

[54] EXPANDABLE TAMPON INSERTER
HAVING A CONSTRAINING RING

3,297,031 1/1967 Bray..... 128/264

[75] Inventors: Charles Reay Hood, Cincinnati;
Bernard Allen Dulle, Montgomery,
both of Ohio

FOREIGN PATENTS OR APPLICATIONS

547,305 8/1942 Great Britain..... 128/263

[73] Assignee: The Proctor & Gamble Company,
Cincinnati, Ohio

Primary Examiner—Richard A. Gaudet

Assistant Examiner—Henry J. Recla

Attorney—Richard C. Witte et al.

[22] Filed: Dec. 17, 1971

[21] Appl. No.: 209,273

[57] ABSTRACT

[52] U.S. Cl. 128/263

[51] Int. Cl. A61m 31/00

[58] Field of Search..... 128/263, 264, 285;
3/53

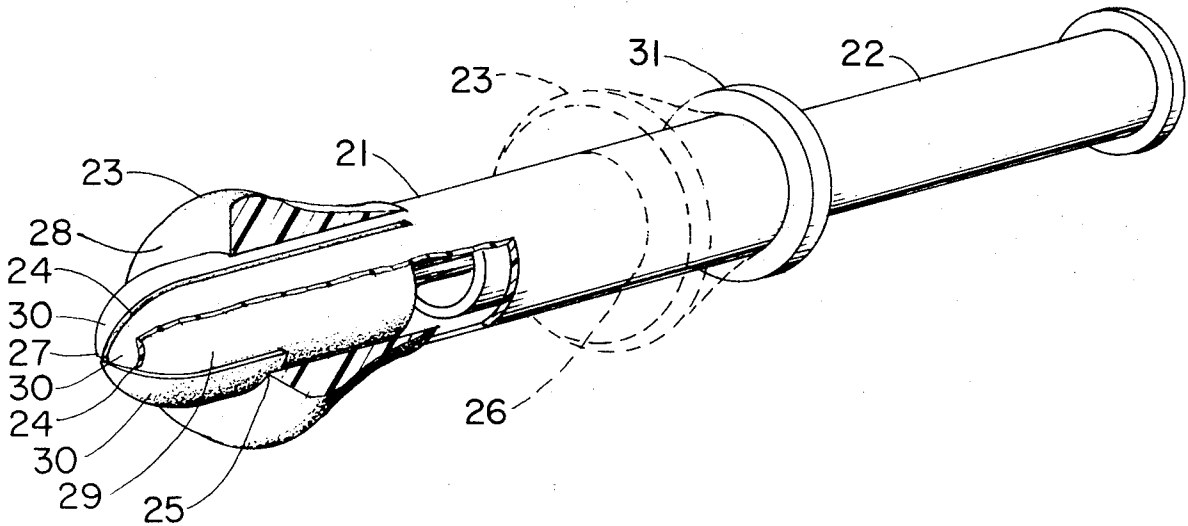
A tampon inserter having one end expandable when subjected to pressure on its interior surface and an externally mounted, moveable member which in a first position constrains such expansion and in a second position allows the one end of the inserter to expand or move outwardly. The expansion relieves the force between the interior wall of the inserter and exterior surface of the tampon, thus lowering the frictional force between the inserter wall and the tampon.

[56] References Cited

UNITED STATES PATENTS

3,204,635 9/1965 Voss et al. 128/263

7 Claims, 7 Drawing Figures



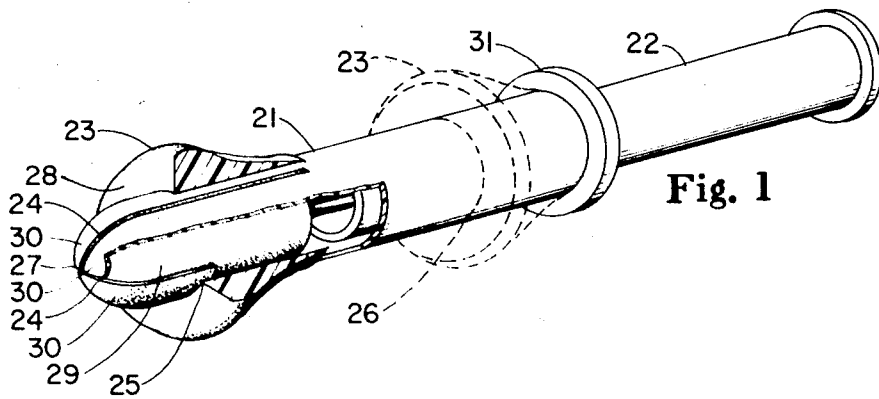


Fig. 1

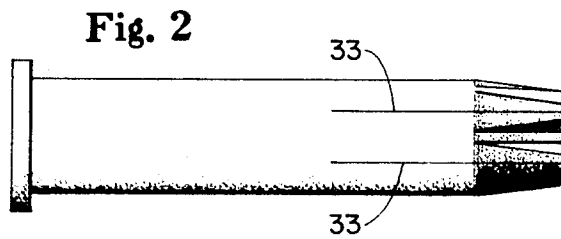


Fig. 2



Fig. 3

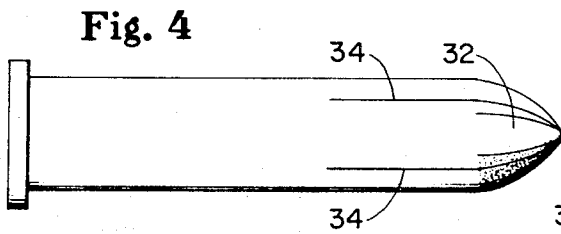


Fig. 4

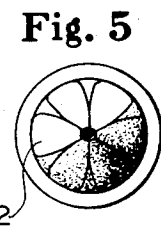


Fig. 5

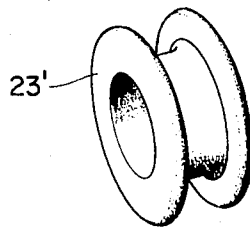


Fig. 6

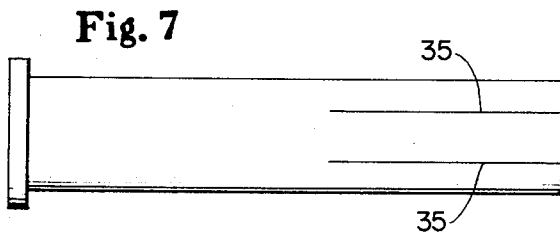


Fig. 7

EXPANDABLE TAMPON INSERTER HAVING A CONSTRAINING RING

FIELD OF THE INVENTION

This invention relates generally to inserters for tampons and more particularly concerns inserters wherein one end is radially expandable to reduce the frictional force between the inserter and a tampon held there-within, thereby providing easier ejection of the tampon from the inserter.

DESCRIPTION OF THE PRIOR ART

In the field of tampon inserters, there have been numerous attempts to reduce the force required to eject a tampon from the inserter. The problem of high ejection forces is especially troublesome when inserting a resiliently compressed tampon having a normal cross section larger than the cross section of the inserter. The ejection force required is at least to some substantial extent dependent on the force necessary to overcome the frictional force between the exterior surface of the tampon and the interior surface of the inserter, which is a function of the coefficient of friction between the inserter and the tampon and the force exerted by the tampon on the interior of the inserter.

One line of endeavor which has been pursued to reduce the ejection force is to highly compress the tampon so that it takes a compressive set and thereby exerts little or no force on the interior of the inserter. Then the tampon does not tend to spread an expandable portion of the inserter prior to insertion. Inserters having an expandable portion and containing therein a compressed tampon are taught in the following U.S. Pat. No. 2,733,714, issued to E. C. Haas on Feb. 7, 1956; 3,204,635, issued to J. A. Voss et al. on Sept. 7, 1965; U.S. Pat. No. 3,347,234, issued to J. A. Voss on Oct. 17, 1967; and U.S. Pat. No. 3,433,225, issued to J. A. Voss et al. on Mar. 18, 1969.

Another approach taken to the problem of the high ejection forces, particularly directed toward inserting resilient tampons, is taught in the following U.S. Pat. Nos. 61,417, issued to W. G. Grant on Jan. 22, 1867; 1,969,671, issued to A. Nelson on Aug. 7, 1934; and 2,884,925, issued to M. J. Meynier, Jr. on May 5, 1959 wherein the expandable portion of the inserter is prevented from expanding during insertion but is expanded or allowed to expand after insertion. While each of these approaches have met with some success, there has been a continuing search for an inserter which provides, especially for a resiliently compressed tampon, a low ejection force, and one-step insertion and placement of the tampon without requiring steps before or after the insertion, in conjunction with an inserter which is simple, reliable, easy to use, and economical enough to be disposed of after use.

OBJECTS OF THE INVENTION

It is an object of this invention to provide an inserter wherein the ejection force required to remove a resiliently compressed tampon from within the inserter is reduced. It is an additional object of this invention to provide an inserter having an expandable portion which is positively constrained from expanding until the inserter is put into the body opening. Also, it is an object of this invention to provide an inserter wherein the means constraining the expandable portion of the inserter is reliably and easily removed during insertion.

It is a further object of this invention to provide an inserter having an expandable portion, said inserter being economical so it can be displaced of after one use.

SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided a tampon inserter comprised of a sleeve for holding a resilient, elastic, dry expanding tampon in a resiliently compressed condition, the sleeve having a radially expandable portion adjacent its proximal end, and the expandable portion being expandable by outwardly directed forces acting on the sleeve's interior surface; ejection means operatively associated with the sleeve and bearing on a tampon within the sleeve; and constraining means operatively associated with the sleeve and being slideably moveable between a first position on the sleeve whereat radial expansion of the expandable portion is prevented and a second position on the sleeve whereat the expandable portion is free to radially expand. The constraining means is intended to prevent expansion of the expandable portion until insertion of the sleeve into a vagina is started.

BRIEF DESCRIPTION OF THE DRAWINGS

While the specification concludes with the claims particularly pointing out and distinctly claiming the subject matter which is regarded as forming the present invention, it is believed that the invention will be better understood from the following description taken in connection with the accompanying drawing, in which the thickness of some of the materials is exaggerated for clarity and in which:

FIG. 1 is a fragmentary perspective view of a preferred embodiment of the inserter of this invention having a tampon resiliently compressed within its expandable end;

FIG. 2 is a side view of a sleeve having an alternative embodiment of the expandable portion of the sleeve;

FIG. 3 is a front view of the alternative embodiment shown in FIG. 2;

FIG. 4 is a side view of a sleeve showing another alternative embodiment of the expandable portion of the sleeve;

FIG. 5 is a front view of the alternative embodiment shown in FIG. 4;

FIG. 6 is a perspective view of an alternative embodiment of a constraining means; and

FIG. 7 is a side view of a sleeve showing an open proximal end configuration.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1 there is shown an inserter of this invention having a sleeve 21, a telescoping tube ejector 22 as the ejection means, an annular member 23 as the constraining means, and a resiliently compressed tampon 29 within the sleeve 21. The tampon 29 is resiliently compressed by forcing it into the sleeve 21 either by hand or with a machine (not illustrated). As used herein resiliently compressed is intended to mean compressed to a degree where permanent set, i.e., cold flow to or a bonding in a compressed configuration, has not occurred. A resiliently compressed tampon will return to its unrestrained shape after being released, although the passage of time or a moderate flexing of the resiliently compressed tampon may be required to return the tampon to its uncompressed form. A resiliently compressed tampon is dry expanding in that it expands

from its resiliently compressed configuration without relying on the actions of fluids to release compression set which may have taken place within the tampon due to compressing it.

The sleeve 21 can be formed similarly to the outer tube of a telescoping tube type inserter, such as are well known to those of ordinary skill in the inserter art. It can have an open proximal end 27 wherein the diameter of the sleeve is uniform out to the proximal end as is shown in FIG. 7, or it can have a closed, inwardly-tapering proximal end, some examples of which are shown in FIGS. 1, 2 and 4. In a sleeve such as is shown in FIG. 1 having a proximal end 27 which is closed by means of inwardly-tapering flexible panels or flaps 30 (hereinafter referred to as flaps), the expandable portion of the sleeve is adjacent the proximal end 27. The expandable portion is formed by providing slots 24 (or slits if so desired, but hereinafter referred to as slots) in the sleeve wall which extend from the proximal end 27 rearwardly for a substantial distance. The slots 24 can, but do not necessarily have to, lie on or be coincident with radial planes of the sleeve 21. A flap in the preferred embodiment is the portion of the sleeve between two adjacent slots 24 in the expandable portion of sleeve 21. A substantial distance is that distance required to permit ejection of the expandable tampon 29 from the sleeve with an ejection force of about 1,000 grams or less, preferably less than 500 grams, exerted on the inner tube 22. Lengthening the slots 24 provides a longer cantilever arm in each of the flaps 30 and permits easier flexure and radially outward movement of each flap 30, thus easier ejection of a tampon 29. The longer the cantilever arm, i.e., the distance from the distal end to the proximal end of a flap 30, the easier and greater will be the expansion of the proximal end of the sleeve for a given outwardly directed internal force. An expandable portion which will expand readily to reduce the ejection force should be at least $\frac{1}{2}$ inch long or extend toward the distal end a distance which is at least 25 percent of the length of the tampon restrained therein.

A sleeve which has been found to work well is about 3 inches long, has an inside diameter of about 0.640 inches, has an outside diameter of about 0.710 inches, has slots which are about 1.5 inches long, and is molded in polyethylene. But it is to be understood that the dimensions may be varied and the sleeve can be made from any of the other materials commonly known to those skilled in the art, for example, paper.

In the preferred embodiment, the sleeve 21 has a stop at its distal end, for example, such as the stop 31 as is shown in FIG. 1. The stop 31 is provided to prevent the annular member 23 from moving beyond the distal end of the sleeve 21.

The expandable portion of the sleeve 21 can also be formed such as is shown in FIGS. 2 and 3, i.e., by dovetailed infolding of the sleeve wall to reduce the diameter of the sleeve in the folded configuration and allow expansion to the original diameter when the folds are removed. In this embodiment, the folds can extend the entire distance of the expandable portion, or slots such as 33 can be incorporated to extend the expandable portion beyond the folds. Such dovetailed folding could also be used in a sleeve wherein the diameter of the expandable portion is originally larger than the diameter of the nonexpandable portion and the dovetailed folding reduces the expandable portion to a diameter equal

to or less than the diameter of the non-expanding portion of the sleeve (not illustrated). Another structure providing an expandable portion of the sleeve is shown in FIGS. 4 and 5 wherein slots 34 are cut into the sleeve wall to form flaps 32. These flaps 32 are then folded together to form a reduced cross section in the end of the sleeve by inwardly tapering the flaps 32 and superposing the edges of some flaps 32 over the edges of adjacent flaps as shown in FIGS. 4 and 5. Slots such as 34 can be incorporated to extend the expandable portion beyond the end closing mechanism. Again, the expandable portion diameter could be originally larger than the nonexpandable portion diameter and reduced to a diameter the same as or smaller than the nonexpandable portion diameter.

An open-end sleeve is shown in FIG. 7 wherein the expandable portion is formed by cutting slots 35 in the wall of the sleeve. There are, of course, many other structures which will provide an expandable portion for a sleeve.

The annular member 23 can be of various shapes and designs, one of which is a teardrop shape as is shown in FIG. 1 and another is a spool shape member 23' such as is shown in FIG. 6. A preferred embodiment is the teardrop shape as is shown in FIG. 1. The annular member encompassing the sleeve 21 in the expandable portion provides a constraining means which prevents the expandable portion from increasing in diameter when there is a resiliently compressed tampon held therein. The annular member preferably has an inside diameter which closely fits the exterior diameter of the nonexpanding portion of the sleeve 21.

The annular member 23 is shown in solid outline in its first position 25 whereat it constrains the expandable portion of the sleeve 21 to a comfortably insertable size. A comfortably insertable size is generally considered to be less than about 0.75 inches in diameter. Larger diameters require excessive dilation of the vaginal introitus. The annular member 23 is slideable along the sleeve to its second position 26, as shown in FIG. 1 by the dotted outline whereat it does not constrain the expandable portion and thus the walls of the sleeve in the expandable portion can move outwardly, relieving the force of the sleeve 21 on the resiliently compressed tampon 29, lowering the frictional force between the sleeve and the tampon.

The coefficient of friction between the annular member 23 and the exterior surface of the sleeve 21 should be low enough so the annular member 23 can be moved from its first position 25 to its second position 26 during insertion with a force of less than about 1,000 grams, and preferably with a force of less than about 500 grams. This force should be the maximum force required with a resiliently compressed tampon positioned within the expandable portion of the sleeve 21. It has been found that insertion and ejection forces greater than about 1000 grams are unacceptable to inserter users.

An annular member which has worked well with the sleeve as above described is about 1 inch long, has an O.D. of about 1.12 inches, an I.D. of about 0.720 inches, and is made from polyethylene.

The preferred embodiment of the annular member 23 should have a proximal end 28, i.e., that end which contacts the labia minora or hymenial area during insertion, which is substantially perpendicular to the longitudinal axis thereof and of sufficient area to provide

a bearing surface on the proximal end 28 of the annular member 23. This bearing surface is provided to prevent penetration of the annular member beyond the introitus and into the vagina during insertion. The bearing surface on the proximal end 28 of the annular member 23 should be of such a shape and area that the annular member 23 moves from its first position 25 to its second position 26 without penetrating the vagina during insertion. It has been discovered that the proximal end 28 of the annular member 23 should be at least about 1/8 inch larger on a radius than the unexpanded diameter of the sleeve 21 underlying the proximal end 28 of the annular member 23 and this larger diameter should cover at least about 1/8 of the circumference, preferably 1/6 at each termini of a diameter, to prevent the annular member 23 from penetrating the vagina. An annular member of the aforementioned dimension provides an acceptable bearing surface on the proximal end 28 of the annular member 23.

As shown in the preferred embodiment, the stop 31 determines the second position 26 of the annular member 23 and controls the depth to which a tampon is inserted by controlling the length of inserter beyond the proximal end 28 of annular member 23.

To establish the first position 25 of the annular member 23, it has also been found preferable, although not absolutely necessary, to displace the bearing surface on the proximal end 28 of the annular member 23 rearwardly from the proximal end 27 of the sleeve 21, as is shown in FIG. 1. This displacement provides a pilot probe, i.e., the portion of the sleeve 21 in front of the proximal end 28 of the annular member 23, for locating the introitus during insertion. The minimum displacement to provide an effective probe is about 1/4 inch, and preferably about 1/2 inch.

It is also preferable to make the annular member 23 long enough so that in its first position 25 it covers and exerts a constraining force on a substantial part of the expandable portion of the sleeve 21, e.g., with a sleeve wall thickness of about 0.025 inch as in the above described sleeve, it is preferable that no more than about 1/2 inch of the expandable portion be exposed unconstrained distally from the annular member 23. The length of expandable portion which can be permitted to be unconstrained distally from the annular member varies with and depends upon the "beam strength" of the flaps in the unconstrained area. Covering and exerting the constraining force is especially important if the sleeve is weak enough that a resiliently compacted tampon therewithin will cause a bulge, i.e., radial expansion, in any part of the expandable portion rearward from the first position 25 which is not overlaid by a part of the annular member 23. A bulge behind the annular member 23 will increase the force required to move it to its second position 26 and therefore bulges are to be avoided. The annular member 23 of the above dimensions in combination with the sleeve 21 as above described is satisfactory to prevent bulges.

The tampon 29 is any tampon which exerts an outwardly directed radial force on the sleeve 21 and in particular the resiliently compressed dry expanding tampons, e.g., one as taught in the co-pending, commonly owned, U.S. patent application entitled Compliant Comfortable Tampon, by Bernard A. Dulle, filed Aug. 18, 1971, Ser. No. 172,694. That co-pending application teaches a generally conically shaped tampon having a polyurethane foam absorbent body which has

a dry material modulus of compression of about 0.4 pounds per square inch. The tampon is hollowed out, has a height of about 2.25 inches, and a base diameter of about 2.25 inches. Said application is incorporated herein by reference.

The inserter of this invention provides benefits, as mentioned above, whether the sleeve 21 is of the open or closed proximal end configuration. But, the fullest advantages of the inserter of this invention are realized when the sleeve 21 is of the closed end design because in that design the ejection force must be sufficient to open up the closed end during ejection in addition to overcoming the static frictional forces between the tampon and the inside wall of the sleeve 21. Making any flap such as 30 weaker, so it can be flexed open easier, greatly reduces the ejection force required to remove the tampon 29 from the sleeve 21. The flaps 30 are appreciably weakened by lengthening the slot 24 in that the cantilever arm is lengthened as above described. Thus, the annular member 23 in its first position 25, i.e., covering at least some of the expandable portion of the sleeve 21, adds strength and rigidity to the flaps 30 and prevents them from expanding until the annular member 23 is moved to its second position 26 whereby the expandable portion of the sleeve 21 is completely uncovered and the flaps are free to expand radially outwardly.

The inserter of this invention may be used in several ways. One way is to hold the inserter between the thumb and middle finger on opposite sides of the distal end of the innertube 22 and spread the labia with the other hand. The user then pushes the proximal end 27 of the sleeve 21 into the vagina. The sleeve progresses into the vagina and the proximal end 28 of the annular member 23, the bearing surface, eventually contacts the labia or the hymenial area, at which time the annular member 23 slides rearwardly along the sleeve 21 to the second position 26 as determined by the stop 31. The inserting pressure is continued and forces the innertube 22 through the sleeve 21, thereby ejecting the tampon 29 through the proximal end 27 of the sleeve 21.

Another method of using this inserter is to grasp the annular member 23 with the thumb and middle finger on opposite sides of the annular member 23 and place the index finger at the distal end of the inner tube 22. The labia are spread with the other hand and the inserter is pushed into the body while simultaneously pulling the annular member 23 toward the distal end of the sleeve 21 to its second position 26, and then ejecting the tampon 29 from the sleeve 21 by pushing on the distal end of the inner tube 22 with the middle finger.

Also this inserter can be used by gripping the distal end of the sleeve 21 between the thumb and middle finger, spreading the labia with the other hand, pushing the proximal end 27 into the vagina with the labia or hymenial area pushing the annular member 23 rearwardly to its second position 26. Then the index finger is placed on the distal end of the inner tube 22 and the inner tube 22 is pushed by the index finger to eject the tampon 29 from the proximal end 27 of the sleeve 21.

Thus it is apparent that there has been provided in accordance with the invention, an inserter that fully satisfies the objects, aims, and advantages set forth above. While the invention has been described in conjunction with the specific embodiments thereof, it is evident that many alternatives, modifications, and varia-

tions will be apparent to those skilled in the art in light of the foregoing description. Accordingly, it is intended to embrace all such alternatives, modifications, and variations as follows in the spirit and broad scope of the appended claims.

What is claimed is:

1. A tampon inserter comprising:

a. a sleeve, the sleeve having a radially expandable portion, the expandable portion being adjacent the proximal end of the sleeve, said expandable portion being expandable by outwardly directed forces acting on the interior surface of said sleeve;

b. ejection means operatively associated with said sleeve to eject a tampon contained within the sleeve; and

c. a constraining member coaxially disposed with and being exterior of said sleeve, said member having minimal frictional engagement with the unexpanded outside diameter of the expandable portion whereby a free sliding fit is provided between the inside diameter of the member and the outside diameter of the unexpanded expandable portion;

d. the member being positioned in a first position, said first position being over the expandable portion of the sleeve, and the member being moveable between the first position and a second position adjacent the distal end of said sleeve, whereby said expandable portion is constrained to a comfortably insertable size with the constraining means in the first position and the ejection force required to eject a resiliently compressed tampon is reduced with the constraining means in the second position

e. stop means at said distal end;

f. said member having a labia bearing surface disposed toward the proximal end of the sleeve, at least 1/2 of the outside periphery of said labia bearing surface being at least about 1/8 inch larger, on a radius, than the unexpanded periphery of the expandable portion, whereby said labia bearing sur-

5

10

15

20

25

30

35

40

45

50

55

60

65

face is large enough to provide a bearing surface to prevent the said member from penetrating a vagina during insertion of the inserter thereinto.

2. The inserter of claim 1 wherein said sleeve has a plurality of slots through the sleeve wall, said slots extending longitudinally from the proximal end towards the other end, said slots forming flexible flaps on the proximal end of said sleeve, said flaps being radially moveable and forming said expandable portion.

3. The inserter of claim 1 wherein the stop means on the distal end of the sleeve is in the form of a ring having an outside diameter larger than the inside diameter of said member.

4. The inserter of claim 1 wherein the wherein the labia bearing surface is essentially perpendicular to the longitudinal axis of the member.

5. The inserter of claim 1 wherein the labia bearing surface is displaced rearwardly from the proximal end of the sleeve with the member in the first position, said displacement being to provide a pilot probe at the proximal end of the inserter to aid in starting the sleeve into the vagina.

6. A catamenial device comprising:

a. the inserter of claim 1, and

b. a tampon resiliently compressed within the sleeve, c. the tampon being positioned at least partially within the expandable portion of the sleeve,

d. whereby the resiliently compressed tampon tends to expand the expandable portion of the sleeve and the member in the first position prevents the expandable portion from expanding any appreciable amount.

7. The device of claim 6 wherein the inside diameter of the member is slightly larger than the outside diameter of the expandable portion in its unexpanded condition such that the member slides easily on the expandable portion.

* * * * *