

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
11 December 2008 (11.12.2008)

PCT

(10) International Publication Number
WO 2008/148396 A2

- (51) International Patent Classification:
A61F 13/20 (2006.01) A61F 13/24 (2006.01)
- (21) International Application Number:
PCT/DK2008/050136
- (22) International Filing Date: 6 June 2008 (06.06.2008)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
PA 2007 00825 7 June 2007 (07.06.2007) DK
- (71) Applicant and
(72) Inventor: **POULSEN, Mariann Lisbeth** [DK/DK]; Tre-
tommervej 93, DK-8240 Risskov (DK).
- (74) Agent: **HØIBERG A/S**; St. Kongensgade 59A, DK-1264
Copenhagen K (DK).
- (81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA,
CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE,
EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID,
IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC,
LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN,
MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH,
PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV,
SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN,
ZA, ZM, ZW.

- (84) Designated States (*unless otherwise indicated, for every
kind of regional protection available*): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL,
NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG,
CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished
upon receipt of that report*



WO 2008/148396 A2

(54) Title: TAMPON

(57) Abstract: The present invention relates to a tampon that has a base, an apex and an axis, comprising an inner core comprising at least one layer and an outer non-absorbent cover comprising at least one layer and wherein the tampon is able to expand to a larger extent at the base than at the apex.

Tampon

Field of invention

5 The present invention relates to a tampon for feminine hygiene or medical purposes. The tampon has a base and an apex, and comprises an inner core and an outer non-absorbent cover. The tampon is able to expand to a larger extent at the base than at the apex.

10 Background of invention

A number of tampons, and in particular catamenial tampons have long been known in the art. Typically, commercially available tampons are made from a tampon pledget which is subsequently compressed into generally a cylindrical form. The pledgets are typically rolled, spirally wound, folded or assembled as a rectangular pad of absorbent
15 material.

The dimension of the internal vaginal cavity differs when comparing the vaginal cavity near the introitus and the vaginal cavity near the cervix. The vaginal cavity has its maximum dimension near the cervix and its minimum dimension near the introitus. To
20 avoid discomfort when inserting a tampon for for example catamenial use, the tampon initially has to have a size and a shape to pass the vaginal orifice. Once the tampon is inside the vaginal cavity, the tampon is no longer restricted by the orifice size but may expand, particularly in the lateral direction.

25 When inside the vaginal cavity, most tampons known in the art expands in the lateral direction contacting the surface of the vaginal walls from one side to the other in the vaginal cavity, see for example U.S. Appl. Ser. No.10/361277.

30 Tampons known in the art normally contain hydrophilic materials such as fibers or foams that are compressed into shape. The hydrophilic material is able to absorb liquid such as menses. The tampons may additionally be surrounded by an outer layer that is made from materials that are non-absorbent and thus reduce surface friction. The resulting tampons thus can be inserted and removed in a more agreeable manner.
35 Furthermore, the non-absorbent outer cover reduces the drying of the inner mucous-lined walls of the vaginal cavity.

US 20030105444 describes a tampon for feminine hygiene or medical purposes wherein the liquid-absorbent core of the tampon is fully enclosed by a non-woven cover.

- 5 US 20040030316 describes a tampon for hygiene including an absorbent body and a variably perforated cover, wherein the cover includes a layer impervious to fluid.

10 The tampon comprises an inner core and furthermore an outer cover that is impermeable to liquid. The outer liquid-impermeable cover of the tampon provides better protection against leakage of menstrual fluids and penetration of liquids from outside the body and makes the tampon well-suited for use during bathing, swimming and the like.

Summary of invention

- 15 The tampon according to the present invention has a base and an apex. When the tampon is placed in the body cavity the base is pointing towards the cervix and the apex is pointing towards the vagina opening (introitus). The base end of the tampon is able to expand to a larger extent than the apex. In contrast, to tampons known in the art the shape of the tampon according to the present invention when placed in the body cavity provides the best possible anatomical fit to the vaginal cavity.

- 20 One aspect of the present invention comprises a tampon, wherein the tampon has a base, an apex and an axis, comprising an inner core comprising at least one layer and an outer non-absorbent cover comprising at least one layer and wherein said tampon is able to expand to a larger extent at the base than at the apex.

Detailed description of the invention

Definitions

- 30 The term "tampon" refers to any type of absorbent structure which is inserted into the vaginal canal or other body cavities for the absorption of fluid therefrom. Alternatively, the term "tampon" refers to any type of absorbent structure which is used for medical purposes, for example during surgery. The term "tampon" also refers to an absorbent structure that may be used in scenarios wherein a need exists for absorption in a unidirectional manner.
- 35

Typically, tampons are constructed from an absorbent material which has been compressed in any or all of the width direction, the radial direction, and the axial direction, in order to provide a tampon which is of a size and stability to allow insertion within the vagina or other body cavity. Once the tampon is inserted and begins to acquire fluid, such as bodily fluids, the tampon will begin to expand. Thus, according to the present invention, the term "tampon" is used to refer to a finished tampon after the compression process referred to above. In one embodiment of the present invention the tampon is a tampon for feminine hygiene. In another embodiment the tampon according to the present invention is tampon to prevent leakage due to incontinence. In yet another embodiment the tampon is a catamenial tampon.

The terms "pledget" or "tampon pledget" are intended to be interchangeable and refer to a construction of layers of the tampon material prior to the compression of such construction into a tampon as described above. Tampon pledgets are sometimes referred to as a tampon blank, and the term "pledget" is intended to include such term as well.

The terms "vaginal cavity", "within the vagina", "vaginal interior" and "body cavity" in the present application are used synonymously and refer to the internal genitalia of the human female positioned in the pudendal region of the body.

The term "wetted" refers to the situation when the tampon is in contact with liquids. The tampon absorbs the liquid and expands.

The terms used are meant to assist the reader in best understanding the features of the invention and not to introduce limitations in the terms not consistent with the context in which they are used in the present specification.

Tampon

One aspect of the present invention relates generally to a tampon for feminine hygiene having a base and an apex. The tampon of the present invention comprises an inner core comprising at least one layer of material and an outer non-absorbent cover comprising at least one layer of material. The inner core of the tampon is thus absorbent. The axis of the tampon extends from the centre of the base to the apex. One embodiment the present invention relates to a tampon, wherein the tampon has a

base, an apex and an axis comprising an inner core comprising at least one layer and an outer non-absorbant cover comprising at least one layer. Another embodiment of the present invention relates to a tampon, wherein the tampon has a base, an apex and an axis comprising an inner core comprising at least one layer and an outer non-absorbant cover comprising at least one layer and wherein the tampon is able to expand to a larger extent at the base than at the apex.

In situations where the tampon is placed in the body cavity the base of the tampon will be pointing in the direction of the cervix, and the apex of the tampon will be pointing towards the vaginal opening (introitus), see figure 1. After insertion the base of the tampon is positioned just below the cervix.

In situations wherein the tampon is used as a unidirectional absorbent means for example during surgery the base of the tampon is pointing towards the fluid to be absorbed.

In a particular embodiment of the present invention the base end of the tampon is able to expand to a greater extent than compared to the apex, when wetted.

The base end of the tampon expands, particularly in the radial direction, to contact the surface of the vaginal walls in the vaginal cavity, thereby preventing early bypass or "escape" of for example menstrual fluids from the cervix. Such bypass of menses typically occurs when menses travels along the length of the vagina without contacting the tampon. To perform well the tampon thus should expand quickly to avoid bypass of menstrual fluids.

In one embodiment of the present invention the tampon is shaped like a cone when placed in the vaginal cavity. In another embodiment the shape of the tampon is like that of a pyramid, however, the tampon may also have a cup-like structure.

The tampon according to the present invention may also be used as a device to avoid incontinence. Incontinence is the inability to prevent leakage of urine by loss of bowel and/or bladder control. In such case the tampon is placed in the vagina, wherein the apex is pointing towards the vaginal opening. The tampon performs a physical pressure against the urethra thereby obstructing the passage of urine.

The wetting of the tampon results in "flowering" of the tampon, wherein at least one layer of the inner core and at least one layer of the outer cover form a carnation-like structure, wherein the apex of the tampon represents the lower part of the carnation flower that extends from the stalk of the flower, and the petals of the carnation flower represent the at least one layer of the inner core at the base-end of the tampon. In another embodiment the carnation-like structure of the inner core is formed by at least two layers, for example three layers, such as four layers, for example five layers, such as six layers, for example seven layers, such as eight layers, for example nine layers, such as ten layers, for example fifteen layers, such as twenty layers, for example twenty five layers of the inner core. In addition, the outer cover of the tampon comprises at least one layer, such as two layers, for example three layers, such as four layers, for example five layers of the outer cover.

When placed in the vagina the tampon with its base pointing towards the cervix and the apex pointing towards the vaginal opening (introitus) provides improved comfort compared to tampons known in the art, as the shape of the tampon provides the best possible anatomical fit to the vaginal cavity, as shown in figure 1.

The at least one layer of the inner core is made from any absorbent means that is able to absorb and/or to retain liquids. In particular the liquids are body fluids, such as menses and/or urine and/or blood. The absorbent materials may be selected from a variety of natural liquid-absorbing materials such as cellulosic materials for example cotton, rayon (viscose), wood pulp, crepped cellulose wadding, cross-linked cellulosic fibers. Also synthetic materials such as for example polyester fibers, polyolefin fibers, absorbent sponges, absorbent foams, absorbing gelling-materials can be used as absorbent materials according to the present invention. In a preferred embodiment the at least one layer of absorbent material comprises fibrous material. Furthermore, the at least one layer of absorbent fibrous material comprises natural and/or synthetic fibers. In a particularly preferred embodiment the absorbent core comprises rayon (viscose) fibers and/or cotton fibers. Also preferred are fibers of cotton. In yet another embodiment the fibers may be rayon (viscose) fibers. Starch-based polymers are also suitable as inner core material. Polymers for example including as a first component a hydroxyl-functional polyester and as the second component a natural polymer such as starch, guar gum, cellulose or the like are particularly useful as inner core material according to the present invention. In a preferred embodiment the polymer is

biodegradable. The list above of materials that are suitable as inner core material is non-limiting. The listed materials may be combined to form the at least one layer of the inner core. The inner core thus may comprise several layers of materials wherein the at least one layer individually comprises a mixture of materials. However, the inner core of
5 the tampon may comprise a number of layers, wherein the individual layers are made from individual materials.

In a preferred embodiment the absorbent material comprises fibers. In particular the fiber length ranges from 0.5 to 5 centimetres, such as 1 to 4 centimetres, such as 2 to 3
10 centimetres. Especially preferred are fibers of 3 centimetres length.

In another embodiment the inner core may comprise at least one liquid permeable layer, such as two layers, for example three layers, such as four layers, for example five layers that may constitute an overwrap-layer of absorbent material. Materials that
15 are suitable for the at least one overwrap layer may comprise, rayon, cotton, biocomponent fibers, or other suitable natural or synthetic fibers known in the art. Mixtures of the components are also suited for the overwrap layer.

The at least one overwrap layer is positioned immediately next to the outer cover.
20

Prior to compression, the tampon pledget, comprising at least one layer of inner core and at least one layer of outer cover, has a circular shape, see figure 2. The shape may alternatively be hexagonal.

During "wetting" the absorbent material will expand in both the longitudinal and transverse direction, whereas the outer cover maintains its original form after insertion. Due to the expansion of the absorbent material the inner core may protrude transversely from the outer cover creating a collar-like structure. The collar-like structure assists in creating lateral /transverse contact to the wall of the vaginal cavity,
30 whereby bypass of menstrual fluids is hindered.

Outer cover

According to the present invention the outer cover is non-absorbent, whereby absorption of liquid from for example the surface of the wall of the vaginal cavity is
35 reduced compared to tampons wherein the absorbent material is in contact with the

surface. The outer cover may be partly impermeable to liquid, or alternatively fully impermeable to liquid. The tampon according to the present invention therefore improves the comfort of using a tampon for feminine hygiene. Furthermore, the tampon according to the present invention is able to perform a unidirectional absorption of fluids in the base end of the tampon, as the sides of the tampon are not able to absorb liquids due to the fact that the outer cover is non-absorbent.

By non-absorbent outer cover is meant that the outer cover has less absorbent capability compared to the absorbent capability of the inner absorbent core of the tampon. Perforations of the outer cover may allow for absorption of liquid but the absorption by the outer cover will be less than the absorption performed by the inner core of the tampon.

The outer cover is preferably made from a smooth material to avoid friction against the walls of the vaginal canal and vaginal cavity during insertion of the tampon.

The outer cover may comprise at least one layer of cover material, such as two layers, for example three layers, such as four layers, for example five layers, such as six layers, for example seven layers, such as eight layers, for example nine layers, such as ten layers of cover material.

The outer cover may be made from at least one layer of silicone or wax. Also elastomers including natural rubber or polyisoprene, synthetic elastomeres such as polybutadiene, polyisobutylene or polyurethanes are useful materials for the outer cover. In a particular embodiment the outer cover comprises elastomers comprising two or more components. In a preferred embodiment synthetic elastomers are used such as for example silicone rubber. In a further embodiment, thermoplastic elastomers may be used for outer cover, such as for example ionomers or block copolymers.

The outer cover may be formed by the spraying of for example liquid silicone or the like on the absorbent core. When spraying the nozzle dimension may be varied to produce a layer of varying thickness. The thickness of the layer may be graduated so that the layer is thickest at the apex of the tampon and thinner at the base end so that the upper 2-3 millimetres, for example 1-4 millimetres, such as 1-3 millimetres, for example 2-4 millimetres, such as 1-5 millimetres, for example 2-5 millimetres, such as 2-6

millimetres of the tampon at the base end is free of cover, creating a collar- like structure at the base end of the tampon, serving to avoid the fluid by-passing the tampon as described elsewhere herein.

5 The outer cover may be made from at least one layer of thermoplastics for example polymers such as polyethylene, for example polypropylene, such as polystyrene, for example polyesters, such as polycarbonates, for example pvc, for example nylon, or such as poly(methyl metaacrylate). To the thermoplastics may be added plasticizers selected from the group of nitrobenzene, carbon disulfide and beta-naphthyl salicylate.

10

The outer cover may be made in any combinations of wax, silicone, elastomers and thermoplastics.

The outer cover is liquid impermeable and thus does not absorb liquid.

15

The outer cover may cover the sides of the tampon entirely, leaving only the base free of outer cover in order for the base to absorb liquid from the cervix. In a preferred embodiment, the outer cover may not cover entirely the sides of the absorbent inner core of the. The apex of the present tampon is essentially covered by the outer cover.

20

The outer cover may however not cover the tampon sides in their entire length from the apex to the base end, whereby the inner core will protrude transversely from the outer cover adding to the creation of the collar-like edge when the inner core expands due to wetting.

25

Fastening of outer cover

Preferably the impermeable outer cover is fastened to the at least one layer of the inner core. The outer cover may be fastened by a fastening agent, for example by means of contact adhesive or by welding using ultrasound, or heat-assisted melting of the cover material. In particular the fastening may be performed by heat sealing. Another
30 embodiment comprises the use of welded seams or sewn seams, either over the entire area of the cover or by fastening in a point-wise fashion. The fastening of the outer cover to the inner absorbent core may be performed using a combination of the mentioned means for fastening the outer cover.

Fastening of the outer cover to the inner core may be achieved by fastening the at least one layer of the outer cover to the at least one layer of the inner core over the entire area of the layers. However, partial fastening or fastening the layer in points only is also within the scope of the present invention.

5

Fastening of the outer cover to the inner absorbent core is in one embodiment performed prior to the "compression" of the tampon into its final shape. In another embodiment the cover is fastened to the inner core after compression of the inner core.

10 Perforations of the inner core and outer cover

The inner core and/or outer cover of the tampon may be microperforated. In a particular embodiment of the present invention the upper 2 millimetres, such as the upper 3 upper millimetres, for example upper 4 millimetres, such as upper 5 millimetres, for example upper 6 millimetres of the compressed tampon (base-end) are microperforated, see figure 3, creating a collar-like structure at the base end of the tampon, serving to avoid fluid by-passing the tampon. Microperforation may be performed prior to or after compression of the tampon pledget into a tampon. In one embodiment of the present invention the microperforations are so small that liquid cannot penetrate through them, but moist gasses and vapors can.

15

20 Compression

The tampon according to the present invention is compressed into a form, wherein a base and an apex appear, see figure 4 and 5. Compression takes part as at least 2 stages, such as at least 3, for example 4, such as 3 stages. One stage of the compression process is a precompression of the absorbent inner core, wherein the maximal dimension of the tampon in wetted form is achieved. After precompression the outer cover is fastened to the inner absorbent core. Another stage of the compression process involves the compression of the tampon into its final shape by the use of pressure and heat.

25

The preferred direction of compression is the radial direction with the centre being that of the centre of the apex. However, compression may also be in width direction, or for example in the axial direction or in any combination of directions. The base formation of the finished tampon may be achieved by subsequent compression in the axial direction.

30

35

The tampon may alternatively be formed by the use vacuum moulding, wherein the inner core of the tampon may be shaped into a cone-like structure with a base end and an apex in a preformed mould under application of vacuum.

5

Retrieval of tampon

Tampons known in the art expand in the body cavity for example in the lateral direction forming a rectangular absorbent pad. The side of the tampon facing the introitus represents a barrier to easy and pleasant removal of the tampon, figure 6. In contrast, the tampon according to the present invention makes its way when retrieved in a smooth and non-obstructive manner, due to the anatomical shape of the tampon, see figure 1.

10

The tampon is fitted with a retrieval device. In a preferred embodiment the retrieval device is attached centrally on the pledget, see figure 2.

15

The retrieval device may in particular be attached to the layers of the tampon by use of for example a seam or other suitable fastening means, see figure 7.

The retrieval device extends from the outer cover at the apex of the tampon as shown in figures 4 and 5. The withdrawal device is made from unbreakable material. In one particular embodiment of the present invention the material is non-absorbent. A preferred material is polyester. The withdrawal device may be in the form of a string. Similarly, the withdrawal device may be shaped like a hook.

20

25

Insertion of the tampon

The insertion end of the tampon is the base end and the retrieval end of the tampon is the apex of the tampon.

30

The tampon may be inserted digitally. Alternatively, an applicator may be used to insert the tampon into the correct position in the vaginal cavity. Any of the available tampon applicators may be used for example the "tube and plunger", or a "compact" type. Preferably, a directional oriented applicator is used, whereby the base end of the tampon is inserted first. The applicator may be of plastic, paper, or other suitable material.

35

Suitable materials

According to the present invention the materials used for the production of the inner core, the outer cover and the retrieval device are approved for such use by the United States Food and Drug Administration. It is also desirable that the absorbance ranges currently required by the United States Food and Drug Administration. For example
5 absorbency of the absorbent inner core ranges from 4 to 20 grams as measured by the industry standard Syngyna test. In one embodiment the absorbency ranges from 5 to 16 grams, such as from 6-15, for example 6 to 9, such as 9 to 12, for example 12-15, such as 9 to 15, for example 15 to 20 grams.

10 All materials are neutral to the organs of the body.

Detailed description of the drawings

Figure 1 shows the tampon of the present invention placed in the vaginal cavity. The base end of the tampon (1) is positioned towards the cervix (2), whereas the apex (3)
15 points towards the vaginal opening (4). The shape of the tampon is anatomically suited for the vaginal cavity. Absorption of menstrual fluids takes place primarily at the cervix (see triangle). During removal, the tampon makes its way.

Figure 2. Top view of tampon pledget prior to compression. A represents the top layer
20 of the pledget. C represents the center of the pledget, serving as attachment site for the retrieval device.

Figure 3. View of the collar-like projection of the upper millimetres of the tampon. Black shading represents the shortened outer cover, or alternatively the upper
25 microperforated part of the inner core and/or outer cover; arrows depict the direction of expansion of the absorbent inner core.

Figure 4. Sectional view of the tampon after compression of the tampon. A represents
30 the inner core comprising at least one layer. B represents the outer cover comprising at least one layer. D shows the retrieval device. Bp and arrows show the position of microperforations.

Figure 5. Sectional view of the tampon after light compression of the tampon. A
35 represents the inner core comprising at least one layer. B represents the outer cover comprising at least one layer. D shows the retrieval device.

Figure 6 shows a tampon known in the art. The tampon absorbs liquids from all directions and similarly expands in all directions. The side of the tampon facing the vaginal opening may act as a barrier when the tampon is removed.

5

Figure 7. Sectional view of the tampon pledget. A represents the inner core comprising at least one layer. B represents the outer cover comprising at least one layer. D shows the retrieval device.

Claims

1. A tampon, wherein the tampon has a base, an apex and an axis,
comprising
an inner core comprising at least one layer and
5 an outer non-absorbent cover comprising at least one layer and
wherein said tampon is able to expand to a larger extent at the base than at the
apex.
- 10 2. The tampon according to claim 1, wherein the axis extends from the center of
the base to the center of the apex.
3. The tampon according to claim 1, wherein said tampon upon wetting unfolds by
flowering.
- 15 4. The tampon according to claim 1, wherein said inner core comprises at least
one layer of absorbent material.
5. The tampon according to claim 4, wherein the at least one layer of absorbent
material comprises fibrous material.
- 20 6. The tampon according to claim 5, wherein the fibrous material consists of
natural and/or synthetic fibers.
7. The tampon according to claim 4, wherein said absorbent material comprises
25 polymers.
8. The tampon according to claim 1, wherein the base of the tampon absorbs
liquid.
- 30 9. The tampon according to claim 1, wherein the outer cover is positioned at the
outer side of the tampon.
10. The tampon according to claim 1, wherein the outer cover comprises at least
35 one non-woven layer.

11. The tampon according to any of the preceding claims, wherein the outer cover comprises at least one layer of silicone.
- 5 12. The tampon according to any of the preceding claims, wherein the outer cover comprises at least one layer of wax.
13. The tampon according to any of the preceding claims, wherein the outer cover comprises at least one layer of two-component elastomers.
- 10 14. The tampon according any of the preceding claims, wherein the outer cover comprises at least one layer of thermoplastic elastomers.
- 15 15. The tampon according to claim 1, wherein the outer cover is fastened to at least one layer of the inner core.
16. The tampon according to claim 15, wherein the outer cover is fastened by heat sealing.
- 20 17. The tampon according to claim 15, wherein the outer cover is fastened by a fastening agent.
18. The tampon according to claim 1, wherein the inner core and/or the outer cover comprise microperforations at the base-end of the tampon.
- 25 19. The tampon according to claim 1, wherein a retrieval device is attached centrally on the tampon pledget, extending from the outer cover at the apex of the compressed tampon.
- 30 20. The tampon according to any of the preceding claims, wherein the inner core and/or the outer cover is compressed radially.
21. The tampon according to claim 1, wherein said base of said tampon is rounded.

1/7

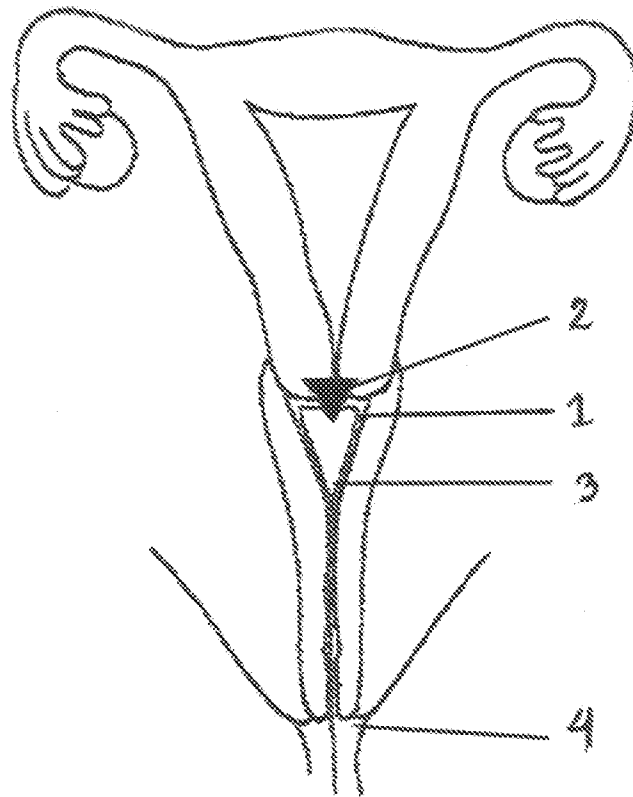


Fig. 1

2/7

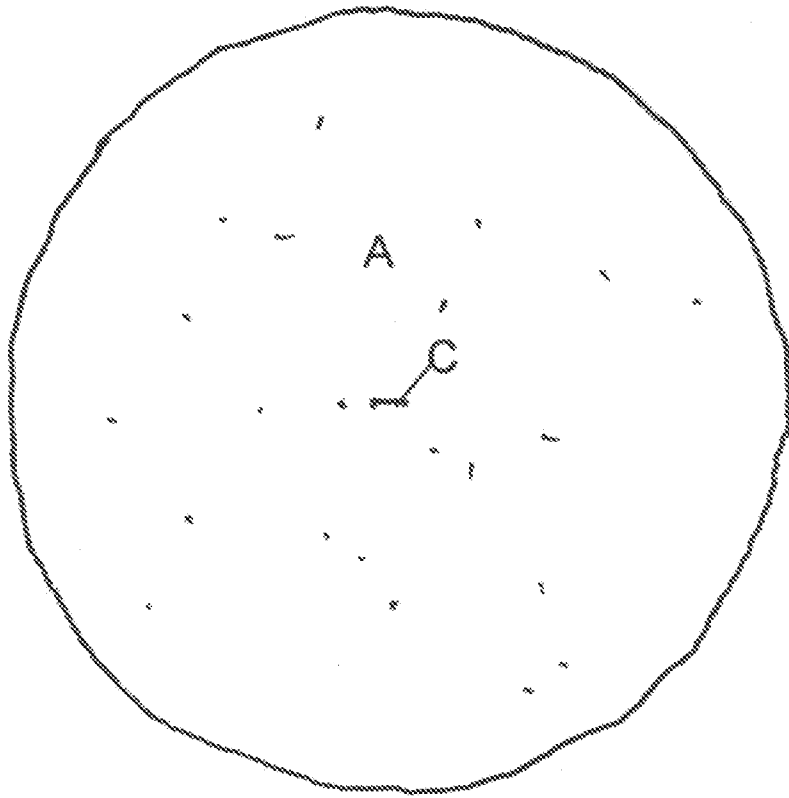


Fig. 2

3/7

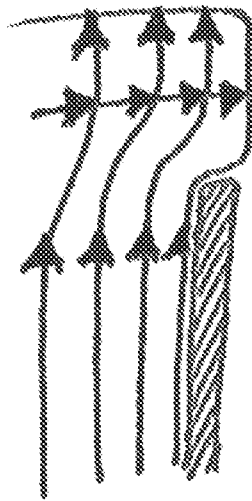


Fig. 3

4/7

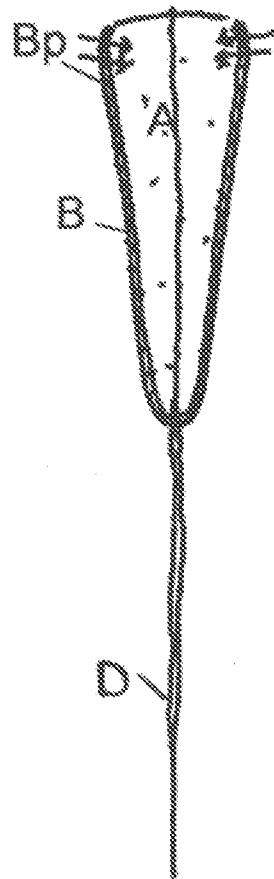


Fig. 4

5/7

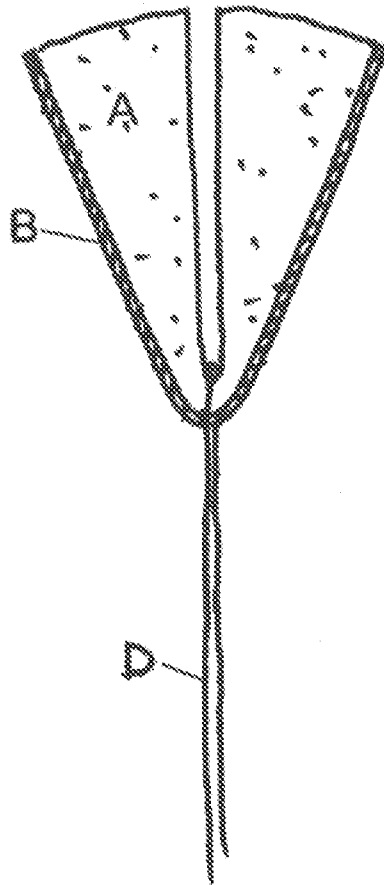


Fig. 5

6/7

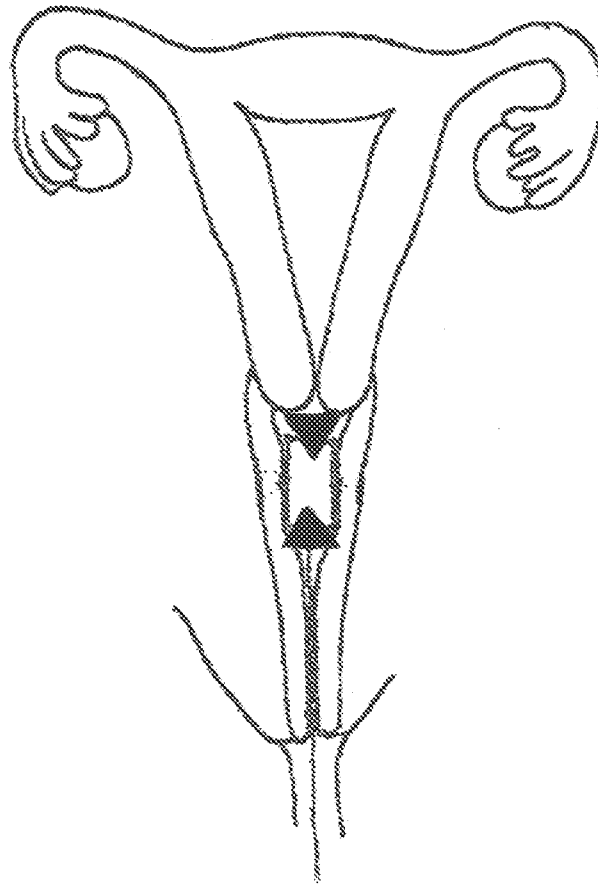


Fig. 6

7/7

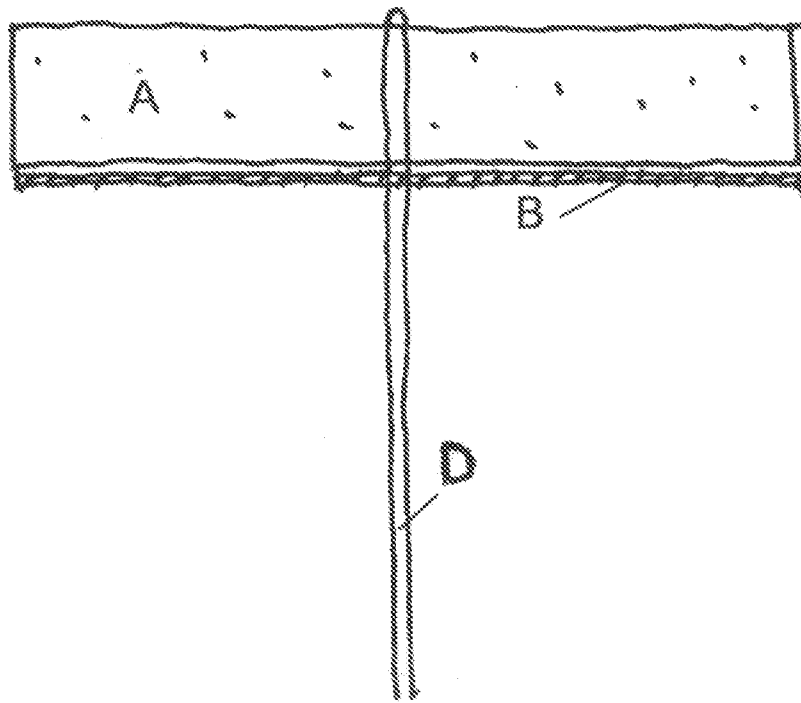


Fig. 7