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Corbin et al.

[11] **3,774,591**

[45] **Nov. 27, 1973**

[54] **CATHETERIZATION ASSEMBLY**

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[52] **U.S. Cl.** ..... **128/2 F,** 128/DIG. 5, 137/572

[51] **Int. Cl.** **A61b 19/00**

[58] **Field of Search** ..... 128/2 F, 349 R, 349 BV, 128/DIG. 9, DIG. 24, 130, 248, 251, 275, 283, 284, 295, 294; 251/331; 137/572

[56] **References Cited**

UNITED STATES PATENTS

2,476,375	7/1949	Kent	128/295
2,133,130	10/1938	Buchstein	128/349 R
3,601,119	8/1971	Engelsher	128/2 F
3,499,327	3/1970	Lane	128/2 F
3,680,543	8/1972	Cox	128/295

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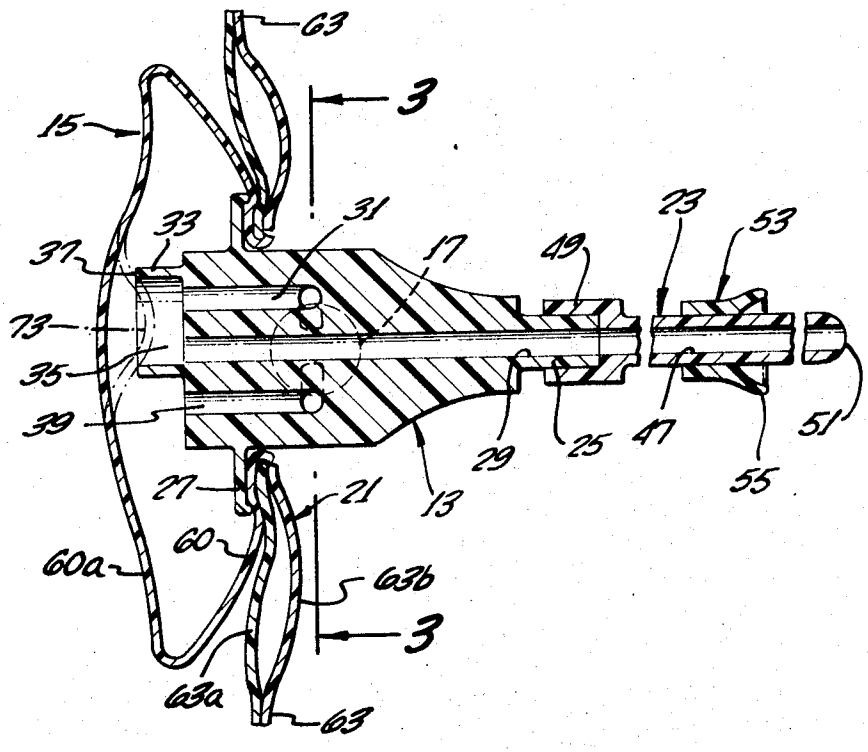
[57] **ABSTRACT**

A catheterization assembly comprising a first container, a catheter, a first conduit leading from the catheter to the first container, a second container, and a second conduit interconnecting the two containers. The flow of urine from the catheter into the respective containers is controllable by an easily operable valve.

6 Claims, 7 Drawing Figures



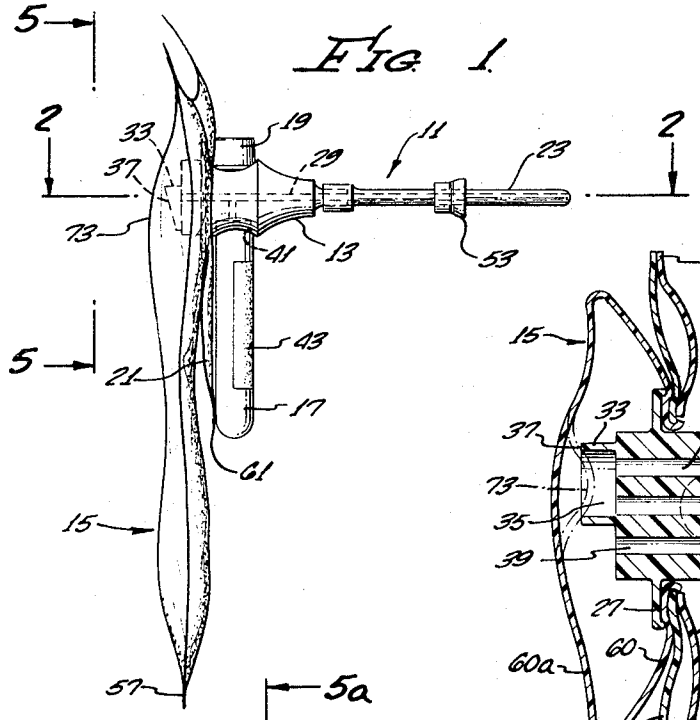


FIG. 1

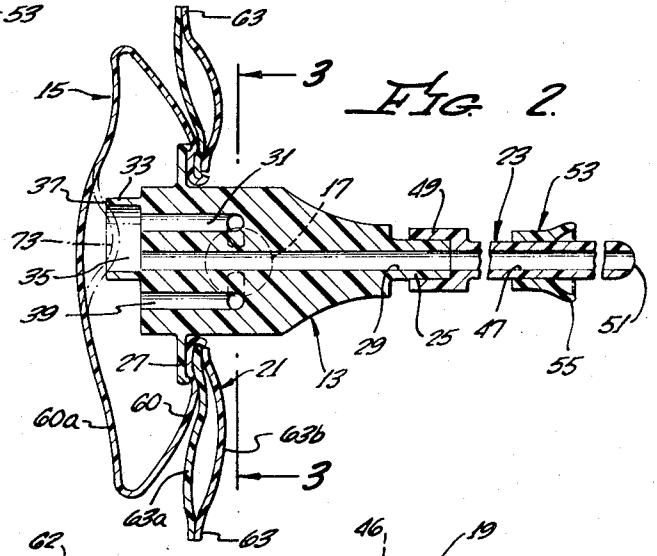


FIG. 2

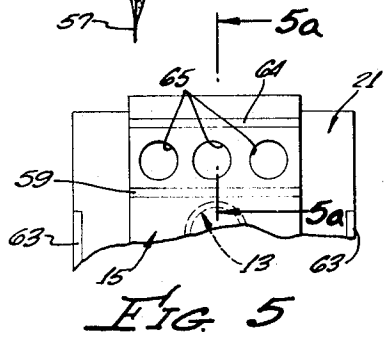


FIG. 5

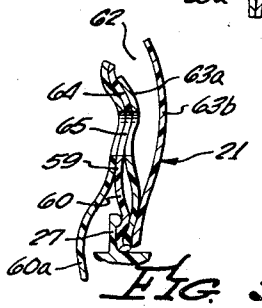


FIG. 5a

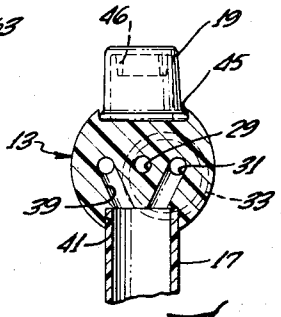


FIG. 3

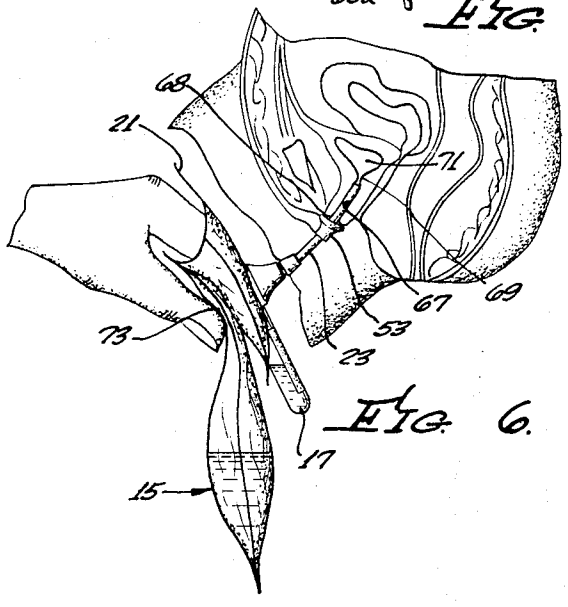


FIG. 6

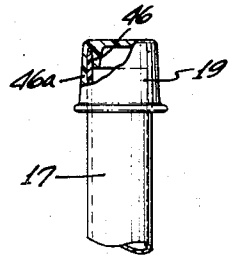


FIG. 4

CATHETERIZATION ASSEMBLY

BACKGROUND OF THE INVENTION

In the examination of a patient, it is usually necessary to obtain a urine sample. There are several problems in obtaining a urine sample from a female patient.

In the female, the urethra terminates inwardly in such a position that urine passing through the urethra from the bladder must also pass through the vagina. In so doing, the urine sample is usually contaminated with vaginal secretions and bacteria. The sample so obtained may not be representative of the urine in the bladder.

To obtain a clean or uncontaminated sample, it is common practice to insert a catheter through the urethra into the bladder. Even then it is necessary to obtain a so-called "midstream sample" as the walls of the urethra, and particularly the outer portions thereof, may contain some contamination. The initial urine flow washes away this contamination so that the "midstream sample" is relatively free of contamination. One danger with a catheterization procedure is that the insertion of the catheter into the urethra may force some external contamination into the bladder thereby giving rise to a bladder infection.

SUMMARY OF THE INVENTION

The present invention provides a catheterization assembly which facilitates the obtaining of a urine sample from the female patient. With the present invention, the doctor can select the portion of the urine stream which will be taken as a sample.

The present invention provides for dividing of the urine sample into two portions, and accordingly, two separate containers are provided. The first of these containers is adapted to receive the majority of the urine including the portion which is contaminated, i.e., the gross specimen. Some useful tests such as the usual urinalysis can be run even on the contaminated sample. The second container may be relatively small and is adapted to receive the uncontaminated urine sample.

The first container is connected by a first conduit to a catheter which is adapted to be inserted into the urethra. A second conduit interconnects the two containers.

A feature of this invention is the provision of a simple, inexpensive, digitally or manually operable valve means which permits the user to control the urine flow into the two containers. As used herein manually or digitally operable valve means a valve under the control of the user. Typically, the valve is operated so that the initial urine flow is into the first container and when, in the opinion of the doctor, the urethra walls have been adequately flushed, the valve is operated so that subsequent flow is into the second container. If there is any overflow from the second container, it is conducted by a vent or overflow passage back to the first container. This permits the doctor to visually scan the entire flow by observing the second container.

The manually operable valve concept can be advantageously implemented by providing a passage for interconnecting the first and second conduits. This passage opens into the first container. At least a portion of the first container is flexible and can be manually forced against the opening in the passage to thereby close the passage to the interior of the first container. By opening and closing of the passage in this manner,

urine flow to the two containers can be manually controlled.

The rim of the opening in the passage defines a valve seat against which the portion of the wall of the first container can be pressed. Preferably this passage is in the form of a short tube and the first and second conduits terminate in the tube. The tube is constructed to prevent trapping of urine within the tube. To accomplish this the tube projects further into the container at one region than at a second region. This projection holds the wall portion of the first container away from the region of the tube adjacent the first conduit so that urine can freely flow by gravity from the tube into the first container.

To eliminate the need for the doctor to "glove up" when obtaining a urine sample, the present invention provides a glove or shield into which the doctor's hand can be inserted. This glove forms part of the catheterization assembly.

In a preferred construction, the first container is a flexible container and a body member of plastic material is attached to the flexible container and to the catheter. The body member may contain all of the passages described hereinabove and may also define the valve seat. The second container is releasably mounted on the body member and a cover or cap for the second container is also releasably mounted on the body member. With this arrangement, the second container and the cap therefor can be removed from the body member and the cap can be placed on the second container to close the latter.

Another feature of the present invention is based, in part, upon the recognition that it may be undesirable to force a catheter into the urethra beyond the sphincter. To accomplish this purpose, the present invention provides a depth limiter on the catheter which is engageable with the meatus to limit the depth of insertion of the catheter. The depth limiter can advantageously take the form of a sleeve-like member press fit onto the catheter to thereby permit movement of the sleeve-like member along a catheter. This permits the doctor to adjust the depth of insertion. Preferably the sleeve-like member has a generally cup-shaped portion opening toward the patient to prevent leakage of urine during the catheterization procedure.

The invention can best be understood by reference to the following description taken in connection with the accompanying illustrative drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational view of a catheterization assembly constructed in accordance with the teachings of this invention.

FIG. 2 is an enlarged fragmentary sectional view taken generally along line 2—2 of FIG. 1.

FIG. 3 is a fragmentary sectional view taken generally along line 3—3 of FIG. 2.

FIG. 4 is a fragmentary side elevational view showing the specimen container removed from the body member and the cover mounted thereon.

FIG. 5 is a fragmentary elevational view taken generally along line 5—5 of FIG. 1.

FIG. 5A is a sectional view taken along line 5A—5A of FIG. 5.

FIG. 6 is a fragmentary perspective view illustrating a typical use of the catheterization assembly. ,6

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 shows a catheterization assembly 11 which generally includes a body member 13, a flexible container or bag 15 mounted on the body member, a specimen or rigid container 17 removably mounted on the body member, a cover 19 for the container 17 removably mounted on the body member, a glove 21 and a catheter 23.

The body member 13, which is shown most clearly in FIGS. 1–3, is preferably constructed of inexpensive plastic material. The body member 13 is relatively rigid except for a reduced diameter tip portion 25 which is relatively flexible to prevent breaking. The body member has a peripheral annular flange 27 to which the flexible container 15 and the glove 21 are attached as by a heat seal. As shown in FIG. 2, the body member 13 projects into the interior of the flexible container 15 and projects through the glove 21 to partially divide the glove into two separate finger receiving compartments.

The body member has a first inlet passage 29 which, in the embodiment illustrated, is an axially extending cylindrical passage that extends from the catheter 23 to the interior of the flexible container 15. A second inlet passage 31 extends from the flexible container 15 to the specimen container 17. The inlet passages 29 and 31 terminate in closely spaced relationship at the left-hand face (as viewed in FIG. 2) of the body member 13.

In the embodiment shown, the body member 13 has an annular wall 33 at the left end thereof as viewed in FIG. 2, and the inlet passages 29 and 31 terminate within the annular wall in the same horizontal plane. The annular wall defines a connecting passage 35 for providing communication between the two inlet passages 29 and 31. The annular wall 33 terminates in a valve seat 37. As shown in FIG. 1, the valve seat 37 is inclined so that the upper edge thereof projects further into the flexible container 25 than does the lower edge when the catheterization assembly 11 is held in the normal position of FIG. 1.

The body member 13 also contains a vent passage 39 which extends from the rigid container 17 to a location outside of the connecting passage 35.

As shown in FIGS. 1 and 3, the body member 13 has a socket 41 in which the upper end of the specimen container 17 is received and releasably held. The passages 31 and 39 terminate in the socket 41. The container 17 has an open upper end which communicates with the passages 31 and 39. In the embodiment illustrated, the container 17 is a rigid cylindrical, plastic tube having an adhesive label 43 adhesively secured on the exterior surface thereof.

The body member 13 also has an upwardly opening socket 45 in which the cover 19 is releasably retained. The container 17 and the cover 19 can be removed from the body member 13. The cover 19 is sized to fit sealingly over the upper end of the rigid container 17 as shown in FIG. 4. The cover 19 has an internal annular flange 46 which cooperates with the peripheral wall 46a of the cover 19 to releasably clamp the upper end portion of the container 17 to thereby mount the cover on the container.

Catheters of different constructions can be used with this invention. In the embodiment illustrated, the catheter 23 is in the form of an elongated flexible, resilient tube having an axial cylindrical passage 47 extending therethrough. The catheter 23 has an integral socket 49 formed on the inner end thereof which fits snugly over the tip portion 25 to thereby removably mount the catheter on the body member 13. The passage 47 communicates with the inlet passage 29 and terminates outwardly in an inlet 51.

An optional but advantageous feature of the invention is a depth limiter 53 which is mounted on the catheter 23. The depth limiter is in the form of a plastic sleeve which is press fit onto the catheter 23. This permits the depth limiter 53 to be forcibly slid along the catheter 23 to the desired position with the depth limiter 53 being held in the set position by the force of friction. The right end (as viewed in FIG. 2) of the depth limiter 53 is flared downwardly to form a cup-like section which opens toward the opening 51.

Although the flexible container 15 can be constructed in different ways, in the embodiment illustrated it is constructed of transparent, flexible, plastic material. The container 15 is in the form of a plastic bag having heat seals 57 and 59 at the lower and upper ends thereof for completely sealing the flexible container. The flexible container 15 may be considered as having two walls 60 and 60a, respectively. The body member 13 projects through the wall 60 of the flexible container 15 as shown in FIG. 3 and is suitably heat sealed to the flange 27 of the body member.

In the embodiment illustrated, the glove 21 is formed from a single sheet of flexible plastic material having a fold 61 (FIG. 1) along the lower end thereof and heat seals 63 (FIG. 5) extending upwardly from the fold 61 along the opposite longitudinal edges of the glove and terminating short of the upper end of the glove. The glove has an open upper end 62 (FIG. 5A) to allow insertion of a hand therein. The glove 21 may be considered to have two walls 63a and 63b, respectively. As the body member 13 projects through the glove 21, it effectively partially divides the glove into two separate finger receiving compartments.

A heat seal 64 interconnects the two walls 60 and 60a of the flexible container 15 and the wall 63a of the glove 21. The heat seal 64 is parallel and spaced upwardly from the heat seal 59 and a plurality of finger receiving apertures 65 (three being illustrated in FIG. 5) project through the container 15 and through the wall 63a of the glove 21. These apertures provide a convenient handle for carrying the catheterization assembly.

A typical use of the catheterization assembly 11 is shown in FIG. 6. The first step in the use of the catheterization assembly 11 is for the doctor to properly position the depth limiter 53 along the catheter 23. The doctor can then insert his hand into the glove 21 through the open upper end thereof as shown in FIG. 6 and insert the catheter 23 into the urethra 67 (FIG. 6) until the depth limiter contacts the meatus 68. Because of the depth limiter 53, the catheter cannot project into the urethra beyond the sphincter or valve 69 to thereby prevent bladder infection As a result of forcing contamination and bacteria into the bladder 71. The patient can then void into the catheter 23.

With reference to FIGS. 1–3, the urine enters the passage 47, passes through the inlet passage 29 into the connecting passage 35. As the initial flow is undoubtedly contaminated, such initial flow is allowed to pass through the connecting passage 35 and be deposited in

the flexible container **15.** When, in the opinion of the attending physician the contamination has been flushed out, he urges a segment **73** of the wall **60***a* of the flexible container **15,** which confronts the connecting passage, into engagement with the valve seat **37** as shown in dashed lines in FIG. **2** and as shown in FIG. **6.** This closes the connecting passage **35** to the interior of the flexible container **15.** Accordingly, urine entering the connecting passage **35** must now flow into the inlet passage **31** to the container **17.** The valve seat **37** and the segment **73** of the flexible container **15** form a manually operable valve for selecting the container into which the urine is to be deposited. This permits the attending physician to select the portion of the flow which will be diverted into the specimen container **17.**

When the container **17** is filled, subsequent flow will enter the vent passage **39** and pass therefrom into the flexible container **15** as the vent passage opens into the flexible container **15** at a region outside of the connecting passage **35.** The vent passage **39** serves three important functions. First, it allows the air in the specimen container **17** to be vented to the flexible container **15** during filling of the specimen container. Second, it serves as an overflow from the relatively smaller rigid container **17.** Third, it permits the doctor to visually observe the entire flow passing through the container **17.** This is much easier than observing the flow as it enters the relatively larger flexible container **15.**

The projecting portion of the valve seat **37** holds the valve normally open. This prevents collection of urine in the connecting passage **35** and premature flow into the passage **31.** By minimizing the extent to which the valve seat **37** projects axially beyond the mouths of the inlet passages **29** and **31,** the likelihood that flow from the passage **29** to the passage **31** will occur with the valve open is minimized. The likelihood of flow into the inlet passage **31** with the valve opened is further reduced by positioning the inlet passage **31** no lower than inlet passage **29.**

When the urine sample has been collected, the specimen container **17** and the cover **19** are removed from the body member **13** and the cover is applied to the container as shown in FIG. **4.** The uncontaminated sample in the container **17** and the contaminated sample in the container **15** may then be subjected to different tests.

The glove **21** prevents any loss of sterility and eliminates the need for a separate glove. The entire catheterization unit is inexpensive and disposable.

The valve means is easily operable without springs to select the container into which urine will be deposited. For example, the valve can be closed to collect a urine sample in one tube **17** and then opened to cause urine to be deposited in the bag **15.** The tube **17** can then be replaced with an identical tube **17** and the valve means closed to collect a second sample in the second tube.

Although an exemplary embodiment of the invention has been shown and described, many changes, modifications and substitutions may be made by one having ordinary skill in the art without necessarily departing from the spirit and scope of this invention.

We claim:

1. A catheterization assembly comprising:

a first container;

a first conduit terminating in said first container;

a second container;

a second conduit interconnecting said containers;

manually operable valve means including a portion of said first container for diverting flow from said first conduit into said second conduit; and

said manually operable valve means including wall means defining a passage terminating in a valve seat, both of said conduits terminating in said passage, said portion of said first container including a section of said first container movable toward and away from said valve seat between an open position in which fluid can flow from said first conduit through said passage and into said first container and a closed position in which said passage is closed off at said valve seat so that fluid entering said passage from said first conduit exits into said second conduit and flows to said second container.

2. An assembly as defined in claim **1** wherein said first container is a substantially flexible container.

3. An assembly as defined in claim **2** wherein said portion of said first container includes a relatively flexible section of the wall of said first container.

4. An assembly as defined in claim **1** wherein said first conduit includes a catheter terminating in a tip, said catheter having a depth limiter thereon spaced from said tip to limit the depth of insertion into the urethra.

5. An assembly as defined in claim **1** including means defining a vent passage leading from said second container to said first container so that when said second container is full fluid can flow from said second container through said vent passage into said first container.

6. An assembly as defined in claim **1** wherein said valve seat is inclined so that the upper end of said valve seat projects a greater distance into said first container than the lower edge of said valve seat when the catheterization assembly is held in a normal position of use.

* * * * *