United States Patent [19]

Alemany

[11] **3,857,394**

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

[54] **GYNAECOLOGICAL DEVICE**

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[22] Filed: **Sept. 8, 1972**

[21] Appl. No.: **287,469**

[30] **Foreign Application Priority Data**

Sept. 17, 1971 France 71.33617

[52] **U.S. Cl.** **128/260,** 128/128, 128/263, 128/290

[51] **Int. Cl.** **A61m 31/00**

[58] **Field of Search** 128/127, 260, 263, 270, 128/271, 285, 128, 138, 251, 168, 289–291

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Primary Examiner—Kyle L. Howell

Attorney, Agent, or Firm—Larson, Taylor & Hinds

[57] **ABSTRACT**

A gynaecological device constituting a vulvar compress of oblong shape with a rim of absorbent material, comprises a support part of a flexible and impermeable material and another part forming a longitudinal bulge formed of a material of the gauze type matching the anatomical contours. The bulge can enclose a medicinal substance, impregnating the gauze, or housed in a compartment bounded by the gauze, for instance, in the form of a gynaecological suppository. The device may comprise a flexible and impermeable envelope, forming a pocket, in which are enclosed, before placing in operation, a medicament or a tampon to be applied, and arranged so that it comprises a first part adapted to cover the hand of the user at the moment of use and a second part constituted by an invagination inside of which a tampon is at least partially housed. A guide element for the positioning of the tampon or medicament may be included.

9 Claims, 16 Drawing Figures

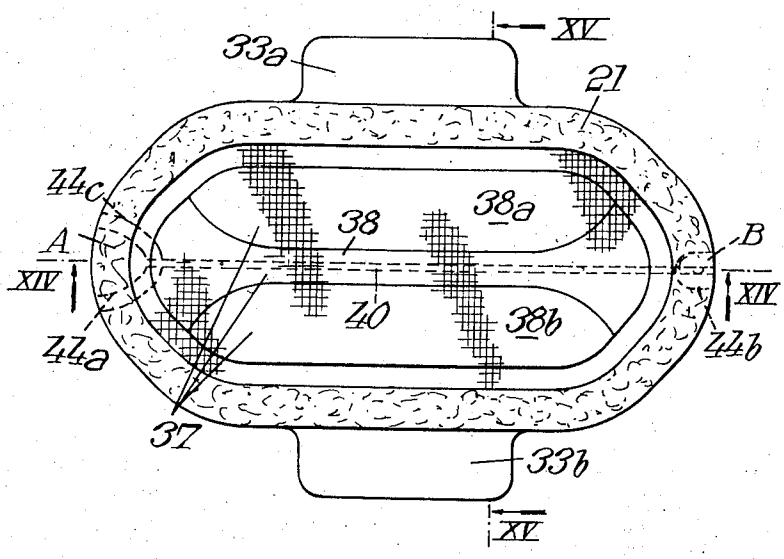

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Fig. 1.

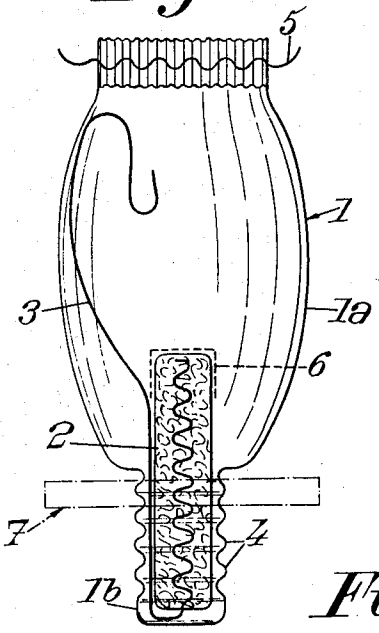


Fig. 2.

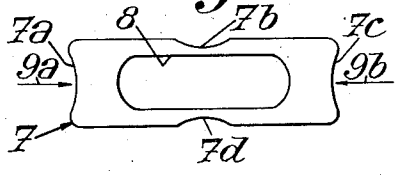
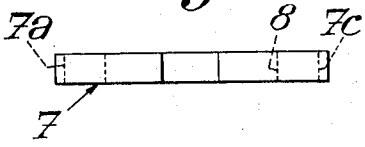


Fig. 3.



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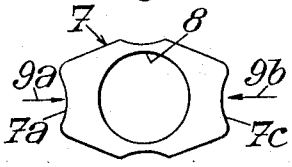
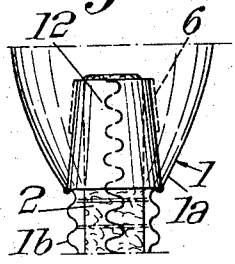


Fig. 5



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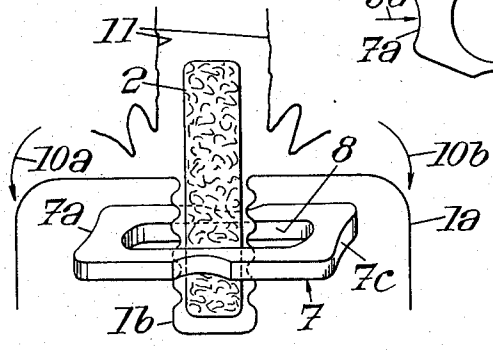
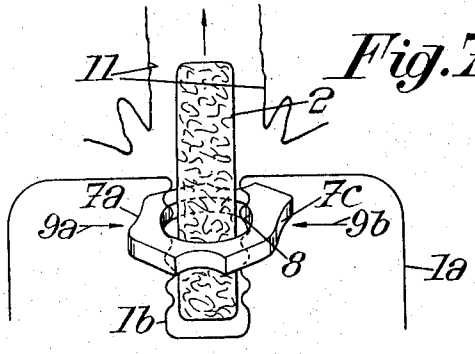


Fig. 7



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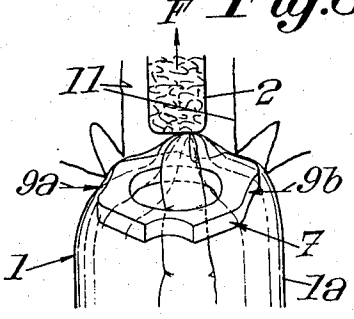

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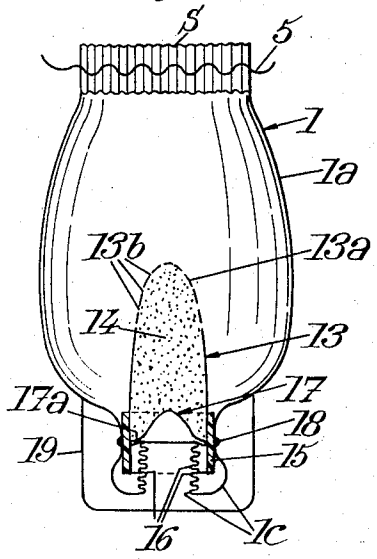

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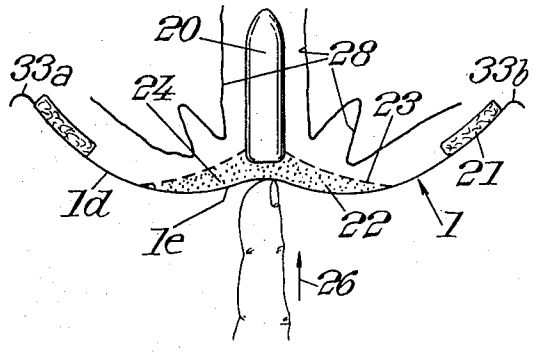


Fig. 12.

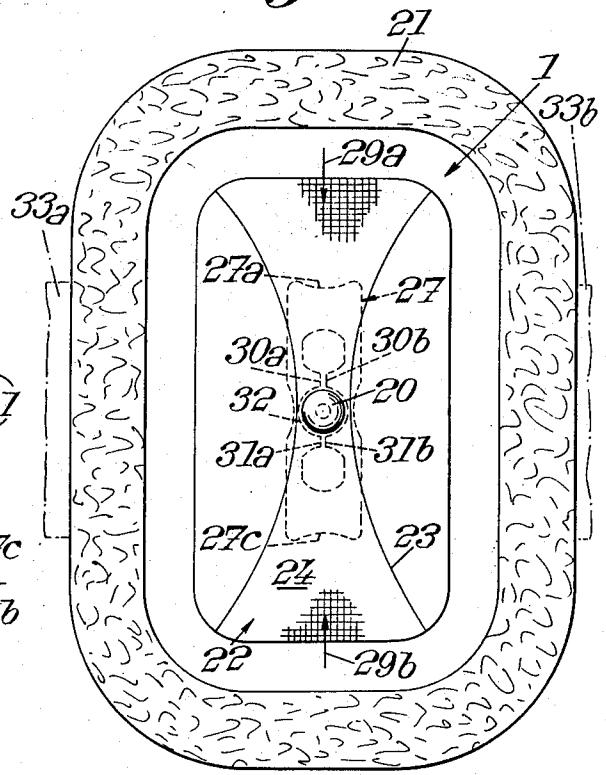
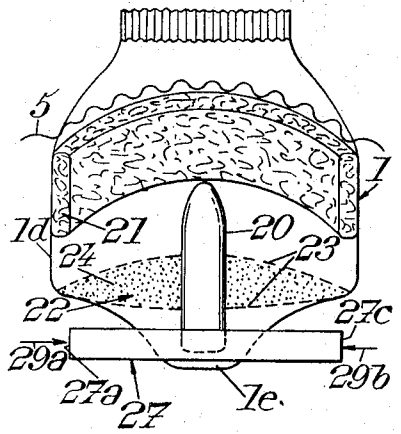


Fig. 10.



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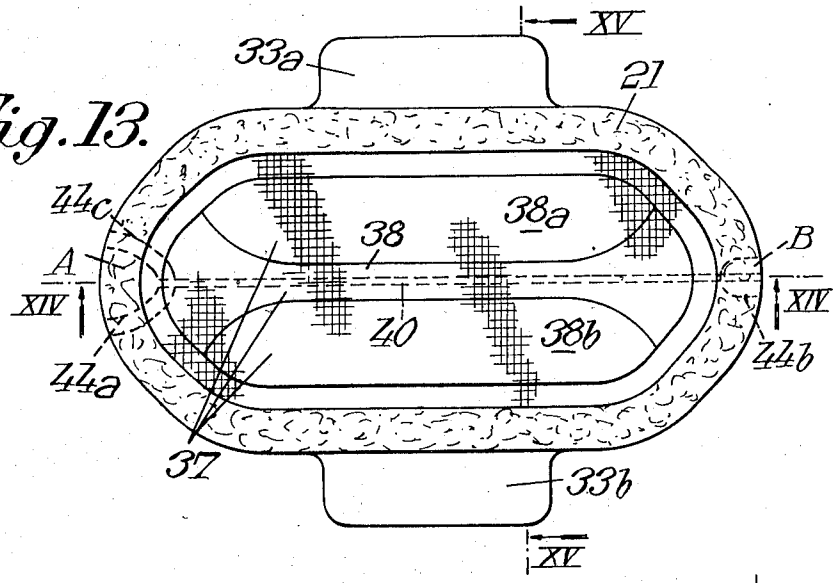

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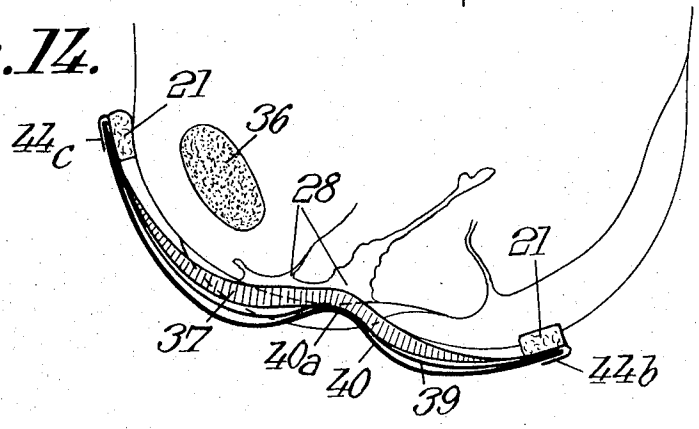


Fig. 15.

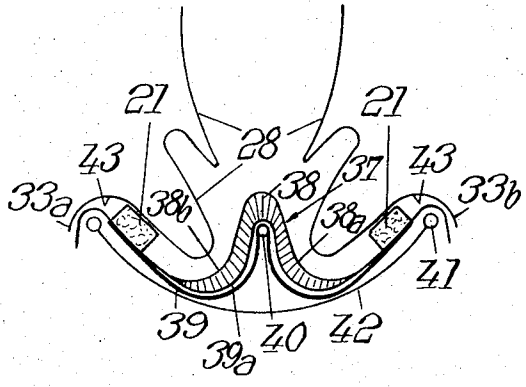
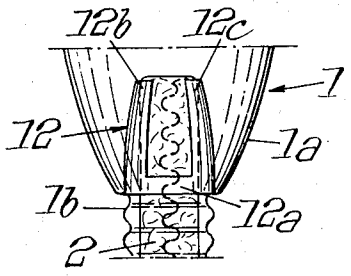


Fig. 16.



GYNAECOLOGICAL DEVICE

The invention relates to a gynaecological means or device, that is to say means used in the field of treatment relating to the female genital organs.

These treatments, which relate to the application of certain medicaments for the vulvo-vaginal area or the use of menstrual tampons pose not only problems of hygiene and of comfort during manual positioning of the tampons or medicaments, but also, in the case of vulvar medicaments, problems arising from the maintenance in position of said medicaments.

It is a particular object of the invention to provide a solution to these problems and to provide means of the type concerned capable of satisfying the user.

The abovesaid gynaecological means according to the invention constitute a vulvar compress of oblong shape with a rim of absorbant material comprising a portion forming a support which is formed of a flexible and impermeable material and another portion forming a longitudinal bulge or swelling formed of a material of the gauze type, matching the anatomical contours and if necessary impregnated with a medicinal substance which can also be housed in a compartment bounded by the gauze or be in the form of an ovule.

According to another aspect of the invention, the abovesaid gynaecological means comprise a flexible and impermeable envelope, forming a pocket in which are enclosed, before the placing in operation, the medicaments or the tampon to be applied, this pocket being arranged so that it comprises a first portion which, at the moment of use, can cover the hand of the user and a second portion constituted by an invagination inside of which the tampon is at least partially housed, a guide element for the introduction or the placing in position of the medicament or the tampon being, preferably, also provided.

The invention consists, apart from the abovesaid features, of certain other features which are preferably used at the same time, but of which certain can be used independently and which will be more explicitly considered below.

The invention will in any case be better understood by means of the additional description which follows, as well as of the accompanying drawings, which description and drawings relate to preferred embodiments, given of course purely by way of illustrative but nonlimiting example.

In the drawings:

FIG. **1** is a diagrammatic view showing the elements entering into the constitution of the means according to the invention within the scope of a first embodiment relating to menstrual tampons.

FIGS. **2, 3** and **4** show, respectively, in plan view before use in elevation and in plan view after being deformed, in more detail, one of the elements entering into the constitution of the means shown in FIG. **1.**

FIG. **5** is a diagrammatic partial view showing a second embodiment of the means shown in FIG. **1.**

FIGS. **6, 7** and **8** show, in perspective, a means according to the embodiment of FIGS. **1** to **4** respectively in three successive stages of their placing in operation.

FIG. **9** shows in diagrammatic view an embodiment of the means according to the invention relating to vaginal medicaments.

FIGS. **10, 11** and **12** show, respectively, in diagrammatic view before use, an elevation at an intermediate stage of the placing in position and in plan view after positioning, yet another embodiment of means according to the invention relating to vulvo-vaginal medicaments.

FIG. **13** shows in plan view a modification of the embodiment illustrated by FIGS. **10** and **12.**

FIGS. **14** and **15** are sections along the lines XIV—XIV and XV—XV of FIG. **13** and show means according to the invention after the placing in position on the user.

FIG. **16,** lastly, shows in diagrammatical partial view a modification of the means shown in FIG. **15.**

According to the invention and more especially according to those of its types of application as well as according to those embodiments of its various parts, to which it would seem that preference should be given, in order to manufacture gynaecological means of the type concerned, procedure is as follows or in analogous manner.

These means are made to comprise:

on one hand an envelope, formed of a supple and impermeable material, especially of a flexible plastics material for example of the polyethylene or thin latex type, of which the shape is such that it can constitute a pocket or purse in which is enclosed, before the placing in operation, a menstrual tampon or a medicament to be applied, and,

on the other hand, preferably a guide element for the introduction or the placing in position of the tampon or the medicament.

The abovesaid pocket or purse is arranged so that it can cover the hand of the user at the moment of use and must enable the realisation of positioning or introduction operations under the best possible conditions of hygiene.

In the embodiment shown in FIG. **1** and more particularly intended for the introduction of menstrual tampons, the abovesaid pocket is denoted as a whole by **1.** This pocket comprises a portion **1***a* playing, at the moment of use, the role of protector for the hand of the user, the portion **1***b* constituted by an invagination inside of which is housed, at least partially, a tampon **2** provided with its extraction cord **3.**

The pocket **1** is formed from a sheet of plastics material, circular or rectangular, in the unfolded position (not shown) in the centre of which the abovesaid invagination is arranged.

The dimensions, both longitudinal and transverse, of the invagination are such that they enable the insertion of an index finger; said invagination, being adapted to the tampon in inactive position, then forms folds **4.**

The pocket **1,** once the tampon **2** has been introduced into the invagination, is closed as shown in FIG. **1,** for example by welding at S, a cord **5** enabling simplified opening by tearing. Instead of the cord, there can be provided a zone of least strength.

To facilitate the introduction of the tampon **2,** there can be provided at its free end a layer **6** of lubricant selected so that it is not absorbed by the constituent cotton of the tampon.

In addition to the pocket **1,** means according to the invention comprise preferably the abovesaid guide element which, in the case of the embodiment shown, is constituted by an oval or rectangular oblong ring **7,** shown in FIGS. **2** and **3** and bounding an elongated hole **8.**

As seen, this ring comprises four flats 7*a*, 7*b*, 7*c* and 7*d* which facilitate its manipulation. The constituent material of the ring is semi-rigid and elastic, enabling its deformation under the influence of pressure along the arrows 9*a* and 9*b* exerted at the level of the flats 7*a* and 7*c*; recourse could for example be had to synthetic material of the polypropylene or polyethylene type such as that known by the trademark "Polythene." The ring then takes the shape illustrated by FIG. **4**, the so-defined hole **8** then being substantially circular and of dimensions such that it permits the passage of the index finger.

To cause it to play the role of guide element, the ring **7** is placed, once it has been brought into the position illustrated by FIG. **4**, on the invagination 1*b* (in discontinuous line, FIG. **1**). The pressure exerted along the arrows 9*a* and 9*b* is then relaxed, the ring coming to grip the invagination and the tampon, thus making fast these elements to one another. By means of the ring gripped on the tampon, it becomes easy to guide the latter. It suffices to seize the ring between the thumb and the index finger placed on the flats 7*b* and 7*d*, to open the pocket **1** by pulling on the cord **5** and to fold back the pocket on the hand along the arrows **10***a* and **10***b*, as shown in FIG. **6**. The free end of the tampon is then introduced into the vaginal passage as seen in FIG. **6** on which the contours of the latter have been shown diagrammatically at **11**. The step following the introduction consists of bringing the ring to the position of FIG. **4** as seen in FIG. **7** (pressure along 9*a* and 9*b*, exerted on the flats 7*a* and 7*c*), then pushing (arrow F) the tampon with the index of the other hand to bring it into the vagina as shown in FIG. **8**. The invagination 1*b* has a sufficient length for the latter operation due to the folds **4**.

It will be easily seen that, during the whole of these operations, both hands remain perfectly protected.

The operation being completed, the pocket **1** is discarded whilst the ring **7**, also protected by the pocket, can be used again.

It suffices, consequently, to provide only a single ring in the box of tampons.

In the modification illustrated by FIG. **5**, the guide element is constituted by a part of generally conical shape, for example a conical tube **12** of flexible plastic material, which can be fixed by welding at the level of its large base to the inner surface of the pocket, at the height of the edge of the invagination. At the level of its small base, the tube **12** can be provided advantageously with a layer **6** of lubricant facilitating introduction. The other features of this embodiment and its method of use are identical with those of the preceding embodiment, the index of the free hand passing, at the moment of introduction, through the tube **12**.

As regards the part **12**, it is indicated that it can be constituted also, as shown in FIG. **16**, by a ring 12*a*, gripped by the pocket at the level of the edge of the invagination and comprising at least two sheathing strips 12*b* and 12*c* applied against the portion of the tampon which is situated inside the pocket **1**. The asembly of the part **12** then forms a sort of minispeculum. The extraction cord passes into the interstice comprised between the two strips. In this regard it is pointed out that, in the case of the conical tube provided above, it is advantageous to provide a hole in the wall of the latter for the passage of the cord.

The embodiment of the gynaecological means according to the invention, shown in FIG. **9**, is more particularly concerned with a device for the introduction of semi-liquid vaginal medicaments, in the form of cream, foam or gel, contained inside a cannula **13** of flexible material, for example of the polyethylene type, of a generally conical shape, whose point 13*a* is perforated with holes 13*b*. The holes 13*b* serve for the passage of a medicinal cream **14** contained inside the cannula.

The means according to the invention comprise, as previously, a pocket or purse **1** and a cylindrical guide element **15** advantageously borne by the canula **13** as shown. The element **15** is constituted preferably by a reinforcement of the base of the cannula, flats facilitating the gripping being provided.

The pocket **1** is composed of a portion 1*a*, similar to the corresponding portion of the preceding embodiments, and of a portion 1*c* in the form of a glove finger folded back on itself by means of folds **16** and of which the end is placed in the opening of the cannula in contact with cream **14**. Advantageously, there is provided at the end of the portion 1*c* a rigid part **17** whose shape which is shown in FIG. **9** is such that it can be adapted into the end of the cannula and enable the expulsion of all the cream **14** through the holes 13*b*, as will be explained below.

The pocket **1** is fixed, for example by welding, to the element **15**, as seen at **18**. It can also be fixed by means of a simple narrowing of the pocket at this level.

Before use and with the object of hygiene, the ring **15** and the portion 1*c* are protected by a removable diaphragm **19**.

It will be advantageous to cover the end of the cannula with a removable protective diaphram to avoid the flow of the cream before use.

The placing in operation is as follows: first of all the diaphram **19** is removed, the ring **15** is seized between finger and thumb, the pocket **1** is opened by drawing on the cord **5** and the portion 1*a* is folded back on the hand. The diaphram protecting the end of the cannula is removed.

The cannula **13** is then introduced into the vaginal orifice. The index finger of the other hand is introduced into the glove finger constituting the portion 1*c* of the pocket **1**, and by pushing the part **17** just within the end of the cannula, expulsion of the cream **14** through the holes 13*b* is caused.

Advantageously, the part **17** comprises a rim 17*a* adapted against the inner surface of the cannula as shown and enabling, by means of a rigidity selected to be sufficiently great, the transportation of the whole of the medicinal cream towards the end of the cannula **13**.

The embodiment which has just been described can be applied to the introduction of menstrual tampons, the guide element being constituted by the abovesaid cylindrical element **15**.

To administer and hold in place a vulvar medicament, if necessary at the same time as a vaginal medicament, recourse can be had to the embodiment of the means according to the invention, shown in FIGS. **10**, **11** and **12**.

In the case of this embodiment, the tampon **2** is replaced by a gynaecological ovule **20**.

As seen in FIGS. **10** and **12**, the means according to the invention again comprise a pocket **1** and a guide element constituted by a ring **27** whose constitution

emerges from FIG. **12** and which enables the pocket to be gripped at the level of the jaws **30***a*/**30***b* and **31***a*/**31***b*, without crushing the ovule which is housed in a hole **32.**

The pocket **1** is this time composed of a portion **1***d* and a fold or diverticulum **1***e* in which, one of the ends of the ovule **20** which passes through the hole **32,** is housed. The assembly of the parts **1***d* and **1***e* is such that in the spread-out condition, as shown in FIG. **12,** the pocket is in the shape of a rectangular compress bounded by a peripheral strip **21** of absorbent material.

By way of example, it is indicated that the dimensions of the elements which have just been described can be as follows with reference to FIG. **12**:

whole of the pad:	length	=	12 to 16	cm
	width	=	6 to 8	cm
central gauze compress:	length	=	6 to 8	cm
	width	=	4 to 6	cm
absorbant peripheral bulge:	length	=	10 to 15	mm
	thickness	=	5 to 8	mm

In additional to the ovule **20,** the pocket **1** encloses a compartment **22** bounded by gauze **23** and enclosing the medicinal cream **24,** the shape of this compartment, which will be clearly apparent from FIG. **12,** being such that it forms a pad which matches the contours of the vulvar zone, the hole constituting consequently, in the spread-out condition, a vulvar compress.

The ring **27** is placed on the portion **1***e* so that it indicates the anterior-posterior direction thus facilitating the placing in position.

As previously, the pocket is closed to form a purse enclosing the ovule and the cream, but the opening cord **5** is placed so that its action enables the compress to be cut at the outer edge of the strip **21** which advantageously comprises two tongues **33***a* and **33***b* which will be more explicitly considered with regard to the FIG. **15.**

The placing in operation is as follows:

The ring **27** is gripped between the finger and thumb which are applied at **27***b* and **27***d*. The cord **5** is withdrawn and the compress thus opened. By means of the ring, the compress is applied in the anterior-posterior direction - indicated by the large dimension of the ring and by the large dimension of the compartment **22** — against the vulvar region. After the introduction of the end of the ovule into the vaginal orifice, the ring **27** is withdrawn by means of compression along **29***a*, **29***b;* the portion **1***e* resumes its normal position through the elasticity of the constituant material of the pocket **1,** then due to pressure along the arrow **26,** FIG. **11,** the ovule **20** is completely introduced into the vaginal passage and the pad formed by the compartment **23** becomes matched with the vulvo-vaginal anatomical contours **28,** the medicinal cream **24** being expelled from the compartment **23.**

The compress thus placed in position can easily be held by the garments, the absorbant peripheral strip **21** effecting protection against any excess of medicament or excretion; the strip **21** can be formed for example of compressed hydrophilic cotton.

The advantage of the tongues **33***a* and **33***b* results from FIGS. **11** and **15**; in fact, these tongues, by cooperating for example with the elastic **41** of the slip **42** of the person using it, are held in the genito-crural furrow **43** and thus ensure the holding in position of the compress. The tongues **33***a* and **33***b* are advantageously formed of flexible gauze or of a soft fabric to render contact with the skin as comfortable as possible.

Of course, it is possible to produce the compresses which have just been described without giving them an ovule **20.** In this case, the ring **27** does not necessarily include a hole **22,** but only the jaws to grip the pocket at the anterior-posterior crease which thus confers on the assembly a suitable rigidity. The ovule could then be replaced by an excess thickness of gauze constituting the anterior-posterior pad. This local thickening will enable better contact with the mucous membranes to be treated.

It is also possible to contemplate the use of the compress thus constituted without having recourse to a guide ring, the orientation then being given by a large dimension of the compress.

It is also possible to produce compresses directly in the shape resulting from FIG. **12,** the active surface of the compress then being protected by a diaphram before use.

In the case of the embodiment shown in FIGS. **13** to **15** (the common elements with the embodiment of FIGS. **10** to **12** are noted by the same reference numerals), the compress preserves the general shape shown in FIG. **12** but is of a more oval configuration by increasing the length, so that, as seen in FIG. **14,** its front end **14***a* is presymphysary (that is to say situated in front of the pubic symphysis **36**) and its posterior end **40***b* is para-anal.

The dimensions of the compress are, within the scope of this embodiment, from 8 to 10 cm in the direction of the width and from 12 to 18 cm in the direction of the length.

Thus as is evident especially from FIGS. **14** and **15,** the compress is generally conch-shaped, that is to say as a whole, concave upwardly both in the frontal plane and in the saggital plane and this, by lifting the circumferential edge covered with its absorbant beading **21.** The compress proper **37,** which is formed of gauze which may or may not be impregnated with medicament, is alone in contact with the mucuous membranes and advantageously has the shape of a longitudinal beading **38** matching well the anatomical contours; this anterior-posterior beading is raised over its whole length and thus bounds two lateral cavities **38***a* and **38***b*, which gives in section the appearance of the upper portion of a heart. To confer on the compress proper the shape which has just been described the plastics support **39** of said compress proper can be made to comprise (contrary to that shown in FIG. **15,** it is possible to arrange that this is the plastics layer **39***a* of the gauze **37** which constitutes the support **39** then being eliminated) an excess thickness constituting an axial ridge which must be sufficiently rigid so that the compress proper permanently has the abovesaid anterior-posterior beading. The relief will be at a maximum at **40***a* at the level of the vulva orifice in order to hold the constituant gauze of the compress **37** in contact with the mucuous membranes to be treated.

It is also possible to make the compress proper comprise a removable strengthening element, for example in the form of rigid whale bone, constituted by synthetic material of the type known under the trademark "polythene"; in the figures, the whale-bone constituting the reenforcing element has been shown diagrammatically at **40.** This reenforcment element in the

shape of a whale-bone is of circular or oval cross section and has a diameter of several milimetres. It includes at its forward portion a flattened zone **44***a* (for example in the shape of a fork or triangular spatula) which is applied to the surface of the body in the presymphysary region thereby facilitating thus the holding in position of the whale-bone. To retain this reenforcing element at the lower surface of the compress, there may be provided at the front A and rear B ends of the latter denoted respectively at **44***c* and **44***b* in which the front and rear ends of the reinforcing elements are housed. The latter is modeled so as to mate at a distance an anatomical contours so as only to affect upward pressure opposite the vulvo-vaginal orifice at **40***a* and consequently lift the support **39** (when one is provided) and the constituent gauze of the compress proper **37** which will thus remain in contact with the mucuous membrane to be treated whatever the position of the patient.

Given that, in the latter embodiment, the reinforcing element in the shape the whale-bone is removable, the user will be able to use the compress as necessary after having drawn the said reinforcing element. The latter is advantageously formed of a deformable material such as an aluminum-based alloy which preserves the shape which is conferred upon it by deformation and which the user will be able to model before use in order to arrange that the constituant gauze of the compress proper is in contact at the level of the mucuous membranes to be treated at a zone which will be selectable by the user as a function of his anatomical configuration.

The surface of the support **39** is in contact with the clothing can be rendered rough (reliefs, asperities) thus resisting sliding.

It is finally possible to place at the disposal of the user a slip specially devised for carrying the abovesaid compresses. This slip comprises at the level of the crotch, a housing formed for example by redoubling the constituant material of the slip (that is to say for example of the nylon) and intended to receive the compress. The corresponding portions of the slip and of the compress could be provided with self-adherent or self-adhesive strips enabling the use of the slip several times.

This being the case and whatever the embodiment adopted, there is thus provided gynaecological means whose characteristics emerge sufficiently from the foregoing for it to be unnecessary to dwell further on this subject and which have numerous advantages, especially that of enabling:

preparation in a completely sterile package of menstrual tampons or of medicinal products for vulvo-vaginal purposes,

simple technique of manufacture

hygienic use since the hands are constantly and completely protected during the various applications,

in its form "tampon introducer," direct control of the perfect positioning of the tampon by the protected index finger,

in its "vulvar compress" form, a complete, sterile and impermeable dressing.

As is self-evident and as emerges already from the foregoing, the invention is in no way limited to those of its types of application, nor to those embodiments of its various parts, which have been more especially indicated; it encompasses, on the contrary, all modifications.

I claim:

1. Gynaecological device constituting a vulvar compress of oblong shape, said device comprising a peripheral rim of absorbent material, a continuous substantially oblong support sheet of a flexible and impermeable material bounded by said rim, and a sheet of a material of the gauze type forming an inner lining on said support sheet, said lining being adapted to match the anatomical contours and said rim constituting the only absorbent part of the device.

2. Gynaecological device according to claim **1**, wherein said inner lining forms a longitudinal bulge in said oblong shape.

3. Gynaecological device according to claim **2**, wherein said bulge encloses a medicinal substance.

4. Gynaecological device according to claim **3**, wherein said inner lining is impregnated with the medicinal substance.

5. Gynaecological device according to claim **3**, wherein said medicinal substance is housed in a compartment bounded by the inner lining.

6. Gynaecological device according to claim **3**, wherein said medicinal substance is in the form of a gynaecological suppository.

7. Gynaecological device comprising a pocket of impermeable plastics material inside of which is housed an oblong compartment bounded by a substance of the gauze type and enclosing a medicinal cream, said pocket being arranged so that in the opened-out state it forms a support sheet and is in the shape of a rectangular or oval, oblong compress, as defined in claim **18**, the compartment being oriented in the direction of greatest length.

8. Gynaecological device, comprising a pocket of impermeable plastics material inside of which is housed an oblong compartment bounded by a substance of the gauze type and enclosing a medicinal cream, said pocket being arranged so that in the opened-out state it forms a support sheet and is in the shape of a rectangular or oval, oblong compress, the compartment being oriented in the direction of greatest length, wherein the support sheet comprises a ridge of material deformable and flexible but sufficiently strong to mate the longitudinal bulge to the anatomical contours.

9. Gynaecological device according to claim **8**, comprising a reinforcing element of the removable whale-bone type cooperating with the support sheet and formed of a deformable and malleable material capable of taking up by deformation and of preserving, a configuration due to which it applies the constituent gauze of the compress proper against the anatomical areas to be treated.

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