

[54] **MID-STREAM URINE SPECIMEN AND FRACTIONAL FLUID COLLECTORS**

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[51] Int. Cl. **G01n 1/18, A61b 10/00**

[58] Field of Search **73/42 R; 128/2 F, 294, 128/295**

[56] **References Cited**

UNITED STATES PATENTS

3,499,327	3/1970	Lane, Jr.	73/421 R
3,625,064	12/1971	Hinman et al.	73/421 R
3,635,091	1/1972	Linzer	73/421 R

FOREIGN PATENTS OR APPLICATIONS

742,118	11/1943	Germany	73/421 R
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Attorney, Agent, or Firm—Buell, Blenko & Ziesenheim

[57] **ABSTRACT**

A disposable urine specimen and fractional liquid collector is provided having an inlet member with an inner connector and 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, pivot means connecting the bottom of said inner bag to the inner wall of said outer bag intermediate its length, said inner bag adapted to disconnect from said inner connector after said inner bag contains a given quantity of liquid and to pivot about said pivot means thereafter to trap said liquid in said inner bag, and to thereafter allow said outer enclosure to receive liquid through said 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.

10 Claims, 20 Drawing Figures

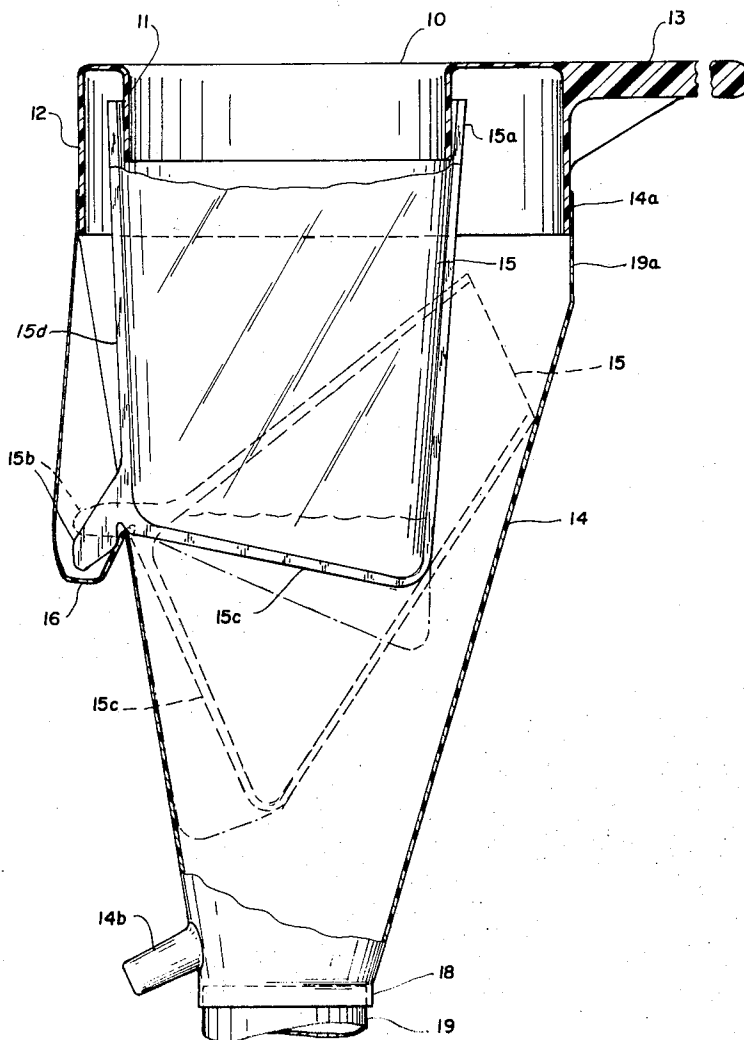


Fig.1.

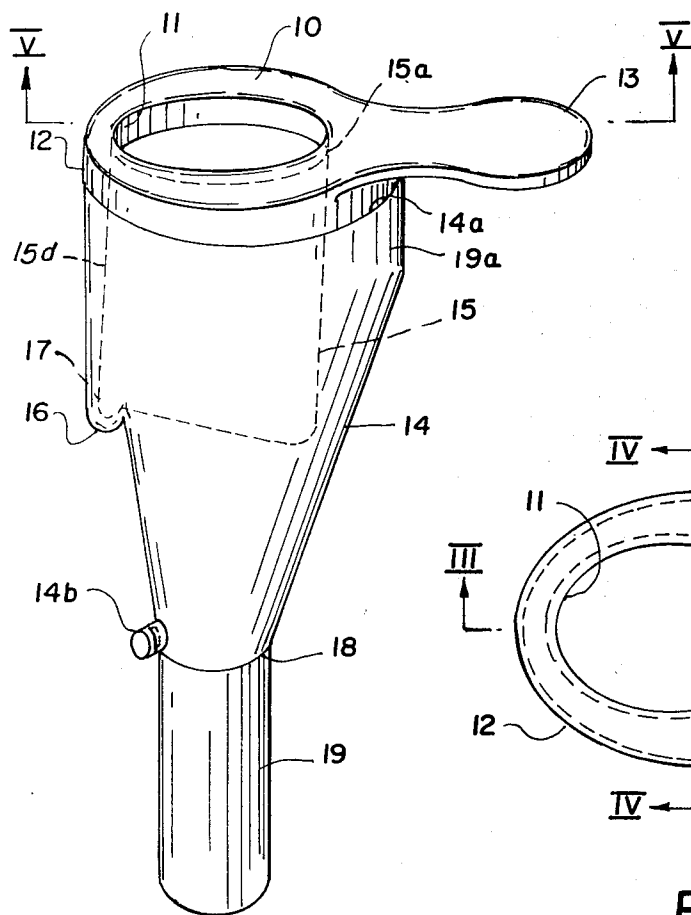


Fig.2.

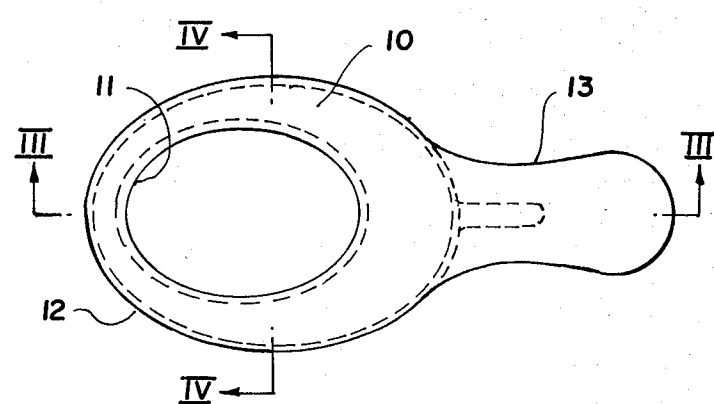


Fig.3.

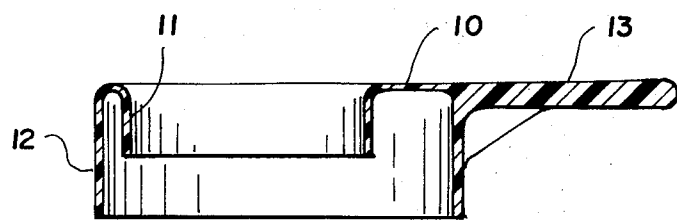
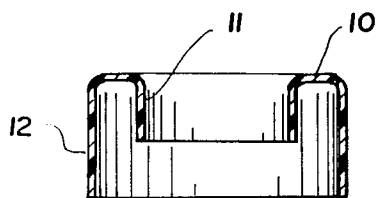


Fig.4.



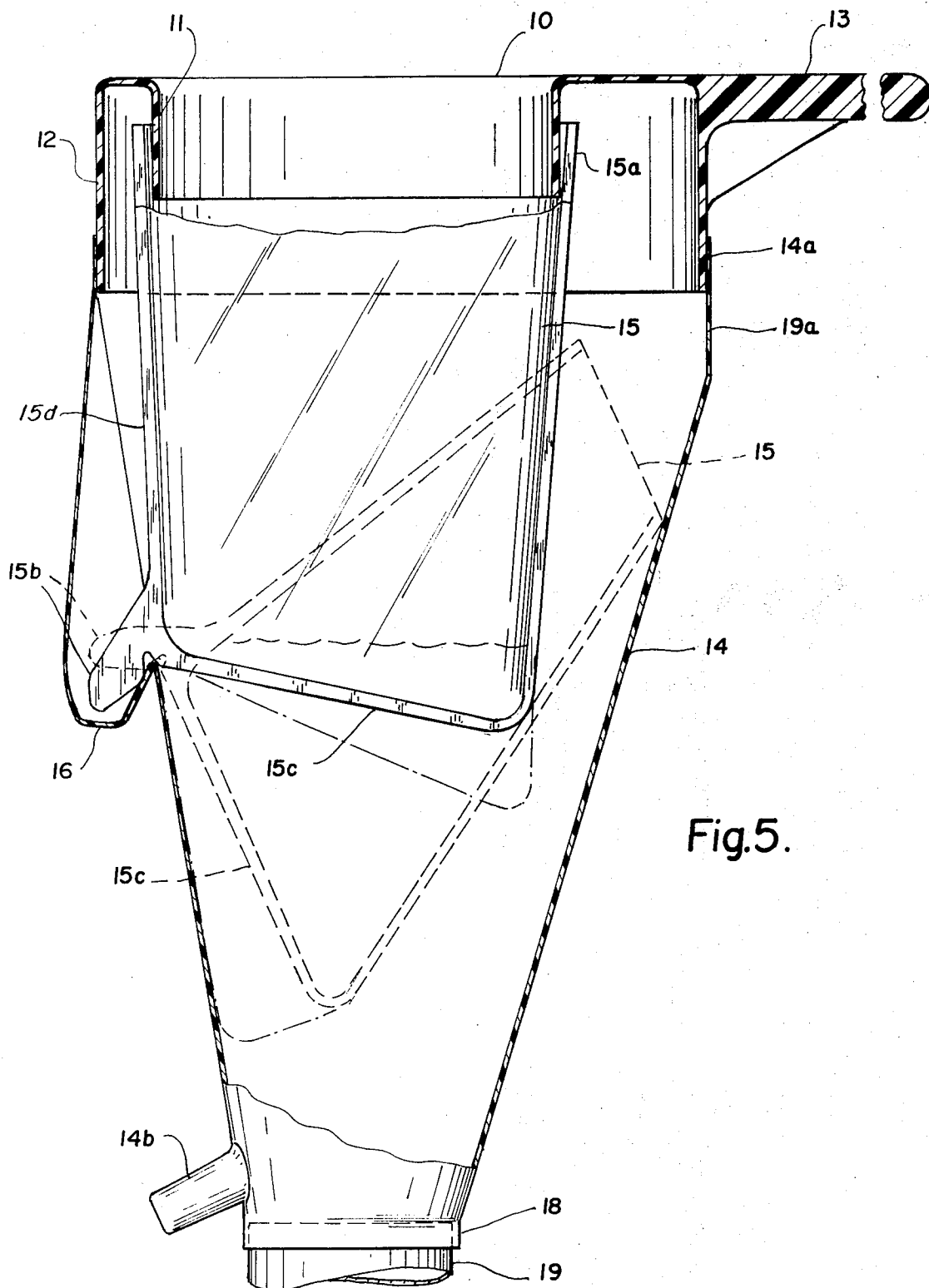


Fig. 5A.

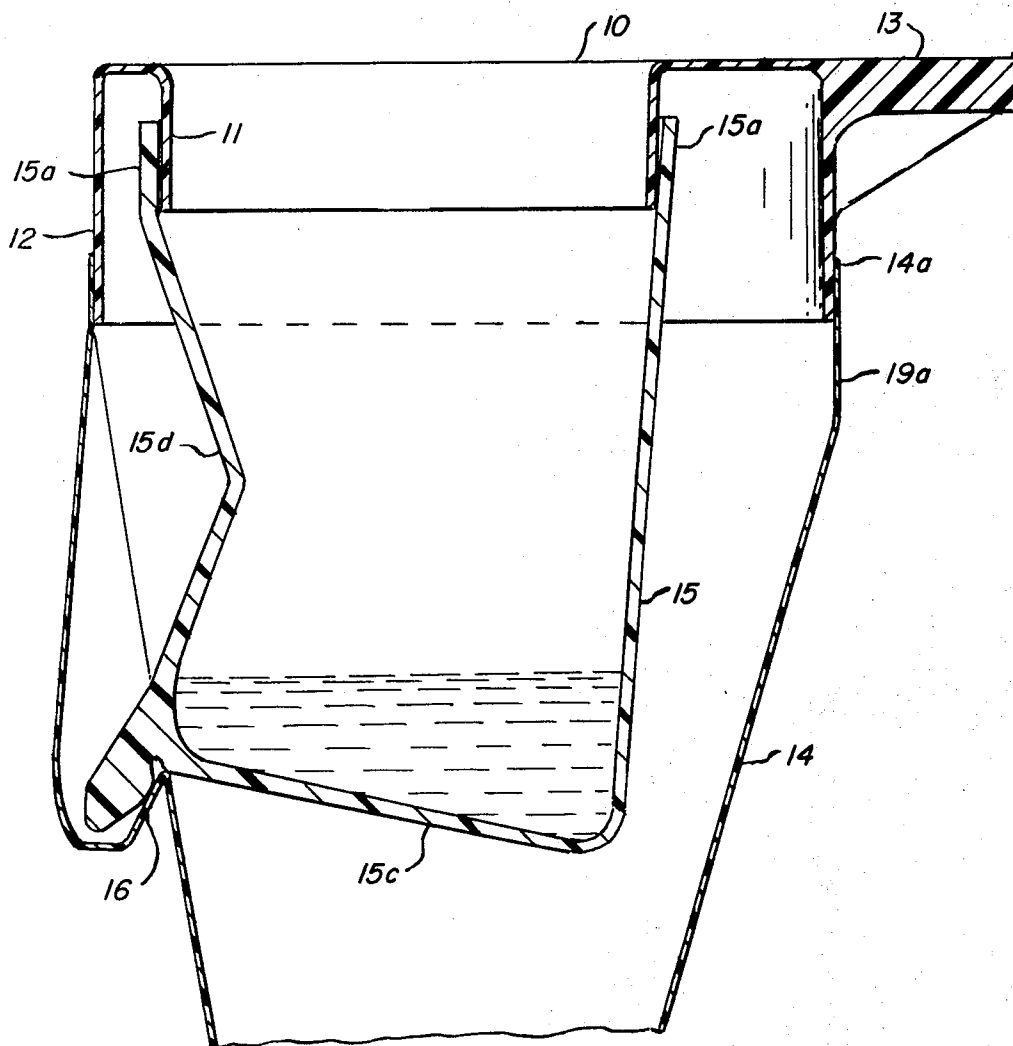


Fig.6A.

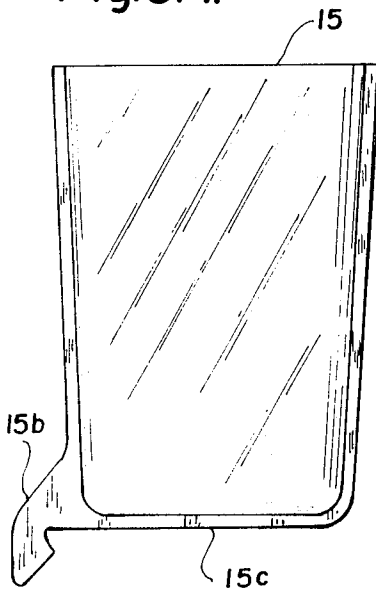


Fig.6B.

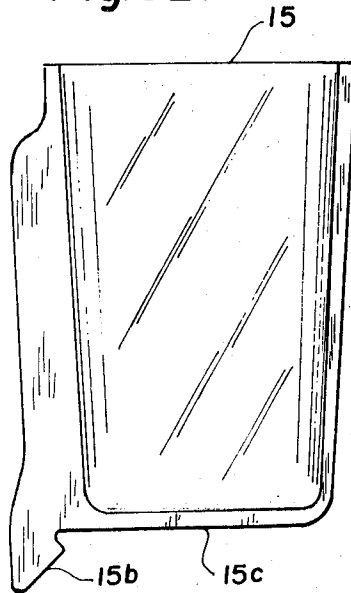


Fig.6C.

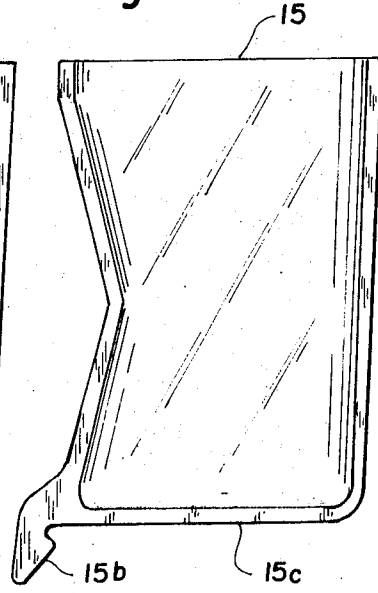


Fig.6D.

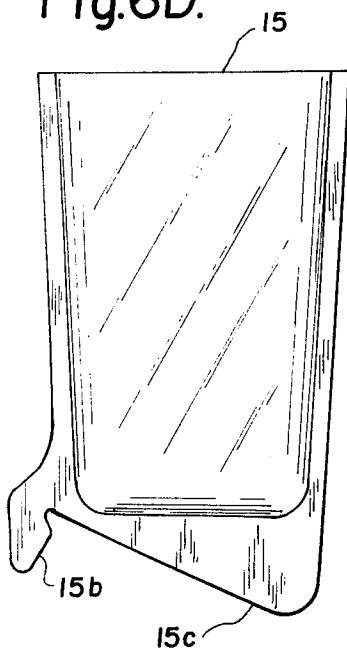


Fig.6E.

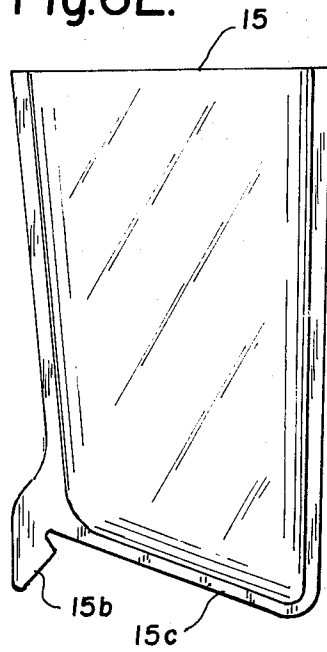
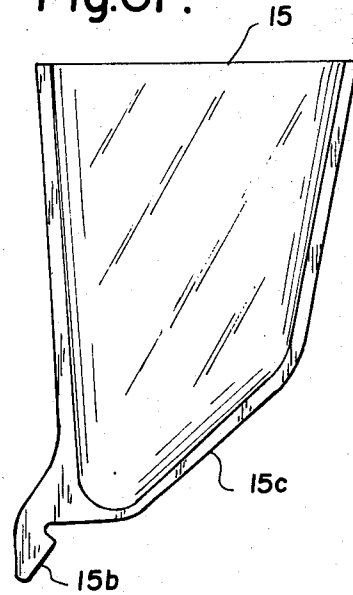


Fig.6F.



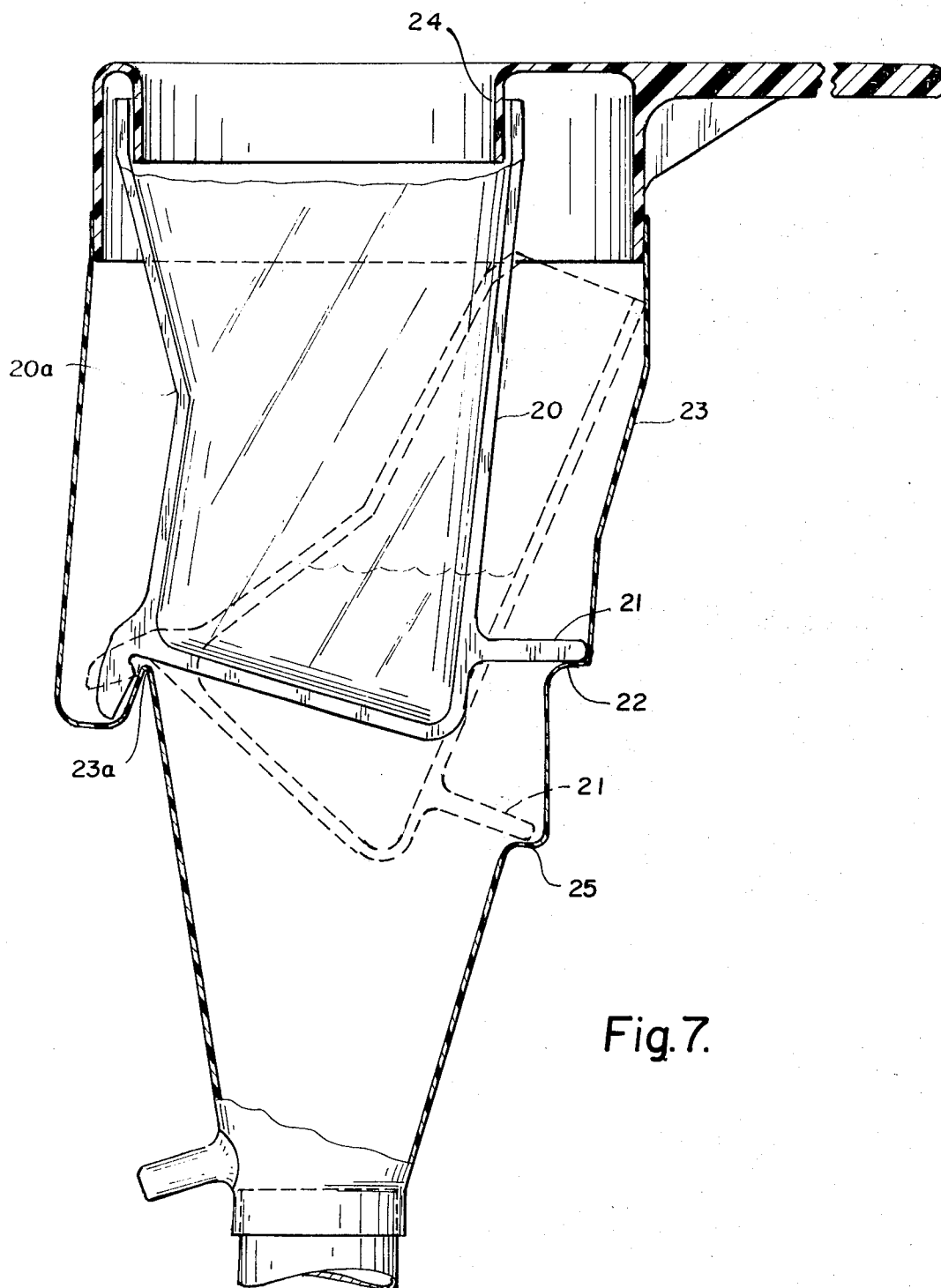


Fig. 7.

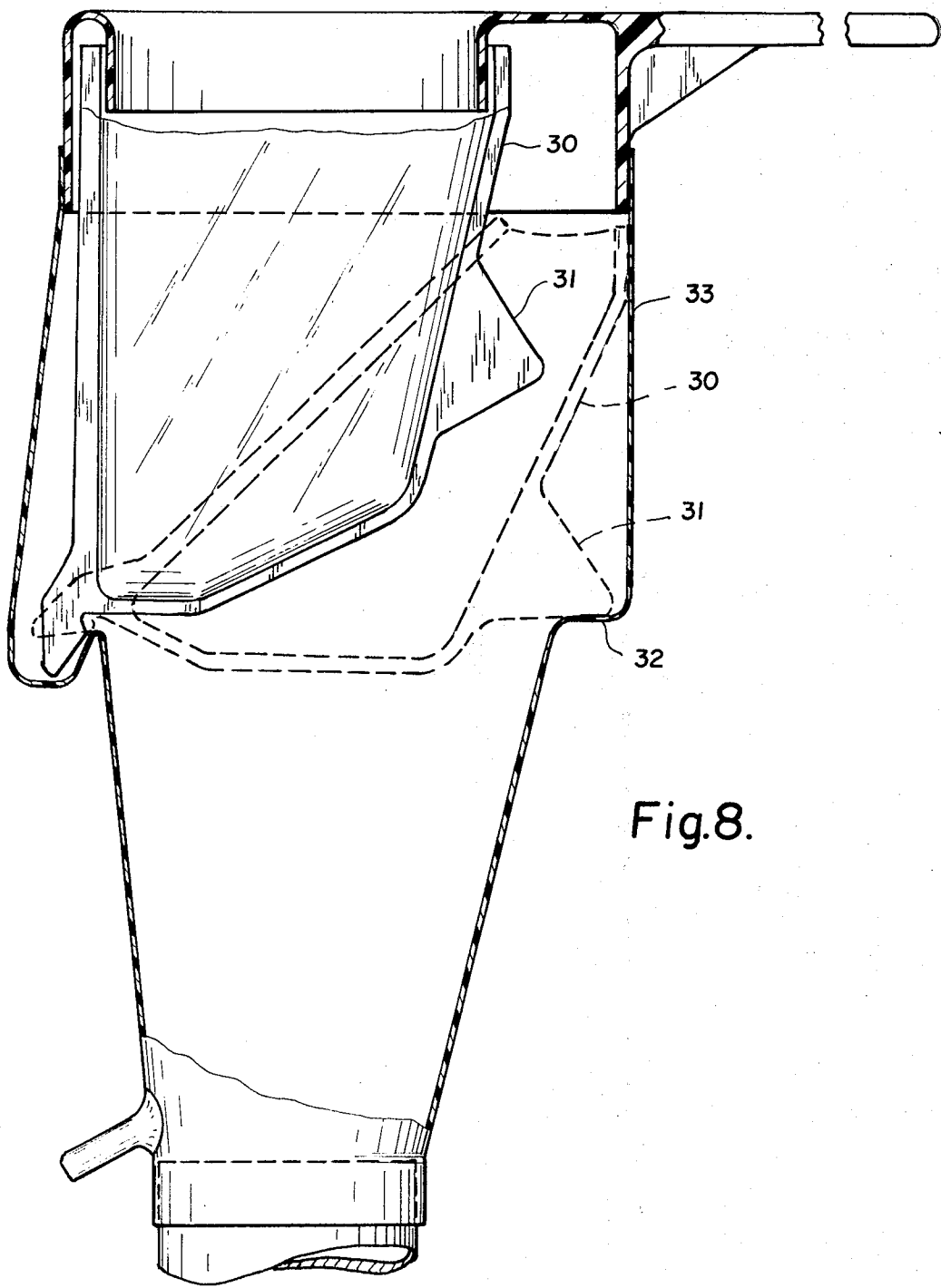


Fig.8.

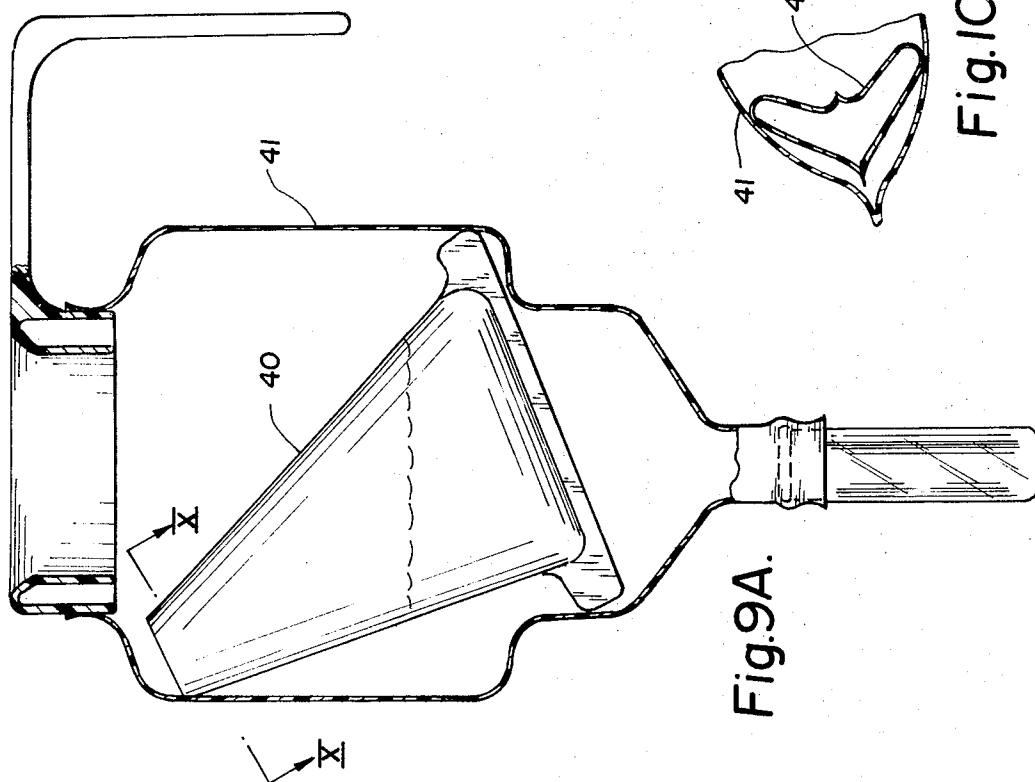


Fig. 9A.

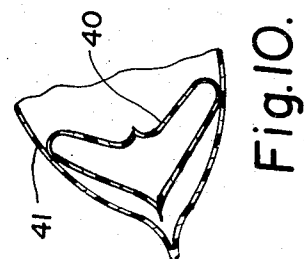


Fig. 10.

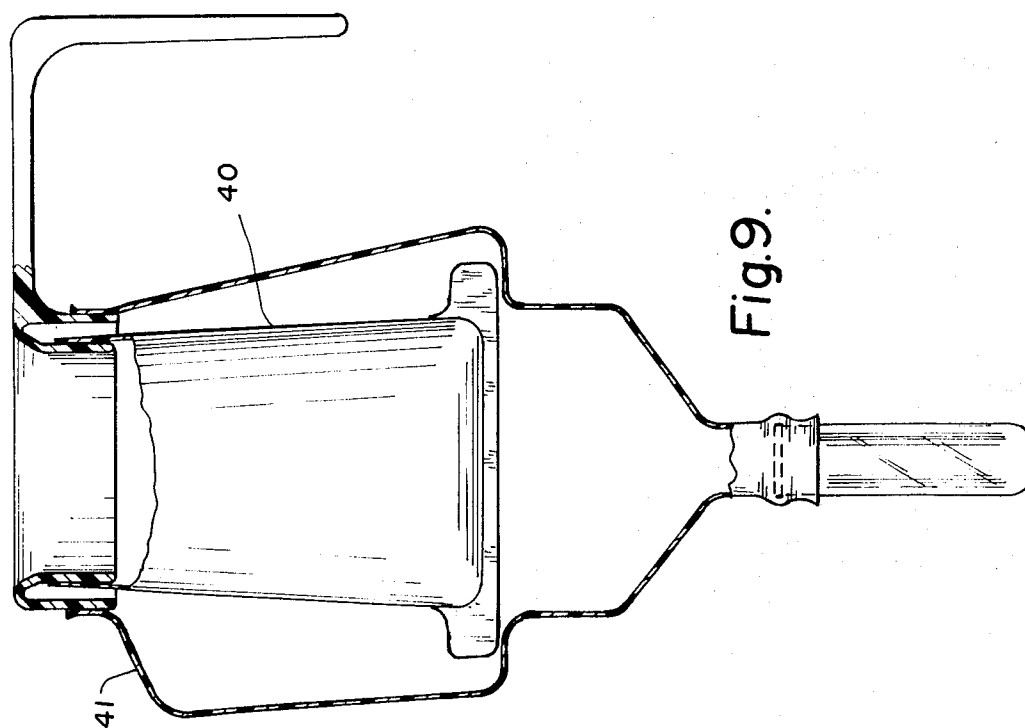


Fig. 9.

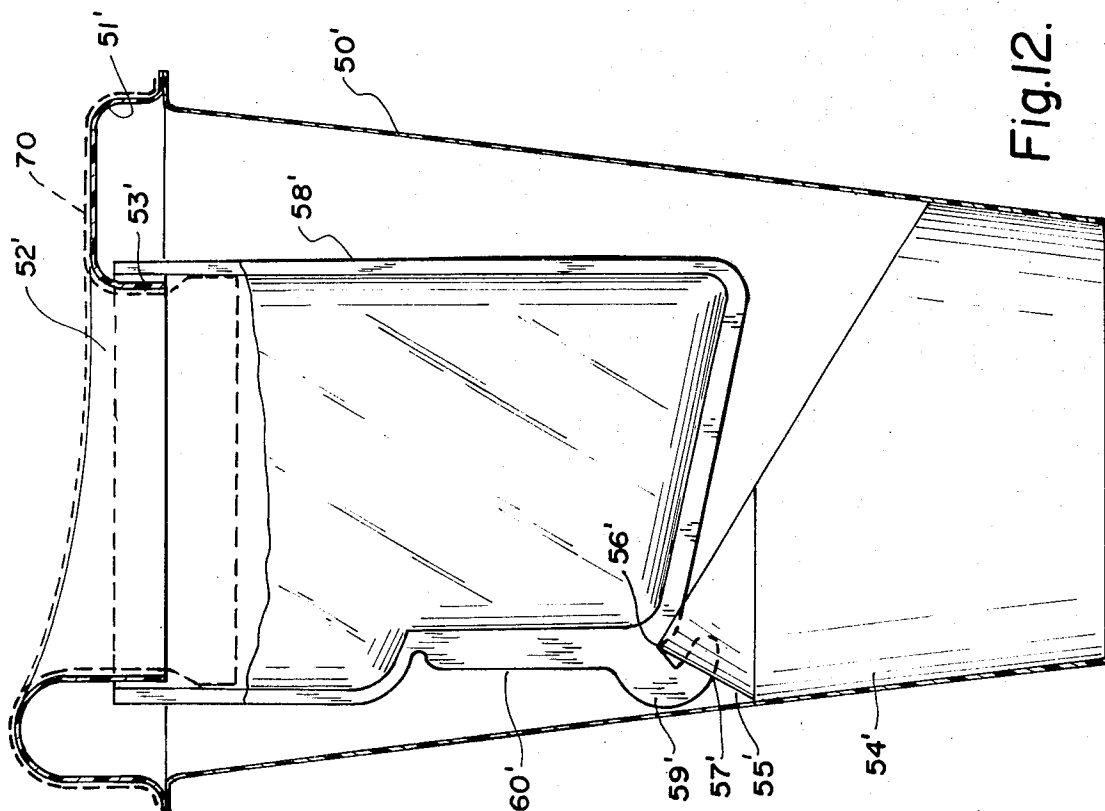


Fig. 12.

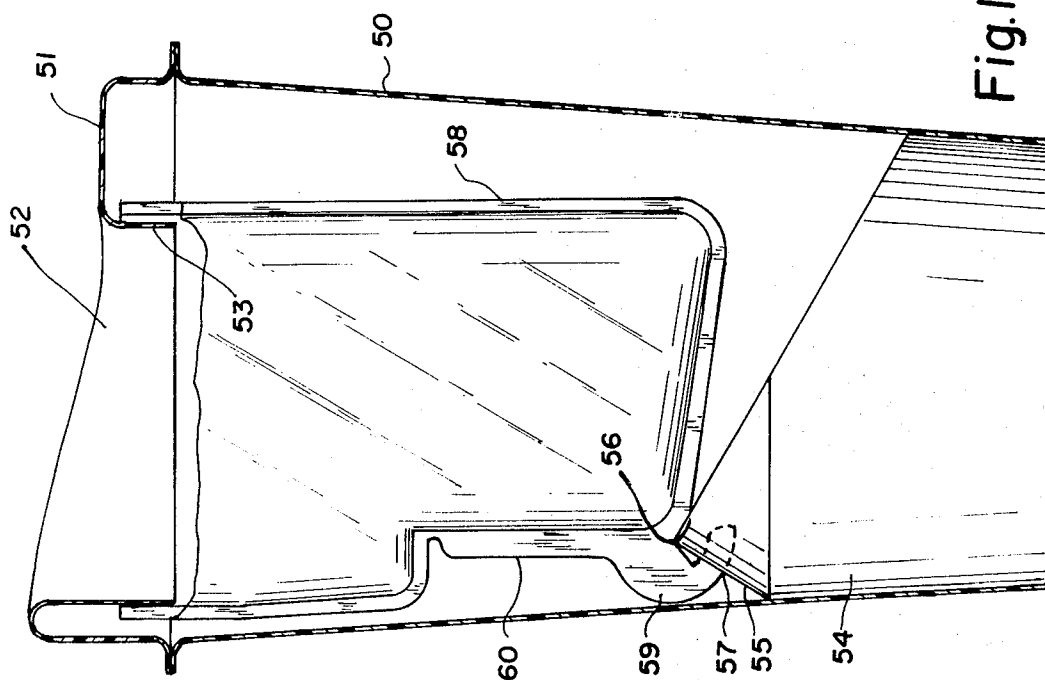


Fig. 11.

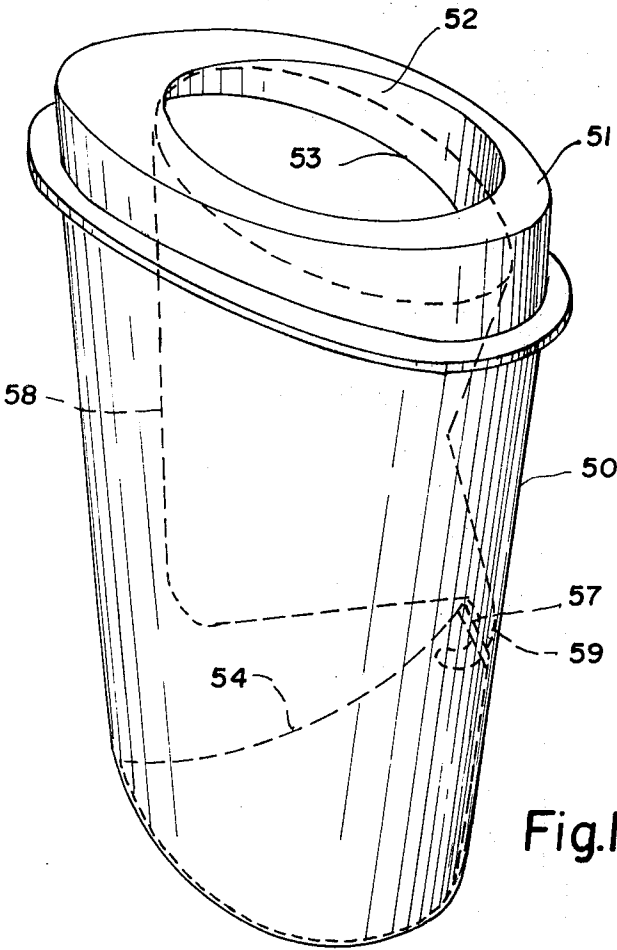


Fig. 13.

MID-STREAM 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. This is an improvement over the mid-stream urine sampler disclosed and claimed in our U.S. Pat. No. 3,635,091 issued Jan. 18, 1972.

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 in the collection of urine specimens is to have the patient pass the initial urine stream into one container, then stop to switch containers start again to pass a mid-stream fraction into this second sterile container. Such procedures cause discomfort to most adult patients and are impossible with infants, small children and some adult 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.

Mid-stream 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 first really practical mid-stream urine sampler was that shown in our U.S. Pat. No. 3,635,091.

The present invention overcomes these difficulties and disadvantages of the prior art and provides a mid-stream urine sample collector that is commercially feasible to build and practical to use and is even more easily used than that of our earlier patent.

We provide a mid-stream 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. It has a flexible inner bag that is pivoted at its bottom around a fulcrum on the sidewall of the outer container. Said fulcrum is intermediate the top and bottom of the side wall and contained in said outer enclosure. The outer enclosure is provided with 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. It thereafter pivots and comes finally to rest against the outer enclosure wall. In rest position the inner bag shape becomes distorted thereby trapping said liquid in said inner bag while allowing said outer enclosure to receive the continuing liquid flow through the inlet member.

Preferably the outer enclosure has at least one pivot point or fulcrum engaged by the inner bag intermediate the top, and a connection at the bottom thereof for receiving the liquid entering the outer enclosure and

adapted to connect a sterile container to receive the liquid received into the bottom 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 pivot point in the outer enclosure intermediate its top and bottom. The inner bag is positioned so that it falls about the pivot point and bulges at its top as the top strikes the sidewall of the outer bag when a given quantity of liquid is contained in the inner bag. The collapsing or bulging of the inner bag sidewalls in the outer bag causes the deformation of the top as the inner bag becomes partly full and 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 which runs over the outside of the inner bag. In another version of the inner bag the collapsing and disconnecting is caused by providing a pocket portion or a shelf in the outer bag and a corresponding finger or projection on the inner bag which finger bends and releases from the shelf letting the inner bag fall away from the inner connector against the sidewall of the outer bag.

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 of a stiff or hard moldable or machinable plastic such as the polyvinyls, or lucite or plexiglass. For more efficient collection the inlet member can take a variety of shapes and sizes 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 made of two plastic films seam welded together along these sides. These seams give stiffness to the bag. At least one bottom corner is provided with a pivot projection or pin. Further, we contemplate that the inner bag should contain at least 10 ml. of liquid to insure proper mechanical action and to obtain 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 film such as polyethylene which has a thickness sufficient to be stiff enough to remain erect. This type of material will insure bag characteristics such that the neck portion of the inner bag is pushed out of the region of the inlet member and yet will bulge and fold at the top so that the mid-stream fraction contained in the outer enclosure is not contaminated by spillage 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 of a thicker, stiffer material than the inner. It should have a flat bottom and be of a somewhat cylindrical shape as shown in FIGS. 11, 12 and 13.

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. The assemblies shown in FIGS. 1-10 will be flat before use. If the device is to be reused after sterilization medical personnel can attach the inner bag and the outer enclosure to an inlet member and also attach a sterile container to said collector portion of the outer enclosure to ready the sample collector for use. 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 re-use.

Alternatively, and preferably the entire assembly may be preassembled and packaged 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 "clean catch" urine specimen is collected. Separation of the urine into a first fraction and a mid-stream contaminate-free fraction is automatic. No manipulation by the patient or medical personnel is necessary. Further, the invention maintains the urine in two separated fractions so that if necessary the initial urine fraction can be compared with the subsequent contaminate free specimen. Moreover, the entire specimen collector, or parts of it, can be inexpensively made and sold as a sterile disposable pre-packaged unit.

In the foregoing general description of our invention we have set out certain objects, purposes and advantages of our invention. Other details, objects and advantages of our invention will become apparent as the following description of the embodiments thereof proceeds.

The accompanying drawings illustrate features, variations, and embodiments of our invention in which:

FIG. 1 is an elevational view of a particular clean-catch urine specimen collector embodying our invention;

FIG. 2 is a top plan view of the entry nozzle for the mid-stream urine specimen collector of FIG. 1;

FIG. 3 is a cross-sectional view taken along line III-III of FIG. 2;

FIG. 4 is a cross-sectional view taken along line IV-IV of FIG. 2;

FIG. 5 is a partial cross-sectional view taken along line V-V of FIG. 1 showing a typical inner bag in its initial and final specimen collection positions;

FIG. 5A is a sectional view of the inner bag partially filling;

FIG. 6A-6F are side elevational views of six alternate inner bags usable in the structure of FIG. 1;

FIG. 7 is a cross-sectional view through the vertical axis of an alternate form of mid-stream urine specimen collector embodying our invention;

FIG. 8 is a cross-sectional view through the vertical axis of another alternate form of our invention;

FIG. 9 is a cross-sectional view through the vertical axis of still another alternate form of our invention;

FIG. 9A is a cross-sectional view through the vertical axis of a modification of FIG. 9;

FIG. 10 is a section on the line X-X of FIG. 9;

FIG. 11 is a cross-sectional view of the preferred mid-stream urine specimen collector embodying our invention;

FIG. 12 is a cross-sectional view of another form of the preferred mid-stream urine specimen collector including a film cover for the entry port surface; and

FIG. 13 is an isometric view of the structure of FIG. 11.

Referring specifically to the drawings the mid-stream urine specimen collector in FIG. 1 has inlet member or nozzle 10 which has inner connector 11, outer connector 12 and handle 13. Outer bag or enclosure 14 has neck portion 14(a) that connects to said outer connector 12 of inlet member 10. Inner bag 15 is contained in said outer enclosure 14 and has neck portion 15(a) that is slip-fit onto said inner connector 11 of inlet member 10.

Outer enclosure 14 has a pivot pocket portion 16 therein intermediate its top and bottom for receiving a pivot arm 17 of inner bag 15. The outer enclosure 14 also has an outlet opening 18 at its bottom adapted to connect to a sterile container 19 to receive the liquid received into the outer bag 14. In this way, the urine received into outer enclosure 14 through inlet member 10 can be collected in sterile container 19, and readily removed from the specimen collector for analysis.

Inner bag 15 is positioned so that it releases from inner connector 11 and pivots into said second pocket portion 19A when a given quantity of liquid is contained in inner bag 15. The pivoting of inner bag 15 into said outer bag is accompanied by a bulging of the top neck portion 15(a) of inner bag 15 as it strikes the wall of the outer container 14 and thereafter trap the liquid in inner bag 15 while allowing outer enclosure 14 to receive liquid through inlet member 10.

More specifically the mode of operation is as follows. The flow of urine through the nozzle opening formed by inner connector 11 enters the inner bag 15. When a prescribed amount has been captured (about 10 to 80 milliliters) its weight causes the inner bag 15 to separate from the nozzle 11. The bag 15 swings downward (chain line in FIG. 5), around the pivot point 16, until it hits the wall of the outer bag 14. The weight of the fluid contained causes this essentially flexible inner bag 15 to distort by bulging in both sideways directions thereby distorting the mouth 15a and bringing it beyond the inner nozzle 11 periphery. This causes the neck or mouth 15a of the inner bag 15 to collapse upon itself closing the inner bag 15 so that urine subsequently passing through nozzle 11 passes over inner bag 15 into the outer bag extension after the inner bag's release from the nozzle. The continuing liquid stream washes over the inner bags outer surface but does not enter it. The continued flow now enters the sample tube 19 which is suspended from the bottom 18 of the outer bag 14.

A sealed drain 14b is shown in FIG. 1. Its function is to drain the urine above the sample tube after the patient has finished urinating. A technician will cut off the drain tip, and when the level drops to the top of the sample tube, the sample tube 19 is torn or cut out of the outer bag 14, capped, and taken away for laboratory analysis.

FIG. 5 shows the inner bag both before and after use. The inner 15 and outer 14 bag shown are only one of a few possible types which can be used. The different shapes and some of their reasons for use will be described in succeeding paragraphs.

An understanding of the forces which act to pull the inner bag off the nozzle and collapse it against it the

outer bag will be helpful to the explanation for the many inner bag shapes which will be described. FIG. 5A shows the major forces acting on an uncollapsed bag which is partially filled with fluid. Support by the pivot acts at pivot point 16. The fluid weight acts through its center of gravity, at the bottom of inner bag 15. This forms a twisting couple which would rotate the bag 15 around pivot point 16, if it were not for the nozzle support force created by the friction between the neck 15a and inner connector 11 combined with the rigidity of inner bag 15. When the inner bag carries a small enough weight of fluid so that the soft plastic bag materials stiffness strength is not exceeded, this bag will not buckle. When the weight of urine in the inner bag 15 passes a certain critical value, the spine seam 15d flexes or buckles and allows the bag 15 to slide off and under the inlet nozzle 11. The spine seam 15d is formed of two thicknesses of sheet material sealed together to form the open mouthed bag 15. All seams have appreciable structural strength. The spine seam 15d as shown in FIGS. 1 and 5 is not straight. Its inflection point is about half way along its length. This "dog leg" is purposely made to weaken the bag structurally and allow it to buckle with a relatively light load of fluid content.

The buckling and drop-off can be further controlled by decreasing the overlap between the inner bag 15 and inner nozzle wall 11. Shape of the inner bag base is also a factor in determining the weight of the "drop-off load." The downward slope shown in FIG. 5 tends to further reduce drop-off load because it shifts the liquid center of gravity away from pivot point 16. Thus for the same weight, the strength of the twisting couple between weight of urine and pivot resistance is increased over that which would result if the bag base were sloped upward as shown in FIG. 6F.

Various inner bag shapes are shown in FIGS. 6A-6F. The bag is generally flat bottomed and flat sided, with seams about one-eighth inch wide. The inner bag pivot support 15b is just a wide seam cut to the shape shown. Its recess, or hook, is meant to engage the outer bag's pivot point 16 after "drop-off" occurs. This keeps the inner bag 15 from slipping down into the outer bag throat. Obviously, location of the inner bag's pivot point support will also affect drop-off load. Moving it outward away from the center of the weight of urine, increases the twisting couple, and tends to decrease drop-off load. Conversely, moving it towards the center of the weight or urine will tend to increase drop-off load.

FIG. 6B is a variation which acts to increase drop-off fluid load. The spine seam is made wider to increase its stiffness and resistance to buckling.

FIG. 6C is a variation which acts to decrease drop-off fluid load by weakening the stiffness of the critical vertical back spine seam. This dog-leg form is one of the best for controlling release point in the inner bag.

FIG. 6E is a side view of the bag shown in FIG. 5. It does not, however, have the spine seam dog-leg of FIG. 6C. It is included as an example of the downward sloped bag bottom used for obtaining drop off with smaller weights of fluid. FIG. 6F is a counterpoint to 6E for it illustrates a bag profile useful when a larger drop off weight is desired.

One other inner bag configuration is shown with an extension used to limit its downward travel after disengagement from the inner nozzle. This is the "Toe

Seam" of FIG. 6D. The inner bag motion after release is stopped when the toe seam strikes the outer bag wall beneath the pivot point.

FIG. 6 shows a total of 6 inner bag configurations. It is to be emphasized, however, that each bag there shown as well as those in other figures are meant to illustrate features which can be used singly or in combination by any other inner bag. Typical combinations appear in FIG. 5, FIG. 7 and in FIG. 8. Any other combinations are possible to achieve the desired inner bag behavior. Similar comments would, of course, apply to outer bags shown by FIGS. 5, 7 and 8.

Another design variation is shown in FIG. 7. This assembly is made to demonstrate another method of supporting the inner bag with a heavy load of fluid before it separates from the nozzle. The important details of this assembly are as follows. The inner bag 20 is provided with a finger 21 protruding from its right hand side seam (viewing FIG. 7). This finger 21 acts as a cantilever beam which rests on a shelf 22 of the outer bag 23. When the weight of urine in the inner bag 20 is large enough, it will simultaneously buckle both the spine seam 20a and the cantilevered finger 21, thus allowing the inner bag 20 to separate from the inner nozzle 24. The inner bag 20 rotates downward about pivot point 23a but is not permitted to drop further than shown in FIG. 7. A second shelf 25 in the outer bag engages the support finger 21 at the same time as the top of the inner bag 20 touches and collapses against the upper part of the outer bag 23.

FIG. 8 is a variation of the structure shown in FIG. 7. Its cantilevered support finger 31 is placed higher upon the inner bag 30, and does not contact any support shelf while the inner bag remains fitted around the inner nozzle. As such it offers no additional support for the liquid load within the inner bag 30. After disengagement, however, the inner bag 30 falls until the finger 31 is caught by a shelf 32 in the outer bag 33. The support shelves in both FIGS. 7 and 8 are best adapted to an assembly which uses a wider than usual mid-stream sample tube. In assemblies such as these, the outer bag's funnel shape can become negligible. The support shelf is therefore used to help stop the inner bag from falling down too far and spilling its "early-sample" urine into that collected later.

The shape of entry nozzle 10 shown in FIGS. 2-4 is preferred. It is made up of two similar spaced eccentrically located elliptical tubes 11 and 12. The inner bag is slid over the inner tube 11 and the outer bag over the outer tube 12. This particular construction is advantageous for the reasons described in more detail below. However, it should clearly be understood that the nozzle does not have to be made of perfect ellipses. In many cases they may be egg shaped, or fully circular depending upon the uses to which they will be put. The important features are eccentricity along, and approximate symmetry about the major axis. Eccentricity is important mainly because of the large space it provides between one pair of ellipse ends. This larger space is needed to contain the open end of the inner bag when it drops away from the inner nozzle. Thus more incoming urine cannot continue to enter it. The collapsed inner bag sketches, shown by the broken lines in FIGS. 5, 7 and 8 indicate this clearly. FIGS. 9, 9A and 10 show the significance of this. As shown in FIG. 10 the mouth of the inner bag 40 does not completely shut after drop-off from the nozzle. Its own material stiffness

plus the shape of the outer bag, and the side forces of the urine volume within causes it to distort to the desired butterfly shape shown in FIG. 10. Help to shape the contour of the outer bag 41 which is an aid toward guiding the collapsed inner bag 40 to the desired butterfly shape, comes also from the eccentric ellipses of the nozzle. The side to side spacing shown in FIG. 4 is necessary here. It moves the sides of the outer bag 41 further from the inner 40. The increased outer bag 41 radius of curvature on the handle end of the nozzle helps the inner bag 40 to fold its reduced size mouth to the desired butterfly shape.

In the embodiments illustrated in FIGS. 11 through 13 we have illustrated mid-stream urine collectors according to our invention in which the outer bag is made of a semi-rigid thin walled plastic cylinder and the pivot point instead of being in the wall of the outer cylinder is located in a separate member located within said outer cylinder. Referring first to FIG. 11 we have illustrated an outer bag 50 in the form of semi-rigid thin walled plastic cylinder having a closed flat base so that the bag is free standing. An elliptical inlet port member 51 is sealed to the top of the bag 50. A port 52 having descending sidewalls 53 is provided in the port member. A short baseless cylinder 54 is provided in the outer bag 50. This cylinder 54 has an obliquely truncated conical top portion 55 with a pivot point 56 at the apex of the truncated cone formed by a small hole or slot 57 just below the apex which forms the pivot point for inner bag 58. The inner bag 58 is made as earlier described and is provided with a pivot hook 59 engaging over the pivot point 56. In the form illustrated the rear seam 60 is in the form of a dog leg to control the folding or buckling. As described above the buckling causes the inner bag to slide off the inlet port wall and forward against the outer cylinder. There is rotation about the pivot point but no translation of the inner bag.

In FIG. 12 we have added a thin liner sheet of polyethylene film 70 to the inner wall of the inner bag 58' adjacent the top, which liner is adapted to pass through the inlet port and cover the inlet port surface to protect it from the incoming urine stream or its spray. When the inner bag 58' is displaced during urination it will carry the film cover inward along with it. Thus any contamination or spray from the initial urine stream will be automatically removed. Without such a liner the mid-stream urine sample might wash the first stream contaminants off the wall into the collected mid-stream or second fraction collected. This film may be used with any of the several inner bag designs if desired. Obviously the film could take other forms and designs e.g. it could be mechanically or adhesively fastened to the inner bag; it could be perforated to tear away in the inlet port at a desired position.

The separation of the inner bag from the inlet port is caused by a predetermined weight of fluid collected by the inner bag. In general, we provide that this separation is affected by a momentary buckling of the bag wall, however, it can be accomplished by buckling of the pivot support, as for example buckling of one of the pivot tab 17 of FIG. 1 or 15' of FIG. 6A. Alternatively the release might be accomplished by temporary deformation of the inlet port side wall (11 of FIG. 1) so that the inlet bag will slip off on it.

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 within the scope of the following claims.

We claim:

1. A "mid-stream" or "clean-catch" 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, pivot means connecting the bottom of said inner bag to the inner wall of said outer bag intermediate its length, said inner bag being adapted to disconnect from said inner connector after said inner bag contains a given quantity of liquid and to pivot about said pivot means, thereafter to trap said liquid in said inner bag, and to allow said outer enclosure to receive liquid through said inlet member, by-passing said inner bag.
2. A mid-stream urine specimen collector as claimed in claim 1 wherein said outer enclosure has a first pocket portion intermediate its length receiving a hook member on the bottom of said inner bag to form said pivot means.
3. A mid-stream urine specimen collector as claimed in claim 1 wherein said outer member has an outlet opening at its bottom below the pivot means adapted to connect a sterile container to receive said liquid by-passing said inner bag and received into said outer member.
4. A mid-stream urine specimen collector as claimed in claim 1 wherein the outer enclosure is provided with at least one shelf-means opposite the pivot means and the inner bag is provided with a projecting finger means engaging the shelf means to hold the inner bag in a first position with the neck portion thereof engaging the inner connector and to release from the shelf when the inner bag has received said given quantity of liquid.
5. A mid-stream urine specimen collector as claimed in claim 4 wherein the pivot means is a shelf means in the outer enclosure, and a finger on the inner bag.
6. A mid-stream urine collector as claimed in claim 3 wherein the outer enclosure is provided with drain means adjacent the outlet opening.
7. The mid-stream urine collector as claimed in claim 1 wherein the outer enclosure is a generally cylindrical semi-rigid member and the pivot means includes an inner cylindrical member fitting within the bottom of the outer enclosure and having a frusto-conical top portion carrying a pivot point on which the inner bag pivots.
8. A mid-stream urine collector as claimed in claim 1 where a flexible film member is fixed to the inner bag and overlays at least partially the inlet member while the inner bag is connected to the inner connector and is withdrawn from the inlet member when the inner bag is disconnected.
9. A mid-stream urine specimen collector as claimed in claim 1 wherein the said inner bag and said outer enclosure are made of plastic.
10. A mid-stream urine specimen collector as claimed in claim 1 wherein said inner bag is made of polyethylene, mylar coated polyethylene, or plastic materials having similar stiffness and buckling characteristics.

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