United States Patent [19]

Johnson et al.

[11] **3,857,395**

[45] **Dec. 31, 1974**

[54] **CONFORMABLE ABSORBENT TAMPON AND INSERTER DEVICE THEREFOR**

[75] Inventors: **Russell L. Johnson,** Weyauwega; **Robert J. Peerenboom,** Little Chute; **Donald M. Fries,** Combined Locks; **Leonard M. Kaczmarzyk,** Neenah; **Arnold J. Buss,** Appleton, all of Wis.

[73] Assignee: **Kimberly-Clark Corporation,** Neenah, Wis.

[22] Filed: **Jan. 28, 1974**

[21] Appl. No.: **437,044**

[52] **U.S. Cl.** **128/263,** 128/242, 128/263, 128/285, 128/345

[51] **Int. Cl.** **A61f 15/00,** A61m 29/00

[58] **Field of Search** 128/263, 285, 303.11, 341, 128/345, 3, 17, 242, 243

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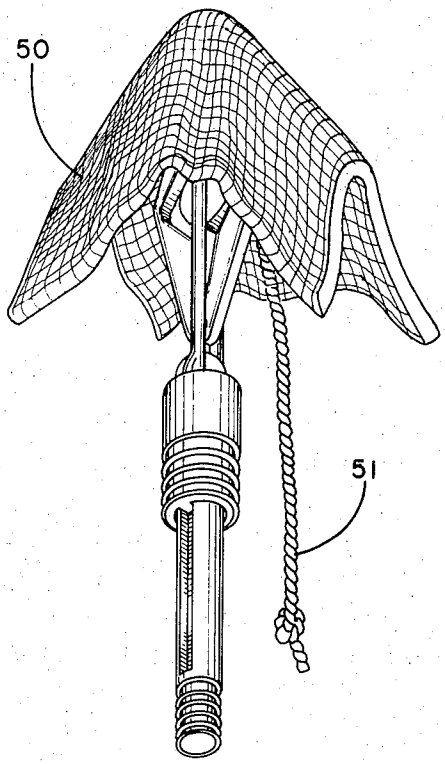
Primary Examiner—Aldrich F. Medbery
Attorney, Agent, or Firm—Daniel J. Hanlon, Jr.; William D. Herrick; Raymond J. Miller

[57] **ABSTRACT**

A conformable absorbent tampon in combination with a device adapted to insert the tampon into the vaginal tract as well as to bilaterally spread the tampon open within the vaginal cavity after insertion at the option of the user. The preferred tampon comprises a soft, thin conformable absorbent pad which is initially of planar configuration. The planar pad is draped at its approximate geometric centerpoint over the leading end of an elongate rod-like inserter device and in this position is inserted through the vaginal orifice. That portion of the inserter device which is disposed internally of the draped tampon preferably is provided with a hinged structure capable of bilaterally spreading the draped tampon within the vagina after insertion. During insertion the draped tampon is effective in wiping clean the lower vaginal canal. After insertion, the bilaterally spread tampon is immediately effective in intercepting vaginal fluids which flow along the walls of the vaginal cavity and which fluids otherwise tend to bypass prior art tampons not possessing positive bilateral deployment capabilities.

30 Claims, 27 Drawing Figures



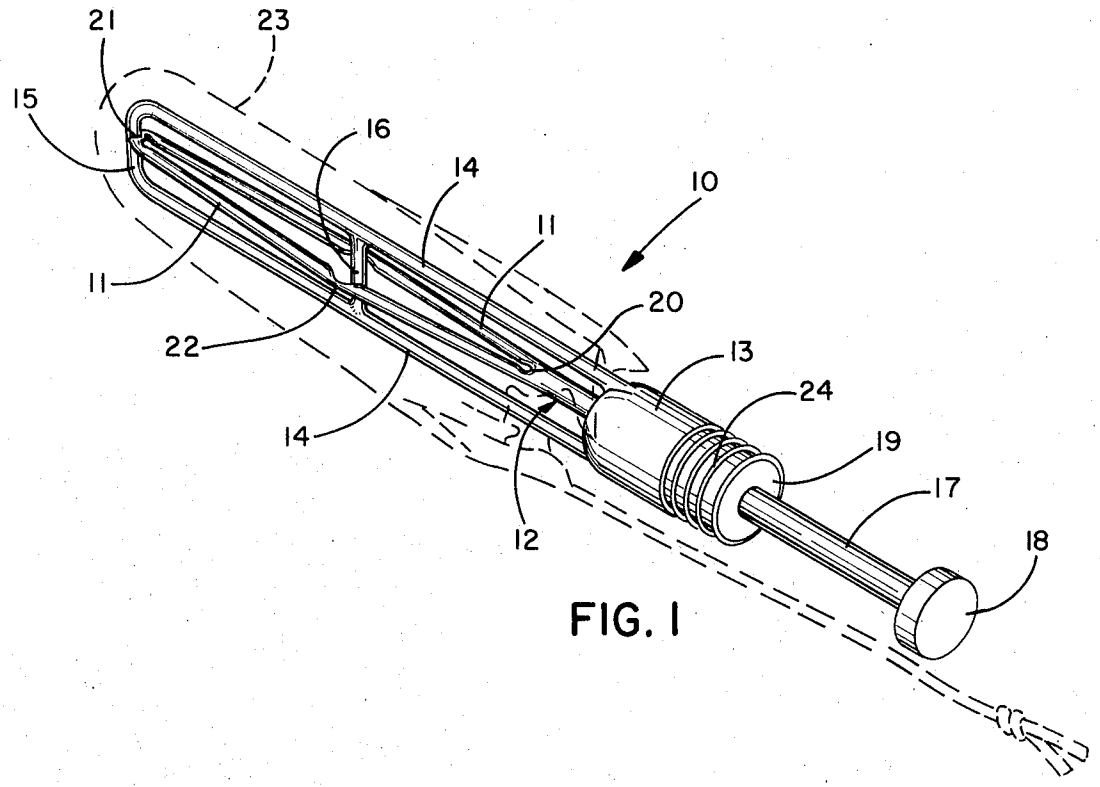

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FIG. 1

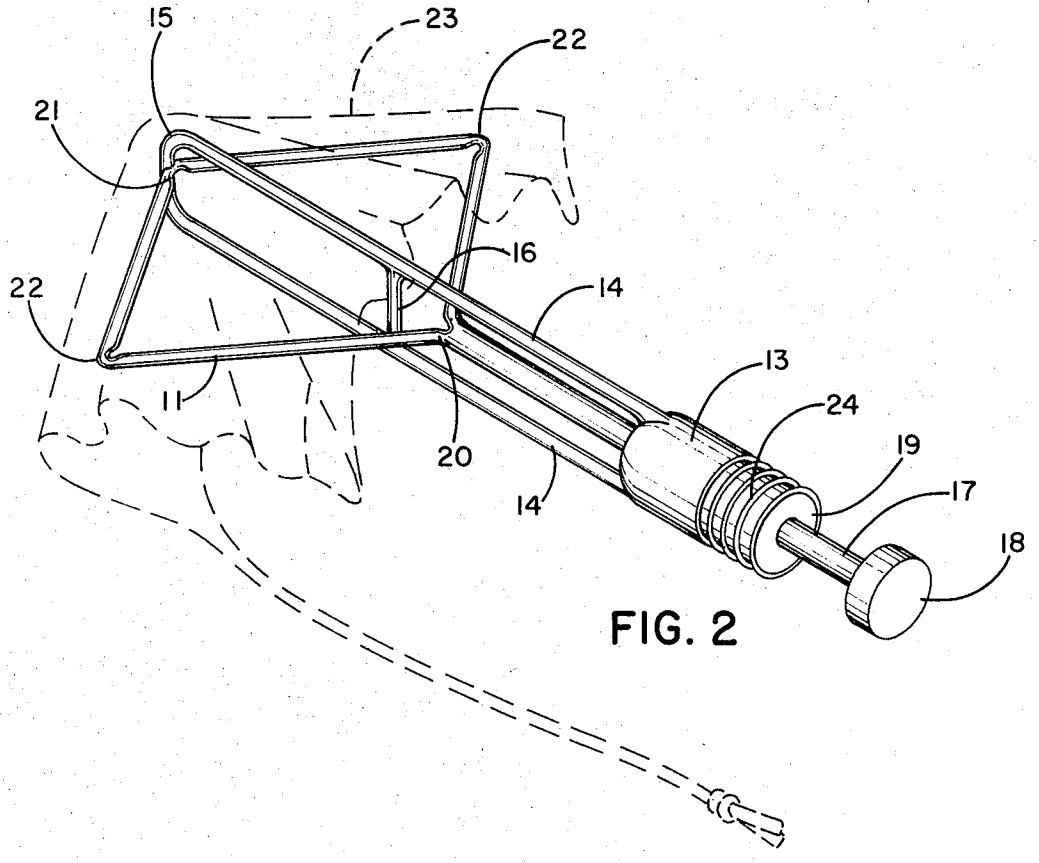
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FIG. 2

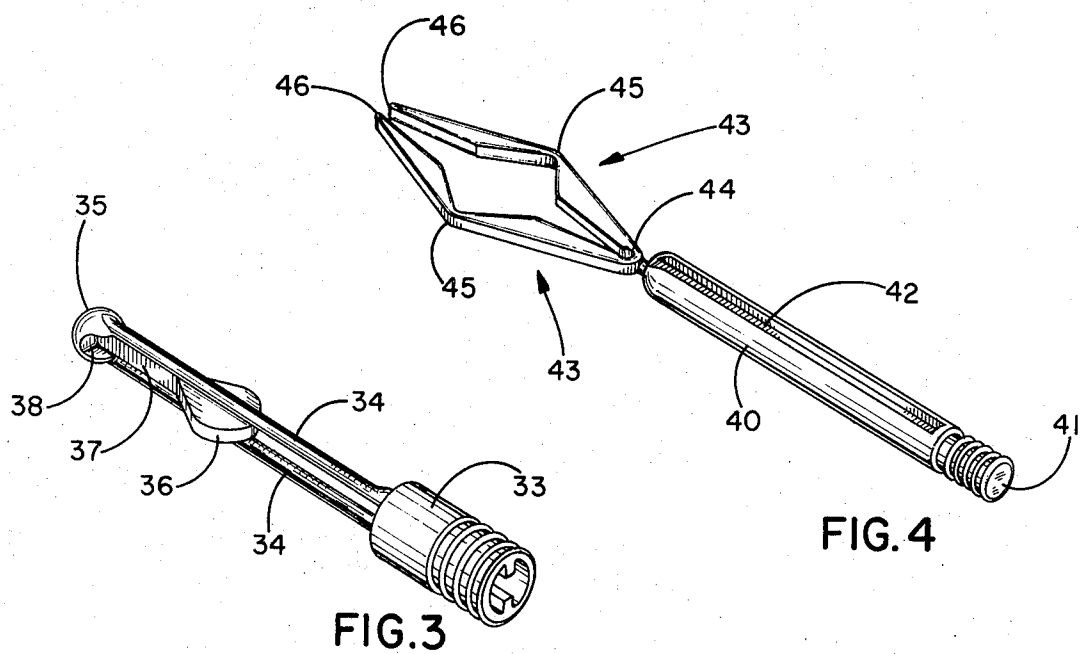

FIG. 3

FIG. 4

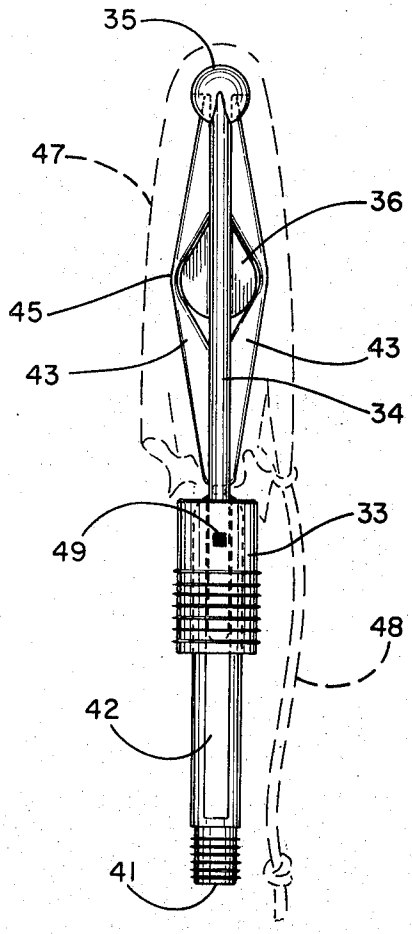

FIG. 5

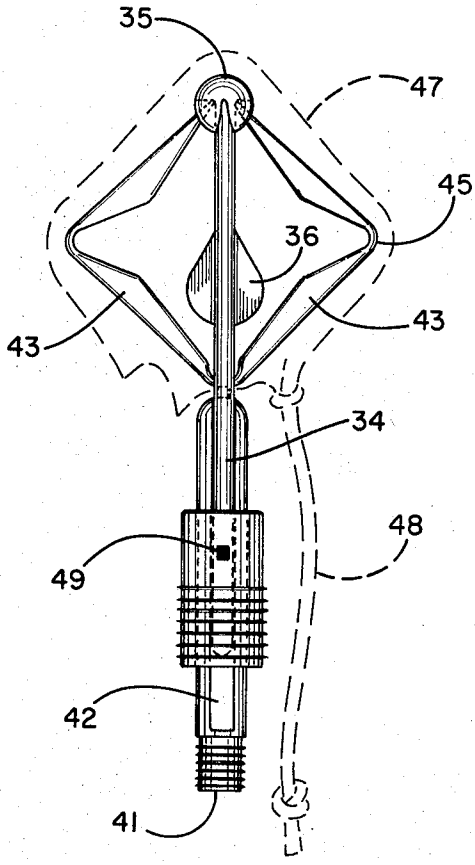

FIG. 6

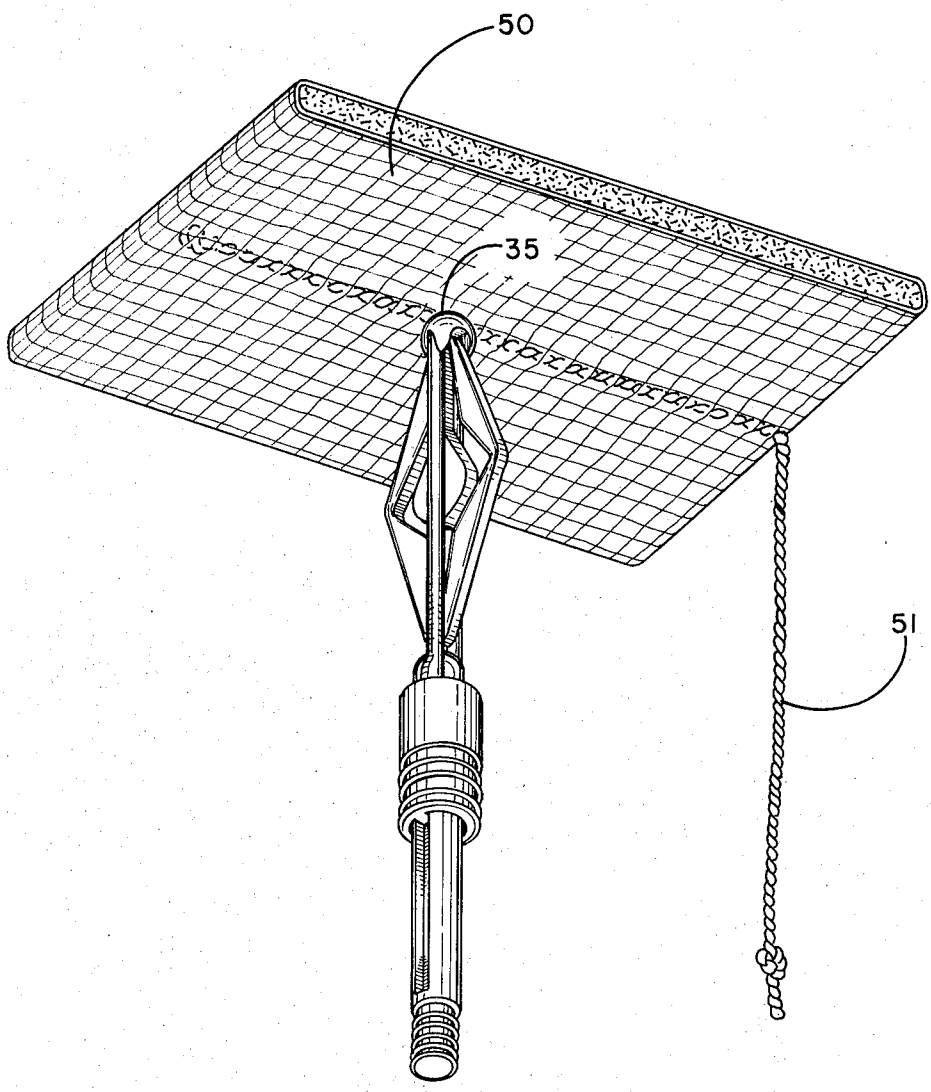

FIG. 7

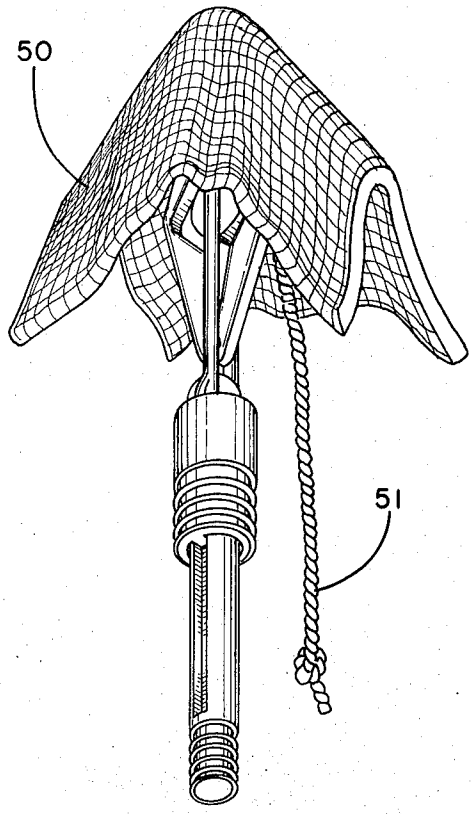

FIG. 8

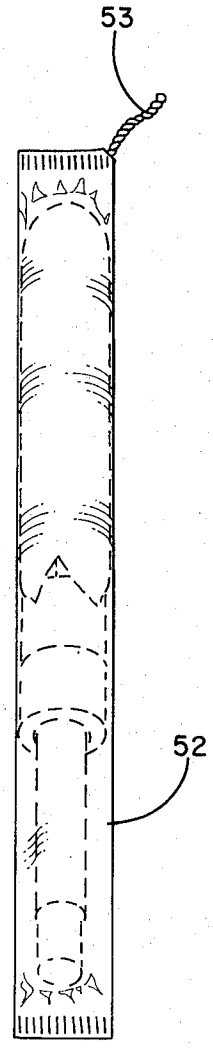

FIG. 9A

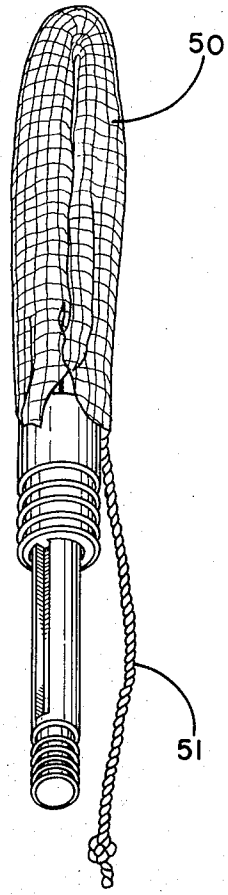

FIG. 9

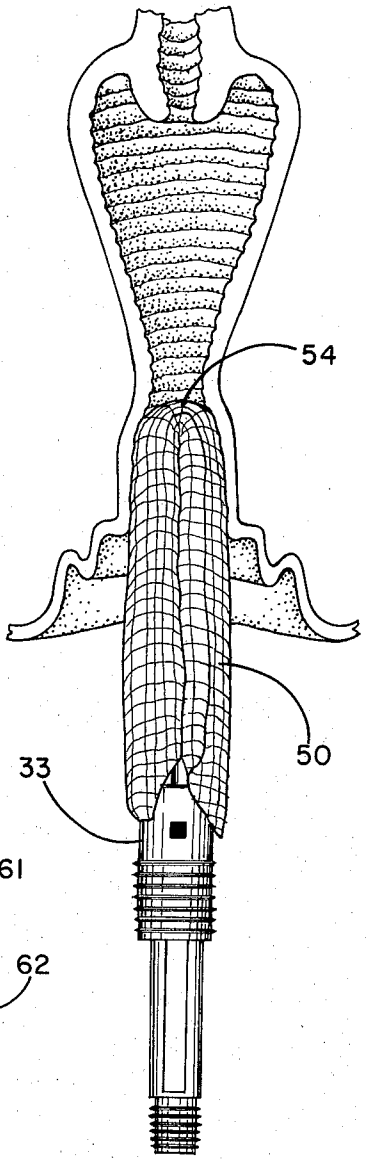

FIG. 10

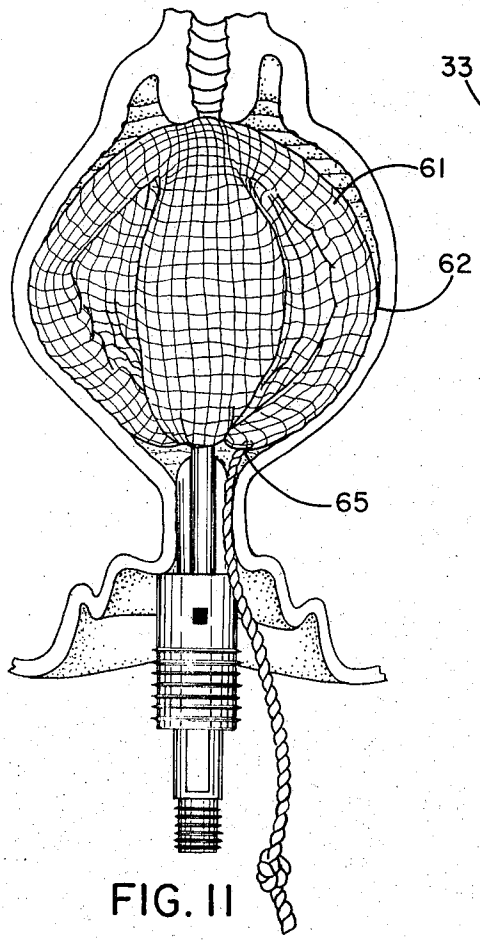

FIG. 11

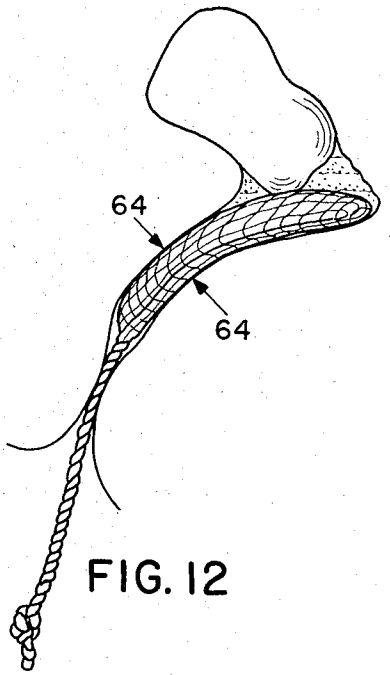

FIG. 12

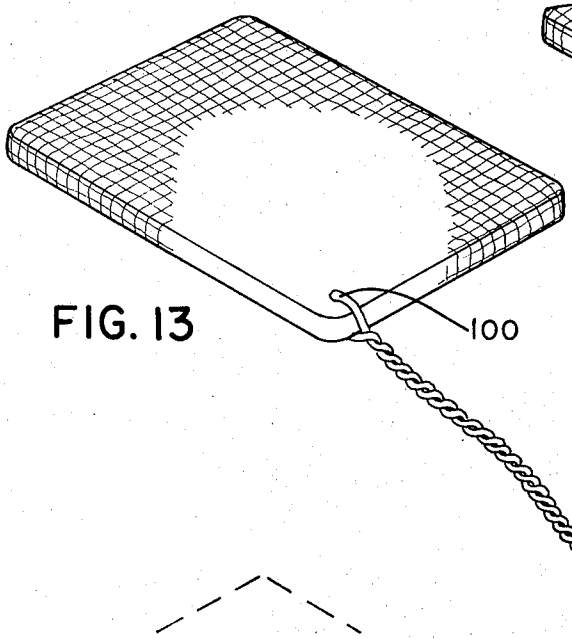

FIG. 13

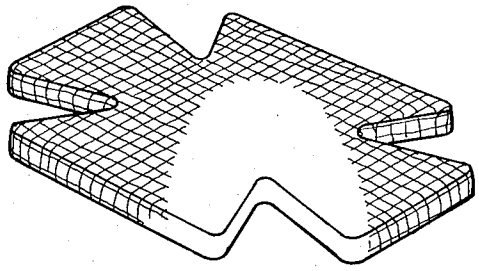

FIG. 16

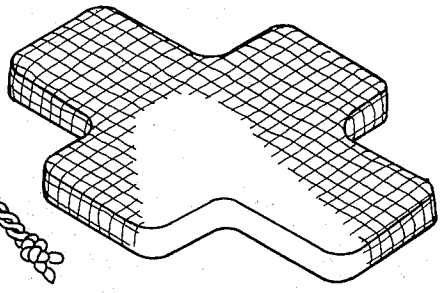

FIG. 17

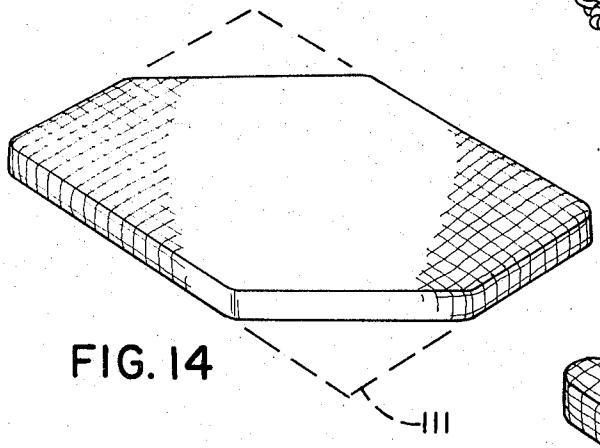

FIG. 14

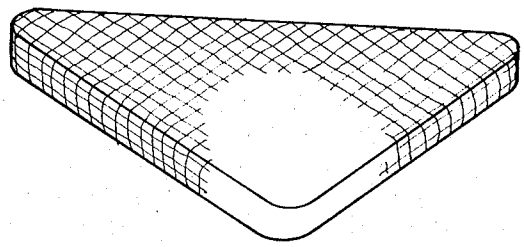

FIG. 18

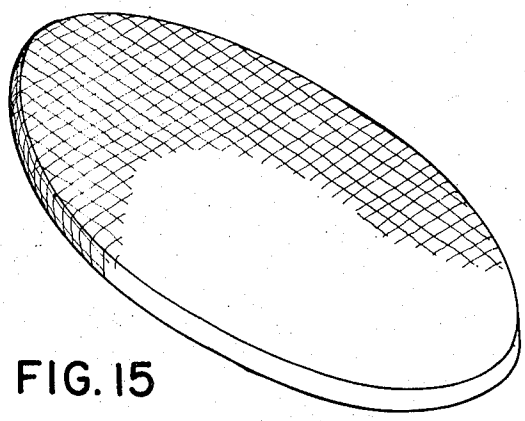

FIG. 15

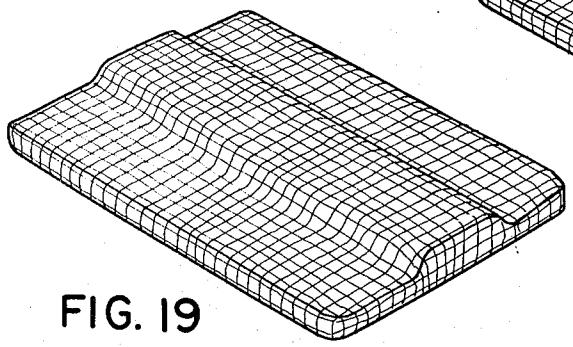

FIG. 19

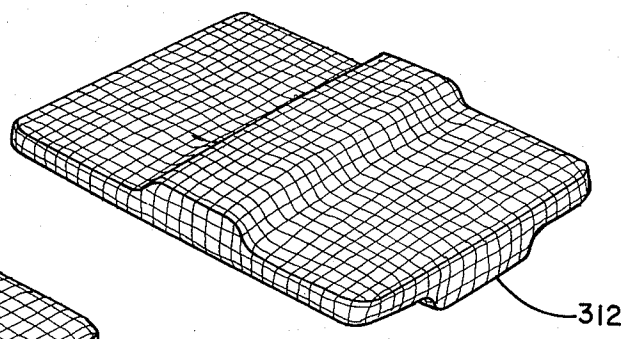

FIG. 20

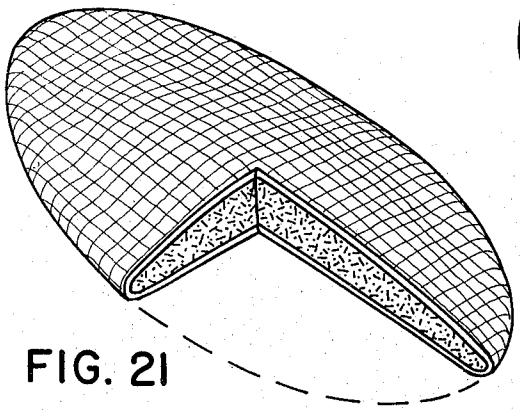

FIG. 21

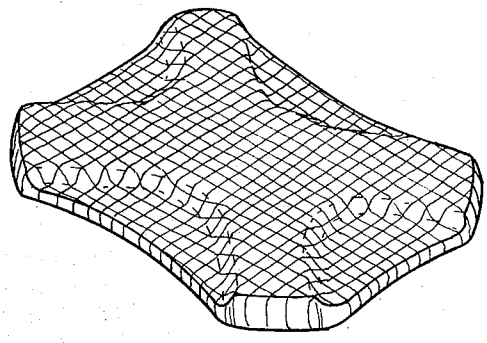

FIG. 22

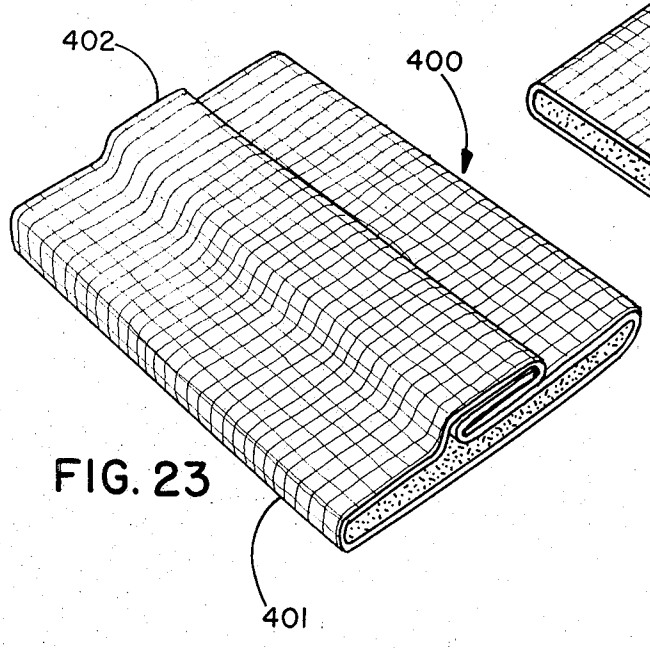

FIG. 23

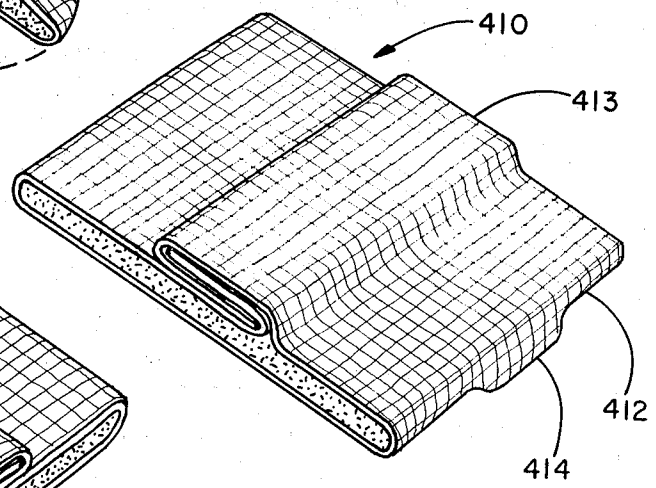

FIG. 24

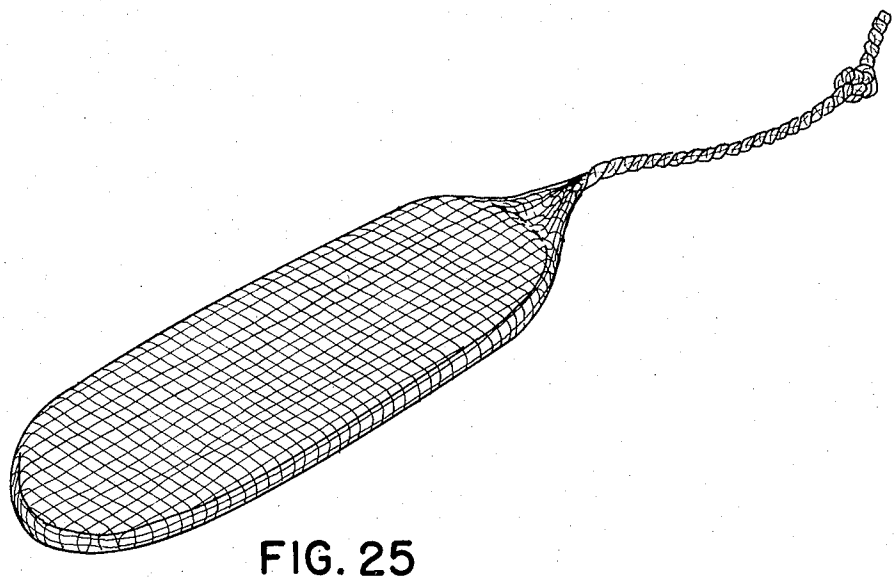

FIG. 25

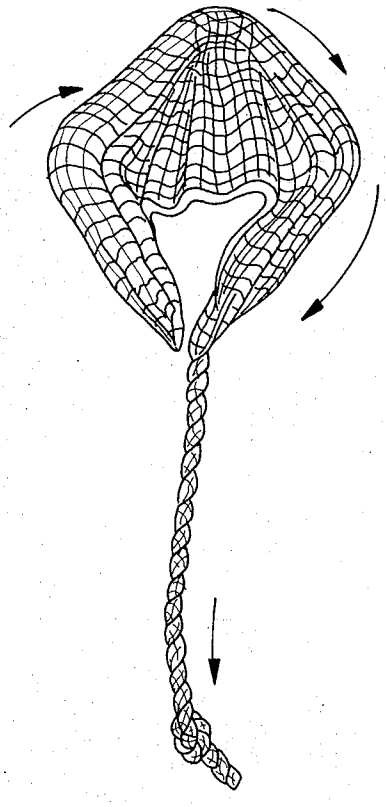

FIG. 26

CONFORMABLE ABSORBENT TAMPON AND INSERTER DEVICE THEREFOR

BACKGROUND OF THE INVENTION

It has long been recognized that the internal vaginal cavity in its normal collapsed state is of much wider dimension in its transverse plane than in its vertical plane. It is equally well known that the minimum dimension of the vagina is at the introitus while the maximum dimension is near the cervix. It is desirable therefore, when considering a tampon for catamenial use, to provide a structure which in its initial state is of a diameter small enough to pass through the vaginal orifice comfortably without undue stretching or friction, and when once inside the vaginal cavity and beyond the restrictions of the orifice may be expanded, particularly in the lateral direction, to contact substantially the entire cross-sectional circumference of the vaginal wall thereby to prevent early bypass of the menstrual discharges from the cervix. Since the vaginal wall in its normal collapsed state is flaccid and has multiple folds and wrinkles which provide channels through which a significant portion of the menstrual fluids normally flow, it is also important that the absorbent tampon be as soft and conformable as possible, in order to fill and block these channels to minimize leakage.

These rather diverse requirements for an ideal tampon structure may be characterized as follows:

(1) the tampon should be initially small enough to permit smooth, comfortable insertion into a small orifice which by virtue of strong sphincter muscles resists distention; (2) the tampon should be capable of immediate expansion after insertion, particularly in the lateral direction, and preferably to several times its initial size in order to substantially fill a cavity much larger in size than the initial unexpanded tampon size; (3) the tampon, after expansion to its operative size, preferably should be soft and conformable, so that after insertion it will closely conform itself to the irregularly folded walls of the vaginal cavity, when the cavity is in its normally collapsed state; (4) the tampon should have sufficient absorbent capacity for receiving and holding menstrual fluid to enable the tampon to be worn for an extended time period; and (5) the tampon, when ready for withdrawal, should be capable of being withdrawn through the small entrant orifice without uncomfortable distention of the orifice while the tampon still retains the fluid it has absorbed.

It is evident that the most popular tampons now being marketed, while acceptably functional, do not meet all of these highly desirable criteria. In most cases, the absorbent catamenial tampons now in general use comprise small, highly compressed, cylindrical plugs about one-half to three-eighths inch in diameter and from 1½ to 2½ inches in length. Because of the need for absorbent capacity, they are usually formed from batts much larger in size than the vaginal orifice, and compressed to the small size indicated above in order to facilitate insertion. As fluid is absorbed, these compressed tampons are expected to re-expand toward their original precompressed size, and to eventually become large enough to effectively block the vaginal cavity against fluid leakage or bypass. While it has been found that these compressed tampons do their intended job tolerably well, even the best of them do not re-expand sufficiently, or fast enough, to provide a good transverse

block against leakage even though the vertical block may be satisfactory. Further, most of these tampons generally use only a small portion of their absorptive capacity before leakage. Since these tampons rely on some fluid absorption to re-expand it is clear that fluid bypass and leakage can occur prematurely, and can particularly occur immediately following the time of insertion. Further, because of size limitations imposed by insertion requirements, it has been found that, even at full expansion, effective leakage control is difficult to achieve.

In the patented art, wherein attempts have been made to solve the premature bypass problems, it is suggested that if compressed tampons are manipulated during insertion to form a transverse arc within the vagina early bypass will be mitigated. Typical of this art are U.S. Pat. Nos. 2,879,769 to Gordon et al.; 2,879,770 to Graham and 3,706,311 to Hanke. However, these tampons still utilize compressed structures because of orifice size restrictions, and therefore do not easily conform to the irregular wall configuration of the collapsed vagina. These tampons also rely primarily on fluid absorption to provide the partial or full expansion needed to block the passageway.

Other approaches in the patented art suggest built-in mechanical expansion means, a typical example being U.S. Pat. No. 3,706,311 to Kohx et al. However, while a good transverse block appears to be produced, the mechanical expansion means disclosed in that patent is in the form of a flat spring-like element which after insertion permanently maintains the spread configuration of the tampon, making it difficult to remove.

Still another approach is described in U.S. Pat. No. 3,512,528 to Whitehead et al, which teaches the use of a sack of absorbent material collapsed to a small size for insertion and which after insertion is expanded by the introduction of a gas or a fluid internally of the sack. The multiple steps and complicated manipulation of the gas or fluid introduction means required when using this type of tampon detract from what otherwise appears to be an effective solution of the problem.

In contrast to these prior art proposals for providng tampons with post-insertion expansion capabilities the preferred embodiment of the tampon of the present invention is a non-compressed soft conformable tampon in its initial form. It is designed for easy insertion by means of a cooperating elongate inserter device of small diameter over which the tampon is draped, and which permits the draped portion of the tampon to be pulled, rather than pushed into the cavity from the point at which the tampon is supported on the leading end of the inserter. In the preferred embodiment, the inserter means is equipped with a simple bilateral expansion mechanism which at the user's option may be operated to transversely spread the tampon at the time of insertion to provide the tampon with the capability of contacting a greater part of the internal circumference of the vaginal cavity walls and thereby substantially seal against leakage immediately after insertion. The withdrawal string preferably is attached to an edge area of the tampon so that during withdrawal the tampon will revert to a relatively small, collapsed state. Other points of attachment may also be used.

OBJECTS OF THE INVENTION

It is the primary object of this invention to provide a soft, uncompressed, conformable catamenial tampon

which when inserted in the vaginal cavity effectively blocks leakage of catamenial fluids at the time of insertion. It is an equally important objective of this invention to provide a convenient means for introducing a soft, substantially uncompressed absorbent tampon in a form small enough in size to pass comfortably through the vaginal introitus. It is also an objective of this invention to provide a means for inserting a soft and absorbent tampon through the introitus without the need for a covering tube, thereby permitting the swabbing of the vaginal canal during insertion. Another objective of this invention is to provide a means whereby the user may by a simple exterior manipulation, transversely deploy a tampon in a predetermined plane inside the vagina. Still another objective of this invention is to provide a means by which the user may easily control the degree of transverse deployment after insertion as desired. It is a further objective of this invention to provide the user with a mechanical deployment means for a tampon hich provides sufficient bilateral force to transversely deploy a tampon against the opposition forces caused by the normal visceral pressures and by the friction of the normally collapsed vaginal wall working against such deployment. It is a still further object of this invention to provide an inserter and deployment device that is easily removed from the vagina without disturbing the location of a tampon after insertion. It is further an object of this invention to provide a means for tampon insertion and deployment that is adaptable for use with a wide variety of tampon styles.

SUMMARY OF THE INVENTION

The preferred embodiment of this invention comprises a soft, uncompressed absorbent tampon structure which, while retaining its substantially uncompressed condition, is conformed to a size and configuration suitable for insertion into the vaginal orifice without discomfort. The tampon is initially in a thin, flat pad form which is conformed to such size by draping it over, and folding it down around, the forward end of an elongate inserter means of small diameter. In the preferred inserter means the forward end portion of the inserter which is covered by the tampon is provided with a hinged construction operable by one hand of the user for the purpose of first inserting and then bilaterally spreading the tampon from its draped and folded condition to a partially or fully-opened condition within the vaginal cavity. Alternatively, the inserter may be used for simply inserting the tampon if no spreading or opening up of the tampon is desired or needed after insertion. After the tampon has been inserted and opened to the desired extent the hinged arms of the spreader are easily returned to their non-extended condition whereby the inserter may be conveniently withdrawn. In the preferred embodiment, the tampon comprises a thin conformable absorbent pad which is initially flat and of an oblong planar configuration. In the preferred embodiment, a suitable withdrawal string is attached at a point on or near the periphery of the pad. In other embodiments, the string may of course be attached at any suitable location on the pad.

In forming the pad to its insertion size, the thin planar pad is draped at its approximate geometric centerpoint over the leading end of the elongate inserter means and folded smoothly downward to enfold the leading end portion and the hinged structure of the inserter means. When the tampon is folded and draped over the inserter means, it is of a size which can be inserted into the vaginal orifice without discomfort. The leading portion of the inserter means, which is covered by the folded tampon, is provided with a pair of hinged arms capable of bilaterally spreading the folded tampon within the vagina after insertion. In the preferred embodiment, the inserter means comprises an internal rod-like plunger element of suitable length with a pair of parallely spaced arms comprising its forward portion. The arms are hinged or jointed near their midpoint to provide them with the capability of bending or bowing outwardly and laterally diverging from each other at the hinge or joint. A piston-like element is disposed externally of the plunger and slidably positioned thereon. The piston-like element is provided with a lower ring-like collar portion and a pair of parallely spaced rigid arms extending forward from the collar and being joined to each other at their forward extremities to form a closed, preferably rounded, end. Each of the forward tips of the hinged arms of the internally disposed elongate plunger are arranged to cooperate with the closed end of the outer element and form a hinge therewith. When the ring-like collar portion of the outer piston-like element is slidably disposed on the internal plunger element and the forward end of the hinged arms cooperatively associated with the closed end of the outer element, longitudinal pressure on the plunger element will cause it to slide within the ring-like portion of the outer element, causing the hinged arms to bilaterally spread away from each other, and thus to bilaterally spread the tampon transversely within the cavity.

When a suitable degree of transverse spreading is obtained, longitudinal pressure on the plunger is discontinued, the inner element is slid back sufficiently to return the arms to their unstressed, substantially parallel position, and the collapsed inserter is then removed leaving the bilaterally spread tampon in place. The draped tampon as described above also serves an important function during insertion in that it swabs or wipes clean the walls of the vaginal orifice as it is inserted, to thereby remove any exudate which may have been unavoidably left thereon when the previously used tampon was removed.

When it is desired to remove the tampon, the fact that the tampon is of a soft conformable structure permits the tampon to readily deform as the withdrawal string is used to draw the used tampon through the introitus for removal. This structure thus permits the tampon to assume a small cross-sectional dimensions during the withdrawal process so that it may be removed with a minimum of discomfort.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagrammatic perspective view of a simplified tampon-inserter assembly in accordance with the invention.

FIG. 2 is similar to FIG. 1 illustrating the disposition of the elements of the assembly after tampon has been inserted and bilaterally spread within the vaginal cavity.

FIGS. 3 and 4 are perspective views showing in detail the arts of a preferred and more sophisticated inserter device.

FIG. 5 is a side view showing the assembled inserter device of FIGS. 3 and 4 in operable condition and ready for insertion.

FIG. 6 is a side view of the assembly of FIG. 5 in its bilaterally spread condition after insertion.

FIGS. 7, 8 and 9 are side views illustrating the steps in draping an initially planar tampon over an inserter.

FIG. 9A illustrates the finished tampon-inserter combination as it would appear when enclosed in a tight-fitting wrapper.

FIG. 10 is a transverse section of the vaginal area showing the tampon partially inserted.

FIG. 11 is a transverse section of the vaginal area showing the tampon after complete insertion and after being bilaterally spread by the inserter.

FIG. 12 is a vertical section of the vaginal area viewed from the side and showing the position of the spread tampon in place in the vagina and after the inserter is withdrawn.

FIGS. 13 through 24 are perspective views illustrating a number of suitable forms which the tampon may take prior to being draped over the inserter.

FIG. 25 is a perspective view showing still another form of a suitable tampon.

FIG. 26 is a frontal view of the tampon of FIG. 25 in the idealized shape it assumes in the vagina after bilateral spreading, and also indicating the course the tampon tends to follow during withdrawal.

DETAILED DESCRIPTION OF THE INVENTION

Reference may now be made to FIGS. 1 and 2 of the drawings which show a simplified version of a tampon-inserter combination of this invention. The simplified structure shown in these figures illustrates the operating mechanism and mechanics of the invention.

As shown therein, the inserter comprises a fixed elongate outer element 10 and a movable elongate inner element 12. The fixed outer element 10 is comprised of a cylindrical collar 13 having a pair of spaced parallel beams 14 extending from the forward end of collar 13 and being joined together at their extremities by a loop-like forward portion 15. The beams may also be strengthened intermediate their length by a medial cross-piece 16.

Slidably disposed within fixed outer element 10 is an inner element 12 which is comprised of a lower rod portion 17 with an enlarged base 18. Rod portion 17 of inner element 12 is slidably associated with collar 13 of outer element 10 by suitable means such as an apertured facing 19 or the like. The upper portion of inner element 12 is bifurcated or divided into a pair of medially bendable arms 11 hingedly joined to rod 17 at rear flex points 20. The upper end of each of the arms 11 comprising the bifurcated section is hingedly joined to loop 15 at forward flex points 21. Each of the arms in the bifurcated section are also provided with flexible hinges at medial flex points 22. The arms preferably should be biased outwardly or otherwise guided away from each other at these points 22 so that when the arms are caused to bend by longitudinal pressure they will diverge from each other.

The entire inserter assembly is preferably made of a flexible plastic such as polypropylene and in its at rest condition assumes the configuration shown in FIG. 1.

By grasping the collar 13 with the thumb and middle finger as is normally done in handling tampon inserters, and by pressing the index finger against base 18, to slide the inner element forward toward collar 13, one arrives at the configuration shown in FIG. 2 whereby each of the arms 11 of the bifurcated forward portion of the movable inner element are caused to bend outward away from each other and bilaterally spread into a cross-bow shape as illustrated.

When a conformable tampon, represented by dotted lines 23 in FIG. 1, is conformably draped over the inserter, the draped tampon is of a size and shape similar to the size and shape of conventional compressed tampons and may be inserted into the vagina to the desired depth by grasping the inserter at collar 13 which is provided with ridges or other well-known nonslip means to assist in gripping.

After the tampon is inserted to the desired depth, rod 17 is pushed forward by applying digital pressure on base 18 as described earlier. The sliding movement of rod 17 through collar 13 causes arms 11 of the inner element 12 to diverge from each other and to bilaterally spread tampon 23 within the vaginal cavity to the desired width, which width can be suitably controlled by the user. In some instances, spreading of the tampon after insertion is not needed, and in such cases the inserter may simply be withdrawn after the tampon is inserted, without activating the bilateral spreading means.

When digital pressure on base 18 is discontinued and the index finger removed therefrom, the flexibility and memory of plastic arms 11 will normally push the rod 17 of inner element 12 back to its original elongate form after which the inserter element may be easily withdrawn leaving the bilaterally spread tampon in place in the vaginal cavity. Reversion of the arms 11 of inner element 12 to their original unextended position may be manually assisted, if desired.

While FIGS. 1 and 2 show a simple structure which will provide the desired results, reference is now made to FIGS. 3 through 6 which illustrate a more sophisticated and preferred form of structure for the inserter device. Both the simple form of FIGS. 1 and 2 and this preferred form of FIGS. 3 and 6 can readily be made by injection molding of plastic materials at a cost which enables the inserter to be used only once and then discarded.

In this preferred embodiment, FIG. 3 illustrates an outer element which consists of a lower cylindrical collar 33, a pair of parallel beams 34 which extend from the base of collar 13 along the inner wall of the collar and past the top of the collar for a suitable distance where the extremities of the beam are joined together by a ball-like end 35. This ball-like end is a preferred embodiment since it permits force to be used against a draped tampon body during forming and use, without causing undesirable distortion or penetration of the tampon body. Medially of the beams 34 there is provided an enlarged cross-piece 36 which in its preferred form is ovate or tapered in section to provide a ramp-like guide to assure that the arms of the inner element diverge outwardly when activated. Forward of cross-piece 36 and filling in the space between beams 34 from cross-piece 36 to an indented portion of ball end 35 is a thin plate-like filler 37. Filler 37 and the indented portion of ball end 35 cooperate to form a socket 38, the purpose of which will be described below in connection with the inner element.

FIG. 4 illustrates a preferred embodiment of an inner element which comprises a lower rod-like portion 40

terminating in a base **41**, and provided with a pair of elongate diametrically opposed grooves **42**, only the upper groove **42** being visible in the figure. These grooves **42** extend substantially the full length of the lower rod-like portion **40**, and as shown, are closed at the rear end while remaining open at the forward end. As stated earlier, only the upper groove **42** is shown in FIG. **4**, it being understood that a similar groove extends along the bottom of rod **40**. At the forward end of rod portion **40** there is provided a bifurcated portion consisting of a pair of slightly bent hinged legs **43**. Each of the legs is provided with a lower flexible joint at **44**, and a medial flexible joint at **45**. Each leg ends in a pointed toe **46**. As shown, each of the legs is bent slightly outward at medial joint **45**.

FIG. **5** illustrates the assembled arrangement of the inserter device with the FIG. **3** outer element slidably disposed around the FIG. **4** inner element. As shown therein the leading end portion of the inner element is inserted through the open bottom of cylindrical collar **33** in a manner which permits grooves **42** of the inner element to coincide with and to slide along beams **34** of the outer element. The toe ends **46** of legs **43** will flex and slide over cross-piece **36** and are then inserted into sockets **38** on either side of ball-end **35**.

When the inserter device is fully assembled as in FIG. **5**, a flexible tampon is draped over ball-end **35** and folded down over ball-end **35** to enclose the bifurcated forward portion of the inner element. When thus draped and folded over the inserter device, a typical round-nosed cylindrical tampon shape is obtained, as illustrated by dotted line **47**. A withdrawal string **48** is also provided at one edge of the draped tampon **47**.

In this convenient and familiar tampon-shaped condition the user is able to grasp collar **33** with the thumb and middle finger of one hand and insert the tampon to the desired depth. Groove **42** of the inner element will ordinarily serve as an indexing means to appraise the user of the radial orientation of the inserter device and to assure the user that the tampon is correctly positioned for subsequent bilateral expansion, but if desired, a solid color mark, such as shown at **49** may be used, as well as some other indicia means, many of which are well known in other devices requiring radial tampon positioning.

After the tampon is inserted to the requisite depth past the vaginal entrance, the index finger is pushed against base **41** of the inner element to slide rod **40** forward within collar **33** causing legs **43**, as they slide against ramp-like crosspiece **36**, to diverge and bend outward, thus bilaterally spreading tampon **47** to a position somewhat as shown by the dotted lines in FIG. **6**.

FIGS. **7** through **9A** illustrate the steps used in one method of assembling the tampon and inserter for packaging and for subsequent use. As shown therein, a thin substantially planar tampon **50** of elongate rectangular shape comprising a flat absorbent core enclosed in a pervious wrapper and having a withdrawal string extending along the midline thereof and depending therefrom, is draped over ball end **35** of the previously described inserter means at the approximate geometric center point of the lat tampon.

The flat tampon **50** is folded down over the leading end of the inserter as shown in FIG. **8**, and is pressed around the inserter device until it assumes the final configuration as shown in FIG. **9**. The thus shaped, rounded nose tampon is then inserted into a snug-fitting plastic sleeve **52** or the like, which may be made to fit still tighter by neat shrinking or a similar process to help maintain the tampon in its final configuration as shown in FIGS. **9** and **9A**. The wrapper preferably is provided with a tear string **53**, perforations, or the like, for convenience in opening.

The draping of the tampon over the inserter and subsequent wrapping can be accomplished by a simple device such as by pushing the inserter rod and draped tampon pad through the flared end of a gradually tapered cylinder or funnel. A preformed tube of wrapping material may be positioned at the opposite end of the tapered forming cylinder to receive and to entube tightly the draped and formed tampon as it is ejected from the forming cylinder into the wrapper. The entubed tampon may then have the open ends of the wrapper appropriately sealed at each end and the wrapper may then also be shrunk by heat or the like to provide a still tighter protective wrap.

When getting ready to use the tampon the user grasps tear string **53** to rip open the protective wrap and to uncover the tampon-inserter assembly as shown in FIG. **9**. As previously described, the assembly is then grasped by the thumb and middle finger of one hand at collar **33**, which in FIG. **10** is marked with printed indicia to show proper radial positioning, and is then inserted into the introitus as shown in FIG. **10**. It should be noted here that as the leading end **54** of the tampon penetrates the introitus and is slid into the vaginal cavity, the draped side portions of the tampon **50**, as they are pulled through the introitus, serve to wipe clean the entire circumferential wall of the entrance channel to remove and absorb any residual menstrual fluid which may have been deposited thereon when the previous tampon was removed. This effective swabbing action tends to give the user a sense of cleanliness as well as the assurance that the tampon is doing its intended job.

After the entering tampon has swabbed the vaginal canal clean at the introitus and is inserted in the vaginal cavity past the entrance to its proper depth, the inserter may be withdrawn, or preferably the bilateral spreading action of the inserter device is activated, as previously described, to deploy the tampon into a configuration having a shape somewhat like that shown in the front sectional view of FIG. **11**. By tactile observation and practice the user is able to control bilateral expansion of the tampon to a point where the side edges **61** will contact side walls **62** as shown in FIG. **11**. It should also be noted here that when the tampon is bilaterally spread by the user it is simultaneously foreshortened in its anterior-posterior dimension, thus enabling the tampon to conform better to the cavity and make it more comfortable to wear.

FIG. **12** is a side sectional view of the vaginal cavity after the inserter has been withdrawn. It will be noted that because of the normal, vertically collapsed condition of the vaginal cavity, the upper and lower walls of the cavity **63** and **64** respectively, will also be substantially in contact with the tampon for effective absorption of fluids.

When the tampon is ready for withdrawal, pulling forces will be applied to only that portion of the tampon edge where the string is attached as shown at **65**, and the soft structure of the tampon will permit it to be reformed to a relatively small cross-sectional diameter as it is being withdrawn, so that withdrawal may be ac-

complished through the narrow vaginal entrance with minimum or no discomfort.

This invention in its preferred embodiments as herein described thus provides a catamenial protection arrangement in which a soft deformable tampon or other style of folded tampon may be effectively inserted into, and deployed within, the vaginal cavity by bilateral spreading of the tampon after insertion to provide maximum and early protection against leakage. In addition, the preferably uncompressed nature of the tampon structure permits it to readily assume a small size and shape as it is being withdrawn.

This tampon arrangement is particularly effective in that it permits the user to exert bilateral spreading forces inside of the tampon body itself to enable the tampon to effectively fill the vaginal cavity, even though the normal pressures within the cavity resist such spreading. Devices which do not have positive spreading means are unable to overcome such resistance effectively. It has been found that positive spreading means are desirable because actual measurement of a representative group of subjects disclosed that the combination of frictional forces and visceral pressure on the vagina when a user assumes the usual position for tampon insertion are in a range which normal expansion of compressed tampon bodies cannot overcome. Visceral pressure on the vaginal vault for example, is on the order of 12 inches of water, or expressed in another way, over 60 lbs. per sq. ft. Considerable lateral force must therefore be exerted in order to laterally spread a tampon against such pressures.

It has also been found that an insertion force of about 1,000 gms is the maximum that a typical user can comfortably assert while manipulating a tampon inserter device. By using the arrangement described herein, it is possible to accomplish both the insertion and bilateral deployment of a tampon at force levels substantially below this maximum.

The size and shape of tampons suitable for use as described herein can be many and varied. Important criteria are that the tampon preferably be soft and drapable, that it have high absorbent capacity, and that when draped over the tampon inserter it should not be too bulky to inhibit insertion. It is well known that absorbent capacity is much higher when the absorbent material is of low density, accordingly the preferred tampon structure is one which is substantially uncompressed, even though partially and fully compressed tampons can be effectively spread after insertion by utilizing the inserter device disclosed herein.

FIGS. **13** through **24** show various shapes of tampons suitable for use in this invention. It should be understood, that there are so many shapes which could be chosen for use that this selective showing should in no way be considered limiting.

FIG. **13** is an elongate rectangular shape comprising a thin central pad of absorbent wood pulp material known as fluff and being about one-eighth inch thick. The fluff is covered by a thin absorbent gauze which may be woven or non-woven and may be coterminous with the fluff pad or completely envelop it on all sides. A representative size for the pad is about 5 inches long by about 3½ inches wide. A withdrawal string is shown attached to one corner of the pad by being looped therethrough. Many other means for withdrawal string attachment may be used, including stitching for the full length of the pad, adhesive attachment, partial stitching, heat bonding, and the like. Many structures for string attachment may be found in the art and further detailing is not required here. For this reason the various styles of tampon shapes shown in the remaining figures are depicted without withdrawal strings attached, it being understood that in complete tampon structures a suitable withdrawal string will be attached to some portion of the tampon body. As indicated earlier, it is preferred that the string be attached near an edge of the tampon in its flat, undraped form.

FIG. **14** is similar to FIG. **13** except that diagonally opposed corners have been cut off. By excising material from the corners, a pad shape is provided which causes the tampon to have less peripheral bulk at its lower end when draped over the inserter.

FIG. **16** shows a pad in the shape of a Maltese or Formee cross which because of the cut-out portions again makes the tampon less bulky at its lower end when draped over the inserter. This configuration also concentrates more absorbent material near the center of the tampon which makes it more efficient in utilizing its fluid holding capacity per unit weight.

FIG. **17** shows a pad in the form of a Greek cross with cut-out portions to facilitate drape. Advantages of this shape are similar to the FIG. **16** pad.

FIG. **18** shows a triangular shaped pad. While as shown here the triangle is intended to show a scalene shape, equilateral or isosceles shapes are also suitable.

FIG. **19** shows a rectangular pad in which the longitudinal center is thick and the edges are thin. This structure provides more uniform densities of material in the folded and draped tampon. It is also of improved effectiveness in utilizing its full absorptive capacity. This pad configuration also promotes less bulk at the bottom of the tampon when formed over the inserter device.

FIG. **20** is similar to FIG. **19** except that it has a thick portion at the transverse mid-line of the tampon pad.

FIG. **21** is an elliptical pad which is thick at the center and thin at the periphery.

FIG. **22** is a cross-shaped pad with thin web-like filler traversing the spaces between the cross-bars.

FIG. **23** is similar to FIG. **19** except that the longitudinal thickened area is provided by gauze-like wrapper material. This structure provides the pad with more tensile strength in the thickened area which permits more force to be applied during the tampon forming process without causing undue distortion of the material.

FIG. **24** is similar to FIG. **20** except that the longitudinal and transverse thickened areas are both provided by the previous wrapper material itself.

FIG. **25** is still another variation of a suitable tampon. In this embodiment the tampon comprises a thin, elongate fluff pad enclosed in a tubular wrapper of open-weave gauze or the like, and a portion of the wrapper extends beyond the pad where it is twisted to form an integral withdrawal string.

FIG. **26** illustrates how the pad of FIG. **25** would appear when disposed within the vaginal tract and bilaterally spread as previously described. This figure is also used to illustrate how the tampon is distorted when being withdrawn. By pulling on the withdrawal string in the direction indicated by the bottom arrow, frictional forces in the vagina will restrain downward movement of the tampon and cause it to rotate in the direction indicated by the remaining arrows. Accordingly as the

tampon is pulled out it will automatically assume a thin elongate form.

Since the preferred embodiments of the inserter-spreader device appear quite complicated, it has been rather surprising to find that by using known injector molding techniques it is possible to mold a suitable device from thermoplastic materials like polyethylene or polypropylene in the forms shown herein, at unit costs which permit the the device to be employed on a single-use basis and thereafter discarded. In fact, costs are comparable to the plastic telescoping tube inserter devices which may presently be found in the marketplace. The device can be injection molded as a single unit such as in FIGS. **1** and **2** or in several parts such as in FIGS. **3–6**. At present the two part structure described in connection with FIGS. **3–6** is preferred.

It is also possible to construct the device from metal, but this is not a preferred embodiment for a number of reasons including the high material costs involved as well as the more complicated structure which would be required.

It is also apparent that while a soft, conformable tampon structure as described herein is the preferred type of tampon for use in this invention a compressed single folded tampon in inverted U-form with a string attached at one end of the U could also be inserted and spread with this device. However such a structure is not preferred because it is not as conformable or absorbent as the preferred embodiments described in more detail herein. Nevertheless, it is intended that this application cover other forms of partially or fully compressed tampons. In such forms, the tampon may be folded on itself at least once and have a withdrawal string attached at one end thereof to facilitate withdrawal in a thin elongate form.

During the development of this tampon, it was observed that in many instances it was not necessary to bilaterally deploy the tampon at all after insertion. It was found that the draped configuration of a soft conformable tampon was effective in swabbing clean the vaginal orifice as it was inserted and that the folds tended to open up slightly as they cleared the introitus and entered the vaginal cavity. Since some vaginal configurations have diameters which are not much greater than the introitus the tampon was found to conform well to such a configuration even when not bilaterally spread after insertion. Also in cases where the vaginal walls are inelastic or where they have a strong nuscular tone it was found that bilateral spreading was not required. Accordingly, some of the advantages of this invention accrue when a soft conformable tampon of the type earlier defined is draped over an elongate rod-like inserter without bilateral deployable capabilities and simply inserted without subsequent deployment. Since the tampon is soft and conformable it does shape itself well to the configuration of the vaginal cavity when visceral and other internal pressures are exerted on the tampon after inserter removal. The invention therefore is intended to cover the combination of a conformable tampon draped over an elongate inserter of small diameter which does not necessarily have a bilaterally spreadable forward section.

As indicated earlier, absorbent materials which are uncompressed or of low density have much higher holding capacity for fluids than high density materials. It is therefore desirable for efficient use to utilize a low density, relatively uncompressed material for internal tamponage. However, an important consideration is how to deliver such uncompressed material in sufficient bulk or volume to provide the desired absorbent capacity without bunching or discomfort when such delivery is attempted. The tampon as described herein overcomes this problem by pushing the forward-most portion of a soft pad into the vagina by means of an elongate inserter device and thereby effectively pulling the major remaining portion of the pad into the vagina behind that small area of the pad against which the pushing force is exerted. The effect of pulling rather than pushing an absorbent material into the vagina enables soft uncompressed material to be used while at the same time effecting a wiping action in the lower vaginal tract during insertion. Such wiping has been found to be virtually 100 percent effective in eliminating soilage of garments due to exudate passed-by during the insertion of conventional compressed tampons. The elimination of this type of soilage is an incremental factor in improving the reliability of this tampon in preventing leakage of all kinds.

Leakage experiences of tampons made according to this invention were compared with leakage experience of conventional compressed tampons as well as with regular exteriorly worn sanitary napkins.

The test tampons made in accordance with this invention comprised a thin uncompressed pad of wood fluff fibers about ⅛ inch thick, 5 inches long by 4 inches wide covered by a fluid pervious non-woven scrim and having a total of about 2.0 grams of absorbent material. The pad was folded over an inserter device as herein described to form a tampon about ⅝ inch in diameter and about 2¾ inches long.

The conventional compressed tampon tested was a super KOTEX tampon having about 4.0 grams of absorbent material.

The conventional sanitary napkin tested was a regular KOTEX napkin having about 13.0 grams of absorbent material.

The test subjects used the products when their menstrual flow was the heaviest and checked for leakage once an hour for the eight hours covering the active part of their day. No tests were made during resting hours, or on waning days of their menstrual period.

The results of the tests are indicated below.

	% of Samples Tested Grams Absorbed at Leakage					
Product Tested	0 to 3.9	4.0 to 7.9	8.0 to 11.9	12.0 to 15.9	16.0 to 19.9	20 and over
4 gm Conventional Tampon (30 tested)	24%	10%	30%	33%	3%	0
13 gm Conventional Sanitary Napkin (40 tested)	28%	22%	15%	15%	13%	7%
2 gm Tampon of this Invention (22 tested)	0	39%	60%	1%	0	0

From the above it will be noted that the conventional protection devices all recorded some leakage in the very early stages while the tampon of this invention had none. Further it will be noted that the majority of the tampons of this invention absorbed from four to six times their weight in fluid before leaking while the efficiency of the other devices was much lower per unit weight. It is also noted here that visual examination of the used tampons and sanitary napkins found that in virtually every instance each of the tampons of this invention were for all intents and purposes completely saturated at the time leakage was recorded, while of the conventional tampons and sanitary napkins tested nearly all had noticeable unstained areas indicating unused capacity. The exceptions in the latter products were those falling in the categories where 12 grams or more of exudate were absorbed.

When the commonly used method of reliability or predictability, i.e., deviation from an average or norm, is applied to these figures, indications are that the deviation from norm of the tampons of this invention is much smaller than the deviation from norm of the two conventional products tested. The tampon of this invention thus can be categorized as providing a much higher predictability with respect to absorbency performance and expected capacity when compareed with more conventional protection devices.

What is claimed is:

1. In combination, a conformable absorbent tampon and an elongate inserter means; said inserter means having a bilaterally spreadable forward end portion and a trailing end portion for grasping by the user when inserting said tampon; said tampon comprising a flat absorbent pad draped over and enclosing the forward end portion of said inserter means; said forward end portion being of hinged construction; said hinged construction comprising a pair of flexible arms having a means for bilaterally diverging the arms from each other at an intermediate portion of their length when longitudinal pressure is exerted against one end of said arms by said trailing end portion; said inserter means being adapted to insert said tampon into the vagina while said tampon is draped over said forward end and to bilaterally spread said tampon within the vaginal cavity after insertion therein.

2. In combination, an absorbent tampon body in association with an elongate inserter for said tampon adapted for inserting said tampon into the vaginal cavity and bilaterally spreading said tampon within said cavity after insertion; said inserter having a forward portion provided with fixed support means for said tampon and bilateral spreading means associated with said fixed support means; said tampon body comprising an absorbent pad spreadably disposed over and around said fixed support means and said bilateral spreading means; said fixed support means comprising a base and a pair of elongate beams extending from said base and being joined to each other at their forward extremities; said bilateral spreading means being disposed within said fixed support means and comprising a bifurcated front portion and a rod-like rear portion slidably disposed within said base; said bifurcated front portion comprising a pair of arms hingedly connected at said forward extremities and at said rod portion; said arms being adapted to flexibly diverge from each other intermediate the points where said arms are hingedly connected, whereby when said rod portion is slidably activated said arms will diverge and bilaterally spread said tampon.

3. The combination of claim **2** wherein said fixed support means and said bilateral spreading means are of unitary construction.

4. The combination of claim **2** wherein said fixed support means is separate from said bilateral spreading means and is provided with sockets at said joined portion of said forward extremities, said sockets providing the hinged connecting means for the front end of said arms.

5. The combination of claim **2** wherein said tampon initially comprises a thin, flat, soft, conformable and substantially uncompressed pad of absorbent material having a withdrawal string attached at a point on the periphery thereof and said pad is draped over said fixed support means.

6. The combination of claim **5** wherein the pad of absorbent material is made up of a core of absorbent fibers enclosed in a fluid pervious wrapper.

7. The combination of claim **5** wherein the pad of absorbent fibers comprises a batt of wood pulp fluff enclosed in a fluid pervious wrapper.

8. The combination of claim **7** wherein said wrapper is woven gauze.

9. The combination of claim **7** wherein said wrapper is non-woven scrim.

10. The combination of claim **7** wherein said wrapper is a non-woven web of staple length fibers.

11. The combination of claim **10** wherein said fibers are synthetic fibers.

12. The combination of claim **11** wherein said fibers are hydrophobic.

13. The combination of claim **7** wherein said wrapper is a non-woven web of continuous synthetic filaments.

14. The combination of claim **13** wherein said filaments are hydrophobic.

15. The combination of claim **5** wherein said thin pad is in the form of an elongate rectangle.

16. The combination of claim **5** wherein said thin pad is in the form of an elongate rectangle with a portion of the diagonally opposed corners excised.

17. The combination of claim **5** wherein said thin pad is in the form of a Maltese cross.

18. The combination of claim **5** wherein said thin pad is in the form of a Greek cross.

19. The combination of claim **5** wherein said thin pad is in the form of a triangle.

20. The combination of claim **5** wherein said thin pad is elliptical in shape.

21. The combination of claim **5** wherein said pad is of rectangular shape and has a thickened portion extending along its longitudinal center line.

22. The combination of claim **21** wherein said thickened portion is comprised of folded areas of a fluid-pervious outer wrap for said pad.

23. The combination of claim **21** wherein said pad also has a thickened portion extending along its transverse center line.

24. The combination of claim **23** wherein said thickened portion is comprised of folded areas of a fluid-pervious outer wrap for said pad.

25. The combination of claim **1** wherein said tampon comprises a compressed strip of absorbent material with a withdrawal string at one end and said strip is folded at its mid-point and draped over said inserter at said mid-point.

26. The combination of claim **1** wherein said tampon comprises an elongate pad of absorbent material enclosed in a fluid pervious wrapper, said wrapper ex-

tending beyond one end of said pad and being twisted to form a withdrawal string therefor, said pad being folded transversely in half and draped over said inserter at said fold.

27. The combination of claim **1** wherein said inserter is comprised of flexible thermoplastic material.

28. The combination of claim **27** wherein said material is polyethylene.

29. The combination of claim **27** wherein said material is polypropylene.

30. The combination of claim **1** wherein said tampon and inserter are enclosed in a tight-fitting removable protective wrapper.

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