

- [54] **METHOD AND APPARATUS FOR COLLECTING URINE**  
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[52] U.S. Cl. .... **128/2 F, 4/110, 128/275, 128/295, 215/12, 215/43 A, 215/73**  
[51] Int. Cl. .... **A61b 19/00**  
[58] Field of Search .... **128/2 F, 2 R, 295, 128/272, 275; 215/43 A, 12, 73, DIG. 3; 206/63.2 R; 4/110**

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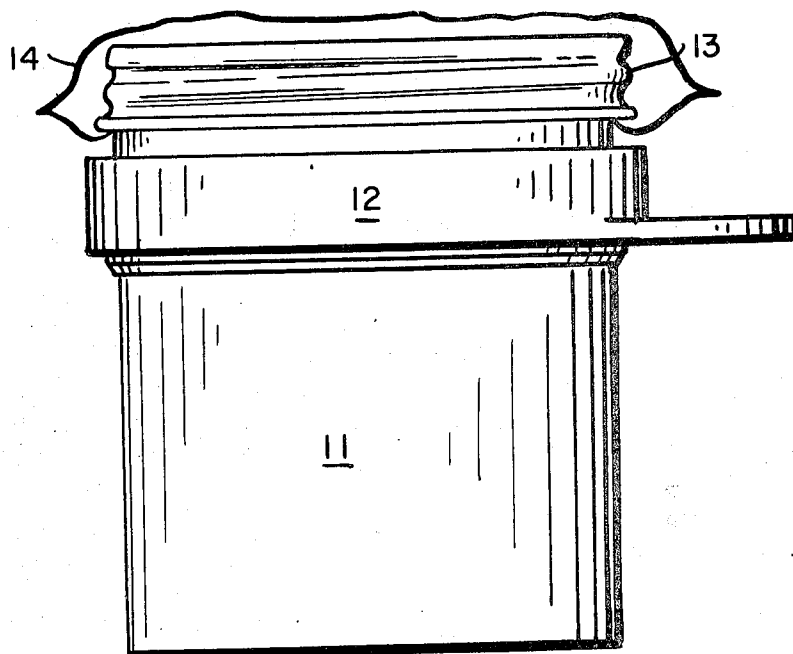
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[57] **ABSTRACT**

A device and method for collecting a liquid, such as urine, with little or no contamination thereof. The device when delivered for use includes a container member, an intermediate member secured to the container and a cap member encased in a closed bag and in turn secured to the intermediate member through the bag. During use the cap member is removed from the intermediate member and placed on a convenient surface, still in the closed bag. The intermediate member has a handle which then permits the user easily to hold the container in position for voiding urine into the container. The intermediate member is then removed from the container and discarded. The uncontaminated cap member is then removed from the closed bag and is threadably secured to the container so that the urine contained therein can be delivered for analysis in a substantially uncontaminated state.

**20 Claims, 4 Drawing Figures**



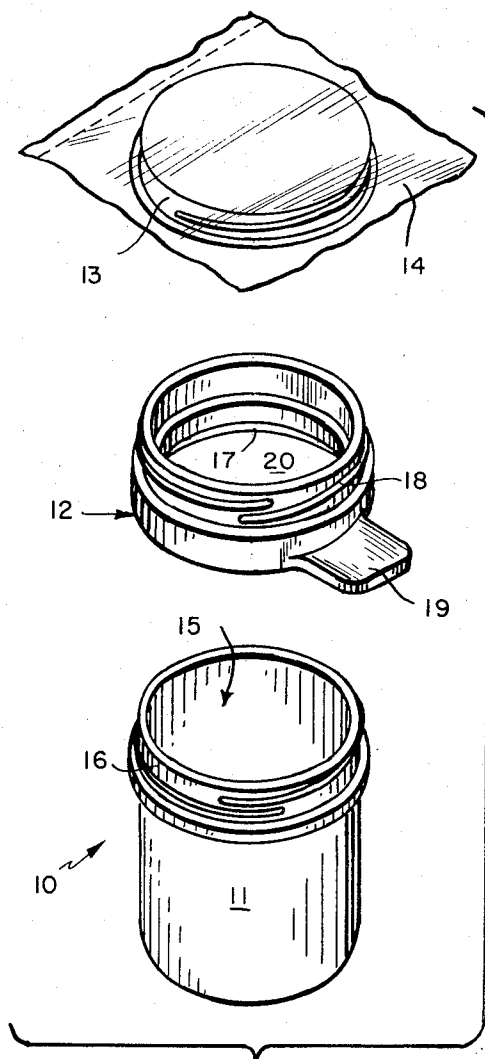


FIG. 1

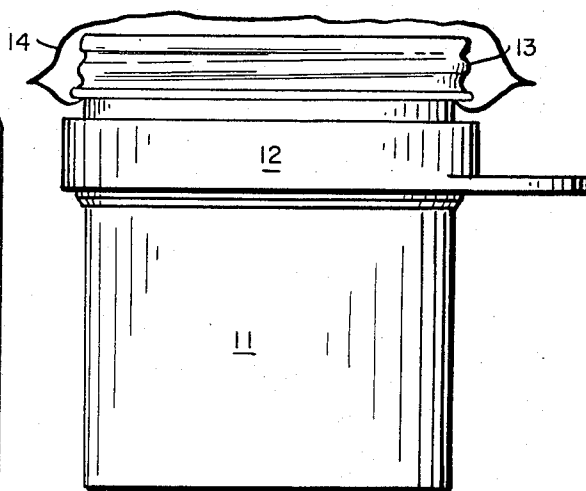


FIG. 2

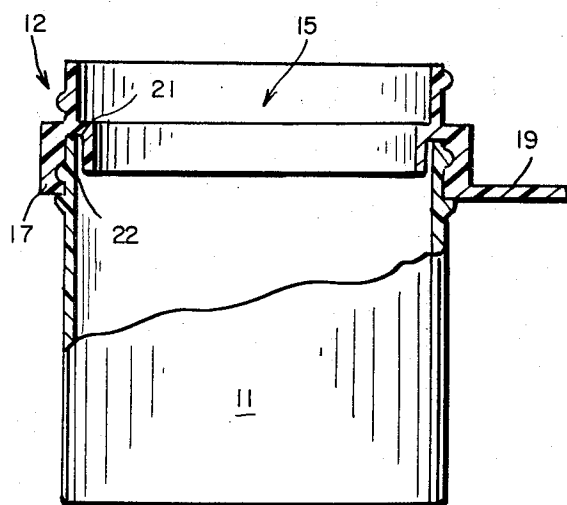


FIG. 3

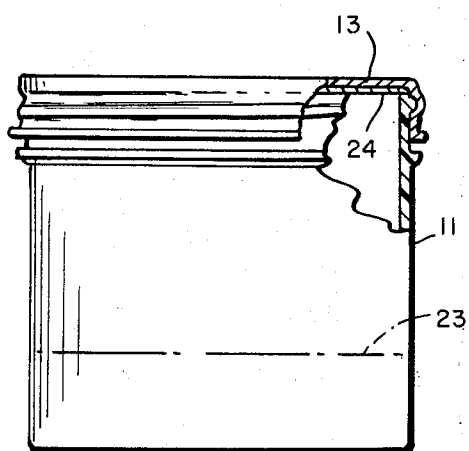


FIG. 4

## METHOD AND APPARATUS FOR COLLECTING URINE

### DISCLOSURE OF THE INVENTION

This invention relates generally to devices and methods for collecting liquids and, more particularly, to an inexpensive and easy to use device and method for collecting urine specimens, while minimizing the chance for contamination thereof during the collection process.

The collection of urine specimens for analysis is standard medical procedure and it is desirable that the specimen be obtained for use with substantially little or no contamination which might adversely affect the results of such analysis. Further it is desirable that such devices be capable of easy use by a patient in a clean manner without soiling the patient or the patient's garments.

Most collecting devices in use at the present time provide a relatively narrow necked container which, while not too difficult for use by male patients, is more difficult for easy and clean use by female patients. Other presently available devices which attempt to avoid such problems may in some instances be inconvenient or uncomfortable to use or generally appear to be relatively more expensive to manufacture than the device of this invention.

This invention provides a collecting device which is simply constructed so that it is not only relatively inexpensive to manufacture but is also relatively easily and cleanly used by the patient in such a way that contamination of the specimen itself is minimized.

The invention comprises three major portions: a container member, an intermediate member and a cap member. In a preferred embodiment thereof, the container member is in the form of a cylindrical receptacle having a threaded opening of a diameter sufficient to provide an easy target to facilitate the catching of urine without spillage and to permit the receptacle to be placed on a surface without danger of being tipped over.

The intermediate member has an opening substantially corresponding to the threaded opening of the container and has a first threaded portion which permits it to be threadably secured to the container. In addition the intermediate member has a second threaded portion displaced from the first threaded portion, which second threaded portion has a diameter substantially the same as that of the threaded opening of the container. In addition, the intermediate member has a lip portion which fits over the edge of the threaded opening of the container when the intermediate member is threaded thereon and a handle which projects outwardly from the intermediate member, which handle is adapted to be readily grasped by the fingers of one hand so that the container may be easily held during use.

A threaded cap member is arranged so that it can be threadably secured either to the second threaded portion of the intermediate member or to the threaded opening of the container. Prior to use the cap member is enclosed in a bag having a thickness and flexibility which permits the cap member to be threaded on to the second threaded portion of the intermediate member without removal of the cap from the bag.

Accordingly, the device is assembled for use so that initially the intermediate member is threadably secured

to the container and the cap member is in turn threadably secured to the intermediate member through the closed bag. When the patient uses the device the cap member is first removed from the intermediate member and, because it is encased in the bag, it can be placed on any surface without fear of contamination thereof. The patient then holds the container by the handle which projects from the intermediate member so that the urine can be voided into the container cleanly and without difficulty. The lip portion of the intermediate member extends over and around the edge of the threaded opening of the container itself and prevents contact of the urine with such edge during voiding so that all of the urine which enters the container is protected from contamination. Such a structure also permits removal of the intermediate member with minimum danger of contamination of such edge.

When the voiding process is completed the patient removes the intermediate member from the container and discards it, while placing the container holding the specimen on a suitable flat surface without fear that it will tip and spill its contents. The uncontaminated cap member is then removed from the closed bag in which it has theretofore been encased and is threadably secured to the opening of the container in a simple manner so that the specimen is retained within the container in a substantially uncontaminated state.

The invention can be described in more detail with the help of the accompanying drawings wherein

FIG. 1 is an exploded perspective view showing each of the three major portions of the collecting device of the invention;

FIG. 2 shows a side view of the device of the invention in the form as provided for a patient;

FIG. 3 shows a view in cross-section of the container and intermediate member of the device in a form for use by the patient; and

FIG. 4 shows a side view of the device including the container and cap member threadably secured thereto after use by the patient.

As can be seen in FIG. 1, the collector unit 10 of the invention, as assembled for use by a patient, comprises three major portions. A first container member 11, a second intermediate member 12 and a third cap member 13, the latter being encased in a closed bag 14, as shown. The container has an opening 15 at the top thereof and an externally threaded portion 16 at the open end thereof. The container may be made of any clear or translucent material, such as glass or a suitable plastic. Intermediate member 12 has a lower internally threaded portion 17 and an upper externally threaded portion 18. A handle 19 projects outwardly from the intermediate member 12 and, in the preferred embodiment shown, is in the form of a substantially flat tab which can be easily grasped between the fingers of one hand when the device is in use. The size of the opening 20 of intermediate member 12 corresponds to the size of the opening 15 of container 11. The cap member 13 is internally threaded and has fitted therein a resilient sealing layer 24 (shown in FIG. 4) made of any appropriate compressible material which provides an effective seal when the cap is secured to container 11, as disclosed below. While the cap is depicted as made of a metallic material, it may also be fabricated from other materials, such as a suitable plastic.

The overall device can be neatly packaged for delivery to the user in the manner shown in FIG. 2, wherein

intermediate member 12 is threadably secured at its lower internally threaded portion to the externally threaded portion at the open end of container 11. Cap member 13 is in turn threadably secured to the upper externally threaded portion of intermediate member 12 while still enclosed in bag 14. Because cap member 13 extends over and around the upper edge of intermediate member 12, it protects such edge from contamination. The bag 14 may be made of a suitable plastic material, such as polyethylene or polyvinyl chloride film, and its thickness is such that the cap can be readily threaded to the intermediate member 12 through the bag, as shown, so that the overall device is conveniently packaged for sale, delivery and ultimate use in a relatively inexpensive and easy manner.

When the device is to be used, the user first removes the cap member 13 from intermediate member 12 simply by unscrewing the cap from the upper threaded portion of intermediate member 12, thereby exposing the opening 15 therein. Because the cap remains enclosed within bag 14 after it has been so removed, it can be placed temporarily on any convenient surface without fear that it will become contaminated by contact with anything other than the bag itself. When the cap has been removed, the device is in the form shown in FIG. 3 wherein the intermediate member 12 remains threadably secured to the container 11. Intermediate member 12 has a lip portion 21 integrally formed with the lower threaded portion 17 thereof which effectively covers the upper edge 22 of container 11 so that such edge is not subject to contact with any contaminating surface or with the urine during the collection. The patient then is able to hold the unit by means of handle 19 in an appropriate position for voiding into the container via opening 15.

When the voiding process is completed the intermediate member 12 is removed from container 11 and discarded. Any liquid which inadvertently splashes on to member 12 is also thereby discarded so that urine which directly enters the container is in no way contaminated. The container 11 can then be placed on any suitable flat surface ready for covering. The diameter of the container is made sufficiently large so that it provides a relatively easy target during use and so that when the container is placed on the surface it is not subject to being easily tipped over. In a preferred embodiment, for example, the container may have a diameter of about 2 inches and a height of about 3 inches.

The cap member 13 is then removed from the closed bag by breaking open the bag in an appropriate manner. For example, the bag may be scored with perforations, or otherwise arranged, for easy opening in any known manner. The cap is then threadably secured to the externally threaded portion at the open end of container 11, as shown in FIG. 4. Because the urine 23 which has entered the container has not touched any contaminating surface and because the cap has been fully protected from contamination throughout the process, there is little or no chance for the specimen to become contaminated. Hence, the specimen can be delivered for analysis with the least chance for contamination to have occurred thereto even when the device has been used by an average user who may not normally be too concerned with the necessity for the use of precautionary measures to avoid contamination. Moreover, the user can avoid the usual mess which

often accompanies the obtaining of a specimen when using prior art devices for that purpose.

Preferably, then, the assembly of container 11, intermediate member 12 and cap 13 enclosed in bag 14, as shown in FIG. 2, is internally sterile. Also, it is preferred that such assembly be internally sealed so that such internal sterility is maintained during handling and shipment. Accordingly, in the assembly of FIG. 2, the upper edge 22 of container 11 is sterile, as well as the upper edge of intermediate member 12 and the internal groove formed by lip 21 of the intermediate member 12. In using the device, the sterile cap 13 enclosed in bag 14 is aseptically removed from the intermediate member 12, the urine is collected aseptically, the intermediate member 12 is aseptically removed from container 11, the sterile cap 13 is aseptically removed from bag 14 and is aseptically secured to container 11. The cap can then be aseptically removed from the container so that the urine specimen can be aseptically removed from the container for analysis. Accordingly, contamination of the urine specimen is minimized throughout the entire procedure.

While the device in the preferred embodiment discussed above is shown as having its various parts adapted to be threadably secured to each other, other means for coupling such parts may be used. Thus, the parts may be arranged to provide a pressure fit, a Luer lock, or other equivalent mechanisms for coupling the parts together.

What is claimed is:

1. An internally sterile device for collecting a urine specimen from a patient in a substantially uncontaminated state, said device comprising

an internally sterile container having a closed end, and, at its other end, an opening through which said urine specimen can be directed for retention therein;

a hollow internally sterile intermediate member open at its ends and having an opening therethrough and including

first coupling means removably securing said intermediate member to and over said container opening with the opening therethrough in unobstructed communication with said opening and second coupling means displaced from said first coupling means;

a cap member removably secured to said second coupling means of said intermediate member to close said opening thereof and thereby the opening of said container to which said intermediate member is removably secured, said cap member having means for removably securing it to said container opening over said opening to close it when said intermediate member has been removed from said container, said cap member being removably enclosed in a flexible bag having a thickness and flexibility which permits said cap member to be secured to said second coupling means of said intermediate member to close the opening thereof without removal of said cap member from said bag.

2. A device in accordance with claim 1

wherein said cap member is sterile and is secured to said second coupling means of said intermediate member through said bag, said bag protecting said sterile cap from contamination and being adapted to be removed from said cap for securing said cap

over said container opening after said intermediate member has been removed therefrom.

3. A device in accordance with claim 1 wherein said container opening and said first coupling means have means for rotatably locking and unlocking said intermediate member in secured position on and over said container opening.

4. A device in accordance with claim 3 wherein said means for locking and unlocking said intermediate member over said container opening comprises said container opening being externally threaded and said first coupling portion of said intermediate member being internally threaded.

5. A device in accordance with claim 1 wherein said intermediate member has a handle projecting outwardly therefrom.

6. A device in accordance with claim 5 wherein said handle is in the form of a substantially flat tab member.

7. A device in accordance with claim 1 wherein said container is substantially cylindrical and is made of a plastic.

8. A device in accordance with claim 7 wherein said intermediate member is made of a relatively rigid plastic.

9. A device in accordance with claim 8 wherein said cap member is metallic and has a layer of resilient sealing material fitted therein.

10. A device in accordance with claim 8 wherein said cap member is a plastic material and has a layer of resilient sealing material fitted therein.

11. A device in accordance in claim 1 wherein said container is substantially cylindrical and is made of glass.

12. A device in accordance with claim 1 wherein the openings of said container and said intermediate member are the same size.

13. A device according to claim 1, said intermediate member having a lip portion covering the edge of said container opening to protect it from contamination, said cap member being adapted to be located over the edge of said container opening to protect it against contamination when said cap is secured to said container opening.

14. A device in accordance with claim 13, wherein the interior of said assembled device formed by said container, intermediate member and cap is sterile and provides a closed system, said lip portion covering the edge of said container opening extending from the inner wall of said intermediate member inwardly and then downwardly to form with said inner wall a recess for receiving said edge of said opening to protect it from contamination prior to and during collection.

15. A device according to claim 1, said flexible bag having a line of weakness therein to facilitate tearing of said bag along said line of weakness to remove said cap from said flexible bag.

16. A device according to claim 1, the assembly of said container and intermediate member having a handle extending sideways therefrom.

17. A method of collecting a urine specimen by use of a device comprising a container having a closed end, and, at its other end, an opening through which said urine can be directed for retention therein; a hollow intermediate member open at its ends and having an opening therethrough and including first coupling means removably securing said intermediate member to and over said container opening with the opening

therethrough in unobstructed communication with said container opening, and second coupling means displaced from said first coupling means; and a cap member removably secured to said second coupling means of said intermediate member to close said opening thereof and thereby the opening of said container to which said intermediate member is removably secured, said cap member having means for removably securing it to said container opening over said opening and its edge to close said container opening when said intermediate member has been removed from said container, said cap member being removably enclosed in a flexible bag having a thickness and flexibility which permits said cap member to be secured to said second coupling means of said intermediate member to close the opening thereof without removal of said cap member from said bag;

said method comprising the steps of removing said cap member from said intermediate member while retaining said cap member in said flexible bag; directing said urine specimen through the openings in said intermediate member and said container into said container for retention therein; removing said intermediate member from said container; removing said cap member from said flexible bag; and securing said cap member to said container at the opening thereof, thereby to retain said urine specimen in said container in a substantially uncontaminated state.

18. A method according to claim 17, wherein the interior of the assembly of said container, intermediate member and cap member is sterile and wherein said cap member in said bag is sterile and is secured to said second coupling means of said intermediate member through said bag, wherein said intermediate member has a lip portion covering the edge of said container opening to protect it from contamination and wherein said method steps are carried out without contaminating said container opening, the interior of said cap or the interior of said container and hence, without contaminating said urine specimen.

19. A method in accordance with claim 17, wherein the assembly of said intermediate member and container has a handle projecting outwardly therefrom, and whereas said assembly is held in one hand by said handle while said urine is being directed into said container.

20. In a device for collecting a urine specimen voided from a patient, said device comprising a container having a closed end, and, at its other end, an opening through which said urine specimen can be voided by said patient for retention therein; a hollow internally sterile intermediate member open at its ends and having an opening therethrough and including

first coupling means removably securing said intermediate member to and over said container opening with the opening therethrough in unobstructed communication with said container opening and second coupling means displaced from said first coupling means; and a cap member removably secured to said second coupling means of said intermediate member to close

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said opening thereof and thereby the opening of  
said container to which said intermediate member  
is removably secured, said cap member having  
means for removably securing it to said container  
opening over said container opening to close it 5  
when said intermediate member has been removed  
from said container, the improvement comprising

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said cap member being removably enclosed in a  
flexible plastic bag having a thickness and flexibil-  
ity which permits said cap member to be secured  
to said second coupling means of said intermediate  
member to close the opening thereof without re-  
moval of said cap member from said bag.

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