

[54] URINARY DEVICE

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[22] Filed: **Mar. 6, 1973**

[21] Appl. No.: **338,612**

**Related U.S. Application Data**

[63] Continuation of Ser. No. 98,624, Dec. 16, 1970, abandoned.

[52] U.S. Cl. .... **128/2 F, 4/110, 128/295**

[51] Int. Cl. .... **A61b 10/00, E03d 13/00**

[58] Field of Search... **128/2 F, 2 R, 294, 295, 270, 128/290; 4/110**

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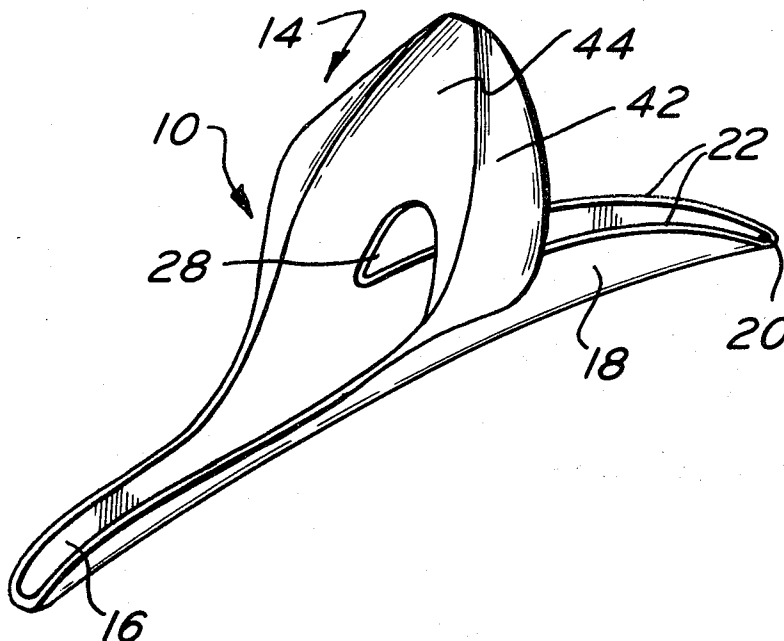
**FOREIGN PATENTS OR APPLICATIONS**

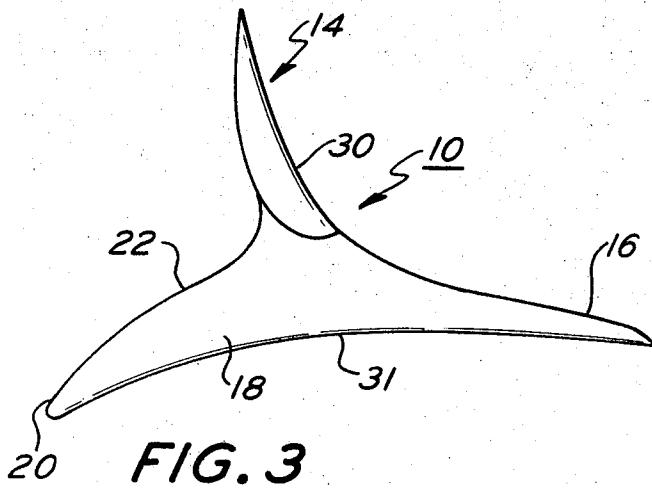
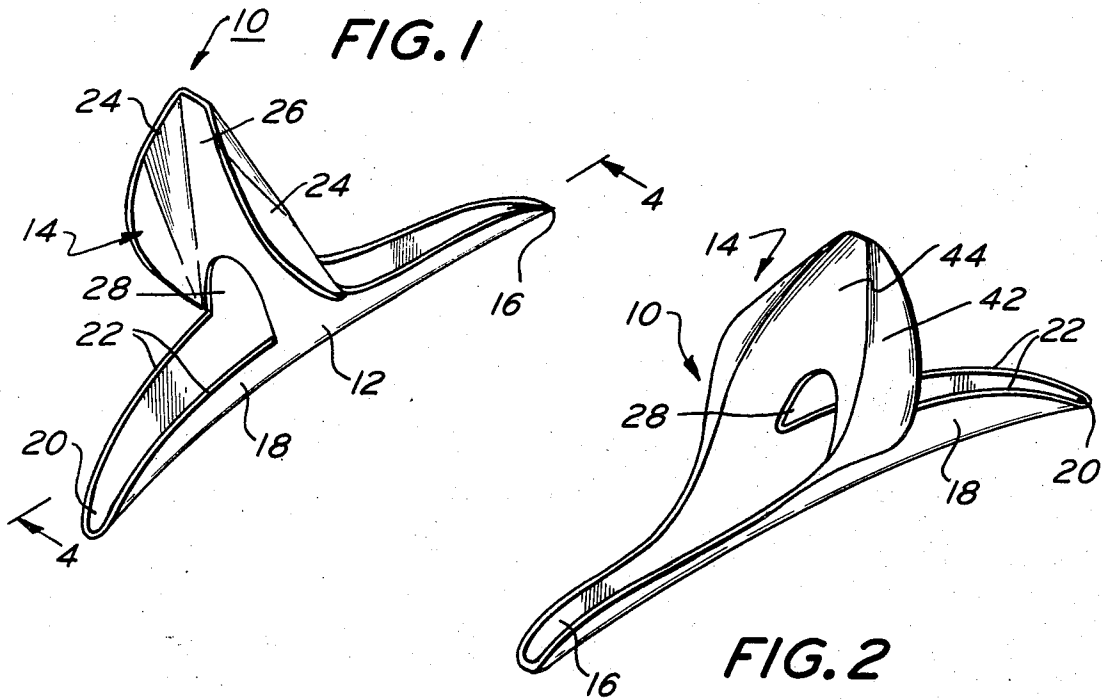
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[57] **ABSTRACT**

A urinary device to obtain a urine specimen from a female which is free of extraurethral contamination. The urinary device includes an extended trough member which is partially inserted into the vaginal passage and serves as a urine guide channel. A holding and placement member formed in one piece construction with the trough is positioned around the urethral meatus to direct urine flow into the urine guide channel. The device is geometrically molded to conform to the anatomy of the female when partially inserted into the vaginal passage and effectively separates as well as shields the structures around the urethral meatus while not imparting pressure on the urethra. A tampon may be attached to the trough to occlude the lower portion of the vagina without impinging on the urethral meatus.

**9 Claims, 9 Drawing Figures**





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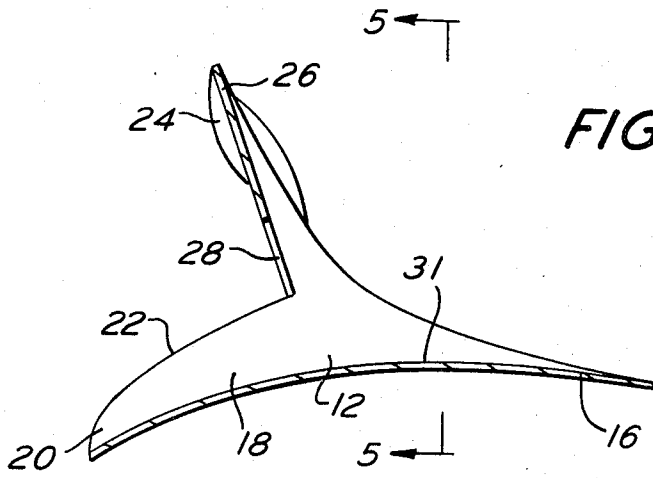


FIG. 4

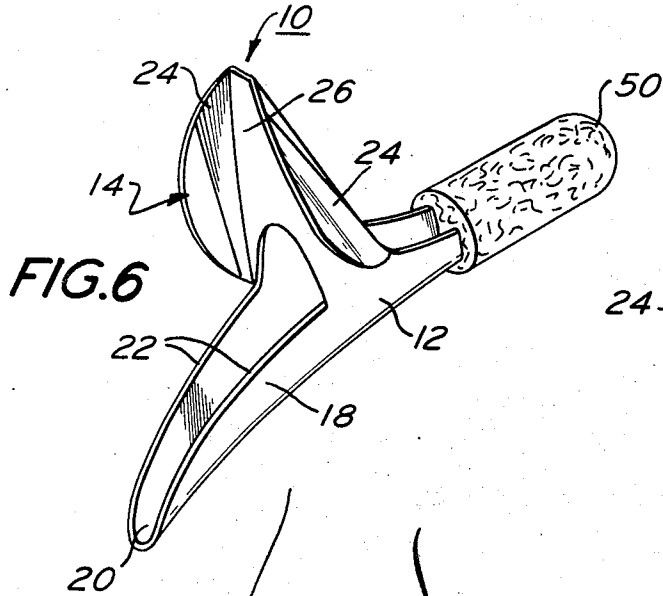


FIG. 6

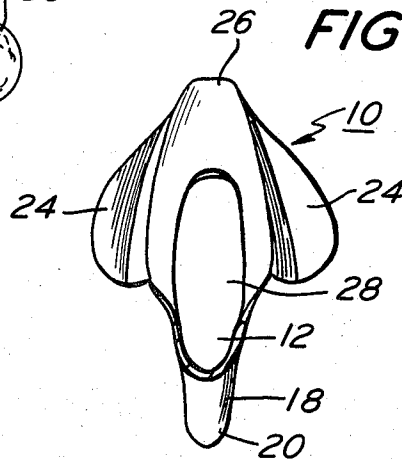


FIG. 5

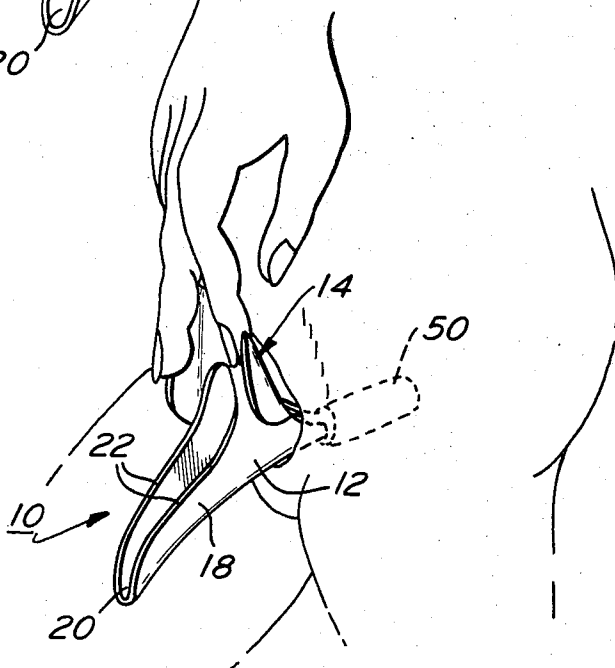


FIG. 7

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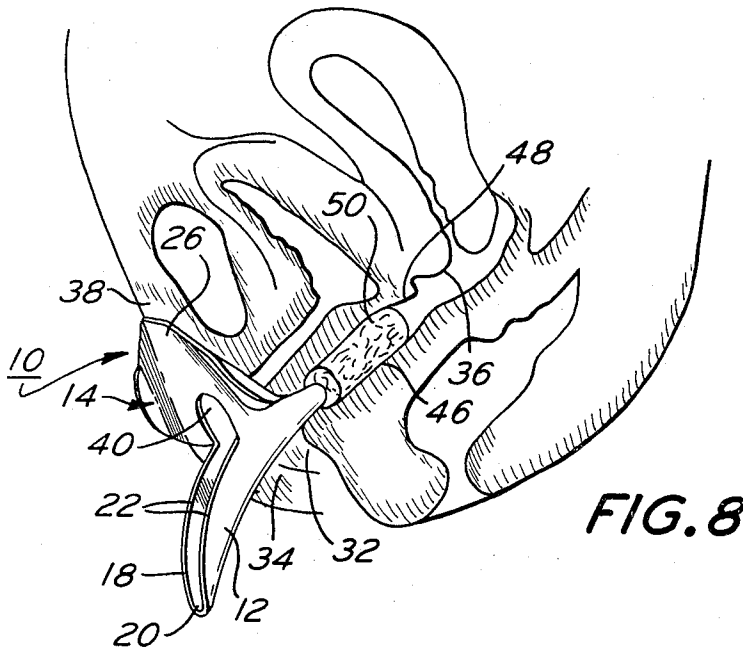


FIG. 8

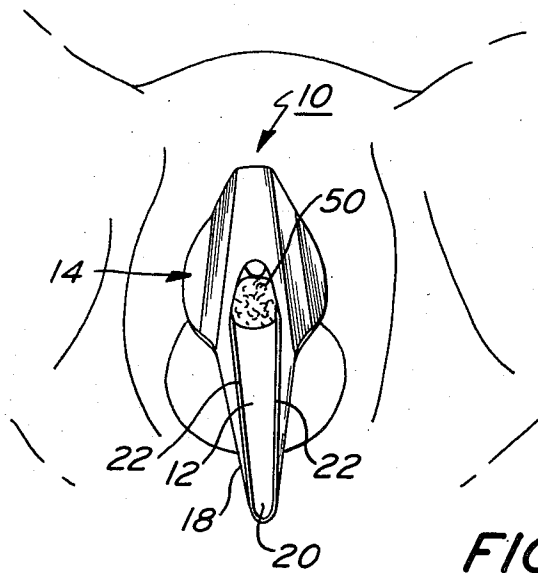


FIG. 9

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## URINARY DEVICE

This is a continuation, of application Ser. No. 98,624, filed Dec. 16, 1970, now abandoned.

## BACKGROUND OF THE INVENTION

## A. Field of the Invention

This invention relates to the field of collecting urine specimens. In particular, this invention pertains to the field of obtaining a clean urine specimen from a female utilizing a device structurally molded to separate and shield body elements around the urethral meatus.

## B. Prior Art

Urinary devices to collect urine specimens otherwise than by painful catheterizing or instrumentation of the bladder are known. Some of such devices have been placed external to the body. However, in this operation included within the urine specimen is a combination of extraurethral contamination such as blood or other vaginal discharge as well as contamination from the labia. In cases of bleeding, there is no practical way to differentiate the sources of blood as coming from the genital or urinary tracts. Additionally in the pregnant female, amniotic secretions must be differentiated. Thus, in known devices placed external to the body, the fluid specimen may be a combination of contaminants and provide uncertainty as to the point of origin.

While internally placed devices are known, they do not conform geometrically with the female anatomy. Vaginal discharge in these devices still is not totally obstructed and they place a stress on the urethra or pressure on the urethral meatus which causes difficulty in voiding. Further, a clean urine specimen is still not obtained since these devices do not effectively separate or shield body elements around the urethral meatus.

## SUMMARY OF THE INVENTION

A urine collecting device to be manually held external to the female body adjacent to the urethral meatus for the purpose of obtaining clean urine samples. The device includes an elongated member having a longitudinal through passage for partial insertion into the vaginal passage. A holding and placement element separating the labia is formed on the elongated member. This element includes an opening positioned around the urethral meatus and directs the flow of urine into the elongated member.

The elongated member has a longitudinally directed open top trough with side edges and opposing first and second ends. The first end is adapted for partial insertion into the vaginal passage with the open top adapted to face the urethra. The holding and placement element is formed on the elongated member defining an arch above the trough having a bottom opening with the arch starting with the first end continuing along the trough side edges and sloping at an angle away from the first end. The holding and placement element includes a pair of wing members extending in a direction away from the arch. There is further provided a bottom opening of the arch joining the open top of the trough to form a combined opening adapted to be substantially larger in area than and to substantially surround the urethral meatus with the meatus lying freely in the combined opening with no compressive force thereon when the holding and placement element is manually pulled up into position.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a perspective view of the urinary device;

FIG. 2 is a perspective view of the urinary device opposite to the view shown in FIG. 1;

FIG. 3 is an elevational view of the urinary device;

FIG. 4 is a cross-sectional view of the device shown in FIG. 1 taken along the section line 4-4;

FIG. 5 is a cross-sectional view of the device shown in FIG. 4 taken along the section line 5-5;

FIG. 6 is a perspective view of the embodiment of the invention including an attached tampon;

FIG. 7 is a perspective view of the device being manually inserted into a female body;

FIG. 8 is a perspective view of the urinary device inserted within the vaginal passage showing surrounding internal body structure; and,

FIG. 9 is a front view of the device inserted within the vaginal passage.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. 1-3, there is shown a urine collecting device or urinary apparatus 10 to obtain a urine specimen from the urethra which is relatively free of extraurethral contamination. Device 10 comprises a longitudinally directed trough 12 formed to serve both as a urine guide channel and an internally positioned placement member. Holding and placement member 14 extending from and formed in one piece construction with trough 12 provides particular body structure placement to insure a clean urine specimen without the use of a catheter or instrumentation of the bladder. Construction of device 10 may be made of molded plastic, plastic coated paper, or other material which is chemically inactive with the surrounding environment when in use.

Trough 12 extends in a longitudinal direction and includes a first end 16 adapted for insertion into vaginal passage 36 as shown in FIG. 8. Second end 18 directed to the frontal portion of device 10 terminates in a spout 20 from which the urine specimen passes into a container for appropriate analysis. First or rear end 16 and second or frontal end 18 longitudinally interface in a continuous manner having a common boundary with holding and placement member 14. As is shown, a continuous urine guide channel is formed having vertically displaced opposing walls 22 throughout the longitudinally extended second end 18. Trough 12 although longitudinally directed, includes vaginal-perineal curvature 31 directed in a vertical manner as shown in FIG. 3. Curvature 31 extends between first end 16 and second end 18 at the base of opposing walls 22 and conforms to the anatomy of posterior vaginal wall 46 and the perineum as shown in FIG. 8. Discussion of curvature 31 in conjunction with proper placement of device 10 will be detailed in the following paragraphs.

Member 14 extends vertically from trough 12 and lies in a plane substantially perpendicular to the longitudinally directed axis of trough 12 but inclined at an acute angle to frontal end 18 to conform with the anatomy of the public region. Member 14 comprises arch element 26 formed on trough 12 on opposing side walls 22 at the continuous interface between first and second ends 16 and 18. Device opening 28 passing longitudinally through arch 26 surrounds the urethral meatus to

permit flow of urine through opening 28 into second end 18 of trough 12.

Pubic-vaginal curvature 30, shown in FIG. 3, is directed toward second end 18 of trough 12. Curvature 30 is continuous throughout the extended length of member 14 in the vertical direction and continues at the interface of member 14 and rear end 16. In this manner, opposing side walls 22 extending in a rearward direction along rear end 16 continually decrease in vertical extension as a function of longitudinal distance displacement from member 14. The combination of decreasing vertically extended side walls 22 on trough 22 and the form of member 14 provides a curvature 30 which conforms to the anatomy of the pubic region between the labia minora 32 and the anterior vaginal wall 48. This area covers the clitoris 38 and spreads the labia minora 32 on the surface adjacent to the body as shown in FIG. 8. When device 10 is internally placed, arch 26 is positioned adjacent to the urethral meatus 40 to permit free flow of urine through opening 28.

Wing members 24 formed on opposing vertically directed sides of arch 26 extend in a transverse direction to the substantially vertical plane of member 14. Wings 24 separate the labia minora 32 and labia majora 34 to prevent contact with the urine specimen when device 10 is in operating placement. Wing curvature 42 substantially directed toward frontal end 18 extends in the substantially vertical plane of wings 24 throughout the arch 26 length. Curvature 42 provides a contact interface between wings 24 and the labia minora and majora 32, 34 to provide transverse displacement of these body elements in an opposing manner away from the urethral meatus 40.

The segment of member 14 between wings 24 and directed above opening 28 includes an arch curvature 44 in a direction facing second end 18 forming a depression in the plane of member 14. Curvature 44 is a concave from one of the wings 24 to the other of the wings 24 and is designed to conform with the anatomy of the symphysis pubis above the pubic arch. This area includes the region of the symphysis pubis above the urethral meatus 40 and spreads the labia minora 32 laterally.

In general, separation of the area of the urethral opening from surrounding body structures to prevent contamination of a urine specimen is accomplished by two triangular areas defined by the construction geometry of device 10. One triangular area is formed by the junction of public-vaginal curvature 30 and the Vaginal-perineal curvature 31 as shown in FIG. 3. This triangular portion separates the anterior and posterior vaginal walls 48, 46 to permit the urethral opening to fit within opening 28 of member 14. Due to the obtuse angle formed at the intersection lines between curvatures 30 and 31, manual pressure on wings 24, shown in FIG. 7, force rear end 16 to exert a vertically directed downward force on posterior vaginal wall 46 and elevates second end 18 thereby allowing the urethral opening to lie freely in opening 28 since there is no compressive force directed on the urethra.

The second triangular area is most clearly shown in FIG. 1 and 2 which defines the area defined by wings 24 adjacent to arch 26 of member 14. This second cross-sectional triangular area separates the labia 34 in a lateral or transverse direction. Displacement of the labia in this manner provides an obstruction free flow path of the urine sample from the urethral opening into frontal end 18 of trough 12.

In operation, as shown in FIGS. 7, 8 and 9, device 10 is partially inserted internal to the body with rear end 16 extending into the vaginal passage 36. Insertion continues until arch 26 and opening 28 contact interface with the urethral opening. The patient then holds device 10 in the proper position with the index and middle fingers of one hand as shown. The combination pubic-vaginal curvature 30 and vaginal-perineal curvature 31 of trough 12 separates the anterior vaginal wall 48 and posterior vaginal wall 46. Concurrently, wings 24 in the manner previously described separate the labia transversely. Urine passing from the urethral opening through opening 28 impinges on frontal end 18 of trough 12 and is carried within the urine guide channel to spout 20. The patient may void in either a sitting or standing position and collect the urine specimen in a suitable container which may be held in the other hand.

An embodiment of the invention is shown in FIG. 6 where tampon 50 is inserted on rear end 16. Tampon 50, generally cylindrical in shape, may be formed of some generally absorbant spongy material such as cotton or the like to absorb heavy vaginal discharge or blood when there is great likelihood of contamination by blood, discharge or when the patient is menstruating. Tampon 50 may be secured internal to opposing side walls 22 of first end 16 or first end 16 may be inserted longitudinally within tampon 50 to provide a removeably secured fitting. Insertion of device 10 in combination with tampon 50 into vaginal passage 36 as shown in FIG. 8 and as previously described increases the diameter of passage 36 to allow a releasably secured blocking action for any discharge and to absorb such thereby preventing any contamination of the urine specimen being taken.

Device 10, with the exception of spout 20 and adjacent areas is molded to conform with the anatomy of the body without impinging upon the urethral meatus 40. No seal is formed around urethral meatus 40 in operation but rather the structures around the urethral meatus 40 are separated thus permitting the urethral opening to lie freely in opening 28. Longitudinally directed upward pressure by the patient's fingers on opposing wings 24 act as a lever to depress the vaginal portion thus lifting opening 28 of device 10 around the urethral meatus 40 without causing pressure on the urethra. Lack of pressure on the urethra or around the urethral meatus 40 eases the task of voiding for the patient. Addition of tampon 50 is made in the presence of heavy vaginal discharge or bleeding to absorb the extraneous material and maintain a relatively clean urine specimen. It will be understood that arch 26 slopes at an acute angle with respect to trough 12 towards the second or frontal end 18. Arch 26 has a maximum transverse dimension substantially similar in value to the maximum transverse dimension of trough 12.

What is claimed is:

1. A urine collecting device for a human female adapted to be manually held adjacent the urethral meatus for obtaining a voided urine specimen comprising:

an elongated member having a longitudinally directed open top trough with side edges and opposing first and second ends, said first end adapted for partial insertion into the vaginal passage with said open top adapted to face the urethra, holding and placement means formed on said elongated member defining an arch above said trough

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having a bottom opening with said arch starting from said first end continuing along the trough side edges and sloping at an angle away from said first end, said holding and placement means includes a pair of wing members extending in a direction away from said arch, and

said bottom opening of said arch joining said open top of said trough to form a combined opening adapted to be substantially larger in area than and to substantially surround the urethral meatus with the meatus lying freely in said combined opening with no compressive force thereon when the holding and placement means is manually pulled up into position.

2. The urine collecting device of claim 1 in which said arch is concave from one wing member to the other wing member and adapted to conform to the symphysis pubis.

3. The urine collecting device of claim 1 in which said arch slopes at an acute angle with respect to said trough toward said second end.

4. The urine collecting device of claim 1 in which said holding and placement means is formed with said elongated member in a one piece construction.

5. The urine collecting device of claim 1 in which said arch is of a size and configuration adapted to par-

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tially fit within the vagina and adapted to separate the anterior and posterior vaginal surfaces when said combined opening is positioned to substantially surround said urethral meatus.

6. The urine collecting device as recited in claim 1 wherein the bottom of said trough has a curvature over its length adapted to substantially conform to the anatomy of the posterior vaginal wall and perineum.

7. The urine collecting device as recited in claim 1 wherein said holding and placement means and continuing along said trough side edges to said first end is formed having a predetermined curvature adapted for substantially conforming to the anatomy of the pubic region between the labia minora and anterior vaginal wall.

8. The urine collecting device as recited in claim 1 including a tampon secured to said first end of said trough.

9. The urine collecting device as recited in claim 1 in which said arch has a maximum transverse dimension substantially similar in value to the maximum transverse dimension of said trough.

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