United States Patent
Linzer et al.

[15] 3,635,091
[45] Jan. 18, 1972

[54] MIDSTREAM URINE SPECIMEN AND FRACTIONAL FLUID COLLECTORS

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[22] Filed: **Aug. 31, 1970**

[21] Appl. No.: **68,434**

[52] U.S. Cl. ..... 73/421 R, 128/2 R, 128/295
[51] Int. Cl. G01n 1/10
[58] Field of Search ..... 73/425.2, 421 R; 128/295, 2 R

[56] References Cited

UNITED STATES PATENTS

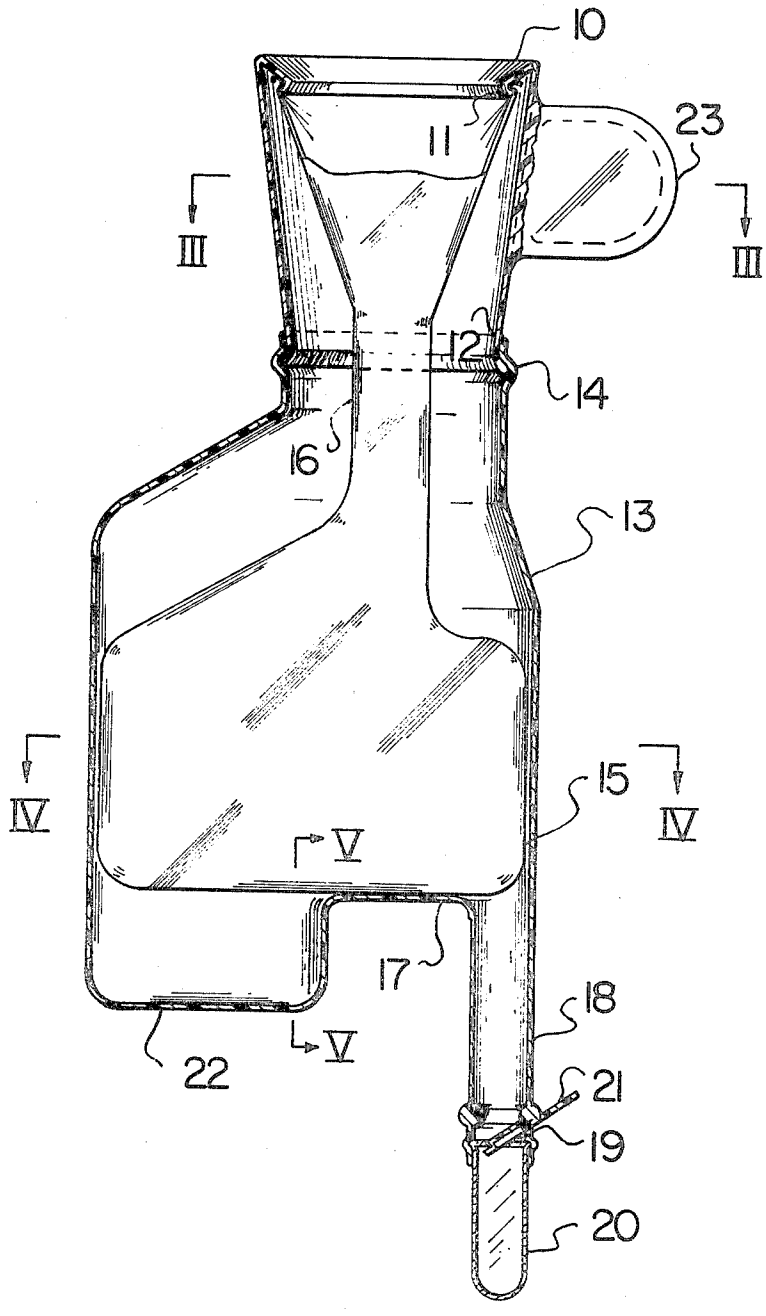
3,499,327	3/1970	Lane, Jr.	73/421
3,463,357	8/1969	MacLean, Jr. et al.	73/421 X
3,292,626	12/1966	Schneider	128/295
3,405,714	10/1968	Moss	128/295

Primary Examiner—Louis R. Prince
Assistant Examiner—Daniel M. Yasich
Attorney—Buell, Blenko & Ziesenheim

[57] ABSTRACT

A disposable urine specimen and fractional liquid collector having an inlet member with an inner connector and an outer connector, and a preferably flexible outer enclosure having a neck portion connected to the outer connector. A flexible inner bag is contained in the outer enclosure, and has a neck portion connected to the inner connector. The inner bag disconnects from the inner connector after the inner bag contains a given quantity of liquid, to thereafter trap the liquid in the inner bag, and to thereafter allow the outer enclosure to receive liquid through the inlet member. The outer enclosure and/or inner bag may be adapted so at least some liquid collected therein can be deposited in independent sterile containers.

18 Claims, 13 Drawing Figures



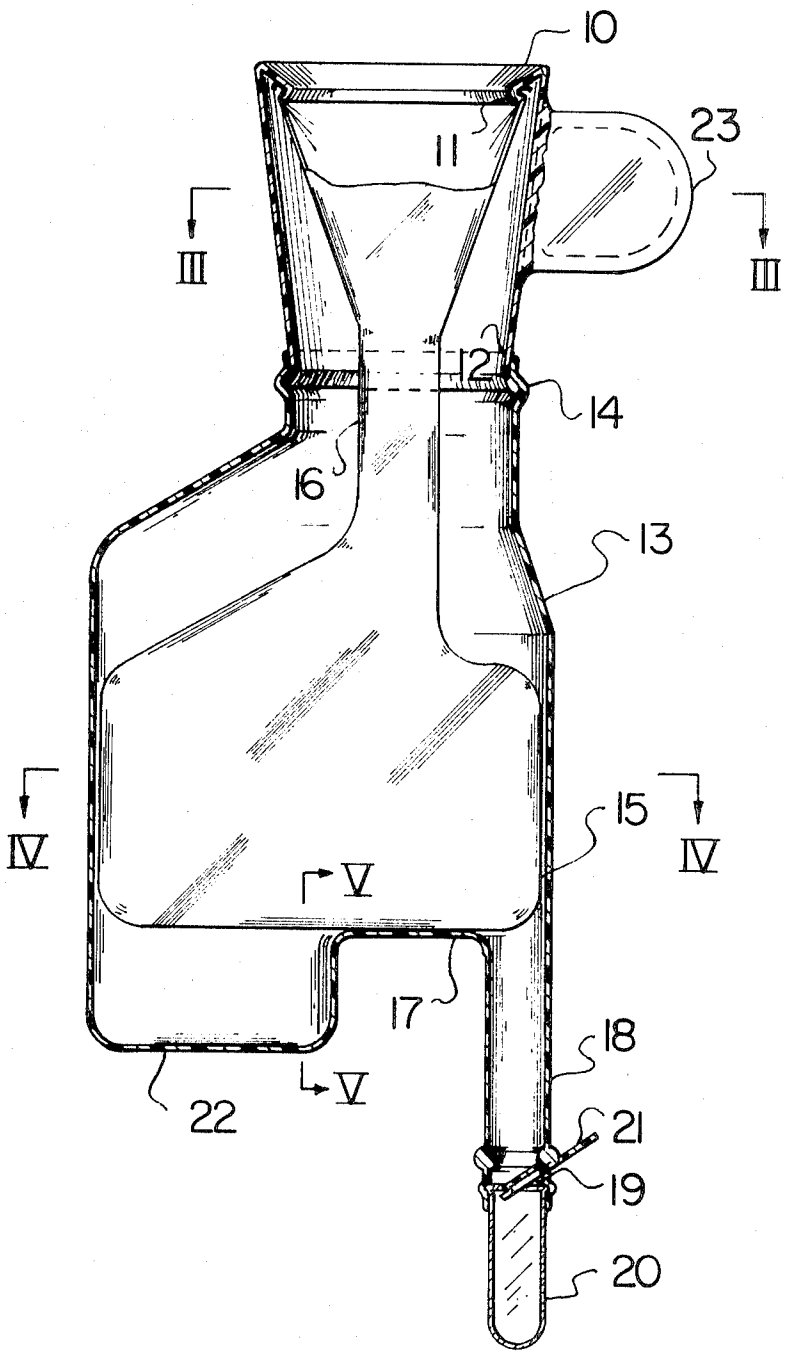


Fig. 1

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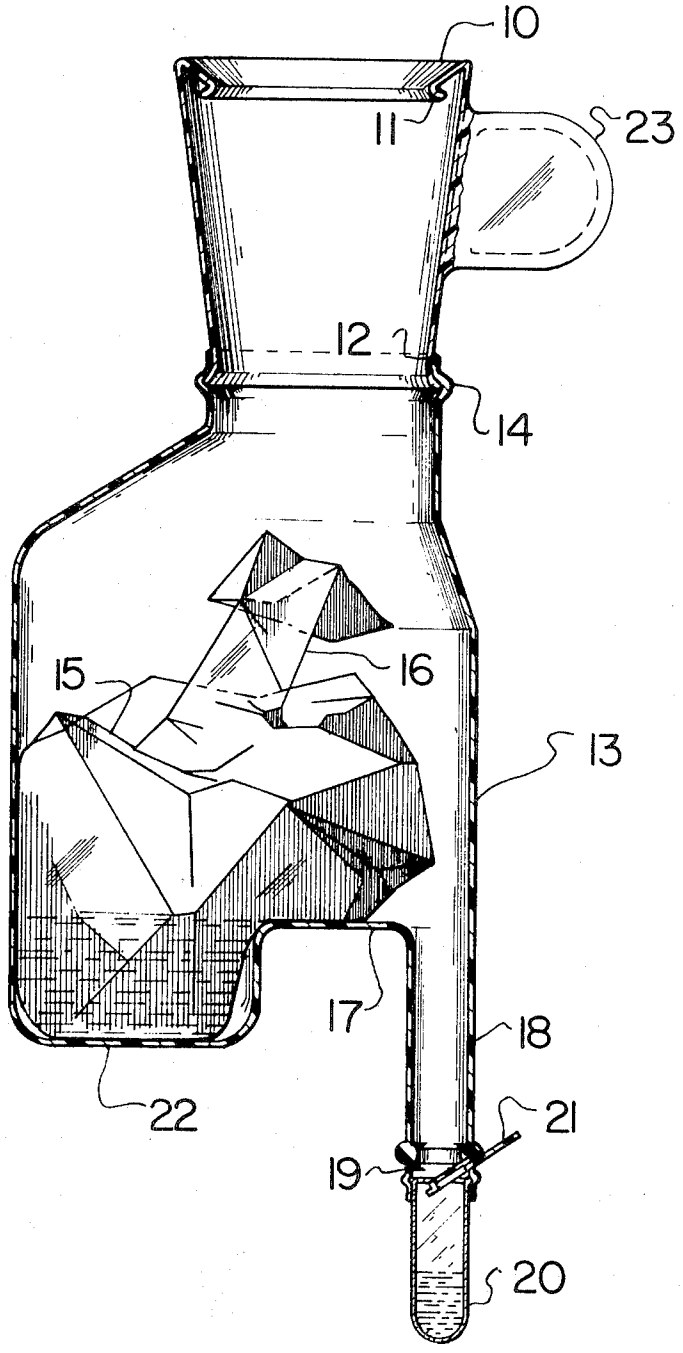


Fig. 2

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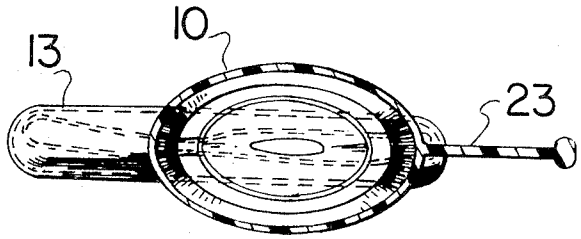


Fig. 3

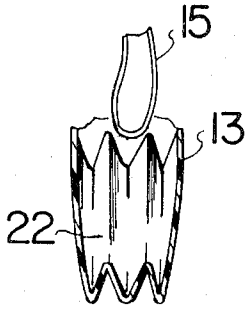


Fig. 6

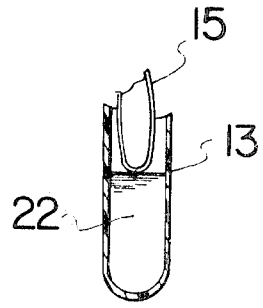


Fig. 5

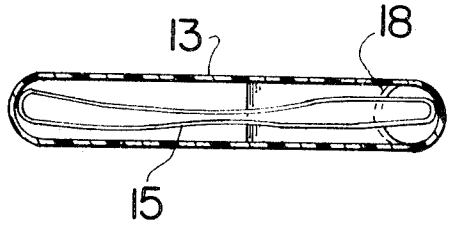


Fig. 4

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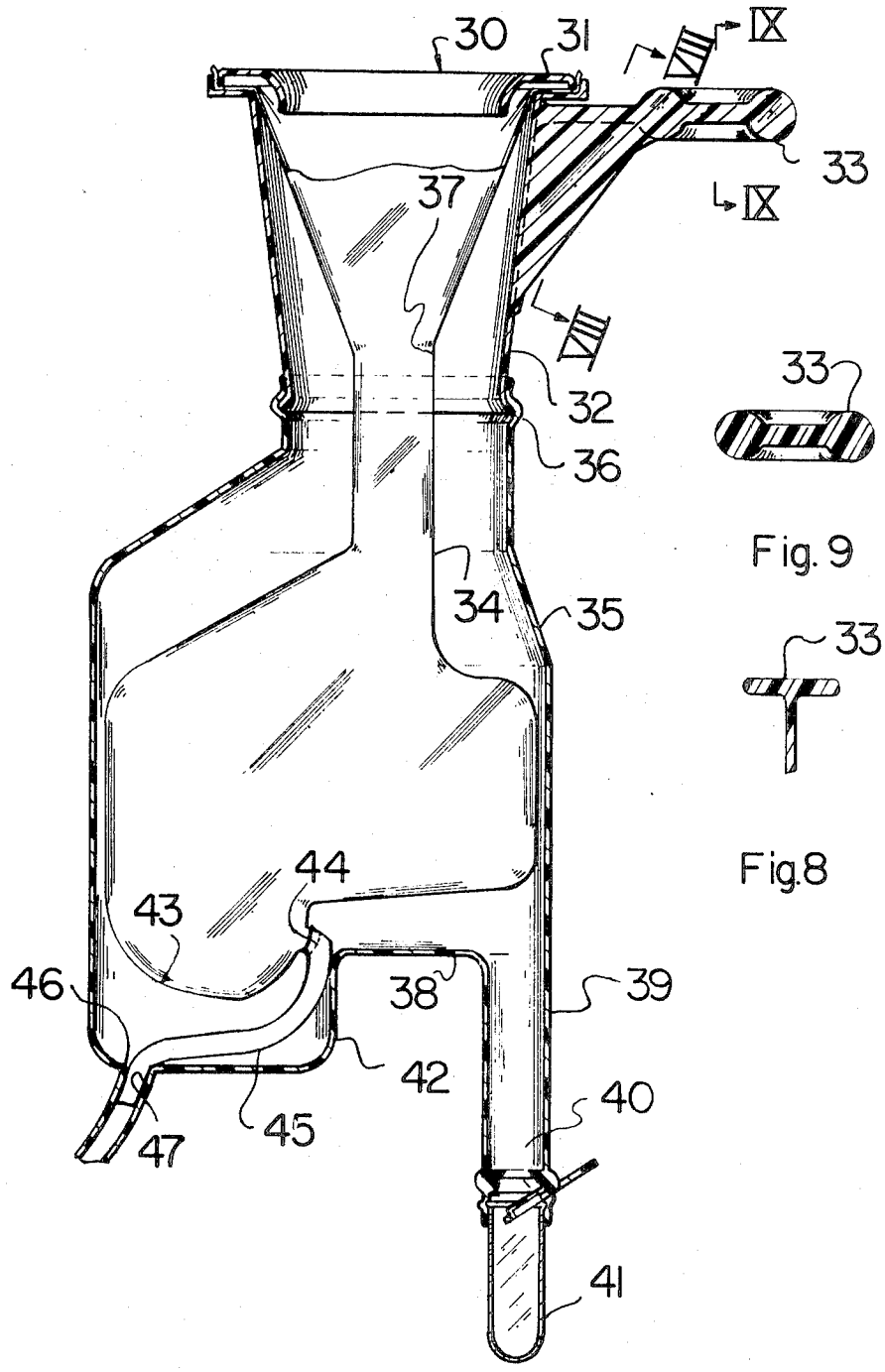


Fig. 7

Fig. 9

Fig. 8

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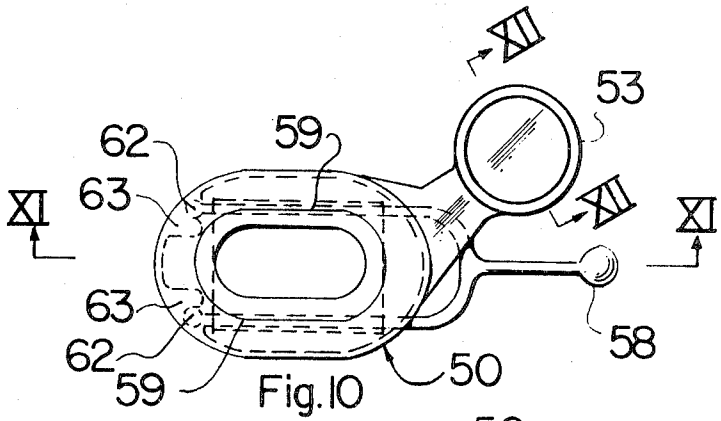


Fig. 10

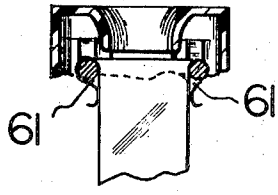


Fig. 13

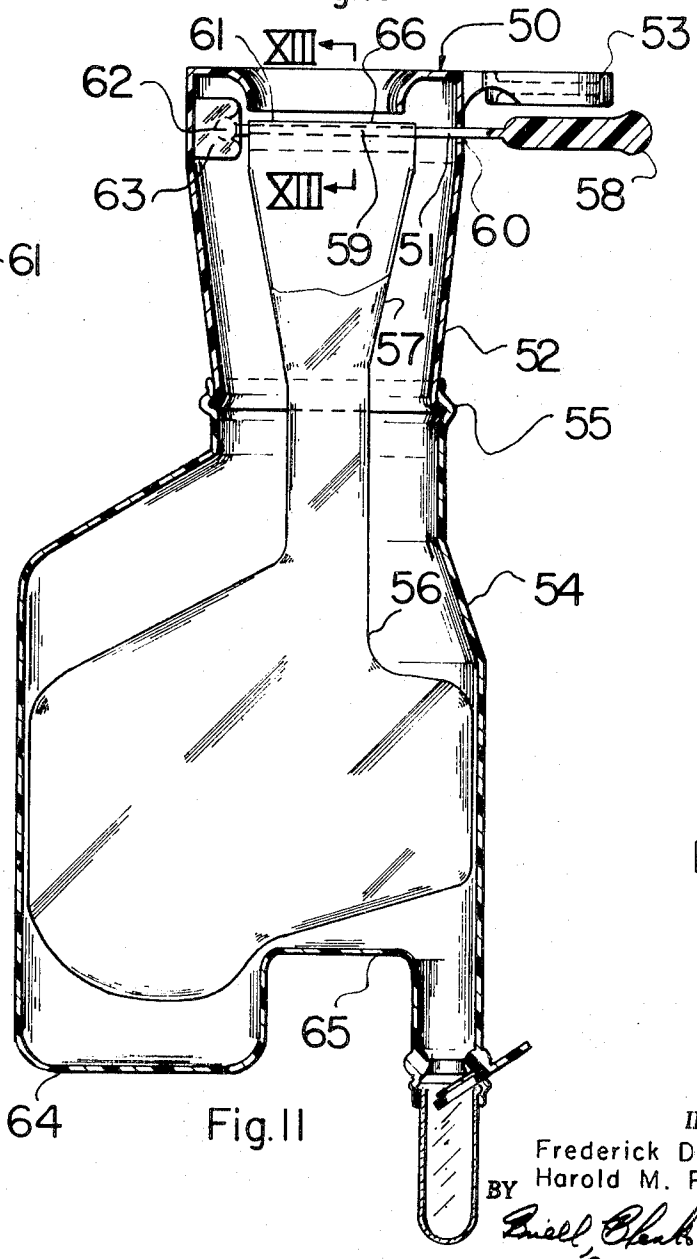


Fig. 11

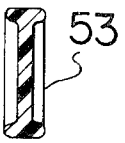


Fig. 12

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MIDSTREAM URINE SPECIMEN AND FRACTIONAL FLUID COLLECTORS

This invention relates to a disposable urine specimen collector which automatically collects a contaminate-free urine sample while the patient urinates continuously.

The evaluation of urine specimens provides valuable information for the physician in the care of his patient, provided the specimen is properly collected. A properly collected urine specimen is one that is free of contamination. The principle sources of contamination are the urethra, the skin surfaces adjacent to the urethra and, in females, vaginal discharges. Routine medical practice is to have the patient initially urinate into one container, then stop and pass the midstream fraction into a second sterile container. This practice is a discomfort to most adult patients and impossible with infants, small children and some patients. The effective alternative is catheterization which is not practical on a routine basis. In addition, contamination can occur in careless collecting and handling by the patient and medical personnel before the specimen reaches the laboratory.

Midstream sample collectors to automatically collect the urine in two specimens are old and generally known in the art. One such proposal is shown in Lane U.S. Pat. No. 3,499,327. But such apparatus was expensive to make and awkward to use. In addition, it had to be cleaned and sterilized after each use, which was time consuming and expensive. In short, such urine sample collectors were not heretofore practical and have not been generally used in medical practice.

The present invention overcomes these difficulties and disadvantages and provides a midstream urine sample collector that is commercially feasible to build and practical to use.

We provide a midstream urine specimen collector comprising an inlet member which has an inner connector and an outer connector. It has an outer enclosure which has a neck portion that connects to said outer connector of the inlet member. And it has a flexible inner bag that is contained in said outer enclosure and has a neck portion that connects to said inner connector of the inlet member. The flexible inner bag is adapted so that the neck portion will disconnect from said inner connector of the inlet member after said inner bag receives a given quantity of liquid and thereafter trap said liquid in said inner bag while allowing said outer enclosure to receive liquid through the inlet member.

Preferably the outer enclosure has a first pocket portion adjacent a base portion thereof for receiving the liquid received by the outer enclosure and said first pocket portion has an outlet opening adapted to connect a sterile container to receive the liquid received into the first pocket portion. In this way, the contaminate-free urine contained in the outer enclosure can be collected in the sterile container and readily removed from the specimen collector for analysis.

We prefer that the inner bag be adapted to disconnect from said inner connector of the inlet member by providing a second pocket portion in the outer enclosure adjacent said base portions thereof. The inner bag is positioned so that it at least partially collapses into said second pocket portion when a given quantity of liquid is contained in the inner bag. The collapsing of the inner bag into said second pocket portion in turn causes the neck portion of the inner bag to disconnect from the inner connector of the inlet member and thereafter trap the liquid in the inner bag while allowing the outer enclosure to receive the liquid. The collapsing and disconnecting can be aided by providing a pocket portion in the inner bag corresponding to the second pocket portion in said outer enclosure for collecting the liquid received by the inner bag and by having the neck portion of the inner bag offset opposite said second pocket portion of said outer enclosure.

Alternatively the inner bag can be adapted to disconnect from said inner connector of the inlet member manually. This can be accomplished by making the inner connector an independent member that is removable.

The inlet member can be made in any convenient shape and can be varied as necessity demands. It can be made in two pieces to facilitate the connection of the inner connector to the inner bag. We contemplate that for the most versatile use the inlet member be made in a funnellike shape. For more efficient collection the shape of the inlet member can however be varied depending upon the anatomic demands of the patient, e.g., age (infant or adult), sex, and position (upright or supine). These variations in shape are readily apparent to a person skilled in the art.

The inner bag can be varied in size as desired. Preferably the inner bag is almost as wide as the outer enclosure or ridges or some other antislip means are provided between the inner bag and the outer enclosure so that the inner bag is not free to shift sideways to any substantial degree. Further, we contemplate that the inner bag should contain at least 10 ml. of liquid to insure a contaminate-free urine specimen in universal use of the specimen collector. In addition, we prefer that the inner bag be made of a plastic such as polyethylene which has a thickness of about 2 mils and can adhere to itself when wetted. This type of material will insure that the neck portion of the inner bag is pushed out of the region of the inlet member and closed securely so that the midstream fraction contained in the outer enclosure is not contaminated by leakage of the initial fraction from the inner bag.

The outer enclosure may be made of a rigid material or a flexible material. In either case it should be of sufficient thickness and stiffness to insure optimum performance of the specimen collector. We contemplate for best results, that the outer enclosure be a flexible material of about twice the thickness (e.g. about 4 mils) of the inner bag.

The outer enclosure and the inner bag of the specimen collector can be made as a separate assembly. We contemplate that such assembly can be prepackaged in a sterile container and will be flat before use. Medical personnel can attach the inner bag and the outer enclosure to an inlet member and also attach a sterile container to said first pocket portion of the outer enclosure to ready the sample collector for use. In this way, the outer enclosure and the inner bag can be easily disposed of after the specimen collector has been used and only the inlet member and possibly the sterile container remain to be easily washed and sterilized for reuse.

Alternatively, the entire assembly may be prepackaged in a flat configuration in a sterilized container and disposed of after use.

In operation the present invention has the advantage of allowing the patient to urinate continuously into a single container while a contaminate-free urine specimen is collected. Separation of the urine into a first fraction and a midstream contaminate-free fraction is automatic. No manipulation by the patient or medical personnel may be necessary save in one embodiment. Further the invention maintains the urine in two specimens so that if necessary the initial urine fraction can be compared with the midstream contaminate-free specimen. Moreover, the entire specimen collector, or parts of it, can be inexpensively made and sold as a sterile disposable prepackage unit.

Other details, objects and advantages of our invention will become apparent as the following description of the presently preferred embodiments thereof proceeds.

The accompanying drawings illustrate presently preferred embodiments of our invention in which:

FIG. 1 is a cross-sectional view through the vertical axis of a midstream urine specimen collector embodying our invention;

FIG. 2 is a similar cross-sectional view showing the midstream urine specimen collector of FIG. 1 in operation;

FIG. 3 is a cross-sectional view taken along line III—III of FIG. 1;

FIG. 4 is a cross-sectional view taken along line IV—IV of FIG. 1;

FIG. 5 is a partial cross-sectional view taken along line V—V of FIG. 1;

FIG. 6 is an alternative partial cross-sectional view taken along line V—V of FIG. 1;

FIG. 7 is an alternative cross-sectional view through the vertical axis of a midstream urine specimen collector embodying our invention;

FIG. 8 is a cross-sectional view taken along line VIII—VIII of FIG. 7;

FIG. 9 is a cross-sectional view taken along line IX—IX of FIG. 7;

FIG. 10 is a top view of a second alternative midstream urine specimen collector embodying our invention;

FIG. 11 is a cross-sectional view taken along line XI—XI of FIG. 10; and

FIG. 12 is a cross-sectional view taken along line XII—XII of FIG. 10;

FIG. 13 is a cross-sectional view taken along XIII—XIII of FIG. 11.

Referring specifically to the drawings the midstream urine specimen collector has inlet member 10 which has inner connector 11, outer connector 12 and handle 23. Outer enclosure 13 has neck portion 14 that connects to said outer connector 12 of inlet member 10. Flexible inner bag 15 is contained in said outer enclosure 13 and has neck portion 16 that connects to said inner connector 11 of inlet member 10.

Outer enclosure 13 has base portion 17 which has first pocket portion 18 therein for receiving liquid received by said outer enclosure 13. First pocket portion 18 has outlet opening 19 adapted to connect a sterile container 20 to receive the liquid received into outer enclosure 13 through inlet member 10 can be collected in sterile container 20, and readily removed from the specimen collector for analysis. Outlet opening 19 can also be fitted with valve assembly 21 so that any excess of liquid of the midstream fraction can be retained in first pocket portion 18 of outer enclosure 13.

Base 17 of outer enclosure 13 also has second pocket portion 22. Said second pocket portion 22 can have an envelope base portion (see FIG. 5) or an accordion base portion (see FIG. 6). Inner bag 15 is positioned so that it partially collapses into said second pocket portion 22 when a given quantity of liquid is contained in inner bag 15. The collapsing of inner bag 15 into said second pocket portion 22 in turn causes neck portion 16 of inner bag 15 to disconnect from the inner container 11 of inlet member 10 and thereafter trap the liquid in inner bag 15 while allowing outer enclosure 13 and in turn first pocket portion 18 to receive liquid through inlet member 10. To aid this operation neck portion 16 of inner bag 15 is offset opposite the second pocket portion 22 of outer enclosure 13.

Alternatively, as shown in FIGS. 7 through 9, the midstream urine specimen collector has inlet member 30. Inlet member 30 has inner connector 31, outer connector 32 and handle 33. Outer enclosure 35 has neck portion 36 that connects to said outer enclosure 32 of inlet member 30. Flexible inner bag 34 is contained in said outer enclosure 35 and has neck portion 37 that connects to said inner connector 31 of inlet member 30. Inner connector 31 and outer connector 32 are made as separate parts for easy connection of inner bag 34. In this way inner bag 34 can be attached to inlet member 30 by simply a friction joint.

Outer enclosure 35 has first pocket portion 39 adjacent base portion 38 for receiving liquid received by outer enclosure 35. First pocket portion 39 has outlet opening 40 adapted to connect a sterile container 41 to receive the liquid received into first pocket portion 39. The operation of this part of the midstream urine specimen collector is the same as previously described.

Base 38 of outer enclosure 35 has second pocket portion 42. And inner bag 34 has pocket portion 43 in its base portion corresponding to second pocket portion 42 in outer enclosure 35. Pocket portion 43 collects liquid received into inner bag 34 and collapses into said second pocket portion 42 when a given quantity of liquid is contained in inner bag 34. The collapsing of inner bag 34 into said second pocket portion 42 in turn causes the neck portion 37 of inner bag 34 to disconnect from inner connector 31 by inlet member 30 and thereafter trap the liquid in inner bag 34 while allowing outer enclosure 35 and in turn first pocket portion 39 to receive liquid through inlet member 30. The base of inner bag 34 is spaced from base 38 of outer enclosure 35 to further facilitate disconnection of inner bag 34 from inner connector 31.

Inner bag 34 also has an outlet 44 connected to tube 45. Tube 45 extends through outer enclosure 35 at 46 by a slidable sealed joint 47. By this arrangement a specimen from the initial urine fraction can be collected for comparison with the midstream urine specimen when this comparison may be important to prognosis.

Alternatively, as shown in FIGS. 10 through 13, the midstream urine specimen collector has inlet member 50 which has inner connector 51, outer connector 52 and handle 53. Outer enclosure 54 has neck portion 55 that connects to said outer connector 52 of inlet member 50. Flexible inner bag 56 is contained in said outer enclosure 54 and has neck portion 57 that connects to said inner connector 51.

Inner connector 51 is made as a separate part that is manually removable. It has a handle 58 and a U-shaped fork portion 59. To connect the inner connector 51 to the neck portion 57 of inner bag 56, the U-shaped forked portion is inserted through openings 60 in inlet member 50 and through openings 61 provided in the top portion 62 of the neck portion 57 of the inner bag 56. End portions 62 of the U-shaped fork member 59 are positioned in seat portions 63 of inlet member 50 opposite openings 60 in inlet member 50. By this arrangement, the inner connector 51 can be manually removed after an initial fraction of liquid has been received into inner bag 56, allowing the inner bag 56 to collapse into second pocket portion 64 provided in the base 65 of outer enclosure 54 and thereafter allowing a midstream fraction to be received into outer enclosure 54.

While we have shown and described a certain presently preferred embodiment and use of our invention, it is to be distinctly understood that the invention is not limited thereto but that it may be otherwise variously embodied and used.

We claim:

1. A midstream urine specimen collector comprising: an inlet member having an inner connector and having an outer connector; an outer enclosure having a neck portion connected to said outer connector; and a flexible inner bag contained in said outer enclosure, having a neck portion connected to said inner connector, and adapted to disconnect from said inner connector after said inner bag contains a given quantity of liquid, thereafter to trap said liquid in said inner bag, and to allow said outer enclosure to receive liquid through said inlet member.

2. A midstream urine specimen collector as claimed in claimed in claim 1 wherein said outer enclosure has a first pocket portion adjacent a base portion thereof for receiving liquid through said inlet member when said inner bag is disconnected from said inner connector.

3. A midstream urine specimen collector as claimed in claim 2 wherein said first pocket portion has an outlet opening adapted to connect a sterile container to receive said liquid received into said first pocket portion.

4. A midstream urine specimen collector comprising: an inlet member having an inner connector and an outer connector; an outer enclosure having a neck portion connected to said outer connector and having first and second pocket portions adjacent base portions thereof; and a flexible inner bag contained in said outer enclosure, having a neck portion connected to said inner connector, and adapted to at least partially collapse into said second pocket portion of said outer enclosure after said inner bag contains a given quantity of liquid, to disconnect said neck portion thereof from said inner connector, thereafter to trap said liquid in said inner bag, and to allow said first pocket portion in said base of said outer enclosure to receive liquid through said inlet member.

5. A midstream urine specimen collector as claimed in claim 4 wherein said first pocket portion adjacent said base portion of said outer enclosure has an outlet opening adapted to connect a sterile container to receive said liquid received into said first pocket portion.

6. A midstream urine specimen collector as claimed in claim 4 wherein said inner bag and said outer enclosure are made of plastic.

7. A midstream urine specimen collector as claimed in claim 4 wherein said inner bag is made of polyethylene.

8. An assembly for a midstream urine specimen collector comprising: an outer enclosure having a neck portion adapted to connect to an outer connector of an inlet member; and a flexible inner bag contained in said outer enclosure and having a neck portion adapted to connect to an inner connector of said inlet member and adapted to disconnect from said inner connector after said inner bag has contained a given quantity of liquid, thereafter to trap said liquid in said inner bag and to allow said outer enclosure to contain liquid through said inlet member.

9. An assembly for a midstream urine specimen collector as claimed in claim 8 wherein said outer enclosure is flexible.

10. An assembly for a midstream urine specimen collector as claimed in claim 9 wherein said inner bag and said outer enclosure are made of plastic.

11. An assembly for a midstream urine specimen collector as claimed in claim 9 wherein said inner bag is made of polyethylene.

12. An assembly for a midstream urine specimen collector as claimed in claim 8 wherein said outer enclosure has a base having a first pocket portion therein for receiving liquid when said inner bag is disconnected from said inner connector.

13. An assembly for a midstream urine specimen collector as claimed in claim 12 wherein said pocket portion has an outlet opening adapted to connect a sterile container to receive said liquid received into said first pocket portion.

14. An assembly for a midstream urine specimen collector comprising: an outer enclosure having a neck portion adapted to connect to an outer connector of an inlet member and having first and second pocket portions adjacent base portions thereof; a flexible inner bag contained in said outer enclosure and having a neck portion adapted to connect to an inner connector of said inlet member and adapted to at least partially collapse into said second pocket portion of said outer enclosure after said inner bag contains a given quantity of liquid through inlet member and disconnect said neck portion thereof from said inner connector of said inlet member, thereafter to trap said liquid in said inner bag and allow said first pocket portion of said outer enclosure to receive liquid through said inlet member.

15. An assembly for a midstream urine specimen collector as claimed in claim 14 wherein said outer enclosure is flexible.

16. An assembly for a midstream urine specimen collector as claimed in claim 15 wherein said inner bag and said outer enclosure are made of plastic.

17. An assembly for a midstream urine specimen collector as claimed in claim 15 wherein said inner bag is made of polyethylene.

18. An assembly for a midstream urine specimen collector as claimed in claim 14 wherein said first pocket portion in said base of said outer enclosure has an outlet opening adapted to connect to a sterile container to receive said liquid into said first pocket portion.

* * * * *

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,635,091 Dated January 18, 1972

Inventor(s) Frederick D. Linzer et al

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 3, line 27, after "into" should read -- first pocket portion 18. In this way, the urine received into --; line 41, "container" should read -- connector --. Column 4, line 50, cancel "claimed in". Claim 6, line 27, after "liquid", should read -- received --.

Signed and sealed this 24th day of October 1972.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents

FORM PO-1050 (10-69)

USCOMM-DC 60376-P69
☆ U.S. GOVERNMENT PRINTING OFFICE : 1969 O—366-334.