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a part interest
Continuation-in-part of application Ser. No. 451,495, Apr. 28, 1965, now abandoned,
Continuation-in-part of application Ser. No. 102,866, Dec. 30, 1970.

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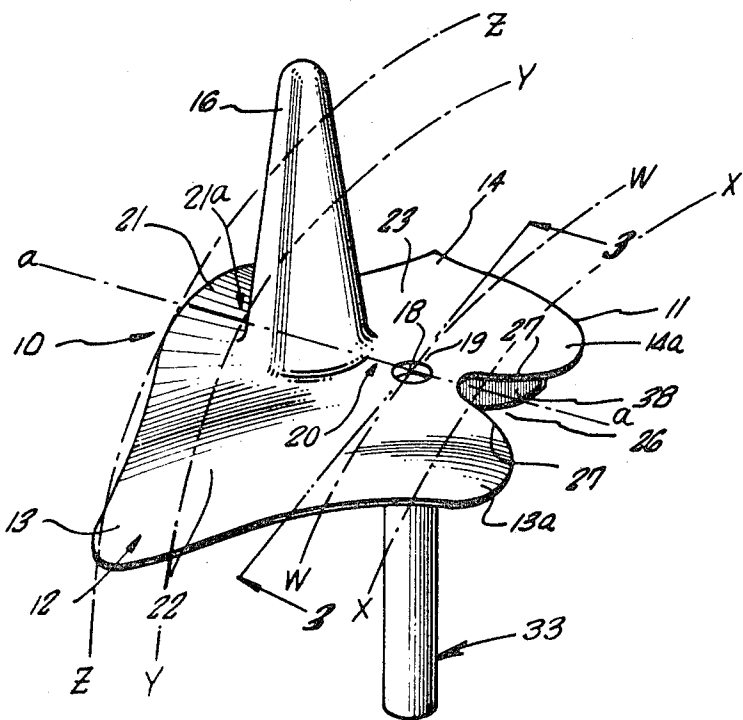
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Attorney—James B. Gambrell

[54] **GUIDE FOR COLLECTION OF URINE IN FEMALES**
17 Claims, 21 Drawing Figs.
[52] U.S. Cl. **128/2**
[51] Int. Cl. **A61b 10/00**
[50] Field of Search **128/295, 2; 4/110**

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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.



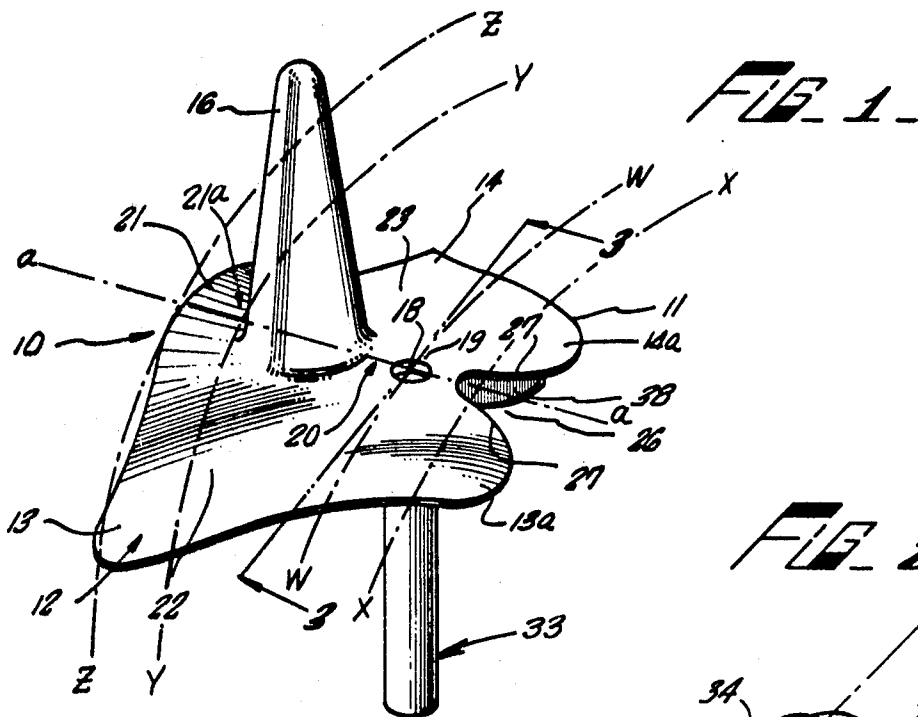


FIG. 2.

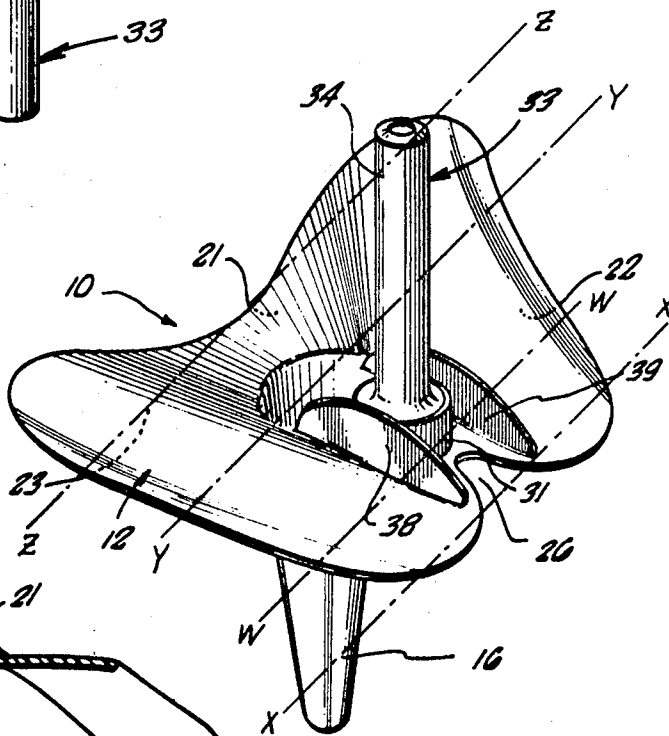
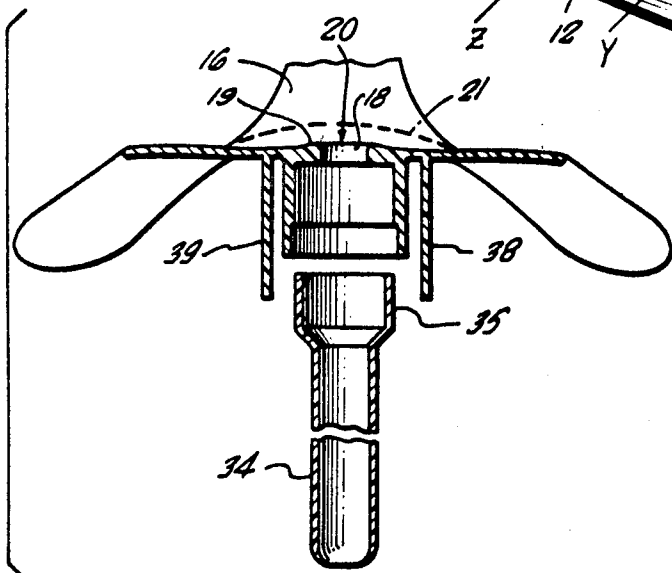


FIG. 3.



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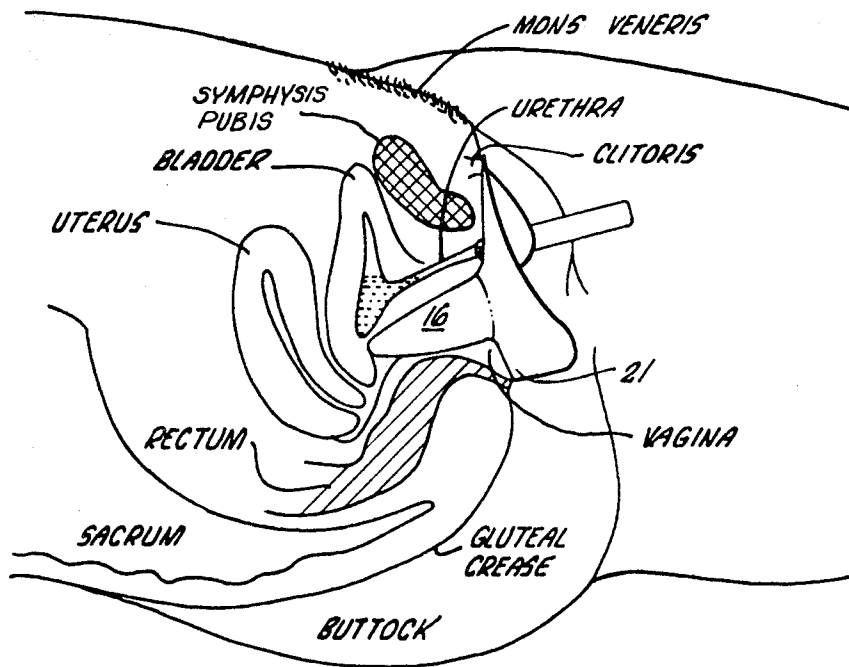
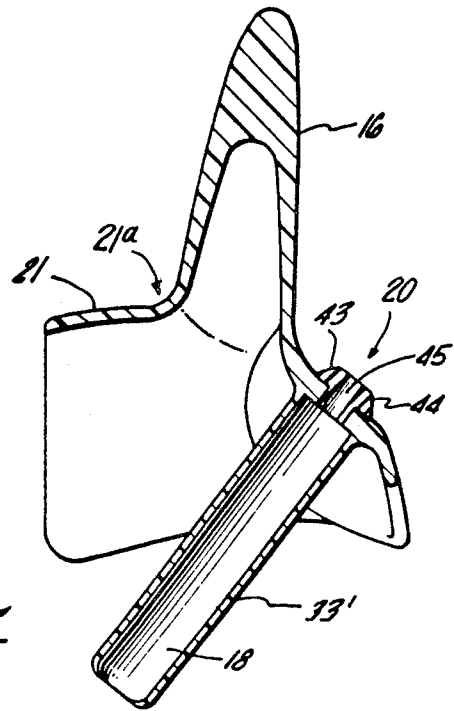
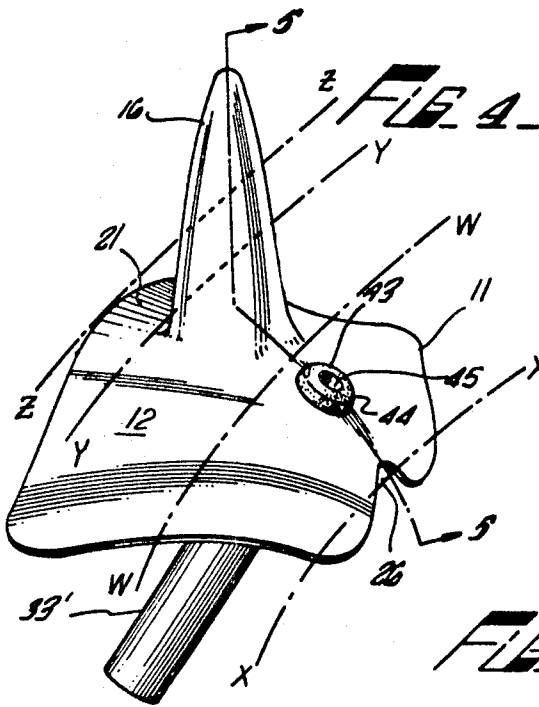
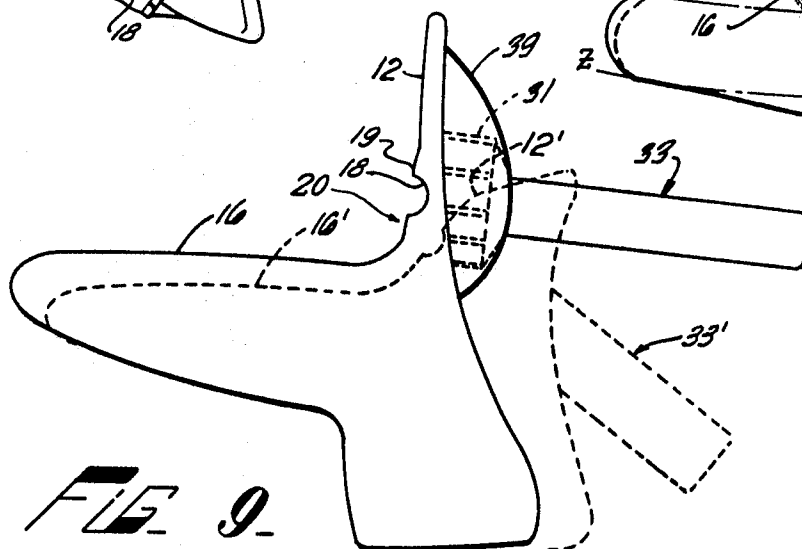
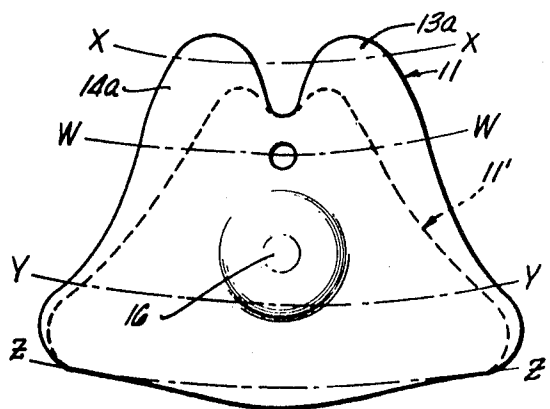
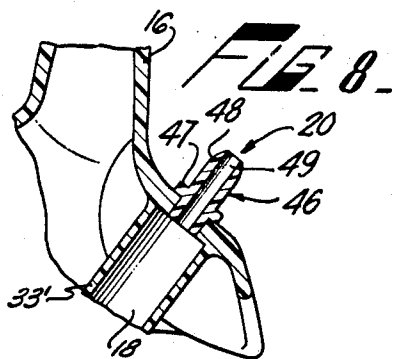
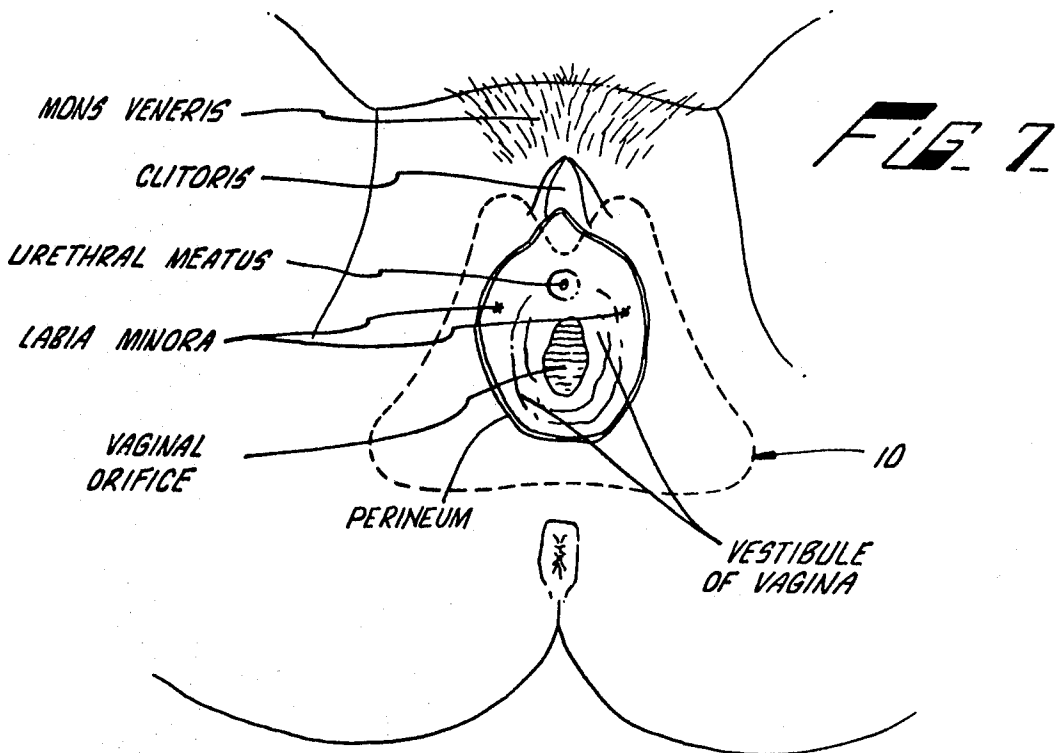


FIG 6

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FIG. 14.

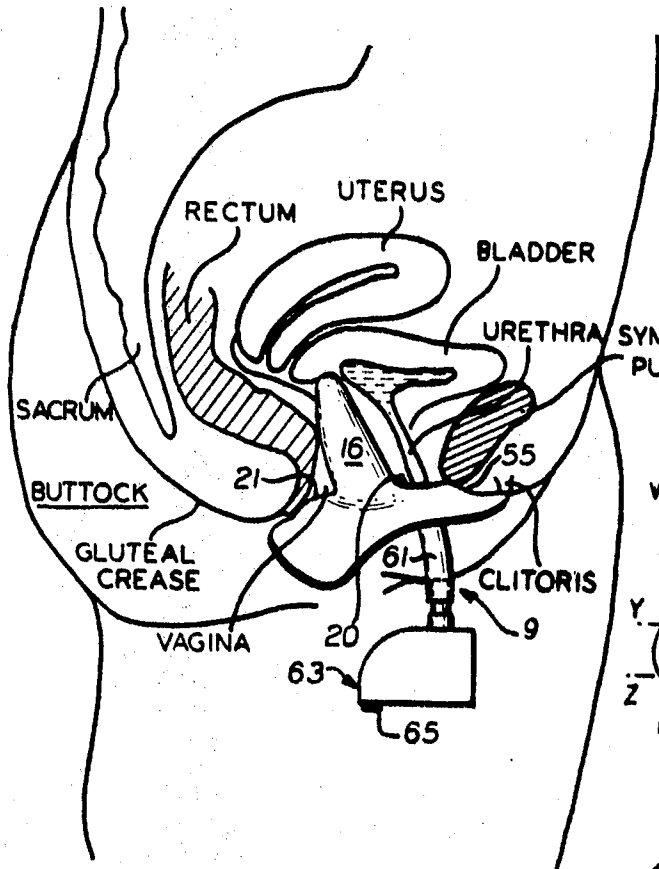


FIG. 11.

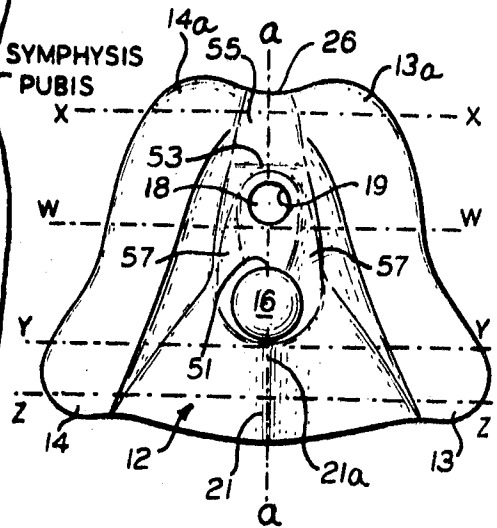


FIG. 12.

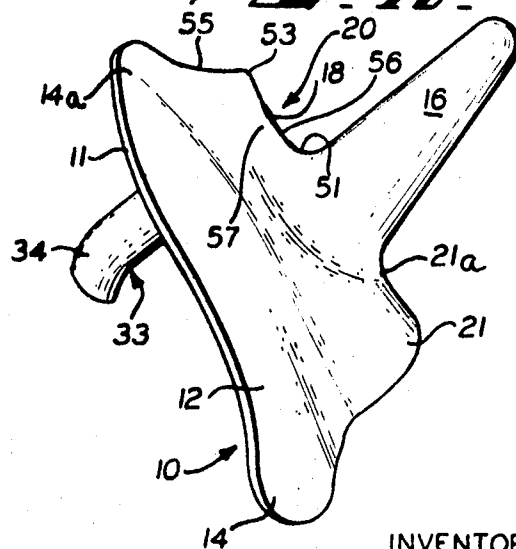
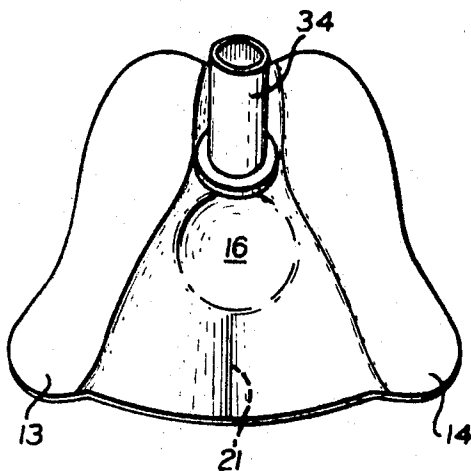


FIG. 13.



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FIG. 16

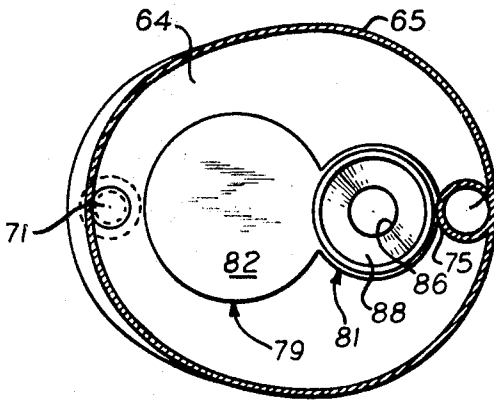


FIG. 15

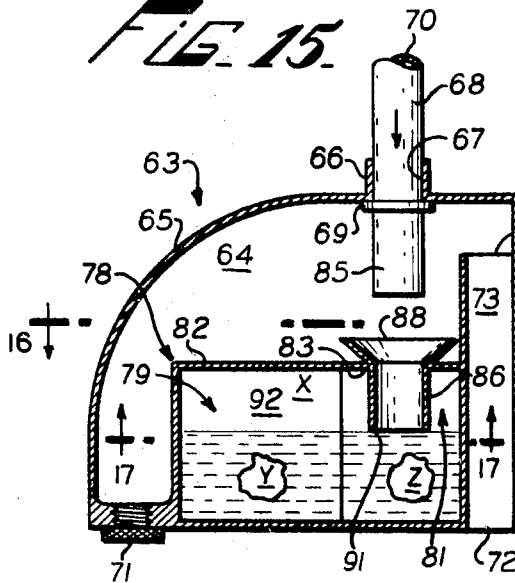


FIG. 17

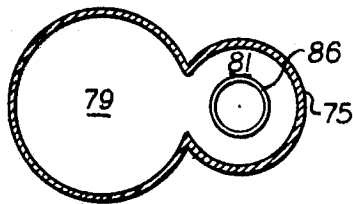


FIG. 18

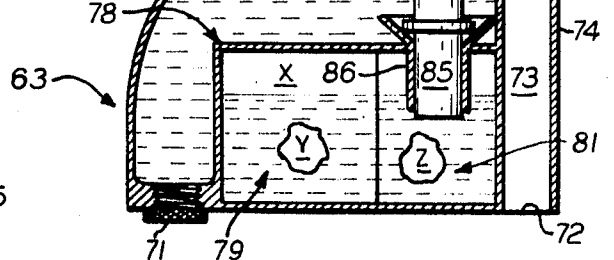


FIG. 20

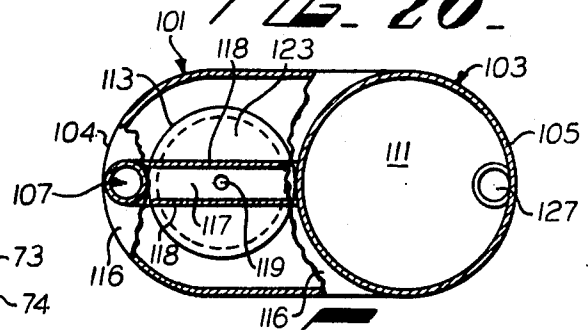


FIG. 19

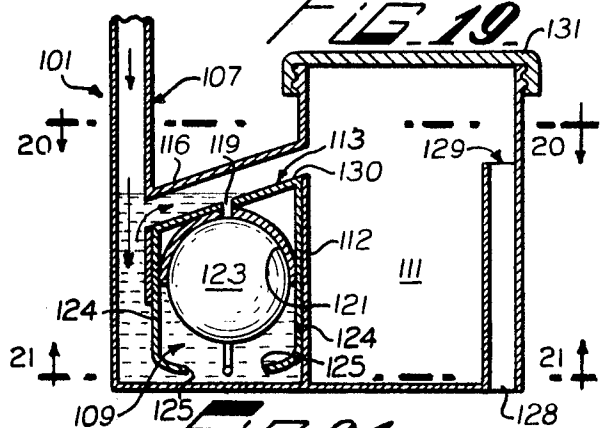
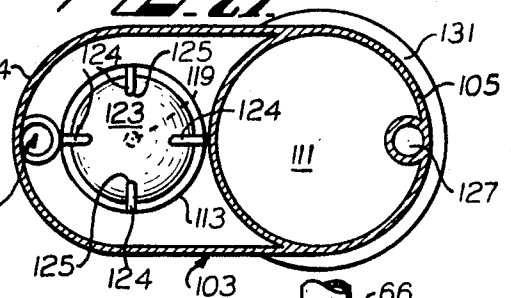


FIG. 21



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GUIDE FOR COLLECTION OF URINE IN FEMALES

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part application of my earlier copending application Ser. No. 451,495, filed on Apr. 28, 1965 for "Apparatus for Collection of Urine in Females." The parent application but not the invention thereof has been abandoned in favor of the present application and, as a result of a restriction requirement, a continuation-in-part, Ser. No. 102,866, filed on Dec. 30, 1970 and copending herewith.

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 tract 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 system 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 some device should be provided which allows the patient, simply, effectively and without help, to obtain a relatively 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 relatively 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 method for urine collection in females is described in an article appearing in the Feb. 1965 issue of Modern Medicine, pages 126—7. The apparatus described therein is also disclosed and claimed in U.S. Pat. No. 3,335,714 issued to J. D. Giesy on Aug. 15, 1967. The authors of the article discuss some of the problems and compare the bacterial levels obtained by clean voided samples, catheterization techniques and a funnel collection method they used. 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 device for obtaining a relatively uncontaminated urine specimens from females which is simple to use and

causes little or no discomfort to the patient or risk of infection. The guide and 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 apparatus disclosed herein 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 by the urinary guide which is disclosed and claimed herein and the latter by the combination of the guide and the collector assembly which is claimed in the divisional application referred to above. By the combination it is 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 approaches the level obtainable by catheterization technique but without the risk of infection.

Broadly speaking, the present invention for obtaining voided urine specimens relatively uncontaminated by labial and vaginal secretions comprises a base with a urinal passageway therethrough, and means on the base including a projecting member which fits interior of the vagina to align the passageway with the female urethra so that voided urine will not entrain labial and vaginal secretions in moving through the passageway.

More specifically, one exemplary embodiment of the present apparatus for the collection of uncontaminated urine samples comprises a 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 provides 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 base of the registering member), a member is provided to receive a tapered rigid cylinder or flexible tube which may be connected to a collector assembly.

The collector assembly has isolation and sample chambers arranged so that a predetermined number of c.c.'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 contamination the sample itself and to empty the sample chamber once the collector assembly is delivered to the laboratory for analysis. Of course, the guide forming the present invention can discharge into a flask or other container rather than a collector assembly as exemplarily illustrated herein.

In other embodiments of the invention, the outer compound or perineal surfaces and registering cone are variously shaped to accommodate females having a wide spectrum of shapes and varied size genitalia. In addition, certain of the alternative embodiments disclose rubber or plastic inserts of selected dimensions and shapes which fit into the front or outer end of the urethra orifice and act, in some cases, to more effectively seal off the urethra from the vaginal tract so that an uncontaminated sample can be obtained.

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; and,

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

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Looking first to the first exemplary embodiment of the urinary guide formed in accordance with the present invention which is 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 made 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 lines 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 21*a*, between the member 16 and the convex portion 21, rests snugly against the perineum of a female user. The perineal contacting surface 21*a* area lies generally along transverse vertical plane *y-y* (FIG. 1).

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 13*a*, 14*a* 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 alternate 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 presterilized 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 promontory 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 1 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. It is well known that 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 alae (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 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 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 cystourethrocoles, 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 subpubic 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 genital 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 subpubic arch, this constriction adds to the stabilizing influence of the promontory 20 disposed between the pubic rami (immediately beneath the subpubic 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. 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.

The urine collecting apparatus shown *in situ* in FIG. 14 includes the urinary guide 10 of FIGS. 11—13 and the collector assembly 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 connected by a flexible tube or cylinder 61 to the collector assembly 63. 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 supply 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 entrapment 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 open 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. in the entrapment chamber 78 and 100 cc. in the sample chamber 64. If the initial 40 to 50 cc. 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 relatively uncontaminated sample can 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 is 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 suggested:

Inside diameter of overflow pipe 73 (or inlet tube 61)—three-eighths inch

Inside diameter of pipe 86—five-eighths inch

Outside diameter of tube 68—five-eighths inch

Y Z volume of urine $\approx$ 40 cc.

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 identical in that it is designed to provide means for entrapping or isolating the first 30 to 50 cc. 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 ever recontaminating the sample in the chamber with the wash urine in the entrapment chamber 109.

Of course, certain modifications in the exemplary collector assemblies can be made without departing from the basic concept of the invention. For example, a drain could be placed in the entrapment chamber of one or both of the collector assemblies so that they could be drained before a collector assembly is transported. Or, instead of using threaded caps such as 71 and 131, a thin membrane (not shown) could be provided adjacent the sample chambers to accommodate a hypodermic syringe which would be used to withdraw the urine sample for subsequent analysis. Or, a sliding cover (not shown) could be used. In addition, these devices could be provided with caps or sliding closures to close off the inlet tubes from the urinary guide and/or the overflow tubes.

Again, as in the case of the first exemplary embodiment of a collector assembly, dimensions for the second exemplary embodiment are not too critical. However, it is desirable to proportion certain of the passageways relative to one another. One appropriate set of dimensions is as follows:

Inside diameter of inlet tube 107 = seven-sixteenths inch
Inside diameter of passageway 117 = three-eighths inch

Inside diameter of outlet tube 127 = three-eighths inch

Inside diameter of vertical aperture 119 = one-sixteenth inch

From the foregoing description of this apparatus for obtaining urine samples from females, it can be appreciated that the general requirements for the invention described herein, irrespective of the size, age or condition of the female user, is a guide conforming to the vulva of the intended user. 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 satisfactorily to provide a urine sample relatively uncontaminated by labial and vaginal secretions. A laboratory will then be able to carry out diagnostic tests on the urine to determine 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 throw-away use if desired. It is, of course, possible to form the guides or collector assemblies out of materials which can be reesterilized after each use, but the inexpensiveness 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 voided urine specimen uncontaminated by labial and vaginal secretions adjacent to the external urethral meatus comprising, in combination, a urinary guide having a relatively nonpliable base with free edges and an outer compound surface adapted to bear against the external female genitalia; a relatively small urine passageway of a diameter approximating that of the urethra formed through said base; and means on said base including a generally centrally located, relatively nonpliable projecting member on said outer compound surface which is adapted to fit interior of the vagina to register said urine passageway and the urethra in a sealed relation so that labial and vaginal secretions are not entrained as urine is voided through said passageway.

2. Apparatus for obtaining from a female a voided urine specimen uncontaminated by labial and vaginal secretions adjacent to the external urethral meatus in accordance with claim 1 wherein said outer compound surface conforms generally to the contours of the external genitalia, and including wings on said base disposed laterally outward from said projecting member and adapted to depress the lips of the labia minora to move them laterally outward to provide unobstructed access to the urethral meatus and urethra when said urinary guide is being positioned adjacent the external genitalia.

3. Apparatus for obtaining from a female a voided urine specimen uncontaminated by labial and vaginal secretions adjacent to the external urethral meatus in accordance with claim 1 and including

a stabilizing section formed on that part of the base of the urinary guide which lies below said projecting member, said section being convexly rounded in the midline so that it fits into the gluteal crease and relatively flat at the outwardly disposed wings of said base to press laterally against the buttocks to minimize lateral deviation of the said passageway from the urethra meatus surrounding the urethra.

4. Apparatus for obtaining from a parous female a voided urine specimen uncontaminated by secretions adjacent to the external urethral meatus in accordance with claim 1 wherein a clitoral cleft is formed in the upper part of said base; the portion of the outer surface of the urinary guide which contact the external female genitalia and contribute to the registration of the urine passageway with the edges of the external urethral meatus include a promontory between the vaginal projecting member cone and said clitoral cleft through which the said urine passageway is formed;

said promontory being concave at its uppermost portion where it becomes flush with the plane of the base at the edge of said clitoral cleft thereby permitting further stabilization of the apparatus by application of the above said concavity of said promontory against the anterior and inferior border of the symphysis pubis and being depressed concavely laterally to become flush with the general plane of the base thereby to spread the lips of vagina adjacent the external urethral meatus as the guide is positioned for use so as to prevent the introduction of external secretions into the urine passageway of the guide or the urethra.

5. Apparatus for obtaining from a female a voided urine specimen uncontaminated by labial and vaginal secretions adjacent to the external urethral meatus in accordance with claim 1 wherein

said outer surface on said guide base is multiplanar and the part of the outer surface which registers the urine passageway with the urethra includes a raised promontory through which said passageway is formed, and other means associated with said base cooperate with the external genitalia to stabilize said urinary guide during use.

6. Apparatus for obtaining from a female a urine specimen uncontaminated by labial and vaginal secretions adjacent to the external urethral meatus in accordance with claim 5 and including

a clitoral cleft formed between the uppermost ends of outwardly disposed wings on said base to prevent the urinary guide from contacting the clitoris when being used, and wherein

the promontory tapers outwardly from the outer perineal contacting surface of the guide base so as to spread the tissue of the urethral meatus adjacent the urethra and

said other stabilizing means includes a concavity which is formed between the flat outermost surface of said promontory and said clitoral cleft and is adapted to fit between the pubic rami and against the inferior border of the symphysis.

7. Apparatus for obtaining from a female a urine specimen uncontaminated by labial and vaginal secretions adjacent to the external urethral meatus in accordance with claim 5 wherein

said other stabilizing means includes a convex section on said base below the urine passageway and said projecting member which rides in the gluteal crease, and said projecting member is a tapered cone.

8. Apparatus for obtaining from a female a voided urine specimen uncontaminated by labial and vaginal secretions adjacent to the external urethral meatus in accordance with claim 1 and including

an apertured insert removably supported at the outer end of the urine passageway through said base,

said insert formed to spread the urethral meatus and seal off the vagina and the major part of the urethral meatus from the urethra when the guide is being used.

9. Apparatus for obtaining from a female a voided urine specimen uncontaminated by secretions present adjacent to the external urethral meatus in accordance with claim 8 wherein said

apertured insert fits tightly into said urine passageway facing the urethral meatus and tapering gently toward its distal opening;

said insert formed to penetrate the outer urethra for a distance of approximately 1 centimeter so as to eliminate from the urine sample the collection of bacteria and pus cells normally found in healthy females in the distal 1 centimeter of the urethra to avoid extraurinary secretions being included in said urine sample.

10. Apparatus for obtaining from a female a voided urine specimen uncontaminated by labial and vaginal secretions adjacent to the external urethral meatus in accordance with claim 1 wherein

the outer surface of said base is a multiplanar, compound surface conforming generally to the female vulva, a clitoral cleft is formed in the upper edge of said base, and the rear of said base includes support means to assist in properly placing and retaining the guide against the female genitalia while a urine specimen is obtained.

11. Apparatus for obtaining from a female a voided urine specimen uncontaminated by labial and vaginal secretions adjacent to the external urethral meatus in accordance with claim 10 and including stabilizing means for said device in the form of a convex section below said projecting member which rides in the gluteal crease and presses against the buttocks.

12. A guide for obtaining a voided urine specimen substantially free from contamination by secretions adjacent to the external urethral meatus comprising, in combination,

a. a relatively nonpliable base having an outer multiplanar surface conforming generally to the vulva adapted to bear thereagainst;

b. surfaces on said base defining a promontory having a urinal orifice therethrough which is approximately the size of the urethra;

c. a relatively nonpliable tapered cone projecting outwardly from generally the central part of said multiplanar surface for insertion into the vagina of the user to assist in registering said orifice with the urethra; and,

d. rearwardly extending means associated with said base to facilitate holding the device in position during use.

13. A guide for obtaining a voided urine specimen substantially free from contamination by secretions adjacent to the external urethral meatus in accordance with claim 12 and including

stabilizing means associated with the upper part of said promontory and the part of said base below said cone to stabilize said guide between the pubic rami and interior of the gluteal crease.

14. A device for obtaining a voided urine specimen substantially uncontaminated by perineal secretions comprising, in combination,

a. a relatively nonpliable base having a front compound surface conforming generally to the female vulva;

b. said base having a notched center section to prevent the base from bearing against the clitoris when the device is placed against the vulva;

c. a promontory on said base having surfaces defining an orifice for the passage of urine therethrough;

d. a relatively nonpliable tapered guide cone projecting outwardly from said front compound surface for insertion into the vagina of the user to register said orifice with the urethra; and

e. means extending rearwardly from said base to conduct urine away from said device for collection into a culture tube or the like.

15. A device for obtaining a voided urine specimen substantially uncontaminated by perineal secretions in accordance with claim 14 and including

upwardly projecting portions of said base on each side of said notched center section to spread the labia minora of parous females to provide unobstructed access to the urethra meatus and

means on said device to facilitate holding said device in place during use.

16. An apparatus for obtaining a voided urine specimen essentially free from external contamination comprising, in combination,

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a urinary guide having a relatively nonpliable base with a multiplanar compound surface, complexly shaped to fit intimately and comfortably against the female perineum, subjacent pubic arch, gluteal crease and adjacent buttocks;
said base having an ovoid passageway formed therethrough;
a relatively nonpliable tapered cone projecting outwardly from the perineal contacting face of said multiplanar surface for insertion into the vagina of the female patient to register said passageway with the external urethral meatus; and,
means extending away from said perineal face to conduct

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urine from said guide for collection in a culture tube, collector assembly, or the like.

17. An apparatus for obtaining a voided urine specimen essentially free from external contamination in accordance with claim 16 wherein

the compound perineal face of said base has outer disposed wings and a promontory through which the ovoid urinary passageway is formed to spread the labia minora upon insertion of said guide to expose the external urethral meatus.

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