTLs can pass when fluid flows in the normal direction out of the device but is stuck against the seat when backflow is present.

The foregoing description conveys the best understanding of the objectives and advantages of the present invention. Different embodiments may be made of the inventive concept of this invention. It is to be understood that all matter disclosed herein is to be interpreted merely as illustrative, and not in a limiting sense.

VII. INDUSTRIAL APPLICABILITY

It is evident that an invention such as a catheter that allows other than liquids to pass through a backflow prevention valve because it can help the patient eliminate and drain fluids with a much lower risk of infection from clogging the catheter. Similarly, the valve when used in to drain fluids not under pressure will prevent the fluids from returning to the body. Many lives can be saved and improved by this medical device helping doctors and patients.

VI. CLAIMS

What is claimed is:

1. A catheter comprised of a tube and a coupling assembly;
the coupling assembly on a first end is connected to an end of the tube;
the coupling assembly on a second end includes a port;
the coupling assembly has an interior volume bounded on a first end by a seat and on a second end by a retainer;
the seat has a first diameter;
the interior volume includes a ball captured between the seat and the retainer;
the ball has a second diameter;
the interior volume between the seat and retainer has a third diameter;
the first diameter is less than the second diameter;
the second diameter is less than the third diameter;
the first diameter is less than or equal to the difference between the third diameter and the second diameter so that an other-than-liquid that enters the interior volume can pass the ball and exit through the port;

the ball freely floats in the interior volume between the seat and retainer;

when an unpressurized fluid flows in a first direction through the coupling assembly the ball does not contact the seat and fluids can flow from the first end of the coupling assembly past the ball and to the port;

when the fluid flows in a second direction though the coupling assembly the ball flows into contact with the seat creating a watertight seal between the ball and seat preventing further flow in the second direction.

2. A catheter as described in claim 1 further characterized in that a density of the ball is the same as the fluid.
3. A catheter as described in claim 1 further characterized in that the difference between the second diameter and third diameter is sufficient to allow the passage of other-than-liquids around the ball when fluid flows in the first direction.
4. A catheter comprised of a tube and a coupling assembly;

the coupling assembly on a first end is connected to an end of the tube;

the coupling assembly on a second end includes a port;

the coupling assembly has an interior volume bounded on a first end by a seat and on a second end by a retainer;

the seat has a first diameter;

the interior volume includes a ball captured between the seat and the retainer;

the ball has a second diameter;

the interior volume between the seat and retainer has a third diameter;

the first diameter is less than the second diameter;

the second diameter is less than the third diameter;

the first diameter is less than or equal to the difference between the third diameter and the second diameter;

the ball freely floats in the interior volume between the seat and retainer;

when an unpressurized fluid flows in a first direction through the coupling assembly the ball does not contact the seat and fluids can flow from the first end of the coupling assembly past the ball and to the port;

when the fluid flows in a second direction though the coupling assembly the ball flows into contact with the seat creating a watertight seal between the ball and seat preventing further flow in the second direction;

the density of the ball is the same as the fluid;

the difference between the second diameter and third diameter is sufficient to allow the passage of other-than-liquids around the ball when fluid flows in the first direction.

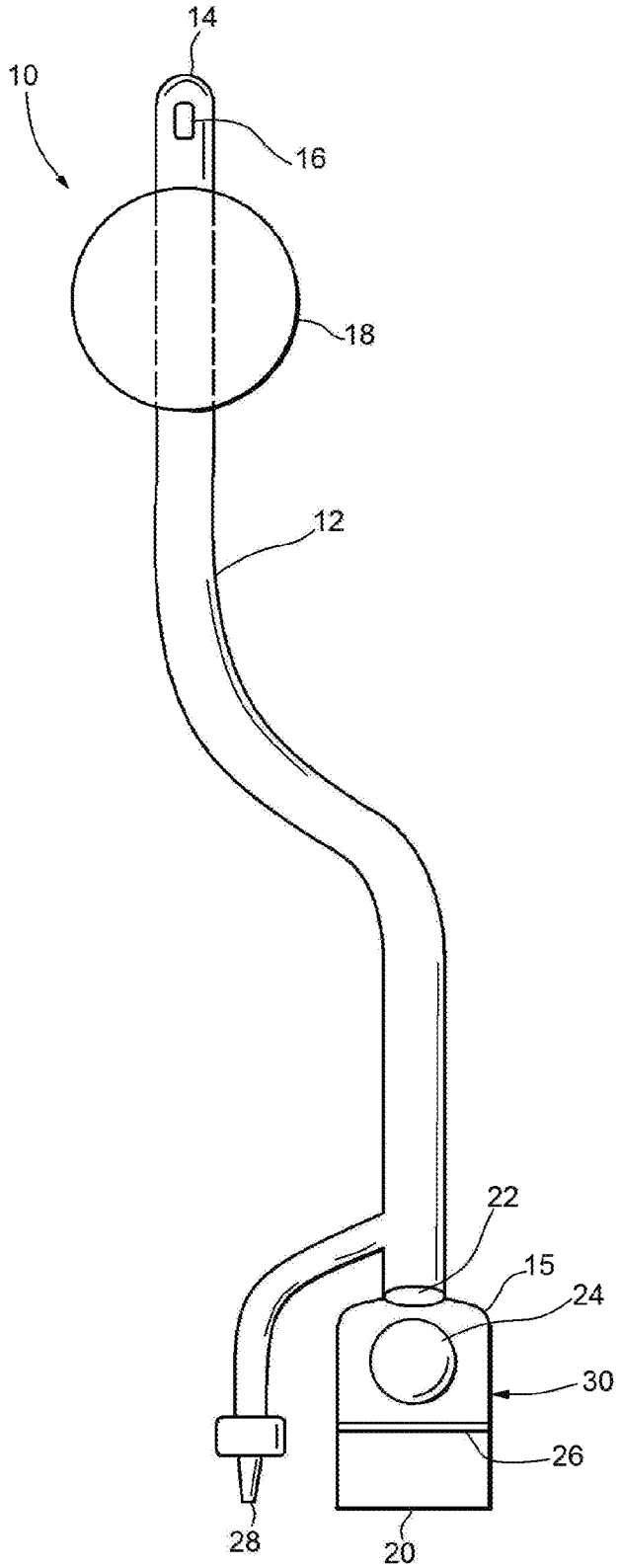

FIG.1

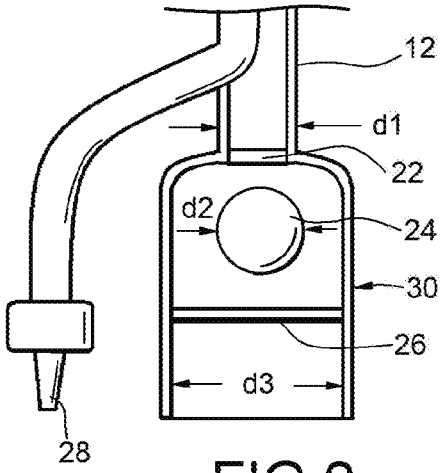

FIG.2

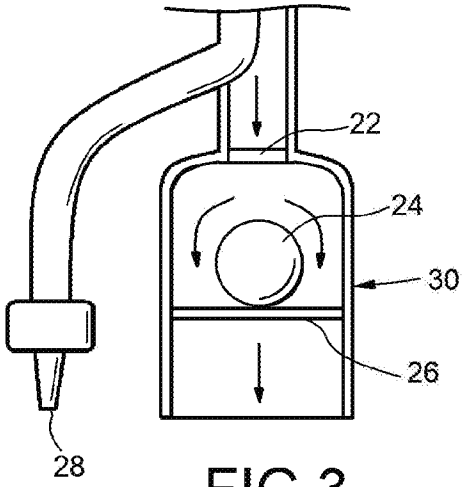

FIG.3

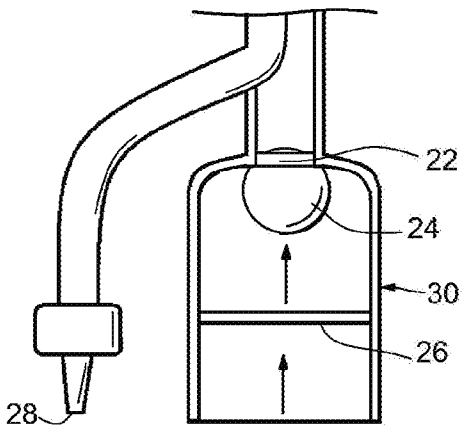

FIG.4

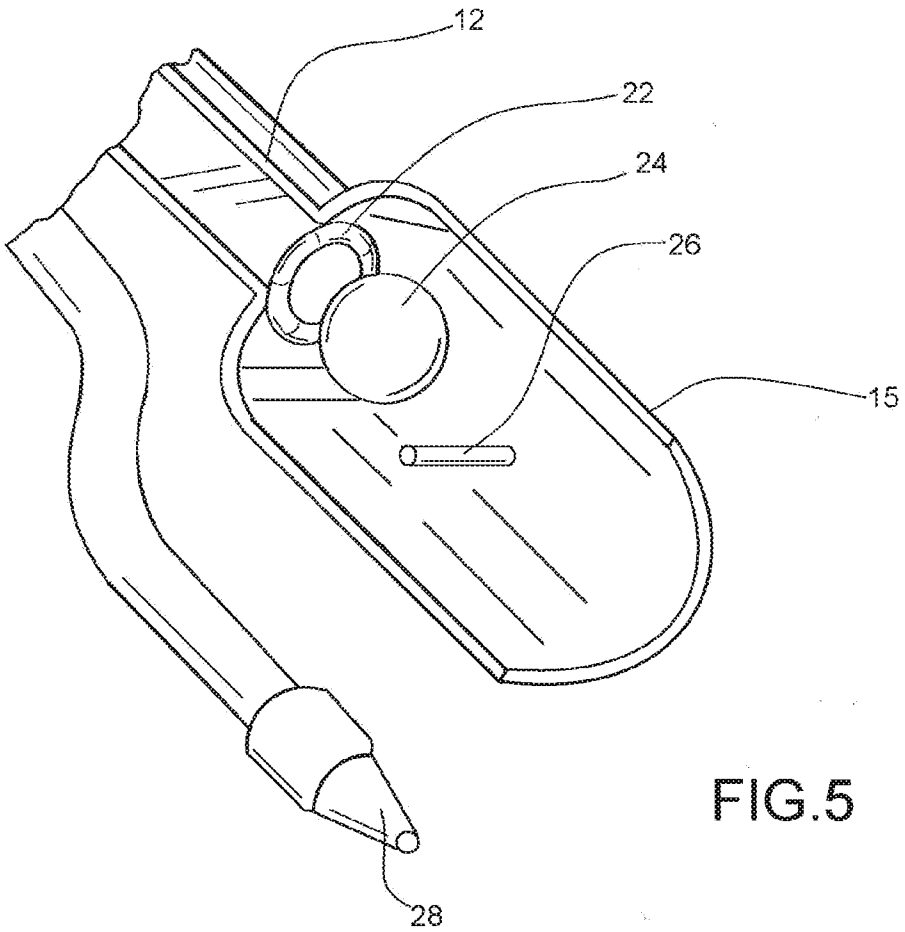

FIG.5

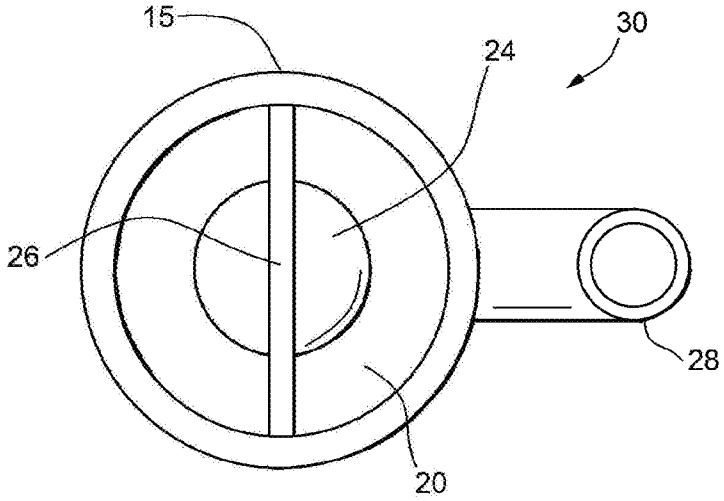

FIG.6

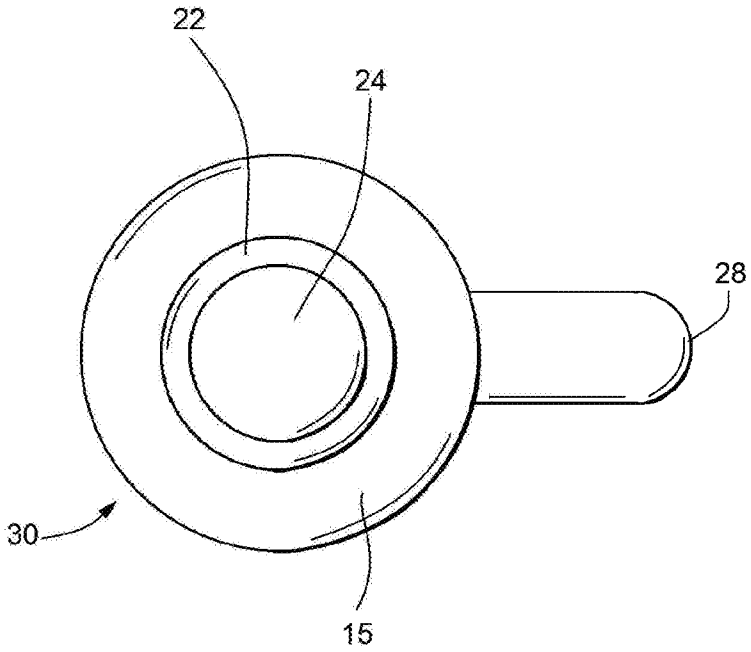

FIG.7