

[54] **APPARATUS FOR COLLECTION OF URINE IN FEMALES**
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[73] Assignee: **James B. Gambrell**, a part interest
[22] Filed: **Dec. 30, 1970**
[21] Appl. No.: **102,866**

Related U.S. Application Data

[60] Division of Ser. No. 703,700, Feb. 7, 1968, Pat. No. 3,583,388, which is a continuation-in-part of Ser. No. 451,495, April 28, 1965, abandoned.
[52] U.S. Cl. 128/2 F, 4/110, 128/295
[51] Int. Cl. A61b 10/00
[58] Field of Search ...128/2 F, 295; 4/110; 73/421 R

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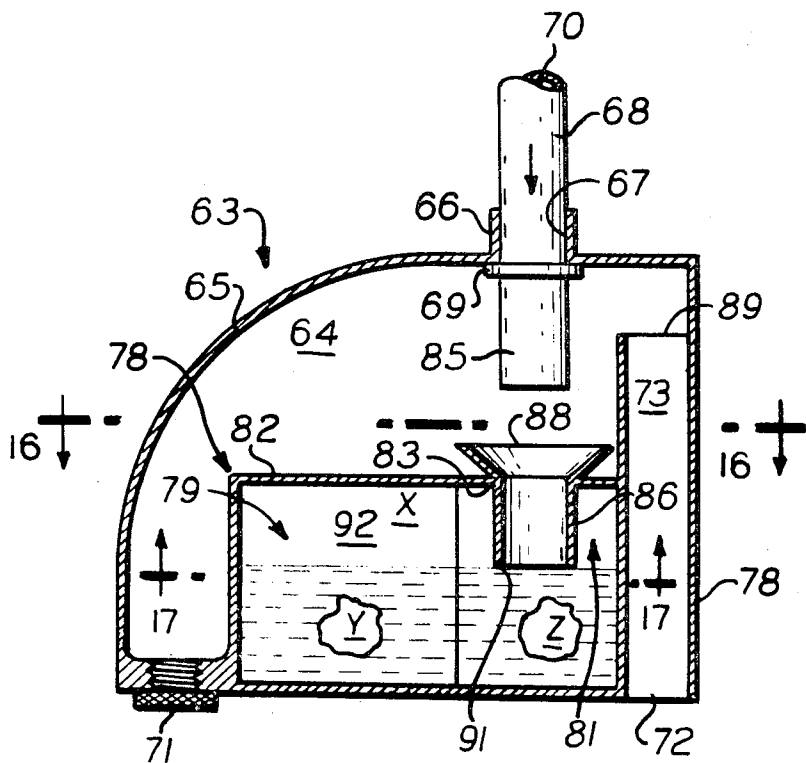
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Primary Examiner—Kyle L. Howell
Attorney—James B. Gambrell

[57] **ABSTRACT**

Apparatus for collecting a midstream urine specimen from a female is described which does not require professional help. The apparatus combines a urinary guide having a urinary passageway, means on the guide to align the passageway with the female urethra so that a minimum of labial and vaginal secretions are entrained and a collector which isolates a predetermined initial volume of the micturition so that the urine sample collected for analysis is uncontaminated for all practical purposes.

7 Claims, 25 Drawing Figures



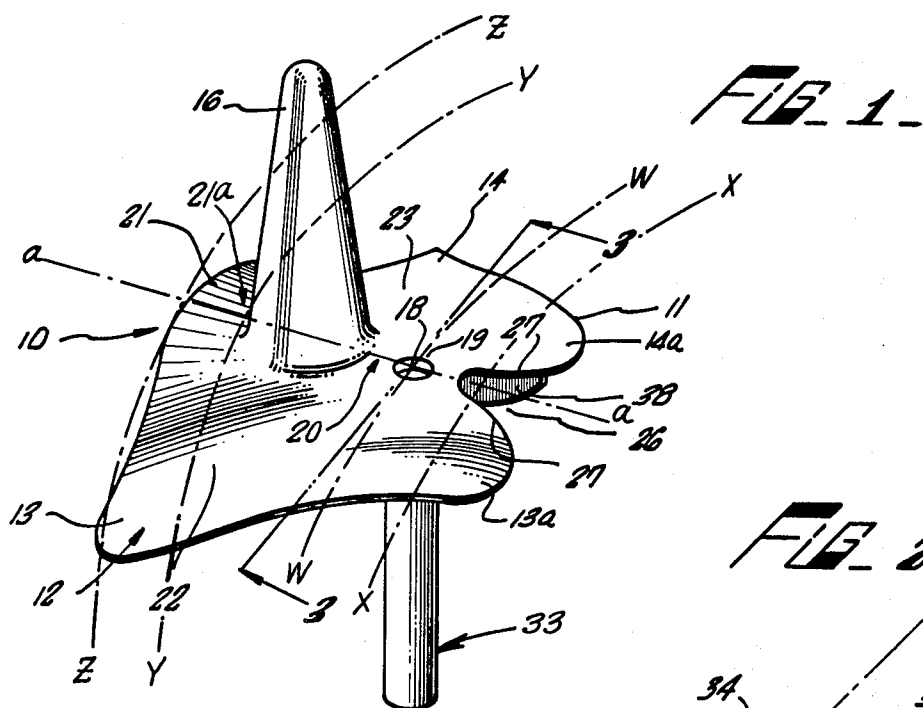


FIG. 2.

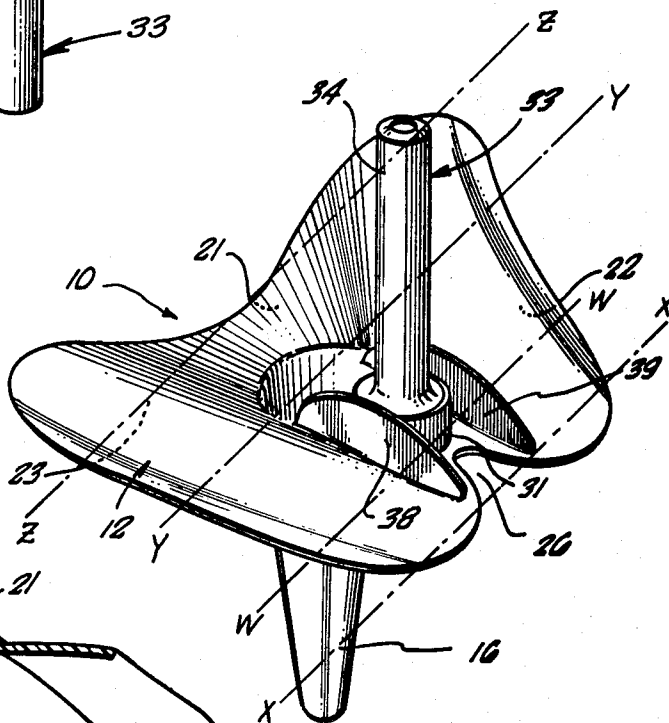
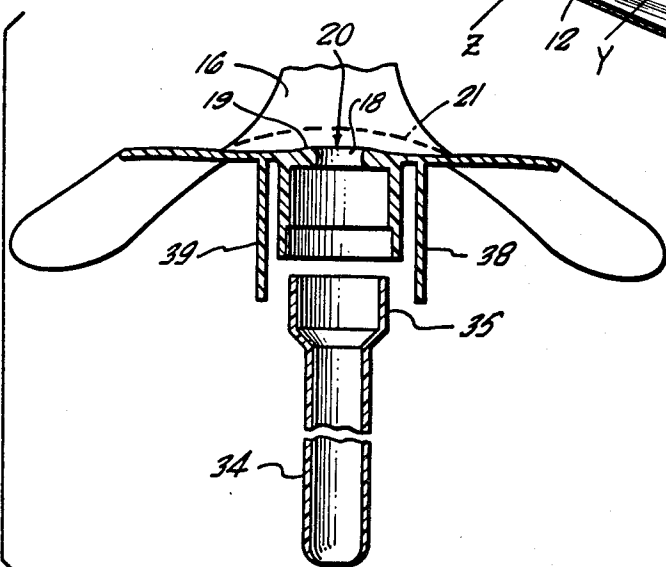
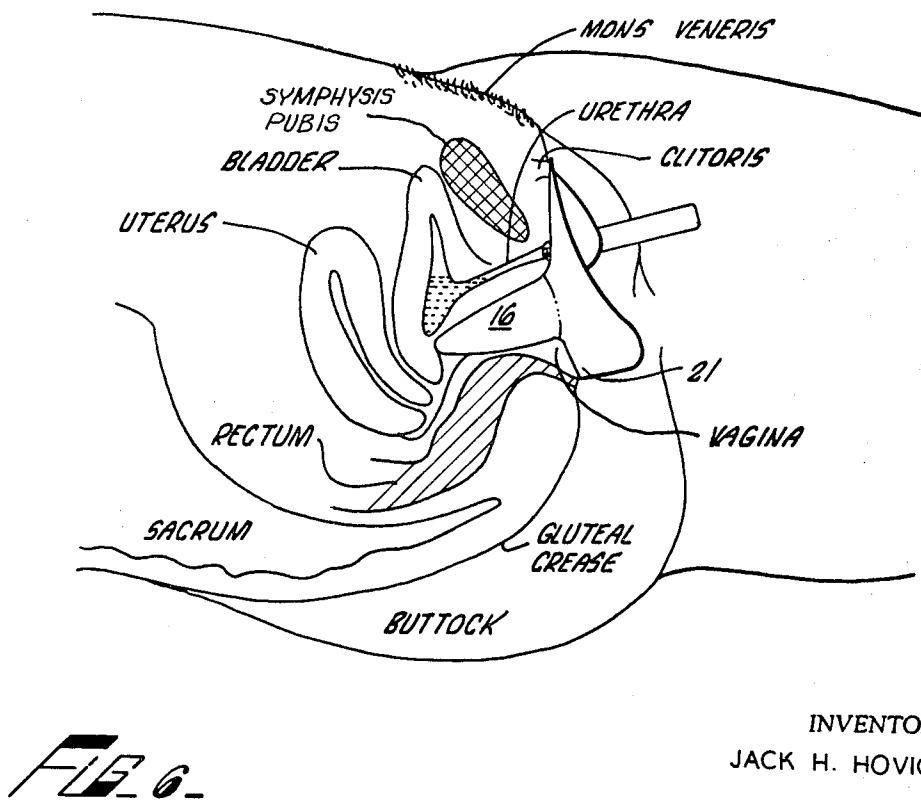
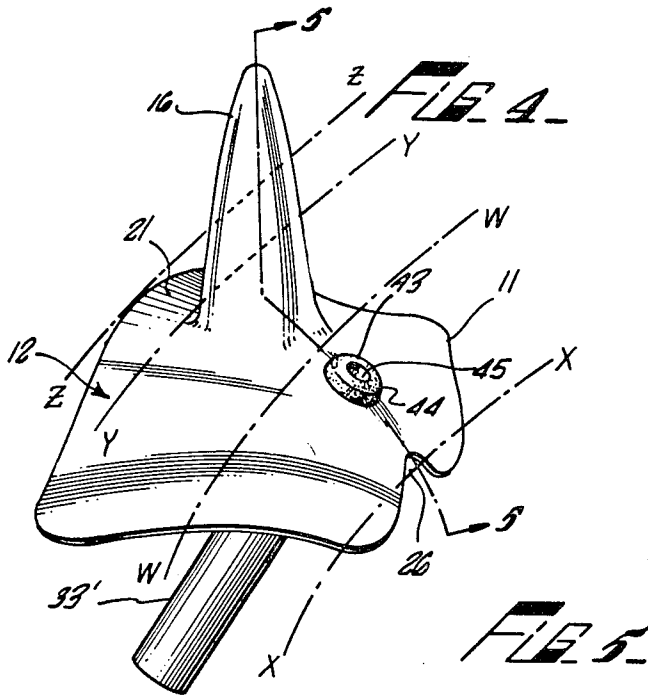


FIG. 3.



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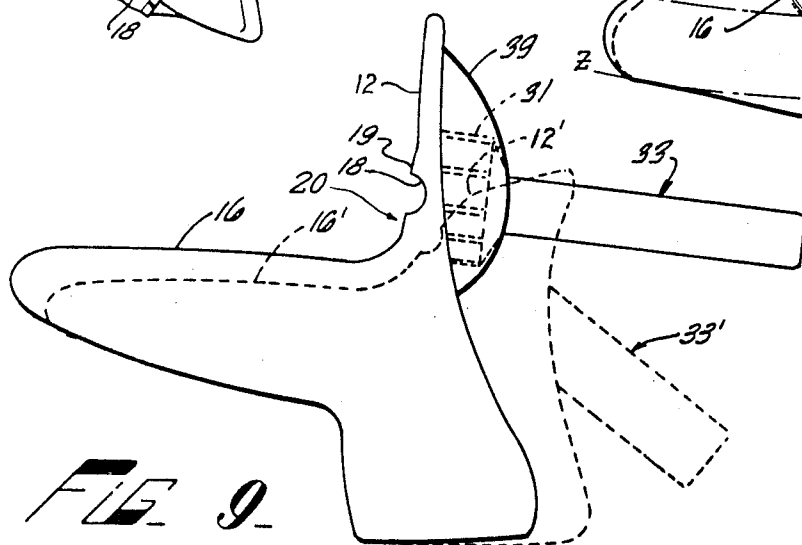
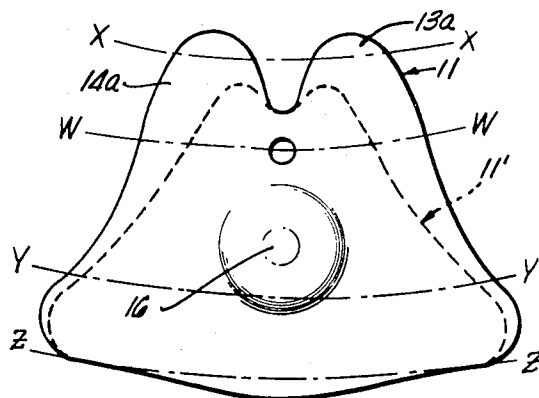
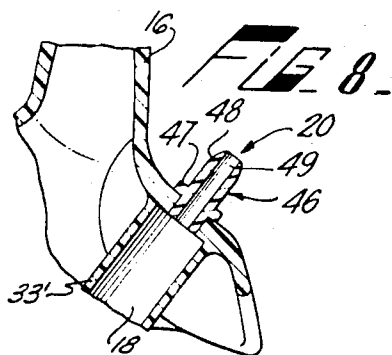
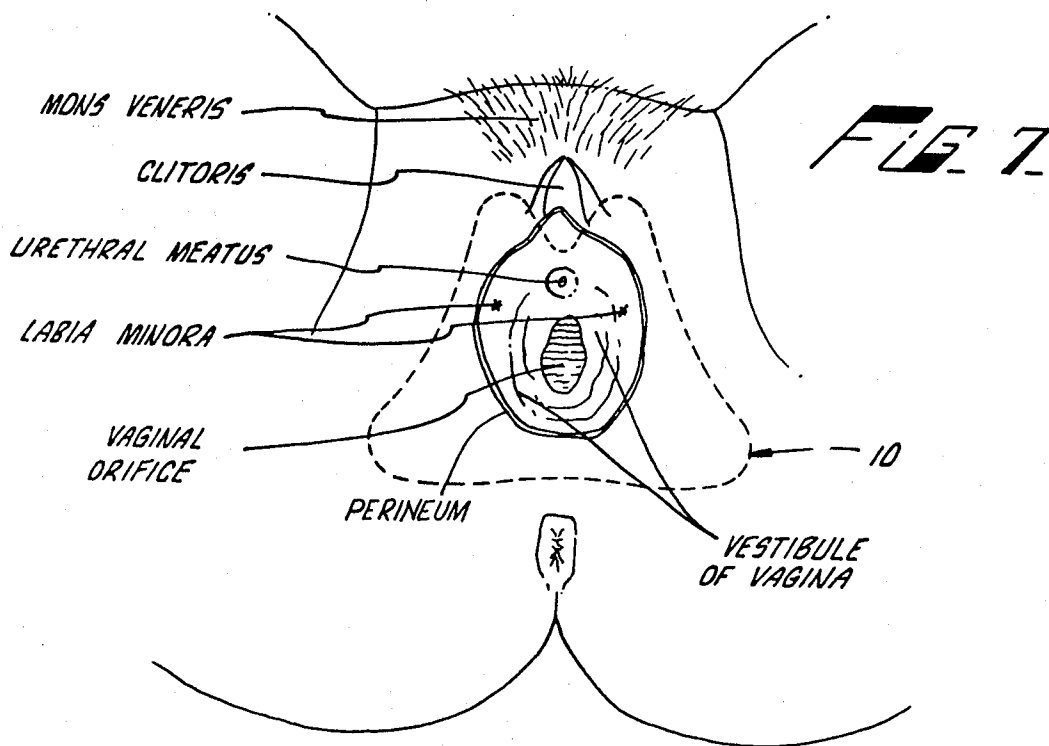


FIG. 10

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FIG. 14.

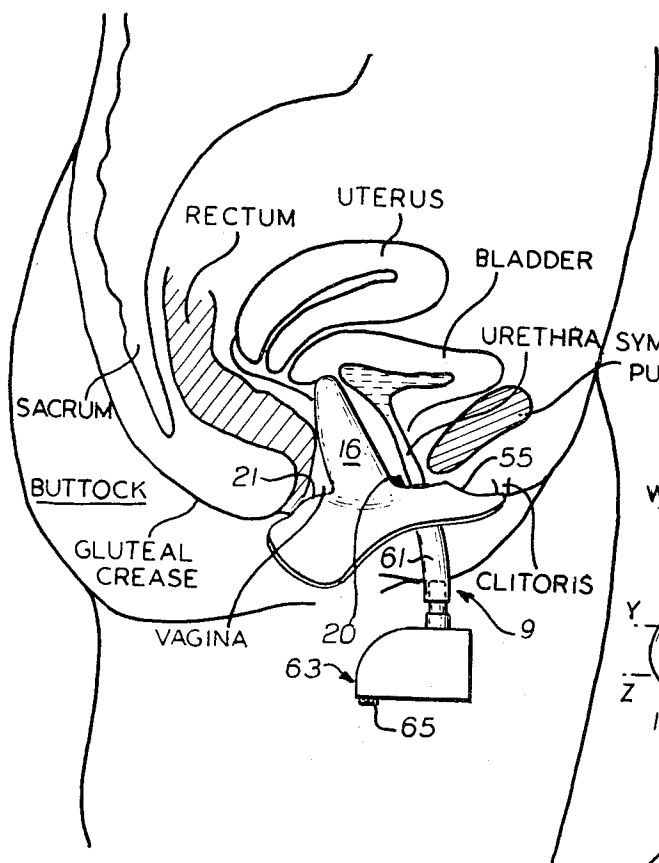


FIG. 11.

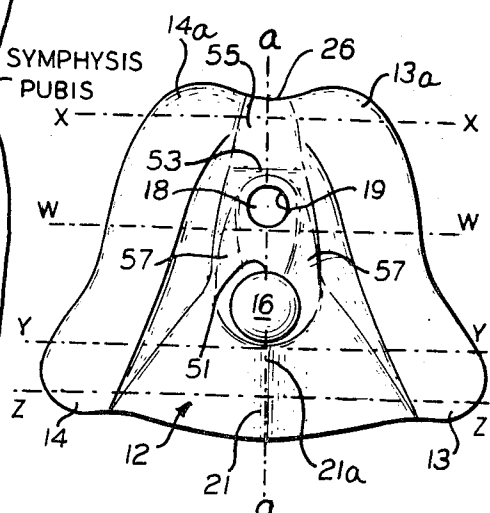


FIG. 12.

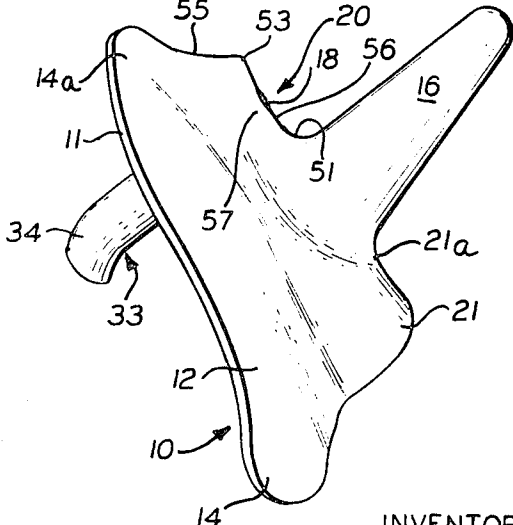
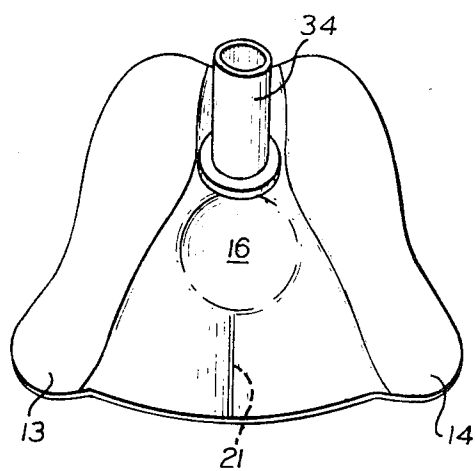


FIG. 13.



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FIG. 16.

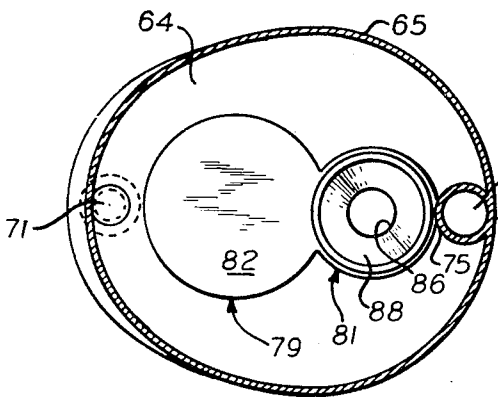


FIG. 20.

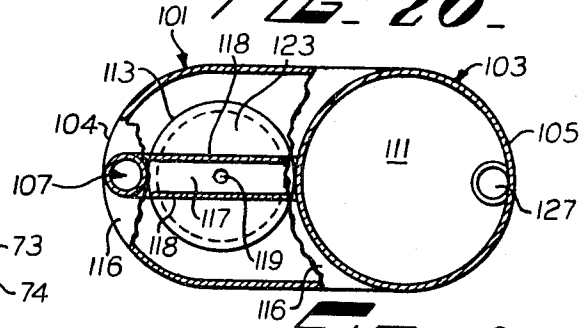


FIG. 19.

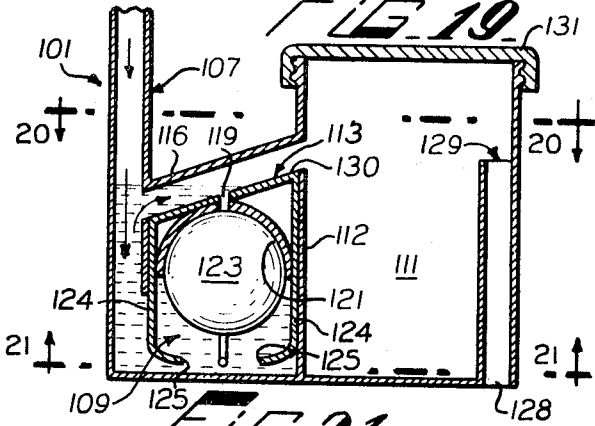


FIG. 15.

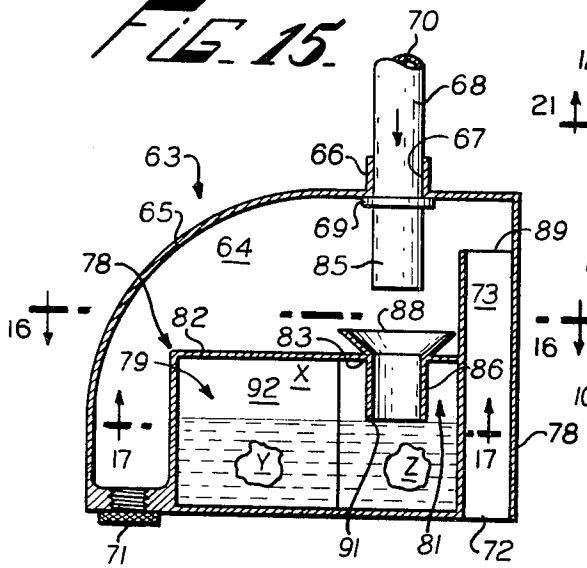


FIG. 21.

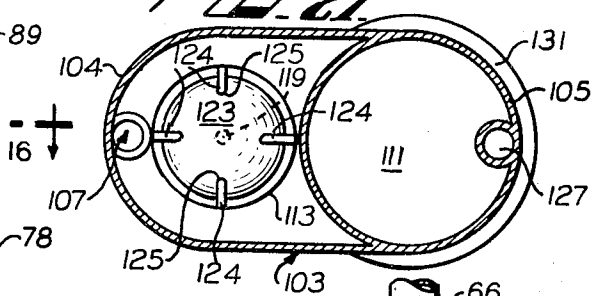


FIG. 18.

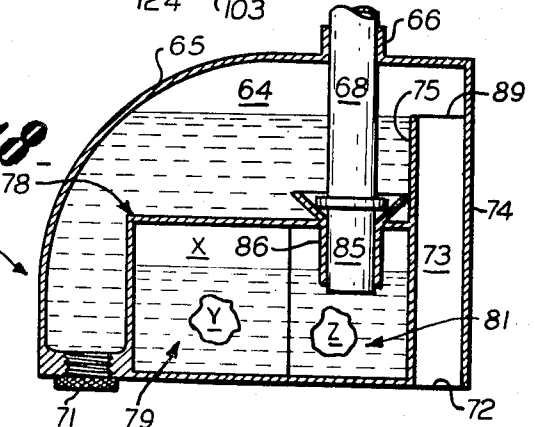
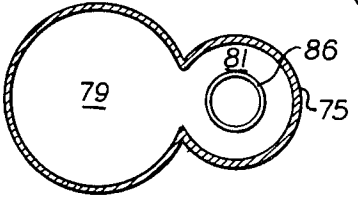
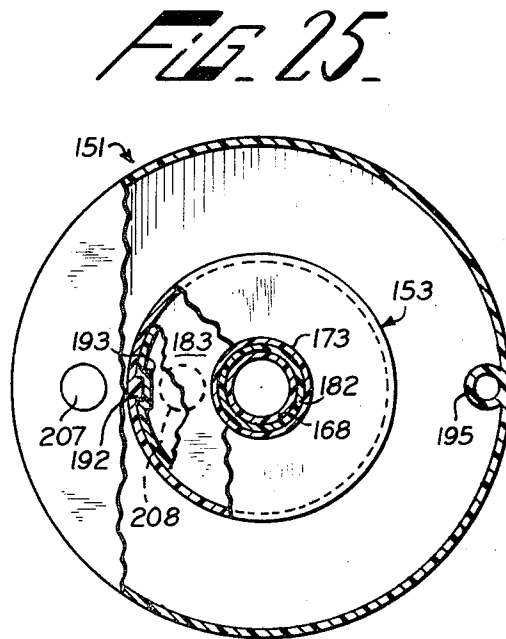
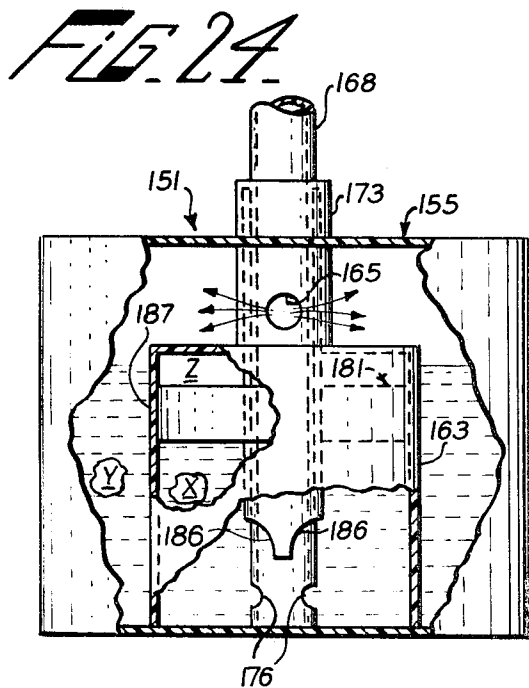
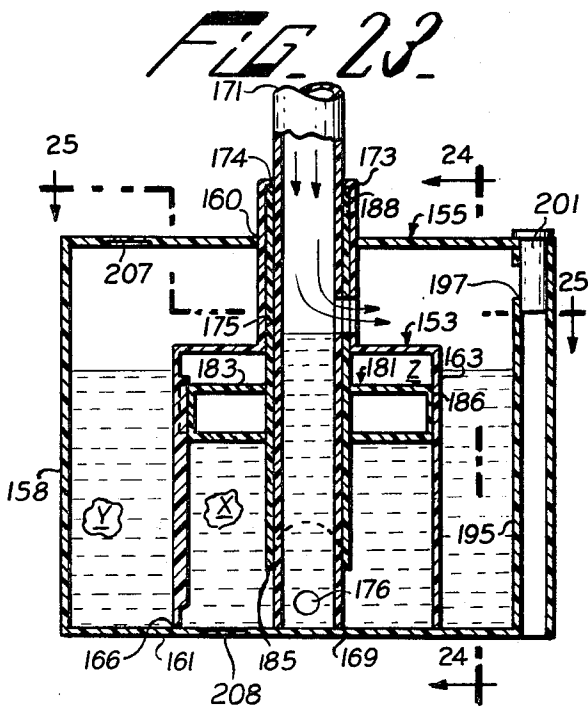
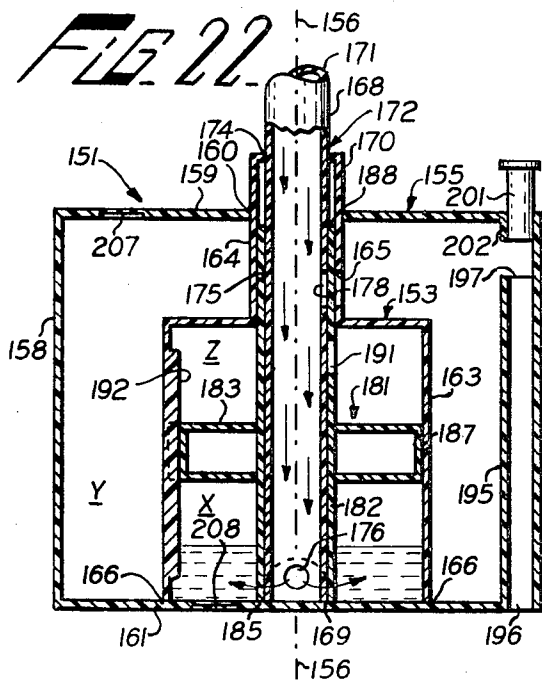


FIG. 17.



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CROSS REFERENCE TO RELATED APPLICATIONS

This is a divisional application of my copending application, Ser. No. 703,700, filed Feb. 7, 1968, for a "Guide for Collection of Urine in Females" which is directed to the urinary guide and which issued as U.S. Pat. No. 3,583,388 on June 8, 1971. My copending application which has issued as a patent and this application are continuation-in-part applications of my earlier copending application Ser. No. 451,495, filed on Apr. 28, 1965 for "Apparatus for Collection of Urine in Females," which is now abandoned.

BACKGROUND OF THE INVENTION

The collection of urine samples for microscopic analysis or culture is an important diagnostic technique for evaluating a patient's urinary tract and identifying the various urinary track infections which may affect female patients. In most cases, when a physician wants to obtain a urine sample from a female, it is obtained either by a "clean-caught" or catheter technique.

In the case of the former, even though the patient's urethral meatus is cleansed with some solution, such as an aqueous solution of benzalkonium chloride, the level of perineal contamination may not only be large enough to give a false indication of the bacterial level in the urine and therefore mislead the physician in his effort to identify and classify the cause of the patient's difficulties, but be so variable in repeated trials that the minimal colony count indicative of infection is difficult to establish. In the case of the catheterization technique, while it permits a urine sample to be obtained which is essentially uncontaminated by labial and vaginal secretions, by the same token, it is both uncomfortable to the patient and raises the hazard of cystitis in the female on which it is performed. Moreover, catheterization has the added disadvantage that it can only be done under controlled conditions in the physician's office.

The disadvantage of any technique which requires the patient in nearly every situation to come to the physician's office or to a hospital is apparent. In many cases, it is desirable to obtain a patient's urine specimen at different times of the day, particularly when the female first arises in the morning. Then, too, it is often important to collect repeated specimens over an extended period of time. Ideally, this suggests that apparatus should be provided which allows the patient, simply, effectively and without help, to obtain an uncontaminated specimen which can thereafter be delivered to the physician or to a laboratory for analysis. Another reason for seeking apparatus which a patient can use without assistance is so the patient can obtain the sample in private. It is well known that micturition is discouraged in many women by the presence of an attendant—professional or otherwise.

There has been specialized apparatus rigged up in an effort to obtain uncontaminated urine specimens, but most of it is relatively complex and commends, if it does not actually require, the use of skilled personnel to assist a patient. One such apparatus, referred to in my U.S. Pat. No. 3,583,388 is a funnel type apparatus. While the funnel collection method has apparently

shown good results, it still requires the patient to be present at the physician's office for assistance and appears likely to entrain unwanted vaginal secretions unless accurately positioned on the first try.

SUMMARY OF THE INVENTION

The primary object of the present invention, therefore, is to provide apparatus for obtaining uncontaminated urine specimens from females which is simple to use and causes little or no discomfort to the patient or risk of infection. The apparatus disclosed herein permits a patient to collect her own uncontaminated urine specimen so that her physician can evaluate her urinary tract on a continuing basis at a nominal cost and with minimum inconvenience.

The present invention provides an uncontaminated urine sample by first isolating the urethral meatus defining the urinary tract from the other parts of the female genitalia, and then utilizing the initial flow of urine to wash the isolated area of the urethral meatus preparatory to collecting the desired sample. The first is accomplished principally by the urinary guide which is claimed in my U.S. Pat. No. 3,583,388, whereas the combination, including the collector assembly, is the subject of this divisional application. With the combination, it should be possible to obtain a urine sample from an uninfected woman which has a colony count well below the minimum bacteria/c.c. level usually obtainable by the clean caught voided urine technique. It should approach the level obtainable by catheterization technique but without the risk of infection.

Broadly speaking, the present invention for obtaining voided urine specimens uncontaminated by labial and vaginal secretions comprises a urinary guide having a base with a urinal passageway therethrough, means on the base to align the passageway with the female urethra so that urine will not entrain labial and vaginal secretions in moving through the passageway, -entrapment chamber adapted to receive the initial flow of urine which washes the labial and vaginal secretions from the urethral meatus juxtaposed to the urinal passageway and a collection chamber for the sample.

More specifically, one exemplary embodiment of the present apparatus for the collection of uncontaminated urine samples comprises a guide base having holding flaps on its rearward side and compound outer surfaces which generally conform to the multiplanar contours of the female vulva, an orifice through the body and an outwardly projecting member which fits in the female vagina to assist in registering the orifice with the urethra. The base also includes a convex central section which rides in the female's gluteal crease to stabilize the apparatus in position against the female genitalia and a notch or cleft in the upper part of the base to permit the outer compound surface to rest intimately against the female vulva without contacting the clitoris. At the rearward end of the orifice (adjacent the flaps), a member is provided to receive a tapered rigid cylinder or flexible tube which is connected to the collector assembly. The collector assembly has isolation and sample chambers arranged so that a predetermined number of cc's of urine flows into the entrapment chamber before urine flows into the sample chamber. An overflow tube is provided from the sample

chamber, and means are provided to prevent the urine in the entrapment chamber from contaminating the sample itself and to empty the sample chamber once the collector assembly is delivered to the laboratory for analysis.

In other embodiments of the invention, the surfaces of the guide and its registering cone are variously shaped to accommodate females having a wide spectrum of shapes and varied size genitals and the collector assemblies are variously constructed to provide the entrapment and sample chambers and access thereto.

DESCRIPTION OF THE DRAWINGS

Other objects, features and advantages of the present invention will be more fully understood when the following detailed description is read with reference to the drawings, in which:

FIG. 1 is a perspective looking toward the front surface of the base of a first embodiment of the guide device formed in accordance with this invention;

FIG. 2 is a perspective looking toward the rear surface of the base of the first embodiment of the device as shown in FIG. 1;

FIG. 3 is a partially exploded section view of the first embodiment taken along line 3—3 of FIG. 1;

FIG. 4 is a perspective looking toward the front surface of the base of a second embodiment of the guide device formed in accordance with the present invention;

FIG. 5 is a side section view of the second embodiment of the guide device taken along line 5—5 of FIG. 4;

FIG. 6 is a sagittal section through the female pelvis exemplarily showing the second embodiment of the guide device of the present invention in place to obtain a urine specimen from a nulliparous female;

FIG. 7 is a perineal view of a parous female in a dorsal lithotomy position with the outline of the base of a representative guide device constructed in accordance with the present invention shown in dotted lines;

FIG. 8 is a partial side section view of the guide device of the second embodiment taken along line 5—5 of FIG. 4 to illustrate an alternative to the insert utilized in the second embodiment of the guide device which is illustrated in FIGS. 4 and 5;

FIG. 9 are superimposed side views of typical guide devices formed in accordance with the present invention and used by parous (solid lines) and nulliparous (dotted lines) females to show the different surface configurations and sizes of the registering cones;

FIG. 10 are superimposed rear views of the typical guide devices illustrated in FIG. 9;

FIG. 11 is a front view of a third embodiment of a guide device formed in accordance with the present invention;

FIG. 12 is a side view of the third embodiment of the guide device illustrated in FIG. 11;

FIG. 13 is a rear view normal to the plane containing the base of the registering cone of the third embodiment of the guide device illustrated in FIGS. 11 and 12;

FIG. 14 is a sagittal section through the female pelvis showing the urine collecting apparatus of the present invention exemplarily utilizing the guide device of the third embodiment juxtaposed to the female genitalia in order to obtain a urine specimen from a nulliparous female;

FIG. 15 is a side cross-section view of a first embodiment of the collector assembly forming part of the urine collecting apparatus of the present invention when it is ready for use by a patient;

FIG. 16 is a top section view of the first embodiment of the collector assembly taken along line 16—16 of FIG. 15;

FIG. 17 is a bottom section view of the first embodiment of the entrapment chamber within the collector assembly taken along line 17—17 of FIG. 15;

FIG. 18 is a side cross-section view of the first embodiment of the collector assembly identical to that of FIG. 15 after a urine sample has been collected;

FIG. 19 is a side cross-section view of a second embodiment of the collector assembly forming part of the urine collection apparatus of the present invention;

FIG. 20 is a top section view of the second embodiment of the collector assembly taken along line 20—20 of FIG. 19 with certain parts cut away;

FIG. 21 is a bottom section view of the second embodiment of the collector assembly taken along line 21—21 of FIG. 19;

FIG. 22 is a side cross-section view of a third embodiment of the collector assembly forming part of the urine collecting apparatus of the present invention when it is ready for use by a patient;

FIG. 23 is a side cross-section view of the third embodiment of the collector assembly, identical to that of FIG. 22, after a urine sample has been collected;

FIG. 24 is a side cross-section view of the third embodiment of the collector assembly taken along line 24—24 of FIG. 23 with certain parts cut away; and,

FIG. 25 is a top section view of the third embodiment of the collector assembly taken along line 25—25 of FIG. 23 with certain parts cut away.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Looking to the first exemplary embodiment of the urinary guide used with the instant apparatus, illustrated in FIGS. 1—3, the guide 10 can be seen to include a base 11 having a compound concave-convex outer or front perineal contacting surface 12 terminating in laterally extending wings or alae 13 and 14. Along generally the central portion (vertical plane *a—*a**) of the base 11 and more or less centrally located is an outwardly projecting member or cone 16 which is adapted to fit interior of the female vagina. The projecting member 16, which can have various shapes although exemplarily illustrated as a tapered cone, constitutes the central axis for generally positioning and registering the urinary guide 10 properly with respect to the female genitalia.

The outer edges of the base 11 are free or unrestrained in that the guide does not need to be strapped or otherwise affixed to the user's body so as to maintain the guide adjacent the external genitalia in sealed relation to the urethral meatus. It is for this reason and others that will become apparent hereinafter that the guide 10 is formed of materials that are relatively nonpliable; i.e., materials sufficiently nonpliable or rigid, although they may be flexible to some extent, so that the parts of the guide will maintain their shapes when held against the female genitalia by the user or an attendant without such excessive deformation that a urine specimen can not be obtained in accordance with the teaching of the invention.

A short distance above the outwardly projecting cone 16 (to the right with respect to the orientation of FIG. 1) and along the plane $a-a$, there is provided an orifice 18 through the base 11. The surfaces 19 defining the orifice 18 are generally slightly raised or convex (which can best be seen in FIG. 3) to define a slight promontory 20 which contacts the tissues immediately around the female urethral meatus to seal off the urethra from the vaginal tract when the device is in situ.

The compound surface 12 of the base 11 generally includes the lower central convex portion 21 lying in plane $a-a$ and a pair of opposite and generally symmetrical concave surfaces 22 and 23 which make a transition into the outer ends 13 and 14. Convex and concave are with respect to the part of the front perineal contacting surface 12 which generally lies in the roughly horizontal plane defined by line 3-3 of FIG. 1. The outer ends 13 and 14 are nearly uniplanar at their terminations. For registration, stability and comfort, the overall compound surface 12 is designed to generally conform to the contours of the typical female vulva for which it is designed. The convex central portion 21 (along transverse vertical plane $z-z$) rides in the gluteal crease to stabilize the device while a urine sample is being obtained and the surface area 21a, between the member 16 and the convex portion 21, rests snugly against the perineum of a female user. The perineal contacting surface area 21a lies generally along transverse vertical plane $y-y$ (FIG. 2).

There is also provided an excised portion 26 defined by the surfaces 27 at the upper end of the base 11 through which the female clitoris extends. By forming this U-shaped excised portion or clitoral cleft 26, the compound surface of base 11 is adapted to fit firmly but comfortably against the female vulva. The clitoral cleft or notch 26 lies generally along the intersection of planes $a-a$ and $x-x$ of FIG. 2. Instead of the notch 26, the clitoral cleft could be obtained by forming a convex, raised surface which would clear the female clitoris during use of the guide.

The upper parts 13a, 14a of the alae or wings 13, 14 act to spread the labia minora of parous females so as to expose the urethral meatus during insertion of the urine collecting apparatus. In most nulliparous and android structured females, the labial lips are small, at least at their ventral margin, so that they do not generally cover the urethra sufficiently to require that they be spread apart to expose the urethra.

A generally cylindrical cup 31 is affixed to or formed integral with the rear or back side of the base 11, concentric with the orifice 18 in the first embodiment of FIGS. 1-3. It acts as a receptacle for a tapered cylindrical tube 33 which may be used to direct the urine flow into a collector assembly as hereinafter described. The exemplary cylinder 33 includes an upper body 35 which fits snugly interior of the cap 31 to prevent leakage of the urine therebetween and a lower body 34.

There are a pair of supporting tabs or holding flaps 38 and 39 affixed to the rear side of base 11 in roughly parallel relation to each other and on each side of the cylindrical cup 31. These holding tabs permit the user to position the device 10 adjacent her external genitalia and maintain it in proper position while a urine sample is being obtained.

The second embodiment of the urinary device is illustrated in FIGS. 4-6 and an alternative insert in FIG.

8. Like numbers are used for like parts of the devices in FIGS. 1-3 and FIGS. 4-6 and 8. Only the differences in construction will be described. In the embodiment illustrated primarily in FIGS. 4 and 5, there is provided an insert 43 which is apertured at 45 and is held by the surfaces defining the orifice 18 to provide a more pronounced promontory 20.

The upper surface 44 of the insert 43 is conformed to contact the outer edge of the inner wall of the urethra and act as a seal between the urethra and the voiding tube or cylinder identified as 33. This insert 43 is removable so that it may be sterilized or alternatively replaced with a pre-sterilized new one for each subsequent use of the device 10.

The first and second embodiments (FIGS. 1-3 and FIGS. 4-5) are proportioned differently to illustrate some of the changes possible and, in some cases, necessary to accommodate the anatomical differences between female genitalia. In the second embodiment of FIGS. 4 and 5, the transverse widths, particularly in cleft plane $x-x$ and perineal plane $y-y$, are smaller and there is a less noticeable change in the convexness and concavity of the surface 12 outwardly of central stabilizing section 21 and perineum contacting surface 21a. In addition, the clitoris cleft 26 is less pronounced and the projecting member 16 is at more of an obtuse angle to the surface of the promontory 20 than in the case of the first embodiment of FIGS. 1-3. These differences permit the device to be used on females whose urethra meatus is more in the plane of the perineum—a characteristic of nulliparous women with a heavy android structure.

Two other minor differences in construction between the first and second embodiments of FIGS. 1-3 and FIGS. 4-5, respectively, may bear mentioning. The second embodiment has a cylinder 33' formed as an integral unit with the base 11, whereas cylinder 33 of the first embodiment is removable, and the tabs 38 and 39 are omitted. The tabs may not be needed where the cylinder 33' is an integral part of the device 10 since it can act as a support member. It is apparent that these or other means of connecting the collector assembly to the urine orifice 18 may be employed.

One of the urinary devices generally approximating the second embodiment is shown in position adjacent the female vulva in FIG. 6, and the base outline of an exemplary device is shown in position in FIG. 7. It can be seen that the registering cone or centering member 16 fits interior of the female vagina and the convex surface 21 of the base 11 fits in the gluteal crease. With the device so positioned, the upper edge 44 of insert 43 rests against the edge of the urethra and forms a seal to prevent the introduction of labial and vaginal secretions into the urethra or into the orifice 45 and cylinder 33 through which the urine is passed to a culture tube or a collector assembly.

It can also be seen in both FIGS. 6 and 7 that the excised portion (clitoral cleft 26) on the upper part of the base 11 allows the female's clitoris to clear the device so that the front surface 12 of the base 11 rests firmly and comfortably against the female vulva and underlying bony pubic arch and rami. FIG. 7 also illustrates how the gradual tapering of alae 13 and 14 spread the labial lips apart and permit unobstructed access to the urethral meatus and urethra for contact by the promon-

tory 20, regardless of whether the insert 43 of the second embodiment is used.

FIG. 8 illustrates an alternative insert for the second embodiment of FIGS. 4 and 5. The insert 46 has a circular shoulder 47 which rests against the outer surface 12 of the base 11 and the outer end 48 of the insert 46 is approximately one centimeter long. The end 48 extends into the urethra when the device is in situ to place the entering end of orifice 49 sufficiently far away from the urethral meatus so as to take the urine sample at a point in the urethra that is not usually reached by vaginal and labial secretions. The major intrusion of vaginal and labial secretions into the urethra occurs in approximately the first centimeter or less of the urethra.

FIGS. 9 and 10 compare the outline and sizes of urinary devices constructed in accordance with the present invention for use with parous and nulliparous (or android structured) females. In the case of parous females, it is desirable to use a larger base such as 11 with the wings 13 and 14 to spread the labial lips as described above (particularly in connection with FIGS. 1-3); whereas in the case of the nulliparous or android-structured females, their external genitalia are not so enlarged and it is desirable to provide a smaller overall size, illustrated as 11'. (The second embodiment of FIGS. 4 and 5 is somewhat in between the two structures compared in FIGS. 9 and 10.)

FIG. 9 also illustrates the different diameters and lengths of the registering cone for use by parous and nulliparous females, identified respectively as 16 and 16', and the different contour of the outer surface 12' called for when the female user is nulliparous or android structured. In both cases, the differences permit the devices to be used comfortably and effectively on females of either condition.

The third embodiment of the urinary guide 10, which is illustrated in FIGS. 11-13, is designed to provide a better fit for certain classes of female external genitalia, particularly with respect to the shape of the promontory 20 and the provision of upper stabilizing surfaces which engage the pubic rami and the inferior border of the symphysis. Differences in the third embodiment are generally expressed in contrast to the first embodiment of FIGS. 1-3 unless otherwise indicated.

The body 11 of the third embodiment is narrower in the transverse clitoral plane $x-x$ and transverse promontory plane $w-w$ which generally cuts across the urinary aperture 18 and promontory 20, than is the counterpart of the first embodiment of the urinary device. In this connection, it is similar to base 11' illustrated in FIGS. 9 and 10. This construction permits easier use of the device by women with heavy thighs.

In addition to the narrowness of the base 11, the promontory 20 has been extended a considerable distance above the perineal surface (defined by the plane along line 3-3 of FIG. 1). This promontory 20 is located between the base of the cone 16 and the clitoral cleft 26. It is approximately the same transverse width as the base diameter 51 of the cone 16 where it is contiguous therewith but narrows somewhat at its other end 53 (upwardly toward the cleft 26). At its upper end 53, it begins a concave depression 55 (along vertical plane $a-a$) to its upper terminating point at the perineal surface adjacent the clitoral cleft 26. The surface 56 of

this promontory 20 is relatively flat with its transverse sides 57 rounding off concavely to become flush with the outer surface 12 of the base 11. The urine aperture 18 is formed in the upper end of the promontory 20.

This projecting promontory 20 serves a number of purposes. By fitting between the pubic rami, it provides better stabilization of the device 10 and allows more accurate and rapid apposition of the urinary aperture 18 to the urethral meatus. Since it fits more deeply within the pubic rami, it diminishes the possibility of leakage by permitting firmer pressure against the tissues adjacent the urethral meatus. The concavity 55 of the promontory 20 rides against the inferior border of the symphysis thereby permitting a more stable application of the unit. And finally, the promontory 20, particularly the transverse sides 57, deflect the labia minora laterally to expose the urethra and urethral meatus.

In one embodiment of the urinary device of FIGS. 11-13 which has been found to work quite well, the promontory 20 is elevated approximately 1.2 cm. above the perineal surface of the device, the width of the promontory tapers from approximately 1.9 cm. at the base of the cone 16 to approximately 1.5 cm. at the margin of the concavity 55. This lower margin of the concavity 55 is approximately 1.8 cm. below the cleft 26. The >1.0 cm. diameter ovoid urinary aperture is centered approximately 0.7 cm. above the lower edge 51 of the promontory (which is contiguous to the base of cone 16).

One of a number of modifications of the urinary device illustrated in FIGS. 11-13 is provided by deeply indenting the part of the base at surface 53 intermediate surface 56 and the concavity 55. In this modification, designed particularly for parous females with prominent cystourethrocoecles, the urinary aperture is centered approximately 0.9 cm. above the upper edge of the base of cone 16. Other departures from the device illustrated in FIGS. 11-13 have also been found useful for females having external genitalia of intermediate dimensions.

In addition to the exemplary urinary guides identified and described in connection with the figures and the specific examples detailed above, still other changes in the outer surface and dimensions generally may be dictated by differently proportioned women. For example, as described briefly above, to permit the device to be used satisfactorily by women, usually nulliparous, having a narrow sub-pubic arch and heavy pubic bones (android structure), it is necessary to reduce the overall size of the urine guides. Since in most women having these genitalia characteristics, the urethral meatus lies in a plane substantially more proximal the perineum than is the case with parous females, for example, the transverse width (in planes $x-x$, $y-y$, $w-w$ and $z-z$) of the device is reduced and the perineal contacting surface 21a is made even more convex. It is usually terminated laterally without becoming less convex as is the case with the embodiment of FIGS. 1-3.

Switching the comparison to the embodiment of FIGS. 11-13, the centering shaft or cone 16 is smaller in diameter, shorter in length and tapers more sharply. In addition, the promontory 20 is made narrower and more pronounced so that the surfaces 19 defining the urinary aperture 18 can be inserted still further

between the heavy pubic rami. For the nulliparous female with a narrow sub-pubic arch, this constriction adds to the stabilizing influence of the promontory 20 disposed between the pubic rami (immediately beneath the sub-pubic arch).

Another modification, which is not illustrated in the drawings but follows the same line as that suggested by the differences between parous and nulliparous females, is the use of such devices with adolescent females. It should be apparent that in using such devices for obtaining uncontaminated urine specimens from adolescent females, it is necessary to reduce the dimensions of the body member 11 and the cone 16 so that they properly contour to the smaller size female genitalia.

In the case of gravid females, which of the devices to be used will depend upon how advanced they are and the particular changes that have taken place as a result of parturition and the current pregnancy. In some cases, it may be necessary to modify certain of the dimensions to obtain a good fit and avoid contacting the cervix with the cone 16.

FIG. 14 illustrates the novel apparatus 9 for obtaining urine samples relatively uncontaminated by labial and vaginal secretions in situ. The exemplary urine collecting apparatus 9 includes the urinary guide 10 of FIGS. 11-13 and the collector assembly embodiment illustrated in FIGS. 15-18. As can be observed in FIG. 14, the cone or centering shaft 16 fits well into the vagina and the promontory 20 rests firmly against the tissues surrounding the urethra. The concavity 55 bears against the symphysis to add a stabilizing effect to that obtained by the convex surface 21 which rides in the gluteal crease. The guide 10 is exemplarily connected by a flexible tube or cylinder 61 to the collector assembly 63 although it could be formed integral with the collector assembly. The assembly 63 includes an isolation or entrapment chamber and sample chamber and means to permit the sample to be removed after it is collected.

Looking more to the first embodiment of a collector assembly illustrated in FIGS. 15-18, the assembly 63 can be seen to comprise a sample chamber 64 defined by exterior walls 65. The upper wall 65 has a circular collar 66 located on its upper surface which defines an aperture 67 through which a longitudinal inlet tube 68 is adapted to move. The hollow tube 68, which is connected by tube 61 to the urinary guide 10 (see FIG. 14), has an outwardly projecting circular shoulder 69 affixed towards its lower end which abuts the under surface of wall 65 to prevent removal of the tube 68 from the sample chamber 64.

There are also provided at opposite sides of the collector assembly 63, a threaded plug 71 and an overflow tube 73 with its lower end 72 open. The overflow tube 73 is defined by the outer wall 74 of the collector assembly 63 and an interior circular wall 75. The hollow tube 73 terminates at a point 89 towards the top of the sample chamber 64.

An entrapment chamber 78 is formed interior of the sample chamber 64 of the collector assembly 63. The chamber 78 consists of a pair of circular compartments 79 and 81 in fluid communication with each other. One edge of the compartments 79-81 abut the interior wall 75 of the overflow tube 73. The top 82 of the entrap-

ment chamber 78 is generally closed except for an aperture 83 which is formed therein immediately beneath and in axial alignment with the lower end 85 of inlet tube 68. Tightly fitted within the aperture 83 is a tubular member 86 which depends interior of the compartment 81 and has an outwardly flared collar or funnel 88 on its upper end to direct the flow of urine from inlet tube 68 into compartment 81 by way of tubular member 86. It will also be observed that the upper end 89 of the overflow tube 73 is substantially above the horizontal surface of the funnel 88.

The collector assembly 63 need only have a capacity in the neighborhood of 50 cc's in the entrapment chamber 78 and 100 cc's in the sample chamber 64 although they could be more or less. If the initial 40 to 50 cc's of urine are used to wash away any immediate labial and vaginal secretions and then sealed off from the urine sample in chamber 64, a substantially uncontaminated sample should be obtained.

In operation, as the urine flows from one of the exemplary devices 10 through the inlet tube 68, it flows through the tube 86 into the entrapment chamber 78. Urine will continue to flow into chamber 78 until the level of urine therein reaches the lower edge 91 of the cylinder 86 at which time the body of air 92 in the isolation chamber 78 is trapped. As urine continues to flow into the cylinder 86, it acts against the trapped air head 92 until an equilibrium position is reached. Thereafter, the urine overflows from the funnel 88 into the sample chamber 64. This chamber 64 will continue filling up until the level of urine reaches the upper edge 89 of the overflow tube 73 at which point excess urine will be discharged through the tube 73 and opening 72. With this arrangement, the female user can place the urinal guide 10 in contact with her urethra and void to fill the collector assembly 63 as described above. As soon as she has finished voiding, the urine collector apparatus is removed and the collector assembly 63 prepared for transportation to the hospital or doctor's office for clinical analysis of the uncontaminated sample.

In order to avoid having the urine in entrapment chamber 78 recontaminate the urine in sample chamber 64 during transportation, etc., the tubular member 68 is jammed downwardly (with respect to the orientation of FIG. 15). By this means, the lower end 85 fits snugly and tightly in the interior of the cylinder 86 to form a liquid tight seal therebetween. By this operation, the entrapment chamber 78 can be sealed off from the sample chamber 64 and the urine therein cannot escape to contaminate the urine sample in chamber 64.

FIG. 15 illustrates the exemplary collector assembly 63 as it appears when a urine sample is being taken; whereas FIG. 18 illustrates the assembly after the axially aligned tube 68 has been jammed into tube 86 to seal off chamber 78 from the urine in chamber 64. It is, of course, necessary to carry the collector assembly 63 in a generally upright position unless caps (not shown) are provided to fit on the lower end 72 of the overflow tube 73 and the upper end 70 of the tubular member 68. When the collector assembly 63 is delivered to the laboratory for analysis, however, the threaded cap 71 is removed to obtain access to the urine sample in chamber 64.

While the dimensions of collector assembly 63 are not too critical, certain proportions will provide a device adapted for efficient use. The following dimensions are illustrative: inside diameter of overflow pipe 73 (or inlet tube 61)— $\frac{3}{8}$ inch; inside diameter of pipe 86— $\frac{3}{8}$ inch; outside diameter of tube 68— $\frac{3}{8}$ inch; $Y + Z$ volume of urine ≈ 40 cc.; and volume Y (liquid) + X (air) > volume $Y + Z$ (liquid).

A second embodiment of a collector assembly 101 is illustrated in FIGS. 19-21. While the structure of collector assembly 101 differs from that of collector assembly 63, its basic function is similar in that it is designed to provide means for entrapping or isolating an initial volume of wash urine before directing the flow into a sample chamber.

Looking particularly to the second embodiment of FIGS. 19-21, the collector assembly 101 can be seen to include generally curved outer ends 104 and 105. An inlet tube 107 is provided for connection to a urinal guide 10. Tube 107 is in open communication with an isolation or entrapment chamber 109 at the left side (with respect to FIG. 19) of the collector assembly 101. The entrapment chamber 109 is separated from the sample chamber 111 to its right by a vertical wall 112 which terminates at the upper edge of a valve seat block 113. The valve seat block 113 forms the top of the chamber 109 and terminates in spaced apart relation between the lower part of inlet tube 107 and wall 112. Block 113, the top or upper wall 116 of the body 103 and parallel walls 118 define a slanting passageway 117 in open communication between the side of tube 107 and the entrance to sample chamber 111. The generally circular passageway 117 slopes upwardly from inlet tube 107 to sample chamber 111.

The valve seat block 113 includes a centrally located vertical aperture 119 which is in open communication between passageway 117 and the entrapment chamber 109. The lower surface 121 of the valve seat block 113 is formed to provide a valve seat for a spherical float valve 123. A plurality of L-shaped flexible arms 124 are affixed as a cage to the lower side of the block 113 at peripherally spaced apart points so that their inwardly disposed ends 125 retain the ball 123 closely adjacent its valve seat 121.

An overflow tube 127 is provided at the right side of the collector assembly 101 which has an open lower end 128 and an upper end 129 (which lies vertically somewhat above the lower edge 130 of the passageway 117). There is also provided a threaded cap 131 on the upper end of the sample chamber 111 to facilitate removal of the urine sample at the laboratory.

In operation, the urine flows from the urinal guide 10 through the tube 107 into the entrapment chamber 109 as shown by the arrows. As urine fills up the chamber 109, it floats the spherical float valve 123 against the valve seat 121 to seal off the vertical aperture 119. At this point the urine level rises in the tube 107 and slowly flows through the passageway 117 into the sample chamber 111. In doing so, by virtue of vertical aperture 119 it pulls a vacuum to more firmly seat the valve. As soon as the sample chamber 109 is filled to the upper edge 129 of the overflow tube 127, the excess urine flows out of the overflow tube 127 to be discharged.

As soon as the female patient has finished voiding, the collector assembly 101 is delivered to the doctor's office or laboratory. At this point, the cap may be removed and the urine sample taken out without even recontaminating the sample in the chamber with the wash urine in the entrapment chamber 109. As in the case of the first exemplary embodiment of a collector assembly, dimensions are not too critical. However, it is desirable to proportion certain of the passageways of the second embodiment relative to one another. One appropriate set of dimensions is as follows: inside diameter of inlet tube 107 = $\frac{7}{16}$ inch; inside diameter of passageway 117 = $\frac{3}{8}$ inch; inside diameter of outlet tube 127 = $\frac{3}{8}$ inch; and inside diameter of vertical aperture 119 = $\frac{1}{16}$ inch.

The third embodiment of the collector assembly 151, which is illustrated in FIGS. 22-25, is designed to function in a manner quite similar to that of the first two embodiments. The first 50 cc's or so of voided urine passes into an entrapment chamber 153 which is then sealed and the voided urine thereafter flows into the sample chamber 155.

The entrapment chamber 155 is located interior of the sample chamber 155. Both chambers are in the form of right circular cylinders concentrically disposed about longitudinal axis 156. The sample chamber 155 includes a cylindrical body 158 with a centrally apertured top 159 and a bottom 161. The entrapment chamber 153 is a relatively self-contained unit comprising a cylindrical body 163 with a reduced upper section 164 having an aperture 165 therethrough which is transverse to the sides of the section 164. The lower edge 166 of the body 163 abuts the bottom 161 of the sample chamber 155 in sealed relation. The upper reduced section 164 thereof extends through the aperture 160 of top 159 sealing off the sample chamber 155 from the entrapment chamber 153.

The upper end 170 of reduced section 164 is also apertured at 172 to receive a hollow tubular guide member 168 in sealed relation thereto. The lower end 169 of the guide member 168 is affixed to the bottom 161 of the sample chamber 155 in sealed relation as is cylindrical body 163, whereas its upper end 171 extends through the upper aperture 172 formed by the inwardly projecting shoulders 174 of the reduced section 164 in spaced apart relation to the interior wall 175 of the reduced section 164.

The tubular guide member 168 has a pair of opposite transverse apertures 176 formed in its lower end 169 and a transverse aperture 178 formed in its upper part in fixed alignment with aperture 165 in the reduced section 164 of the entrapment chamber 153. Apertures 176 place the interior of tubular guide member 168 in fluid communication with the space X in the entrapment chamber 153 at all times.

A float assembly 181 which includes a tubular slide 182 with cylindrical float 183 affixed thereto is supported between the guide member 168 and the interior of the reduced section 164 of the entrapment chamber 153 for movement along axis 156. The lower end 185 of slide 182 normally rests against the common bottom 161 of the entrapment and sample chambers when the collection assembly 151 is empty. It has oppositely disposed portions 186 cut away so that the apertures 176 in tubular guide member 168 is unobstructed at all

times. The float 183 is affixed to the slide 182 in spaced apart relation to the bottom of the chambers as illustrated in FIG. 22, and its outer edge 186 extends to the inner surface of cylindrical body 163 of the entrapment chamber 153.

The float assembly 181 is freely movable between its normal lowermost position described above and an upper position reached when the upper end 188 of the slide 182 abuts the inwardly disposed shoulder 174 of the reduced section 164 which forms part of the entrapment chamber 153. The presence of fluid in space X will cause the float assembly to move to its upper position against the head of an air space Z as hereinafter described.

The tubular slide 182 has a transverse aperture 191 formed in its upper end which registers with the apertures 165 and 178 of the reduced section 164 and guide member 168, respectively, when the slide 182 is in its uppermost position. This places the inside of tubular guide member 168 in fluid communication with the sample chamber space Y. To maintain the slide 182 in circumferential alignment with the apertures 165 and 178, a longitudinal disposed key 192 may be formed on the inner wall of cylinder 163 and a slot 193 in the float 183 to cooperate therewith. By this means, the alignment of the apertures is assured when the float assembly reaches its uppermost position. Of course, other alignment means may be used including a rectangular-shaped float cooperating with a rectangularly-shaped entrapment chamber.

The sample chamber 155 also has an overflow tube 195 affixed longitudinally to one interior side of body 158 with its lower end 196 opening through the bottom 161 of the sample chamber and its upper end 197 terminating somewhat below the undersurface of the top 159 of the chamber 151. A tapered vent tube 201 having an outside diameter slightly larger than the inside diameter of the overflow tube 195 is slidably supported in the top 159 by support 202 in axial alignment with the overflow tube 195.

The vent tube 201 acts as an air vent as urine flows into the cylindrical body 158 as hereinafter explained. It also acts to seal off the vent 201 and overflow tube 195 from the sample chamber 155 when a sample is transported. This is accomplished by forcing the vent tube 201 downwardly so that it jams into the open end 197 of the overflow tube 195 to seal the sample chamber 155.

In order to permit the urine sample to be removed from the sample chamber, a membrane 207 may be placed in the top 159 of the sample chamber 155. The membrane may be perforated by a large bore needle to withdraw the urine samples. Of course, a removable cap could be substituted for the membrane to permit removal of the sample. In addition to means to permit removal of the sample urine, a membrane or cap 208 can be located in the entrapment chamber 153 to permit the removal of the "wash urine" if it is desirable to analyze the urine which has entrained labial and vaginal secretions.

In operation, the collector tube from a urinary guide is connected to the end 171 of guide member 168. Initially, urine can only flow through tubular member 168 and apertures 176 into the space X below the float 183. The urine continues to flow into the entrapment

chamber 153 against the air head above the float 183 until the float assembly 181 reaches its upper position at which time tubular member 168 is in fluid communication with the space Y in the sample chamber 155.

Urine then flows into space Y until voiding is completed or urine reaches the top of overflow tube 195 and spills out of the tube. When voiding is completed, the vent 201 is jammed downwardly sealing off the sample chamber and the collector assembly is transported to a laboratory for analysis. By this third embodiment, the user can obtain a substantially uncontaminated urine sample which has been preceded by a 30-50 cc urine wash.

In the third embodiment, as in the others, dimensions are not too critical. While volume X in the entrapment chamber should be at least 40-50 cc's and the volume Y in the sample chamber at least 100 cc's, they can be varied considerably without any difficulty arising. One or two dimensions need to be controlled but even they are not too critical. First, the aperture in the float assembly slide must line up with the apertures in the reduced section of the entrapment chamber and guide member when the float assembly reaches its upper position. Second, the vertical distance in space Z above the float should be greater than the length of travel of the float assembly so that the float assembly will reach its uppermost position without developing an excessive air head in space Z.

Certain modifications of these exemplary collector assemblies can, of course, be made without departing from the basic concept of the invention disclosed and claimed herein. For example, threaded caps, membranes or sliding covers could be used interchangeably in the assemblies. Caps or other closure devices could also be used to completely seal off the assemblies for transportation. Moreover, the guide and collector assemblies could be made as one part. Thus, from the foregoing description of this apparatus for obtaining urine samples from females, it can be appreciated that the general requirements for the apparatus described herein, irrespective of the size, age or condition of the female user, is a urinary guide conforming to the female vulva of the intended user and a cooperating collector assembly. The proportioning of the convex-concave surfaces, placement of the clitoral cleft, the size, cross-section and length of the projecting member or cones and promontory configuration all more or less depend on the typical structure of the female genitalia. The urinary guide coupled with a collector assembly designed to isolate a predetermined number of cc's of the initial wash urine before the urine sample is collected assures that the overall apparatus will operate most effectively to provide a urine sample uncontaminated by labial and vaginal secretions. A laboratory will then be able to carry out diagnostic tests on the urine to determined specific sources of infection in females.

While the urine guides and collector assemblies described herein can be formed of a variety of materials, including various metals, they can also be formed of any number of conventional plastic resins. Either or both parts of the apparatus may be presterilized for throwaway use if desired. It is, of course, possible to form the guides or collector assemblies out of materials which can be re-sterilized after each use, but the inex-

pensiveness of plastic molding techniques commends the use of presterilized disposable urinary guides and assemblies.

While this invention has been described with respect to certain preferred embodiments which can be variously combined to provide a wide variety of sizes and types for various anatomical structures, it should be apparent that various changes and modifications can be effected by those skilled in the art without departing from the spirit and scope of the invention. For this reason, the invention should be limited only to the extent of the appended claims.

I claim:

1. Apparatus for obtaining from a female a urine specimen which is relatively uncontaminated by labial and vaginal secretions comprising, in combination, a urinary guide having a passageway formed through its base,

means formed on said base adapted to register the female urethra with the passageway and seal off the urethra from the vagina, the vaginal vestibule and contiguous parts, and

a collector assembly in fluid communication with said guide to collect a urine sample after the initial flow of urine washes the tissue adjacent the urethra orifice,

said collector assembly including an entrapment chamber in fluid communication with the end of said urinary passageway remote from the urethra sealing means, a sample chamber, and means responsive to a preselected quantity of urine in said entrapment chamber to cause the urine flow to be transferred into said sample chamber.

2. Apparatus for obtaining from a female a urine specimen which is relatively uncontaminated by labial and vaginal secretions in accordance with claim 1 wherein said transfer means includes

an upwardly sloping passageway between said urine passageway and said sample chamber overlying said entrapment chamber to permit the flow of urine to move interior of said sample chamber after said entrapment chamber is full, and

a ball float valve adapted to seat and seal off an air vent between the entrapment chamber and said sloping passageway when said entrapment chamber is full.

3. Apparatus for obtaining from a female a urine specimen which is relatively uncontaminated by labial and vaginal secretions in accordance with claim 1 wherein

said entrapment chamber is disposed interior of said sample chamber concentric to a tubular member which connects said urine passageway to said entrapment chamber, and

said transfer means comprises a float assembly slidably mounted on said tubular member for movement between a first position when said tubular member is not in fluid communication with said sample chamber and a second position when said tubular member is in fluid communication with

said sample chamber, and means responding to a preselected volume of urine in said entrapment chamber to move said float assembly to said second position whereby urine will thereafter flow into said sample chamber.

4. Apparatus for obtaining from a female a urine specimen which is relatively uncontaminated by labial and vaginal secretions in accordance with claim 1 and including

means to permit urine in excess of that collected in the entrapment and sample chambers to overflow from said collector assembly, and

vent means to vent said sample chamber and operable to seal off said overflow means after a urine specimen is obtained.

5. Apparatus for obtaining from a female a urine specimen which is relatively uncontaminated by labial and vaginal secretions in accordance with claim 1 wherein the transfer means responsive to the preselected quantity of urine seals off the entrapment chamber so that the urine flowing into said sample chamber cannot be contaminated thereby.

6. Apparatus for obtaining from a female a urine specimen which is relatively uncontaminated by labial and vaginal secretions in accordance with claim 1 and including

overflow means associated with said sample chamber of said collector assembly to permit the urine in excess of the capacity of the entrapment and sample chambers to flow out of said collector assembly, and

means operable to seal off said entrapment chamber from said sample chamber.

7. Apparatus for obtaining from a female a urine specimen which is relatively uncontaminated by labial and vaginal secretions in accordance with claim 5 wherein

said entrapment chamber is disposed interior of said sample chamber in open communication with the interior of said sample chamber through an opening in the top of said entrapment chamber,

an open funnel is disposed through said opening in the entrapment chamber but spaced apart from the remote end of said urinary guide passageway,

a tubular member forming part of said remote part of said urinary guide passageway slidably supported in the top of said sample chamber in axial alignment with the funnel retained in said entrapment chamber,

said tubular member adapted to direct the urine flow from said urinary guide into said entrapment chamber until the level of urine therein rises above the lower edge of said funnel to trap a body of air in said entrapment chamber which in turn causes the subsequent flow of urine to overflow the funnel into said sample chamber, and

means operable to axially wedge said tubular member into said funnel to seal off said entrapment chamber from said sample chamber.

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