United States Patent [19]

Schaefer

[11] **3,815,601**

[45] **June 11, 1974**

[54] **CATAMENIAL AGGREGATE ABSORBENT BODY**

[75] Inventor: **Jean Edward Schaefer,** Cincinnati, Ohio

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

[22] Filed: **May 9, 1973**

[21] Appl. No.: **358,773**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 254,004, May 17, 1972, abandoned.

[52] **U.S. Cl.** **128/285**
[51] **Int. Cl.** **A61f 13/20**
[58] **Field of Search** 128/263, 270, 285, 290, 128/287, 296

[56] **References Cited**

UNITED STATES PATENTS

3,013,558	12/1961	Leupold	128/285
3,306,966	2/1967	Matejcek et al.	128/285
3,431,911	3/1969	Meisel, Jr.	128/287
3,559,646	2/1971	Mullan	128/270
3,674,025	7/1972	Bleuer	128/263
3,712,305	1/1973	Wennerblom et al.	128/285

FOREIGN PATENTS OR APPLICATIONS

606,627	12/1934	Germany	128/285
718,042	1/1932	France	128/285
805,662	5/1951	Germany	128/285
1,121,770	1/1962	Germany	128/285

Primary Examiner—Charles F. Rosenbaum
Attorney, Agent, or Firm—Frederick H. Braun; John V. Gorman; Richard C. Witte

[57] **ABSTRACT**

A tampon wherein the absorbent body is an aggregate of separate pieces of low modulus, resilient, absorbent foam. The aggregate is held together by an encasing overwrap which is relatively loose about the aggregate to permit some relative motion between adjacent pieces of foam. The mesh of the overwrap is fine enough to totally contain the absorbent pieces and thereby prevent surfaces of the absorbent pieces from penetrating the overwrap and forming part of the external surface of the tampon.

30 Claims, 9 Drawing Figures

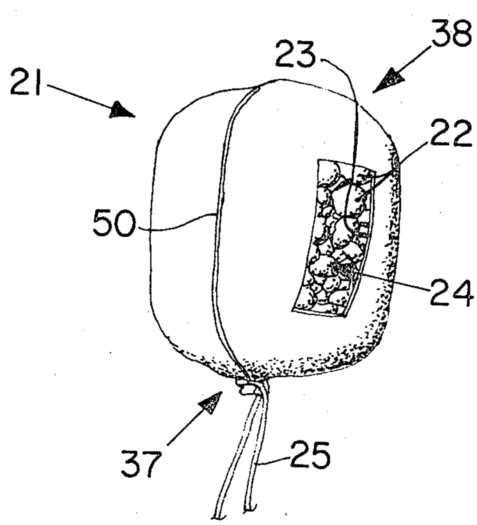


Fig. 1

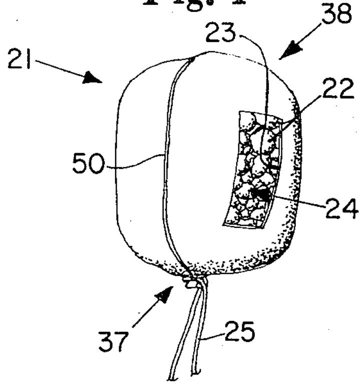


Fig. 2

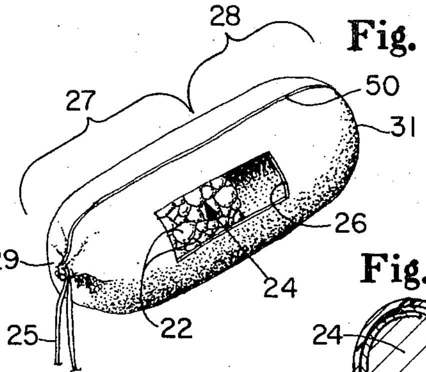


Fig. 8

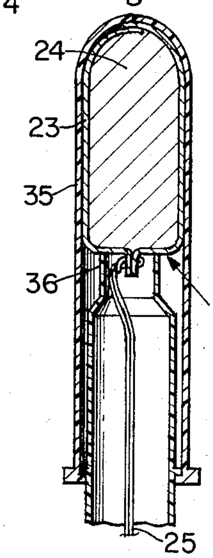


Fig. 4

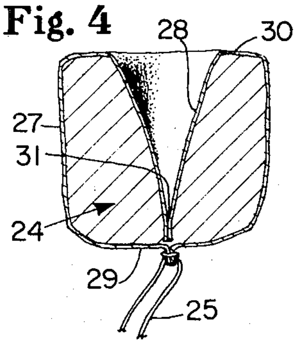


Fig. 3

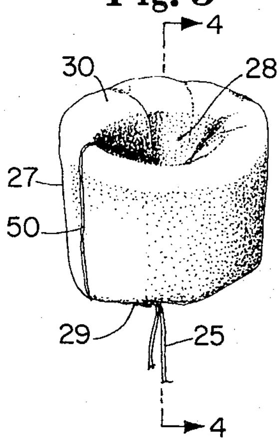


Fig. 5

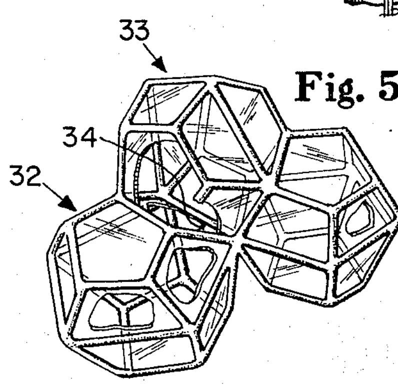


Fig. 6

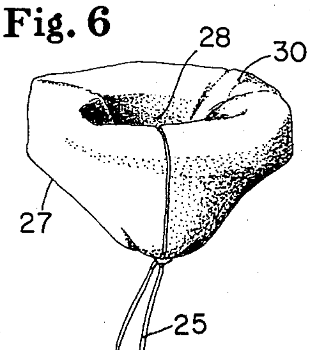


Fig. 7

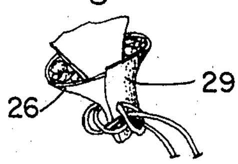
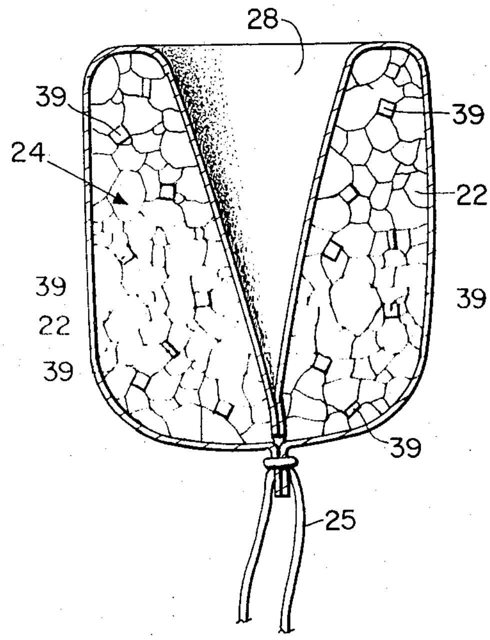


Fig. 9



CATAMENIAL AGGREGATE ABSORBENT BODY

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part application of copending U.S. application Ser. No. 254,004, filed May 17, 1972 and now abandoned.

FIELD OF THE INVENTION

This invention relates generally to absorbent products designed to absorb body fluids and more particularly concerns catamenial receptors designed to be worn within the vagina while receiving catamenia of women and most particularly concerns tampons having an absorbent body which comprises pieces of absorbent foam held together as an aggregate by an overwrap.

DESCRIPTION OF THE PRIOR ART

Tampons of the prior art which can be inserted by the user herself are generally rigid, i.e., have a high modulus of compression, have a very low resiliency, and are small in cross section in order to attain insertion, wearing and removal comfort. Tampons presently in use generally are fibrous assemblies which are highly compressed into cylinders approximately 1½ to 2 inches long and ½ inch in diameter. These fibrous tampons are highly compressed to facilitate insertion and do not expand, if they expand at all, until contacted by the fluid to be absorbed.

The tampons of the prior art do not allow the absorbent material to perform as effectively and efficiently as possible due to the limited absorption surface available and/or stresses imposed on the absorbent material which prevent full utilization of its potential capacity as an absorbent material.

Prior art tampons are generally limited with respect to capacity, containment, and absorption rates. They are limited in capacity in that the tampon contains a relatively small amount of absorptive material and is highly compressed. Thus, a large "void volume," i.e., unoccupied space within the absorbent body in the vagina which will act as a reservoir for the menstrual fluid is not available. They are limited in containment because they are small in size and do not fill out the vagina to prevent fluids from flowing around them or bypassing them. They are limited in absorption rate because they have a small surface area available for contact with the fluid and can only take on so much fluid within a given time even though the wicking within them is good.

Applicant's invention provides a solution to the drawbacks of the prior art tampons in that it establishes and thereafter maintains a large void volume within the vagina and, therefore, has a greater capacity; it is large enough to fill out substantially the entire cross-section of the vagina and, therefore, provides containment; it has a large available surface area which has resulted in unexpectedly high absorption rates; and is comfortable to insert, wear, and remove.

OBJECTS OF THE INVENTION

Accordingly, it is an object of this invention to provide an absorptive device which establishes a large void volume very soon after insertion into a body cavity and thereafter maintains said void volume.

It is another object of this invention to provide an absorptive device having a large volume and cross section in its dry state.

It is also an object of this invention to provide an absorptive device having high initial and overall absorption rates.

In addition, it is an object of this invention to provide an absorptive device which is readily disposable in conventional sewage systems.

It is also an additional object of this invention to provide a tampon with the above features which is comfortable to insert by the user, and is confortable during wearing and removal.

SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided an absorptive device comprising an aggregate of individual pieces of absorbent foamlike material encased within a flexible fluid-permeable overwrap, the absorbent material is flexible and resilient and has a dry aggregate modulus of compression at 25 percent compression in the range of about 0.004 to about 0.050 pounds per square inch, whereby the aggregate is maintained by the overwrap and also the catamenial device is soft, highly compressible and conformable to its surroundings, and resilient.

BRIEF DESCRIPTION OF THE DRAWINGS

While the specification concludes with 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 drawings, in which the thicknesses of some of the materials are exaggerated for clarity and in which:

FIG. 1 is an elevation of a tampon of this invention with the overwrap partially cut away to permit illustration of the tampon interior;

FIG. 2 is a perspective of another embodiment at one stage in its formation and wherein the overwrap is cut away for illustrative purposes;

FIG. 3 is a perspective view of the embodiment of FIG. 2 in its formed configuration;

FIG. 4 is a sectional view taken along line 4—4 of FIG. 3;

FIG. 3 is an enlarged schematic perspective view of a series of polyurethane cells;

FIG. 6 is a perspective view of an alternate embodiment;

FIG. 7 is an enlarged fragmentary perspective view illustrating the attachment of a withdrawal string to a tampon of this invention;

FIG. 8 is a cross-sectional view of the tampon of FIG. 1 in a telescoping tubular inserter; and

FIG. 9 is a cross-sectional view, similar to FIG. 4, showing an alternate embodiment.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to FIG. 1, there is shown a tampon 21 of this invention comprising an aggregate 24 of individual and separate pieces 22 of absorbent foamlike material. The aggregate 24 is wholly encased within the overwrap 23 and the withdrawal string 25 is securely attached to the overwrap 23.

A tampon of this invention as shown in FIG. 1 can be made in the following manner. The overwrap can be formed from a rectangular piece of material by bringing two opposite edges of the rectangular piece together to form a tube having a longitudinal seam such as seam **50** which is secured by any of well known methods, such as sewing or gluing. One end of the formed tube can then be gathered radially inwardly and fastened to form a closure, such as distal end **37.** This closure can be held by any of many various well known means such as sewing, gluing, or tying with a string. The overwrap at this stage is tubular with distal end **37** closed and proximal end **38** open. The pieces 22 comprising the aggregate **24** then are placed within the bag and the proximal end **38** of the tubular overwrap is gathered radially inwardly and fastened to form a closure so that the finished overwrap has both ends closed. Thus the overwrap is essentially tubular and the tampon cylindrical.

A withdrawal string **25** is attached to the overwrap of the tampons of this invention due to the lack of tensile property within the aggregate **24** itself. The withdrawal string **25,** of course, provides a means of withdrawing the tampon from the vagina after the tampon is soiled. A withdrawal string **25** can be attached to or otherwise associated with the overwrap in many different ways, some of which are: threading a doubled string through the overwrap, preferably through a gathering of the overwrap such as may exist at a closed end, to form a loop and passing the free ends of the string **25** through the loop, such as is shown in more detail in FIG. **7,** or fixing the string **25** to the surface of the overwrap by sewing or bonding it thereto sufficiently to withstand forces encountered during withdrawal, or by tying the string **25** around a gathered end of the overwrap. In a tampon of the structure of FIG. **4,** i.e., having a reentrant portion **28** of the overwrap, the string **25** can also be threaded, if desired, through reetrant end **31** to insure reentrant end **31** remains adjacent closed end **29.**

The expression "gathered" as used herein is intended to include any bringing together of the overwrap at a longitudinal end to form a closure of the overwrap at that end, e.g., a closure in which the overwrap is omnidirectionally gathered radially inwardly, as if drawn by a drawstring; a fin seal wherein the terminal end is flattened to a single plane by forces perpendicular to the plane; a lapped joint wherein the terminal end is folded inwardly and diametric portions of the end overlap, etc. A terminal end of the overwrap or any portion of the overwrap can be any extremity or margin of the overwrap, such as is indicated by end **31** in FIG. **2.**

Referring now to FIG. **3,** an alternate embodiment tampon of this invention (hereinafter referred to as rosette) is shown which has a cavity therein formed by a reentrant portion **28** of the overwrap. The tubular shaped overwrap used for the rosette is slightly longer than the overwrap **23** of FIG. **1** and it comprises an exterior portion **27** and a reentrant portion **28** as indicated in FIG. **2.** The distal end **29** of the rosette is gathered and secured by any of the means well known for forming a closure, for example, sewing or gluing the gathered end. The overwrap is about twice as long as the overwrap **23** for the tampon of FIG. **1,** and the exterior portion **27** and the reentrant portion **28** each are about 50 percent of the length of the tubular overwrap. The absorbent body which is an aggregate **24** of pieces **22** is placed within the overwrap and, depending upon the packing factor (defined infra) desired, the aggregate **24** may or may not completely fill out the overwrap. The terminal end of the reentrant portion **28** at the reentrant end **31** of the overwrap may be, but does not necessarily have to be, gathered and closed. The reentrant portion **28** is folded inwardly along the longitudinal axis of the tampon and the aggregate **24** is shaped to form the cavity in the tampon of FIG. **3.** The surface of the cavity within the tampon is formed by reentrant portion **28,** i.e., reentrant portion **28** is folded around the cavity end **30** of the aggregate **24** and inwardly through aggregate **24** to form the rosette structure. This structure is shown in cross-section in FIG. **4** wherein the reentrant end **31** is adjacent to the closed end **29.** Thus there is formed a tampon wherein the absorbent body, aggregate **24** of pieces **22,** is encased by an overwrap having an exterior portion **27** forming the exterior surface of the tampon and a reeentrant portion **28** forming the surface of the cavity. A withdrawal string **25** can be attached as described above.

The embodiment shown in FIG. **6** is another rosette, similar to that of FIG. **3,** in that it has the aggregate **24** absorbent body which is enclosed by an overwrap having an exterior portion and a reentrant portion, but the shape of the overwrap before the reentrant portion is tucked inwardly is essentially that of two truncated cones joined at their large bases. Thus the embodiment of FIG. **6** is generally conically shaped and has a cavity. Also, it can have a withdrawal string attached as has been described above.

The rosette shape is advantageous because its lateral spread when subjected to a force normal to the tampon's longitudinal axis is greater than the lateral spread of a tampon without a cavity in the middle, e.g., a cylindrical tampon. The greater lateral spread is beneficial because the vagina exerts a normal force on the tampon causing the tampon to spread outward toward the lateral walls of the vagina and the spreading prevents menses from bypassing the tampon. Another advantage of the rosette shape is that it provides a larger periphery for a given amount of aggregate than a tampon without a cavity therein.

The tampon of this invention can be inserted into a vagina via a telescoping tube type inserter, as is well known to those of ordinary skill in the tampon art. One such inserter having inwardly tapering flexible segments at the leading end to form a normally closed, smooth, openable, leading end is shown in FIG. **8** with the tampon **21** of FIG. **1** held therein. The inserter used with the tampon of this invention was molded from polyethylene, but can also be made of other materials well known to men of ordinary skill in the tampon inserter art. The tampon **21** is resiliently compacted and maintained in that condition before and during insertion by placing it in the tubular inserter **35.** Resiliently compacted as used herein means compressed to a degree such that the absorptive body takes on a readily releasable temporal set, i.e., a set which dissipates in the absence of liquids after the tampon is ejected from a constraining means such as an inserter. The overwrap **23** of the tampon **21** is in contact with the inner surface of the inserter 35. An ejecting means, such as the ejector **36,** removes a tampon from the inserter. In the embodiment of FIG. **8,** ejector **36** pushes against the rear end of tampon **21** to move it forward in the inserter, open the closure at the forward end of the inserter and expel the tampon from the inserter **35.**

The tampon, in the inserter used, forces open the segments at the forward end of the inserter. The inserter 35 is inserted into the vagina and the tampon 21 is ejected from the outer tube by pushing the ejector 36 so that it telescopes within the inserter 35. The inserter 35, with the ejector 36 therein, is removed from the vagina after the tampon 21 has been fully ejected from inserter 35 and deposited within the vagina.

An alternate embodiment of the tampon of this invention is shown in FIG. 9 wherein pieces 39 of ancillary absorbent material are distributed within the aggregate 24 of the foamlike pieces 22. The ancillary absorbent material is stiffer, i.e., has a highter modulus of compression, than the absorbent material from which the pieces 22 are made.

Many different ancillary absorbent materials can be used for various purposes. One of these purposes is to hold liquids within the abosrbent body after they have been absorbed and thus reduce squeeze-out when a liquid loaded tampon is compressed. An ancillary absorbent material which has been found to perform satisfactory in the tampon of this invention is a cross-linked carboxymethyl cellulose such as is disclosed in U.S. Pat. No. 3,589,364 issued to Dean et al. on June 29, 1971, said patent being incorporated herein by reference. Other ancillary absorbent materials may be used, for example, carboxymethyl cellulose, primarily insoluble, polyacrylamides, primarily cross-linked, specific starch derivatives, all of which are well-known to those of ordinary skill in the art. Of course, there are many other ancillary absorbent materials which can be included in the tampon of this invention and applicant does not disclaim any of these.

The pieces 39 of ancillary absorbent material included in a tampon of this invention can be of many various sizes, shapes and forms and located in various positions within the tampon. In a preferred embodiment, the pieces 39 are small, i.e., regular parallelepipeds approximately ⅛ × ⅛ inch squares cut from a 1/16 inch thick sheet of the cross-linked carboxymethyl cellulose. These pieces 39 are then substantially uniformly distributed throughout the aggregate 24. The percentage, by weight, of the pieces 39 based on the aggregate 24 ranges from approximately 10 precent to 50 percent, preferably from about 15 percent to 30 percent. The most preferred percentage of cross-linked carboxymethyl cellulose used in several instances was about 20 percent to 25 percent.

Alternate forms of small pieces 39 of the ancillary absorbent material are pellets and individual cellulosic fibers. Thin rods or bars of the ancillary material can also be used. These alternate forms of the pieces 39 can be located in many positions within the absorbent body of the tampon, such as uniformly distributed throughout the aggregate 24, as shown in FIG. 9, or concentrated in particular positions in the aggregate 24, such as near the reentrant portion 28 of the overwrap.

The fit of the overwrap 23 about the aggregate 24 is preferably loose to a degree rather than tight and can be described by a packing factor or a volume-length factor in conjunction with an overwrap cross-sectional area (defined infra). A loose overwrap makes the tampon look and feel fluffy and soft. A loose overwrap also promotes absorption characteristics and wearing and removal comfort as indicated by the data in Table III infra.

The fit of the overwrap 23 about the aggregate 24 also affects ejection force such that with equal amounts of absorbent material, the ejection force is generally lower if the packing factor is higher, i.e., if the overwrap fit is tighter. See Table III infra. For this reason and others explained hereinafter, the looseness of overwrap, i.e., packing factor, is critical to achieve an optimum balance of certain desirable tampon characteristics. A loose overwrap about an aggregate 24 of low modulus of compression (defined infra) pieces 22 to give a packing factor within a range defined infra will promote removal comfort, i.e., lack of discomfort when the tampon is removed from a vagina. It is believed that removal comfort is enhanced because the pieces 22 can shift with respect to each other as they are compressed to conform to the introital orifice; thus dilation of the introitus during removal is gradual and easier due to the low modulus of the aggregate 24 and relative motion permitted between adjacent pieces 22. Relative motion between pieces 22 occurs because the pieces 22 are relatively loose within the overwrap 23 rather than being tightly packed within the overwrap. Thus, since the introitus is a constricting band of muscles which can be dilated, a soft, conformable tampon will take on a wedge shape having a gradually increasing diameter to gradually dilate the introitus, rather than sharply dilating the introitus, to enhance the removal comfort of the tampon. During removal, as can be visualized from FIG. 4, the closed end 29 is the leading end and the cavity end 30 is the trailing end. The eccentric portions of closed end 29 are forced towards the rear by the constriction of the introitus such that end 29 is formed into a conically shaped leading end. The aggregate 24 near the closed end 29 is thus compressed and moved toward the rear to form a tampon with a gradually increasing diameter so that the largest diameter encountered during removal is not at the leading end.

The looseness of the overwrap can be more precisely defined in terms of a volume packing factor. The volume packing factor is the volume of the integral, i.e., uncut, absorbent material used to provide the aggregate 24 divided by the maximum volume enclosable by the overwrap, i.e., cubic inches of absorbent material per cubic inches within the overwrap. The volume of absorbent material as used in the packing factor can be calculated for any specific tampon by dividing the weight of the aggregate 24 by the density of the absorbent material before it is cut up. A weight packing factor can also be determined for tampons of this invention by dividing the weight of aggregate 24 by the maximum volume enclosable by the overwrap.

A tampon which will conform and gradually ease the introitus open to promote removal comfort should have a packing factor which will allow some conformation by the aggregate to the introital openings but not be loose enough to permit all of the aggregate to shift to the rearmost portion of the overwrap as the tampon is withdrawn. A shift to the rearmost portion of the overwrap of too much of the aggregate 24 could allow an accumulation at the rear of the tampon which would require an abrupt dilation of the introitus and increased removal discomfort.

The pieces 22 were cut or made from an absorbent foamlike material having a low dry bulk modulus of compression preferably in the range of about 0.2 to about 2.0 pounds per square inch and more specifically in the range of about 0.2 to about 0.8 pounds per square inch. The work "dry" when used herein in conjunction with modulus of compression is intended to indicate the moisture content condition of the material as it is compacted within an inserter or before it is released from the inserter, generally the conditions as set forth in ASTM Test D1564, "2. Test Conditions." The word "wet" when used with modulus of compression indicates the material has been fully wetted by an excess of water and then squeezed or centrifuged to remove the excess water. The minimum modulus of compression is required to acquire absorption capacity and the maximum modulus of compression is required to achieve a comfortable tampon. This bulk modulus of compression is established in accordance witn ASTM test D1564, Compression Load Deflection Test (suffix D) at 25 percent compression. The term "absorbent foamlike material" is intended to encompass three dimensional absorptive materials such as gas blown foams, natural sponges, cellulose sponges, and composite fibrous based structures such as taught in U.S. Pat. Nos. 3,311,115 and 3,430,630 (incorporated herein by reference).

Bulk moduli of compression of two foamlike absorptive materials are given in Table I below. The samples from which the bulk moduli were obtained were 2 inches on a side for the washed Hydro-Foam™ and 1 inch on a side for the unwashed Hydro-Foam™ and the Grecian silk sponge which is taught by the prior art. All wet bulk moduli were based on the dry dimensions of the samples because the samples swelled when wetted.

All Hydro-Foam™ referred to infra is washed unless unwashed is specifically stated. The absorptive material was washed by running it in the rinse cycle of a standard home-type automatic clothes washing machine with distilled water for about 20 minutes and then drying it in a standard home-type clothes dryer for about 3 hours.

TABLE I

BULK MODULUS OF COMPRESSION OF FOAMLIKE ABSORBENT MATERIALS

	DRY			WET		
	Avg. (psi)	High (psi)	Low (psi)	Avg. (psi)	High (psi)	Low (psi)
25% Compression						
Hydro-Foam™ 0.38			0.19			
Hydro-Foam™ (unwashed)	0.62	0.64	0.60	0.26	0.27	0.25
Grecian Silk Sponge (unwashed)	6.9	11.7	4.5	0.90	1.2	0.5
80% Compression						
Hydro-Foam™ 1.30			1.10			
Hydro-Foam™ (unwashed)	2.74	2.80	2.70	2.60	2.97	2.00
Grecian Silk Sponge (unwashed)	40.7	50+	26.8	6.1	11.1	2.8

Another and perhaps more relevant measure of the stiffness of the absorbent material is the modulus of

compression of the aggregate **24** of pieces **22** comprising the absorbent body (said modulus hereinafter referred to as the aggregate modulus). The aggregate modulus indicates the compression force required to effect a specified deflection of a mass of the particulate absorbent body. The aggregate to be measured is at an equilibrium undistorted condition as set forth in ASTM D1564, "2. Test Conditions." The aggregate modulus is perhaps a more relevant measure to use because this is the actual modulus of the absorbent body forming the tampon of the invention, and as such more directly influences the ejection force of the tampon from an inserter and the wearing and removal comfort of the tampon.

There is a difference in both degree and kind between the bulk modulus and aggregate modulus of a foamlike absorptive material. The bulk modulus is different in degree in that it is substantially greater than the aggregate modulus. The bulk modulus under ASTM Test D1564, (Suffix D) at 25 percent compression of one polyurethane foam used was 0.40 psi, while the aggregate modulus of the same material at 25 percent compression was 0.03 psi. The bulk modulus is different in kind in that the behavior of the bulk, i.e., integral, absorbent foamlike materials under compression is such that the stress-strain curve of the bulk material is initially steep, i.e., a large increase in deformation for a small increase in force applied, and then appears to take on the general form of deformation equals $K + L$ log (force) where K and L are constants. In contrast, the stress-strain curve of the aggregate as appears to immediately follow the general form of deformation equals $K' + L'$ log (force) where K' and L' are constants.

The aggregate modulus of the aggregate for the tampon of this invention was measured in accordance with ASTM test D1564, Compression Load Deflection Test (Suffix D), modified as follows: A cylinder-piston device with a low height-to-diameter ratio was used to contain the aggregate. The cylinder was filled with aggregate to a uniform depth. The cylinder in this instance was made of a transparent plastic, plexiglas, had a bottom which closed one end, had an inside diameter of 240 millimeters, and was 10 centimeters deep. The piston also was made of plexiglas and consisted of a 44 millimeter diameter rod about 5 inches long glued to a 239 millimeter diameter, 5 millimeter thick plexiglas plate. The plate or piston head of the piston had holes drilled through it in order that air trapped between the cylinder and the piston head could escape without exerting a noticeable force on the piston head.

The force and deflection measurements for determining modulus of compression were made with an Instron Universal Testing Instrument. The cylinder was attached to the Instron compression cell and the piston was attached to the Instron crosshead.

Each specimen of aggregate absorbent body used in obtaining an aggregate modulus of compression was preflexed twice to 75 to 80 percent of its original volume within the cylinder and then allowed to rest under no load for 10 minutes prior to testing. Three different specimens of aggregate absorbent material were measured to determine the aggregate modulus of a specific aggregate, i.e., a sample of aggregate. Each specimen was a fresh refill of the compression cylinder to a minimum depth of 1 inch. The aggregate modulus reported for an aggregate absorbent body was the mean of the specimens. If the aggregate modulus of compression of any specimen deviated from the mean by more than 20 percent, two additional specimens were run. The aggregate modulus of that aggregate absorbent body then was reported as the mean of all 5 specimens.

The aggregate modulus of any one specimen of an aggregate absorbent body was determined as follows: First the Instron was warmed up and the compression cell of the Instron was calibrated with a known weight and with the empty compression cylinder on the compression cell table. The piston was attached to the crosshead of the Instron. Second, the chart speed was set at 5 inches per minute and the crosshead speed was set at 2 inches per minute. Third, the compression cylinder was filled with the specimen to a level of 1 inch in depth by allowing the aggregate to fall from a height of about 5 inches above the bottom of the cylinder. Any and all clumps within the specimen were broken up before they were allowed to fall into the cylinder. The top surface of the sample within the cylinder was made as level as possible. The depth of the aggregate absorbent body was measured by placing a spare plate, i.e., one identical to the plate used as the piston head but not having the 5 inch, 44 millimeter diameter rod attached thereo, on top of the specimen and measuring the thickness of the specimen from the bottom of the cylinder to the bottom of the spare plate. This depth was not less than 1 inch. Fourth, the pen of the Instron was zeroed with the filled cylinder on the compression table of the Instron. Fifth, the piston was brought into contact with the specimen and a preload of 0.02 pounds per square inch (psi) was applied to the specimen. The depth of the specimen was then measured while it was under the preload of 0.02 psi, and the crosshead travel required to produce the desired percent compression was determined based on the depth of the specimen at the specified preload. Sixth, the specimen was compressed to the desired percent compression and held at that compression for 1 minute. The load required after 1 minute to produce the desired percent compression was recorded. Seventh, the specimen was returned to 0 percent compression by retracting the piston from the sample.

The aggregate modulus for the specimen was then determined by dividing the load measured at the desired percent compression by the contact surface area of the piston.

The dry aggregate modulus of the absorptive body used in a tampon of this invention must be below a certain level to provide an acceptable tampon. If the dry aggregate modulus is too high, the tampon will be too stiff, thus causing unacceptably high ejection forces and/or discomfort during wearing or removal. Preferably, the dry aggregate modulus at the 25 percent compression level should be in the range of 0.004 to 0.050 psi, more preferably in the range of 0.004 to 0.030 psi.

The aggregate **24** of this invention should preferably be, but need not necessarily be, mensesphilic, i.e., have surface characteristics such that the menstrual fluid tends to spread readily or spontaneously on the surface and in the capillaries. Since the menstrual fluid is primarily an aqueous solution, materials onto and into which it spreads readily could be loosely described as hydrophilic. However, the state of the art respecting wetting of materials allows a more precise description in terms of contact angles and surface tensions of the fluids and solids involved. This description is disclosed in detail in the American Chemical Society publication entitled *Contact Angle, Wettability and Adhesion*, edited by Robert F. Gould, and copyrighted in 1964; said publication being incorporated herein by reference.

Menstrual fluid has a surface tension range of about 35 to 60 dynes per centimeter. It will have a contact angle of less than 90° and will tend to spread spontaneously on a solid which has a critical surface tension value greater than its surface tension. Since the surface tension of water is higher than that of menstrual fluid, any solid which is hydrophilic is also usually mensesphilic.

The absorptive material used for making the aggregate **24** should desirably have a critical surface tension at least greater than 35 dynes per centimeter, preferably greater than 60 dynes per centimeter, and more preferably greater than the surface tension of water which is about 72 dynes per centimeter.

The absorptive foamlike material and the aggregate **24** made from these materials which is used in a tampon of this invention should be resilient. One test for resiliency is a Compression Set Test, a modification of ASTM D1564, Compression Set Test, run on an Instron Universal Testing Instrument wherein the sample is compressed to 80 percent of its dry height, released, and the percent recovery of the sample is measured. The percent recovery can be measured by placing a quantity of aggregate **24** in a 4 inch diameter cylinder, placing a piston connected to the Instron load cell within the cylinder, compressing the aggregate to 20 percent of its dry height, backing the piston away from the compressed aggregate, and measuring the rebound height of the aggregate after about 30 seconds. The percent recovery then is [rebound height divided by the initial height] times 100. The percent recovery for a dry aggregate of pieces **22** should be a minimum of about 91 percent and preferably about 97 percent in order that a resiliently compacted aggregate tampon will expand before being wetted after being placed in a vagina, so that the tampon fills the vaginal cross-section soon after placement.

Absorptive materials which work well for the pieces **22** for the tampon of this invention are absorbent materials having adjacent cells such as cells **32** and **33** shown in FIG. **5** wherein adjacent cells can communicate with each other if a common wall **34** is ruptured, in which case a fluid within cell **32** can move from cell **32** to adjacent cell **33**. Hydrophilic polyurethane foams have adjacent cells such as cells **32** and **33**, which can be made communicating by reticulation, a breaking of inter cellular walls, of the foam, and such foams are described in detai in the commonly owned, copending, U.S. Pat. application entitled COMPLIANT CONFORMABLE TAMPON, U.S. Ser. No. 172,694, filed Aug. 18, 1971, incorporated herein by reference. One of those polyurethane foams, i.e., Hydro-Foam^{TM}, which has been used and produces a satisfactory tampon of this invention is available from Scott Paper Company, Foam Division, Eddystone, Penna. The Hydro-Foam^{TM} is hydrophilic and wet swelling. It was found to have a cell count of approximately 80 cells per inch, a density of about 1.9 to 2.3 pounds per cubic foot, and a dry bulk modulus of compression of about 0.4 pound per square inch after being washed.

In a successfully executed embodiment of a tampon of this invention, the foam forming the absorbent body, i.e., Hydro-Foam™, had a density of about 0.596 grams per cubic inch, weighed about 2.5 grams and was cut into pieces **22** which had a size of ⅜ inch and smaller. "Size" as used herein in describing pieces **22** is intended to indicate the size of piece which will pass, with vibration, through a U.S. Standard Sieve having a mesh opening of the stated size, but not through the next smaller sieve. Thus, a piece **22** having a size of ⅜ inch will pass through a sieve having a ⅜ inch mesh opening, but not through a 0.265 inch sieve. The size of the pieces **22** can vary widely, with a maximum size of about 1 inch, but preferably having a size in the range of about 1/16 inch to about ⅝ inch. The smallest acceptable size is determined by whether the piece **22** will absorb and whether it will be retained by the overwrap. The largest acceptable size for a piece **22** is determined by whether that size piece will form a smooth aggregatable absorbent body.

Of course, the absorbent body can be an aggregate of various sized pieces or of substantially uniformly sized pieces. When uniformly sized pieces **22** are used as the absorbent body, there is a minimum acceptable size for the pieces **22** in order that the tampon has the resiliency required to fill the vaginal cross-section and the modulus of compression required to maintain a void volume as a fluid reservoir within the vagina. Band Compression Modulus (hereinafter defined) was measured on rosette tampons wherein the maximum outer diameter of the overwrap was about 2 inches and the length of the rosette was about 2½ inches. Unwashed HydroFoam™ was used as the absorptive material, the pieces **22** within any one rosette were essentially uniform in size, each rosette had a different sized piece **22**, and the aggregate **24** within each rosette weighed about 2.5 grams. The Band Compression Modulus for each tampon having uniformly sized pieces **22** is shown in Table II below. The minimum acceptable piece **22** size for a tamping of this invention is about 1/16 inch. The aggregate **24** of pieces **22** need not be coherent in and by itself because the overwrap will maintain the aggregate.

TABLE II

UNIFORM PIECE SIZE VS. BAND MODULUS HYDRO-FOAM™ ROSETTE

PIECE SIZE		BAND MODULUS LB. TO REDUCE CIRCUMFERENCE 25%	
		UNWASHED	WASHED
1"		0.53	—
¾"		—	0.30
⅝"		0.55	—
½"		—	0.34
⅜"		0.48	0.42
PASSES THROUGH SIEVE SIZE	CAUGHT ON SIEVE SIZE		
⅜"	0.265"	0.4	0.33
0.265	0.187	—	0.25
0.187	0.132	—	0.28
0.132	0.0937	—	0.28
0.265	0.0937	0.25	—
0.0937	0.0661	0.24	0.22
0.0661	0.0469	0.17	0.19
0.0469	0.0197	0.12	0.13

Also, the pieces **22** need not necessarily be uniformly shaped, in fact, they preferably are very irregularly shaped such as would result by chopping in a Waring kitchen blender. Pieces **22** were chopped for the tampon of this invention in a Waring kitchen blender by putting blocks of Hydro-Foam™ in the blender. Pieces **22** also have been made irregularly shaped by comminuting Hydro-Foam™ and other similar polyurethane foams in a fixed blade comminutor, such as a Fitz Mill available from the Fitzpatrick Company. Pieces **22** have also been cut from polyurethane foams with a scissors into uniform shapes, i.e., in the form of cubes of various sizes.

The material used as the overwrap of this invention preferably is a soft, flexible, fluid permeable material having small apertures therethrough. A biodegradable material is desirable for the overwrap because it will enhance the destructability of disposed tampons. Two nonwoven fabrics which have functioned well as the overwrap and are believed to be biodegradable are: Dexter X-2172, a nonwoven fabric consisting of approximately a 60:40 cotton:rayon blend, saturation bonded with a mixture of HA8 and HA24, Rohm & Haas acrylic binders, said fabric having a measured weight of about 0.6 to 0.7 ounce per square yard and being hydrophobic and available from C. H. Dexter & Sons Co., Windsor Locks, Connecticut; and Viskon, a 100 percent rayon, nonwoven, line-bonded material, which is hydrophilic, has a measured weight of about 0.47 ounce per square yard, and is available from Chicopee Mills, 1450 Broadway, New York, N.Y.; Reemay, a hydrophobic, spunbonded, low basis weight, polyester nonwoven fabric having a measured weight of about 0.4 ounce per square yard and available from E. I. Du Pont de Nemours, Wilmington, Del., is another nonwoven which has performed satisfactorily as an overwrap for tampons of this invention. Use of a highly hydrophobic material as the overwrap with a highly absorptive absorbent body can be advantageous in that it insulates the vaginal wall from collected menses and thus maintains, during menstruation, the slightly acidic condition of the vagina which exists during non-menstrual times.

The above nonwoven fabrics have no noticeable apertures therein, but some materials having noticeable apertures have been used satisfactorily. The purpose of keeping the apertures small is to prevent small pieces **22** from escaping through the overwrap and to prevent edges or corners of larger pieces **22** from projecting through the overwrap. The nominal and potential apertures, i.e., opened areas or areas encompassed by adjacent fibers, in the overwrap should not exceed a size which will prevent pieces **22** from escaping from the overwrap or from protruding therethrough such as to interfere with the ejection force of the tampon from a tubular inserter. Some foam-like materials, e.g., polyurethane, have a high coefficient of friction with inserter materials like polyethylene or paperboard. The static coefficient of friction of polyurethane with polyethylene is about 1.05. Therefore, the nominal and potential apertures within the overwrap should be no greater than the smallest piece **22** comprising aggregate **24**. The potential apertures can be much larger than the nominal apertures when the crossover points within the overwrap are not bonded. It has been found that a woven overwrap having an interfiber distance of about ⅛ inch in both directions and having no attachment at the crossover points is not acceptable in that the ejection force from a telescoping tubular inserter for that tampon is increased (see Table V below). For such an inserter, it is thought preferable to exclude the pieces

22 from the exterior surface of the tampon in order to maintain a smooth exterior surface and a low coefficient of friction. It has been found that overwraps having apertures with diameters as large as 1/16 inch, when the pieces 22 are a mixture of sizes from about 1/16 inch to about ⅜ inch, do not prove detrimental to the functioning of the tampon.

It is believed desirable to maintain the exterior surface of the tampon as smooth and having as low a coefficient of friction as possible for at least two reasons: to achieve a low ejection force, i.e., the force required to eject the tampon 21 from a tubular inserter such as inserter 35 (see FIG. 8), and to prevent scraping of the soft, tender tissue within the vagina during insertion, wearing, and removal. In general, the absorbent material from which the pieces 22 are made has a higher coefficient of friction than the overwrap material and, therefore, any protrusion of the pieces 22 through the overwrap would result in an increase in the ejection force and the scraping of the tissue within the vagina.

The overwrap should have a static coefficient of friction with the interior of the inserter of less than about 0.40, and preferably less than about 0.37, to provide acceptable ejection forces with larger tampons of this invention. Overwraps having a coefficient substantially higher than 0.40 result in ejection forces which are substantially higher and prove to be objectionable by users.

The overwrap should have strength characteristics so as to prevent the nonwoven material from rupturing during removal or from vaginal pressures while in vivo. The overwrap should have a wet tensile strength in the machine direction of at least about 600 grams per inch and in the cross direction at least about 250 grams per inch. The minimum wet internal tearing resistance as measured by TAPPI Standard T 414 ts-65 in the machine direction for the overwrap should be about 100 grams to tear 16 plies 2 inches to prevent the overwrap from tearing during removal of the tampon from the vagina.

A material which has worked well as a withdrawal string is a waterproofed cotton string having a 5/3 ply and a 9 pound tensile strength. Such a string is available from Bibb Manufacturing Company, Macon, Ga. under the name of 5/3 ply Sno-Spun bleach 108 cotton.

Any string sufficiently strong to withstand removal forces can be used as the withdrawal string 25. The polyester strings generally have a higher tensile strength and can be used if a stronger string is desired. Polyester strings are available from UniRoyal Fiber & Textile, Division UniRoyal, Incorporated, 350 Columbia Road, Winnsboro, S.C., 29180.

A tampon of this invention made with the aforementioned Hydro-Foam™ as the absorbent material requires a minimum of about 1.00 gram and preferably more than about 1.5 grams of the absorbent material to acquire adequate performance with the tampon. Adequate performance encompasses at least both absorption capacity of the tampon and bypass control. To achieve bypass control, the tampon should preferably have a nominal outside diameter of at least about 1.75 inches, which provides a nominal periphery of at least about 5.5 inches. The nominal diameter, periphery, cross-sectional area, and volume available within the overwrap (hereinafter referred to) is intended to be the dimension of the overwrap in its fullest radially extended form, resulting in a generally circular cross-section, rather than a partially collapsed form which occurs when the aggregate is not large enough to fill the overwrap. Also, the cross-sectional area or volume available within the overwrap does not include the area or volume in the cavity of the rosette. The overwrap for a rosette shaped tampon was made from the above mentioned Reemay, and was a rectangular piece about 6½ by 6¾ inches. The overwrap material was formed into a tube in the manner described above with a 6¾ inch dimension forming the circumferential periphery of the overwrap and allowing approximately ½ inch of the 6¾ inch dimension for the seam. A rosette made from the above size overwrap is about 2½ inches long and about 2 inches in diameter.

The maximum amount of the above mentioned Hydro-Foam™ which can be incorporated into a tampon of this invention appears to be limited by the maximum inserter diameter which can comfortably be inserted by a user. Thus limited by an inserter having an inside diameter of about 0.71 inch, the maximum amount of the absorptive material which could be used in a 2½ inch long tampon of this invention was about 5.25 grams when the pieces 22 were a mixture of 1/16 to ⅜ sized pieces. The inserter size limited the inclusion of more absorptive material because the ejection force required became too great to allow comfortable ejection even with a tight, low coefficient of friction overwrap. The ejection force encountered with 5.25 grams of the absorptive material and the Reemay overwrap in a polyethylene inserter such as shown in FIG. 8 having an inside diameter of about 0.71 inch was about 3.5 pounds.

A preferred embodiment, which is certainly not the only operative embodiment, was made as follows: Rosettes were made in accordance with the structure shown in FIG. 3 from 6½ by 6¾ inch rectangles of the above mentioned Reemay overwrap material, 2½ grams of the aforementioned Hydro-Foam™ absorbent material, and the 5/3 ply withdrawal string. The overwrap material was formed into a tubular shape by folding the rectangle on the 6¾ inch dimension, overlapping the oppositely disposed marginal edges, and sewing together the superposed marginal edges and one of the terminal ends to form a bag configuration. The bag was then inverted and the sewing along the marginal edge formed a seam such as seam 50 in FIG. 3 and the sewing along the terminal end formed a closed end such as distal end 29 in FIG. 3. The 2½ grams of absorptive material was chopped up as above described in a Waring kitchen blender such that the pieces 22 were of various sizes and the largest sized piece 22 was about ⅜ inch. The absorbent material was placed within the inverted bag and the terminal end of the bag such as reentrant end 31 of FIG. 2 was sewn shut. The reentrant end 31 was then moved inwardly along the longitudinal axis of the tampon through the aggregate 24 until the reentrant end 31 was adjacent the closed end 29. The withdrawal string 25 was then threaded through the closed end 29 with a surgical needle and secured to the overwrap. Rosettes made according to the above description are about 2 inches in diameter and about 2⅓ inches long. They have been used as a tampon, both in vivo and in the "syngyna." The ejection force required to remove them from tubular inserters is low and their absorption characteristics are unexpectedly good. Their characteristics are shown in Table III as Example VIII.

A syngyna is an artificial device used to simulate a vagina. It consists of a thin rubber membrane which holds the tampon, said membrane being within an outer case such that water can be introduced between the membrane and the outer case so that a hydraulic head can be placed on the exterior of the membrane, and a tube entering the membrane at its interior end such that the tube orifice into the membrane simulates the cervical os. A reservoir of syngyna fluid, said fluid having a viscosity and salinity equal to that of menstrual fluids, is connected to the tube with a flow regulator such that the syngyna fluid can be admitted to the membrane through the tube at a known and variable rate. There are both static and dynamic syngynas. The hydraulic head is constant in a static syngyna and the hydraulic head is varied in a dynamic syngyna. All absorption capacities and rates herein described were determined in a dynamic syngyna wherein the head was varied from 4 to 16 inches of water at a regular cycle rate of about 4 cycles per minute. Syngynas are known to persons of ordinary skill in the tampon art.

Rosettes of various diameters and amounts of aggregate Hydro-Foam™ absorbent material were made in the aforedescribed manner of Example VIII with various sized overwraps to give the tampon sizes of Examples I through X of Table III. The tampons of Examples I through X have been tested both in vivo and in a syngyna. The physical characteristics, unexpected absorption performance, especially the absorption characteristics being dependent on the packing factor, and the average weighted comfort grades of these tampons are given in Table III below and discussed. The infra "Band Modulus" was measured by slipping a 1 inch wide Teflon band around the tampon and measuring the force on an Instron Universal Testing Machine to reduce the circumference of the tampon to 75 percent of its normal circumference. The "Plate Modulus" was measured by placing the tampon between two flat plates with the tampon's longitudinal axis parallel to the plates and measuring the force on an Instron Universal Testing Instrument required to reduce the tampon's diameter to 75 percent of its normal diameter. The ejection force was measured as the force required to eject the tampon out of a polyethylene inserter such as shown in FIG. 8 wherein the inserter had a 0.71 inch inside diameter, four segmented petals at its leading end, and a nominal wall thickness of about 0.015 to 0.025 inch in the petal area. The tampons had been resiliently compressed in the inserter for at least 2 hours. The static ejection force is the force required to start the tampon moving and the dynamic force is the force required to open the petals and overcome dynamic friction. The "Packing Factor" was calculated both as the weight and volume of Hydro-Foam™ per cubic inch of volume available within the overwrap. The volume of aggregate was calculated by dividing the integral foam density into the weight of foam used. It is of interest that the relation between the Band Modulus and the Volume Packing Factor is essentially a straight line function. The absorption characteristics were determined in a syngyna. The syngyna fluid was "fed" to the tampon as fast as the tampon would absorb it and the test was stopped as soon as syngyna fluid escaped from the end of the tampon opposite the end at which the fluid was fed. The "Weight Gain" was calculated by subtracting initial weight from final weight of the tampon, "Initial" rate was taken from the time required for the tampon to absorb the first 5 milliliters of fluid. "Overall" rate was calculated from "Weight Gain" and time required to absorb that amount of fluid. "Efficiency" was calculated by dividing the "Weight of Absorption Material" into "Weight Gain." Each of the "Average Weighted Comfort Grades" entries are calculated as:

$$\frac{\sum_{g=0}^{3} n_g g}{\sum_{g=0}^{3} n_g}$$

where

n_g = number of panelist responses in comfort grade g for that Example tampon; and

g = a comfort grade.

TABLE III

CHARACTERISTICS OF HYDRO-FOAM™ ROSETTE TAMPONS HAVING REEMAY OVERWRAP

Example	Tampon Nominal Size Diameter (inches)	Tampon Nominal Size Length (inches)	Volume within Overwrap (inches³)	Weight of Absorption Material (grams)	Packing Factor Weight (g. foam/in.³ tampon)	Packing Factor Volume (in.³ foam/in.³ tampon)	Average Weighted Comfort Grades Insertion	Average Weighted Comfort Grades Wearing	Average Weighted Comfort Grades Removal
I	1.0	2½	1.81	5.0	2.76	4.64	0.35	0.06	0.18
II	2.0	2½	6.08	5.0	0.82	1.38	0.29	0.12	0.12
III	2.7	2½	10.10	5.0	0.50	0.84	0.17	0.44	0.33
IV	1.0	2½	1.81	3.75	2.08	3.50	0.06	0.17	0.22
V	2.0	2½	6.08	3.75	0.61	1.03	0.31	0.06	0.13
VI	2.7	2½	10.10	3.75	0.37	0.62	0.16	0.26	0.37
VII	1.0	2½	1.81	2.50	1.39	2.34	0.17	0.06	0.17
VIII	2.0	2½	6.08	2.50	0.41	0.69	0.28	0.11	0.11
IX	2.7	2½	10.10	2.50	0.26	0.44	0.11	0.11	0.17
X	2.0	2½	6.08	1.25	0.21	0.35	0.06	0.06	0.06

Table III – Continued

Example	Band Modulus (lbs./25% deflection)	Plate Modulus (lbs./25% deflection)	Ejection Force Static (lbs.)	Ejection Force Dynamic (lbs.)	Syngyna Fluid Weight Gain (g.)	Absorption Rate Initial (ml./min.)	Absorption Rate Overall (ml./min.)	Efficiency of Absorption Material (G. of Syngyna Fluid/G. Absorption Material)
I	2.05	2.45	3.45	3.51	29.8	21.7	16.6	5.9
II	0.44	0.35	3.24	3.45	33.6	26.3	16.3	6.7
III	0.19	0.15	3.66	3.50	41.2	26.4	15.6	8.2
IV	1.53	1.85	1.22	1.72	24.9	8.8	9.6	6.6
V	0.38	0.20	1.97	2.22	28.9	29.4	26.2	7.7
VI	0.19	0.08	2.39	2.75	28.5	29.4	19.9	7.6
VII	0.98	0.49	0.68	1.16	18.8	31.3	23.5	7.5
VIII	0.23	0.11	0.75	1.21	19.9	10.4	15.9	8.0
IX	0.15	0.05	1.14	1.55	20.9	14.7	21.6	8.4
X	0.11	0.04	0.35	0.82	13.7	13.9	13.6	9.1

The comfort grades used were 0, 1, 2, and 3 with 0 being no discomfort, 1 being slight discomfort, 2 being moderate discomfort, and 3 being severe discomfort. The responses were subjective evaluations given by a panel of users of the tampons, with each user using at least one complete array of Examples I through X.

The wearing and removal comfort of the 3.75 gram and 5.00 gram tampons was unexpected for such large tampons and, of course, is advantageous in that since they are comfortable, then can be used and give excellent protection due to their large size which gives them much more absorbent capacity, and also the capability to block the vagina and prevent bypass. Also, the fact that comfort is influenced by packing factor is unexpected and advantageous because the comfort can be controlled by optimizing the packing factor for a given weight of absorbent material, modulus of compression of the absorbent material, and cross-sectional area of the tampon. The packing factor can be expressed in terms of a volume-length factor in conjunction with the cross-sectional area available within the overwrap.

The comfort of a tampon of this invention is dependent on the size of the pieces **22**, the modulus of compression of the absorptive material, the cross-sectional area available within the overwrap, and the amount of aggregate **24** within the overwrap. The amount of aggregate can be defined in terms of a volume-length factor, the volume of aggregate per unit length of the tampon, which is related to the volume packing factor for a specific tampon of this invention and the relationship is: volume-length factor = volume packing factor X cross-sectional area within the overwrap for the specific tampon. The volume as used in this factor is the same as used in the volume packing factor, i.e., the volume of the integral absorbent material — not the volume of the aggregate itself. The volume-length factor thus is expressed in terms of cubic inches of integral absorbent material to form the aggregate within the tampon per inch of tampon length. A tampon of this invention that will be comfortable and provide acceptable protection, i.e., absorption, to the user has the following structure: The pieces **22** are sized from about 1/16 inch to about ⅝ inch, preferably from about 1/16 inch to about ⅜ inch. The dry aggregate modulus of the pieces **22** is in the range of about 0.004 to about 0.050 psi, preferably about 0.010 to about 0.030 psi. The cross-sectional area within the overwrap is greater than about 1.75 square inches, preferably greater than about 2.35 square inches. The volume packing factor is equal to or less than 2.0 cubic inches of absorbent material per cubic inch available within the overwrap. The volume length factor is about 1.07 to about 4.0 cubic inches of absorbent material per inch of longitudinal axis of the tampon; but preferably from about 1.07 to about 3.02 cubic inches of absorbent material per inch of longitudinal axis of the tampon when the cross-sectional area within the overwrap is from about 1.75 to about 3.60 square inches, and from about 1.07 to about $3.02 - \sqrt{0.99\,(x - 3.6)}$, wherein x is the cross-sectional area within the overwrap, cubic inches of absorbent material per inch of longitudinal axis of the tampon when the cross-sectional area within the overwrap is from about 3.60 to about 6.0 square inches.

The absorption performance of the tampon of this invention is surprisingly influenced by the packing factor of the tampon as can be seen from a comparison of equal foam weight rosette tampons having varying packing factors as shown in Table III. The foam weight is equal within the set comprising tampons I, II, and III; the set comprising tampons IV, V, and VI; and the set comprising tampons VII, VIII, and IX. Now looking closer at the set of tampons VII– VIII; and IX, just as an example, it is seen that the volume packing factor for these tampons is 2.34, 0.69, and 0.44, respectively. That is, tampon VII is packed the tightest and tampon IX is packed the loosest. The syngyna fluid weight gain for tampon VII, which has the highest packing factor in the set, at 18.8 grams is less than the syngyna fluid weight gain for tampon IX, which has the lowest packing factor in the set, at 20.9 grams.

Also, it is unexpected and surprising to note that the absorption rates of the variously packed tampons is also affected by the packing factor in that the absorption rate per square inch of overwrap cross-sectional area exposed to menses decreases as the packing factor decreases. In addition, it is noted that the "Efficiency" of the absorbent material is affected by the packing factor. The relationship appears to be such that the "Efficiency" is inversely proportional to the packing factor.

The tampon of this invention has several unexpected advantages over integral tampons made from foamlike materials, i.e., nonaggregate tampons, for example, a higher absorption rate, lower ejection force from a tubular inserter, more rapid fluffing out, and greater comfort both during wearing and during removal.

The characteristics and absorption performance of 1 × 1 × 2 inch rectangular parallelepipeds, i.e., solid blocks, and rosettes of two different kinds of foamlike absorptive material in a dynamic syngyna are shown in Table IV to illustrate the advantages of operating within the defined limits of this invention. The higher absorption rate for the aggregate tampon can be noted by comparing the initial and overall absorption rate for

TABLE IV

ABSORPTION PERFORMANCE OF AGGREGATE VS. SOLID TAMPONS

Tampon Type	Fluid* (Type)	Overwrap (Reemay)	Dry Weight of Sponge or Foam (gm.)	Dry Weight of Tampon (gm.)	Weight of Fluid Absorbed (gm.)	Initial Absorption Rate (gm./min.)	Overall Absorption Rate (gm./min.)	Efficiency (gm. fluid/gm. tampon)
Grecian Silk Sponge Solid Block	S	No	2.1	2.1	14.6	1.3	1.5	7.5
Aggregate	S	Yes	2.5	3.0	28.8	15.8	11.5	9.7
Aggregate	C	Yes	2.5	3.0	23.7	—	2.4	8.0
Hydro-Foam™ Solid Block	S	No	2.3	2.3	25.4	2.0	0.8	10.8
Aggregate	S	Yes	2.5	3.0	23.6	25.4	15.4	8.0
Aggregate	C	Yes	2.5	3.0	24.6	—	1.9	8.2

*S=Syngyna Fluid
C=Citrated Blood

the aggregates versus the solid blocks. For example, in the Hydro-Foam™ samples, the initial absorption rate went from 2.0 grams of syngyna fluid per minute for the solid block tampon to 25.4 grams of syngyna fluid per minute for the aggregate tampon, and the overall rate went from 0.8 gram per minute to 15.4 grams per minute when changing from the solid block tampon to an aggregate tampon. This increase in the rate of absorption in the aggregate tampons is unexpected and advantageous. A high absorption rate is an important attribute of a tampon in order to prevent partitioning failure which occurs when the rate of fluid flow to the tampon exceeds the absorption rate of the tampon. In that instance, the excess fluid flows past the tampon and down the vaginal walls without being absorbed.

Another unexpected advantage of an aggregate tampon is that the ejection force, i.e., the force required to eject a tampon from a tubular inserter is lower than the ejection force for an equal weight and approximately equal length integral tampon. The ejection forces for four types of tampons, i.e., cut cones, rosettes, round sacks, and solid cylinders are shown in Table V. The cut cones were made by superposing two trapezoidal blanks, sewing the blanks together along both sides and the short base, and inverting the sewed blanks as more fully taught in the commonly owned, copending application entitled HOLLOW FOAM TAMPONS FROM FLAT BLANKS, U.S. Ser. No. 353,058, filed Apr. 20, 1973. The rosettes were made as above described for Example VIII except the amount of aggregate is varied. The round sacks were made by taking a square of the overwrap material, placing the aggregate in the middle of the square, and enclosing the aggregate within the square by bringing together the corners and edges of the square around the aggregate into a neck which was fastened to prevent the square from opening. The ⅛ inch scrim overwrap is a cotton gauze-type material wherein the interfiber distance is about ⅛ inch in both directions and the crossover points are not bonded. The cylinders were cut from a block of the absorptive material. Table V includes tampons outside the scope of this invention to illustrate the effect of operating outside the limits of this invention.

The ejection force of an aggregate rosette tampon having a proper packing factor is substantially less than the ejection force for a cut cone of equal weight and absorbent material, even if the cut cone is overwrapped with Reemay, the same as used for the rosette. This is seen by comparing the ejection forces of the 2½ gram cut cone of Hydro-Foam™ with Reemay overwrap with the 2½ grams of Hydro-Foam™ rosette. In the

TABLE V

EJECTION FORCE FOR VARIOUS TYPES OF TAMPONS

	EJECTION FORCE (lbs.)			
	Regular Inserter (ID=0.605 in.)		Super Inserter (ID=0.71 in.)	
TAMPON*	Static	Dynamic	Static	Dynamic
2.5 g., cut cone, H-F	13.0	9.6	4.1	3.5
2.5 g., cut cone, H-F, R-O	2.5	2.7	1.5	1.5
2.5 g., rosette, H-F, R-O	1.8	1.8	1.3	1.8
0.5 g., rosette, S, R-O	1.1	1.4	1.1	1.5
1.0 g., do.	2.9	2.9	2.4	2.0
1.5 g., do.	4.3	3.9	3.3	3.4
2.0 g., do.	Inserters split while loading tampon			
2.5 g., round sack, H-F, R-O	3.0	3.1	1.7	1.7
2.5 g., round sack, H-F, S-O	—	—	3.2	3.0
0.5 g., round sack, S, R-O	0.75	1.5	1.45	2.13
1.0 g., round sack, S, R-O	2.9	3.2	3.27	3.45
1.5 g., round sack, S, S-O	—	—	1.8	2.5
1.0 g., 2 in. long cylinder, H-F	0.6	1.3	0.62	1.38
1.0 g., 2 in. long cylinder, S	6.3	7.3	4.4	4.7
0.5 g., 2 in. long cylinder, S, R-O	1.0	1.6	0.5	1.0
1.0 g. do.	4.1	4.2	1.8	1.9

* H-F=Hydro-Foam™ as absorbent material
S=Grecian Silk Sponge as absorbent material
Rosette=Aggregate of pieces in structure of FIG. 3
R-O=Tampon had Reemay overwrap
S-O=Aggregate had ⅛-inch mesh scrim overwrap

regular inserter the static ejection force for the rosette was 1.8 pounds while the ejection force for the cut cone was 2.5 pounds; and in the super inserter the static ejection force for the rosette was 1.3 pounds while the cut cone took 1.5 pounds. It is also to be noted from Table V that the rosette, which is a tubular aggregate tampon, has a lower ejection force than a round aggregate tampon by comparing the 2½ grams of Hydro-Foam™ rosette with the 2½ grams of Hydro-Foam™ round sack wherein the static ejection force in the regular inserter for the rosette is only 1.8 pounds while the static ejection force for the round sack in the same inserter is 3.0 pounds. A similar decrease in ejection force for the rosette versus the sack aggregate tampon is shown for the super inserter.

Also unexpectedly in an aggregate tampon, the ejection force is affected by the packing factor. Note tampons IV, V, and VI of Table III have equal weights of foam therein and that the ejection force increases as the packing factor decreases. Thus to obtain an "optimum" packing factor, the effect of the packing factor on absorption, comfort, and ejection force must all be considered.

The aggregate tampon of this invention also provides quicker dry expansion from the temporal set imposed on the foamlike absorbent materials such as are used in this invention while the absorbent material is resiliently compressed within the tubular inserter. The aggregate tampon fluffs out quicker than an integral tampon made of the same absorbent material in that the aggregate regains its unrestrained size after ejection from an inserter in a shorter time period. This difference in temporal resiliency, i.e., the ability of a tampon having a nonpermanent set to expand to its original size, has been shown by placing several Hydro-Foam™ rosettes made in the manner of Example VIII and several 2.5 gram Hydro-Foam™ integral tampons, specifically cut cone tampons without overwrap as described above, in two different conditions, i.e., in a closed chamber suspended by the withdrawal string over water at room temperature (75° F.) so that the humidity in the chamber approached 100 percent; and in vivo during nonmenstrual times. Before the tampons were placed in either condition, they were stored resiliently compacted within a tubular inserter having an inside diameter of about 0.71 inch for over 2½ months. The in vivo tampons were withdrawn at predetermined intervals to determine the percent of full expansion, i.e., expansion to the original uncompacted size, which had occurred while the chambered tampons were photographed at time intervals to record their expansion.

The tampon of this invention, i.e., the aggregate tampon, results in greater wearing and removal comfort due to the capability for relative motion between pieces **22** of the aggregate **24.** The aggregate tampon has essentially no tensile forces within the absorbent body and therefore the absorbent body can more easily conform itself to the vagina or the introital opening, whereas an integral tampon does have tensile strength which holds it together and prevents it from conforming as readily as the aggregate tampon. The aggregate tampon lacking the structural integrity of an integral tampon thus is somewhat amorphous and can more easily change it shape to conform to its structural environment. The amorphous character of a tampon of this invention can be controlled by varying the amount of absorption material within the overwrap, i.e., the packing factor. To achieve wearing and removal comfort, the volume packing factor should be less than about 2.0 and preferably less than about 1.38.

Also the aggregate tampon of this invention need not rely upon tensile strength of the absorbent material to insure removal of the entire tampon from the vagina after the tampon is used. In an integral-type tampon, the tensile strength of the absorbent material itself is relied on to remove the tampon from the vagina because the withdrawal string is attached at only one or several points on the absorbent body. In the aggregate tampon, the tensile strength relied on for removal resides in the overwrap, and therefore the tensile strength of the absorbent material is not a critical parameter. It is desirable to eliminate tensile strength as a requirement for the absorbent body because other desirable properties of some absorbent materials such as polyurethane foams are in inverse relationship to the tensile strength of the material, i.e., when the absorption properties are bettered, the tensile strength decreases. Thus it is advantageous to be able to eliminate tensile strength of the absorbent material as a requirement.

Thus it is apparent that there has been provided, in accordance with the invention, a catamenial aggregate absorbent body that fully satisfies the objects, aims, and advantages set forth above. While the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications, and variations 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 fall within the spirit and broad scope of the appended claims.

What is claimed is:

1. An absorptive device, comprising: an aggregate of individual pieces of absorbent foamlike material, said aggregate being encased within a flexible fluid-permeable overwrap, said pieces being wholly contained within the exterior portion of said overwrap such that substantially none of the absorbent foamlike material protrudes through the exterior portion of the overwrap whereby the exterior surface of the tampon is formed by the overwrap, said aggregate being flexible and resilient and having a dry aggregate modulus of compression at 25 percent compression in the range of about 0.004 psi to about 0.050 psi, whereby said aggregate is maintained by said overwrap and said device is soft, highly compressible, conformable to its surroundings, and resilient.

2. An absorptive device, comprising: an aggregate of individual pieces of absorbent foamlike material, said aggregate being encased within a flexible fluid-permeable overwrap, said aggregate being flexible and resilient and having a dry aggregate modulus of compression at 25 percent compression in the range of about 0.004 psi to about 0.050 psi, the volume packing factor of said device being equal to or less than about 2.0 cubic inches of the absorbent material per cubic inch available within the overwrap, whereby the overwrap has low tensional forces therein and said device has an amorphous character.

3. The device of claim **2** wherein said pieces are irregularly shaped.

4. The device of claim **2** wherein said overwrap is essentially tubular, each longitudinal end of the tubular overwrap is gathered radially inwardly to form a closure, one longitudinal portion of the overwrap is a reentrant portion and another longitudinal portion of the overwrap is an exterior portion, said exterior portion forms the outer surface of said device, and said reentrant portion is reentrant upon the combination of said aggregate and said exterior portion, whereby said device has a cavity therewithin, said cavity extending substantially from one longitudinal end of said device toward the opposite longitudinal end and the interior surface of said cavity is formed by said reentrant portion.

5. The device of claim **2** wherein an ancillary absorbent material is distributed within said aggregate.

6. The device of claim **2** wherein the size of substantially all of said pieces is within the range of from about 1/16 to about 1.0 inch.

7. The device of claim **6** wherein

A. said overwrap is essentially tubular, each longitudinal end of the tubular overwrap is gathered radially inwardly to form a closure, one longitudinal portion of the overwrap is a reentrant portion and another longitudinal portion of the overwrap is an exterior portion, said exterior portion forms the outer surface of said device, and said reentrant portion is reentrant upon the combination of said aggregate and said exterior portion, whereby said device has a cavity therewithin, said cavity extending substantially from one longitudinal end of said device toward the opposite longitudinal end and the interior surface of said cavity is formed by said reentrant portion; and

B. an ancillary absorbent material is distributed within said aggregate.

8. The device of claim **1** wherein said pieces are irregularly shaped.

9. The device of claim **8** wherein said overwrap is essentially tubular, each longitudinal end of the tubular overwrap is gathered radially inwardly to form a closure, one longitudinal portion of the overwrap is a reentrant portion and another longitudinal portion of the overwrap is an exterior portion, said exterior 1 street. Therefore, Amber portion forms the outer surface of said device, and said reentrant portion is reentrant upon the combination of said aggregate and said exterior portion, whereby said device has a cavity therewithin, said cavity extending substantially from one longitudinal end of said device toward the opposite longitudinal end and the interior surface of said cavity is formed by said reentrant portion.

10. An absorptive device, comprising: an aggregate of individual pieces of absorbent foamlike material, the pieces being irregularly shaped, an ancillary absorbent material being distributed within said aggregate, and said aggregate being encased within a flexible fluid-permeable overwrap, said aggregate being flexible and resilient and having a dry aggregate modulus of compression at 25 percent compression in the range of about 0.004 psi to about 0.050 psi.

11. The device of claim **1** wherein said overwrap is essentially tubular, each longitudinal end of the tubular overwrap is gathered radially inwardly to form a closure, one longitudinal portion of the overwrap is a reentrant portion and another longitudinal portion of the overwrap is an exterior portion, said exterior portion forms the outer surface of said device, and said reentrant portion is reentrant upon the combination of said aggregate and said exterior portion, whereby said device has a cavity therewithin, said cavity extending substantially from one longitudinal end of said device toward the opposite longitudinal end and the interior surface of said cavity is formed by said reentrant portion.

12. An absorptive device, comprising: an aggregate of individual pieces of absorbent foamlike material, an ancillary absorbent material being distributed within said aggregate, and said aggregate and ancillary absorbent material being encased within a flexible fluid-permeable overwrap, said aggregate being flexible and resilient and having a dry aggregate modulus of compression at 25 percent compression in the range of about 0.004 psi to about 0.050 psi, said overwrap being essentially tubular, each longitudinal end of the tubular overwrap being gathered radially inwardly to form a closure, one longitudinal portion of the overwrap being a re-entrant portion and another longitudinal portion of the overwrap being an exterior portion, said exterior portion forming the outer surface of said device, and said re-entrant portion being re-entrant upon the combination of said aggregate and said exterior portion; whereby said aggregate is maintained by said overwrap and said device is soft, highly compressible, conformable to its surroundings, and has a cavity therewithin, said cavity extending substantially from one longitudinal end of said device toward the opposite longitudinal end and the interior surface of said cavity being formed by said re-entrant portion.

13. The device of claim **11** wherein the size of substantially all of said pieces is within the range of from about 1/16 to about 1.0 inch.

14. An absorptive device, comprising: an aggregate of individual pieces of absorbent foamlike material, an ancillary absorbent material being distributed within said aggregate, and said aggregate and ancillary absorbent material being encased within a flexible fluid-permeable overwrap, said aggregate being flexible and resilient and having a dry aggregate modulus of compression at 25 percent compression in the range of about 0.004 psi to about 0.050 psi.

15. The device of claim **14** wherein the size of substantially all of said pieces is within the range of from about 1/16 to about 1.0 inch.

16. The device of claim **1** wherein the size of substantially all of said pieces is within the range of from about 1/16 to about 1.0 inch.

17. An absorptive device, comprising: an absorptive tampon, a tubular inserter, and ejection means operatively associated with said tampon and said inserter for releasing said tampon from said inserter into a body cavity; said tampon being an aggregate of individual pieces of absorbent foamlike material, said aggregate being encased within a flexible fluid-premeable overwrap, said pieces being wholly contained within the exterior portion of said overwrap such that substantially none of the absorbent foam-like material protrudes through the exterior portion of the overwrap whereby the exterior surface of the tampon is formed by the overwrap, said aggregate being flexible and resilient and having a dry aggregate modulus of compression at 25 percent compression in the range of about 0.004 to about 0.050 psi, said tampon being resiliently compacted within said inserter, whereby said tampon is easily ejectable, and fluffs out rapidly after in vivo ejection from said inserter to fill the vaginal cross-section.

18. An absorptive device, comprising: an absorptive tampon, a tubular inserter, and ejection means operatively associated with said tampon and said inserter for releasing said tampon from said inserter into a body cavity; said tampon being an aggregate of individual pieces of absorbent foamlike material, said absorbent material having a dry aggregate modulus of compression at 25 percent compression in the range of about 0.004 to about 0.050 psi, and said aggregate being encased within a flexible fluid-permeable overwrap, the volume packing factor of said tampon being less than or equal to about 2.0 cubic inches of the absorbent material per cubic inch available within the overwrap, said tampon being resiliently compacted within said inserter, whereby the tampon is easy to eject from the inserter.

19. The device of claim **18** wherein said pieces are irregularly shaped.

20. The device of claim **19** wherein

A. said overwrap is essentially tubular, each longitudinal end of the tubular overwrap is gathered radially inwardly to form a closure, one longitudinal portion of the overwrap is a reentrant portion and another longitudinal portion of the overwrap is an exterior portion, said exterior portion forms the outer surface of said device, and said reentrant portion is reentrant upon the combination of said aggregate and said exterior portion, whereby said device has a cavity therewithin, said cavity extending substantially from one longitudinal end of said device toward the opposite longitudinal end and the interior surface of said cavity is formed by said reentrant portion;

B. an ancillary absorbent material is distributed within said aggregate; and

C. the size of substantially all of said pieces is within the range of from about 1/16 to about 1.0 inch.

21. The device of claim 18 wherein the size of substantially all of said pieces is within the range of from about 1/16 to about 1.0 inch.

22. The device of claim 18 wherein said overwrap is essentially tubular, each longitudinal end of the tubular overwrap is gathered radially inwardly to form a closure, one longitudinal portion of the overwrap is a reentrant portion and another longitudinal portion of the overwrap is an exterior portion, said exterior portion forms the outer surface of said device, and said reentrant portion is reentrant upon the combination of said aggregate and said exterior portion, whereby said device has a cavity therewithin, said cavity extending substantially from one longitudinal end of said device toward the opposite longitudinal end and the interior surface of said cavity is formed by said reentrant portion.

23. The device of claim 18 wherein an ancillary absorbent material is distributed within said aggregate.

24. The device of claim 17 wherein said pieces are irregularly shaped.

25. The device of claim 24 wherein the size of substantially all of said pieces is within the range of from about 1/16 to about 1.0 inch.

26. The device of claim 17 wherein the size of substantially all of said pieces is within the range of from about 1/16 to about 1.0 inch.

27. The device of claim 17 wherein said overwrap is essentially tubular, each longitudinal end of the tubular overwrap is gathered radially inwardly to form a closure, one longitudinal portion of the overwrap is a reentrant portion and another longitudinal portion of the overwrap is an exterior portion, said exterior portion forms the outer surface of said device, and said reentrant portion is reentrant upon the combination of said aggregate and said exterior portion, whereby said device has a cavity therewithin, said cavity extending substantially from one longitudinal end of said device toward the opposit longitudinal end and the interior surface of said cavity is formed by said reentrant portion.

28. An absorptive device, comprising: an absorptive tampon, a tubular inserter, and ejection means operatively associated with said tampon and said inserter for releasing said tampon from said inserter into a body cavity; said tampon being an aggregate of individual pieces of absorbent foamlike material, said absorbent material having a dry aggregate modulus of compression at 25 percent compression in the range of about 0.004 to about 0.050 psi, an ancillary absorbent material being distributed within said aggregate, and said aggregate and ancillary absorbent material being encased within a flexible fluid-permeable overwrap, said tampon being resilient compacted within said inserter, whereby the tampon is easy to eject from the inserter.

29. An absorptive device, comprising: an absorptive tampon, a tubular inserter, and ejection means operatively associated with said tampon and said inserter for releasing said tampon from said inserter into a body cavity; said tampon being an aggregate of individual pieces of absorbent foamlike material, said aggregate being encased within a flexible fluid-permeable overwrap, the volume packing factor of said tampon being less than or equal to about 2.0 cubic inches of the absorbent material per cubic inch available within the overwrap, said tampon being resiliently compacted within said inserter, whereby the tampon is easy to eject from the inserter.

30. An absorptive device, comprising: an absorptive tampon, a tubular inserter, and ejection means operatively associated with said tampon and said inserter for releasing said tampon from said inserter into a body cavity; said tampon being an aggregate of individual pieces of absorbent foamlike material, an ancillary absorbent material being distributed within said aggregate, and said aggregate and ancillary absorbent material being encased within a flexible fluid-permeable overwrap, said tampon being resiliently compacted within said inserter.

* * * * *

PO-1050
(5/69)

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,815,601 Dated June 11, 1974

Inventor(s) Jean Edward Schaefer

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 5, line 19, "liuqid" should read --liquid--.

Column 7, line 49, delete "0.38" under caption "Hydro-Foam™" and insert --0.38-- under caption --DRY Avg. (psi)--.

Column 7, line 48, delete "0.19" under caption "DRY Low (psi)" and insert --0.19-- under caption --WET Avg. (psi)--.

Column 7, line 59, delete "1.30" under caption "Hydro-Foam™" and insert --1.30-- under caption --DRY Avg. (psi)--.

Column 7, line 58, delete "1.10" under caption "DRY Low (psi)" and insert --1.10-- under caption --WET Avg. (psi)--.

Column 11, line 38, "tamping" should read --tampon--.

Column 13, line 32, "in vivo" should read --in vivo--.

Column 14, line 66, "in vivo" should read --in vivo--.

Column 15, line 29, "in vivo" should read --in vivo--.

Column 21, line 23, "in vivo" should read --in vivo--.

Column 21, line 28, "in vivo" should read --in vivo--.

Column 23, line 22, delete "1 street.".

Column 23, line 23, delete "Therefore, Amber".

Signed and sealed this 29th day of October 1974.

(SEAL)
Attest:

McCOY M. GIBSON JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents