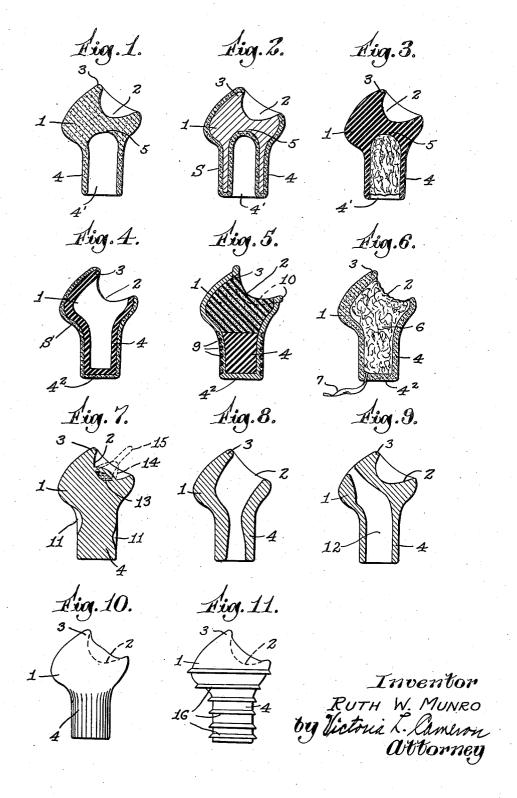
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MEDICAL DEVICE

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MEDICAL DEVICE

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This invention relates to means for simultaneously isolating, protecting, and sterilizing certain internal body organs, and particularly relates to the devices usually referred to as pes-5 saries, suppositories or tampons. It is a continuation and development of and improvement upon the subject matter of my Patent No. 2,049,270. Broadly my invention comprises means for isolating and protecting an internal organ 10 from dangerous or undesired matter, means for collecting or entrapping and sterilizing any matter present in surrounding regions which it is desired should not reach the organ to be protected; or means for collecting secretion from 15 one of said organs and preventing its entrance into the other organ; means for sterilizing the organ and surrounding regions; means if desired for supporting said organ; and means for self-positioning the said isolating, sterilizing $_{20}$ and supporting device in proper relation to said organ to be protected.

For example, the uterus is an internal body organ from which there is at certain periods a normal discharge through its mouth or cervix, $_{25}\,$ and through which mouth other matter may find its way from the vagina into the uterus. In such connection my device finds a field of great usefulness. It may also be used in the rectum to shut off, protect and sterilize portions of the 30 rectal passage, and adaptations of the same device may be used in the urethra, though in this case a physician's services usually are required. It may also be of value in operations on the nose, throat and ears, its combined isolating, protect-35 ing and sterilizing properties having many possibilities of usefulness. In its several uses its design necessarily will be changed so that it may be inserted and retained in effective position, but in all forms, the elements providing isola-40 tion, protection and sterilization of some predetermined body organ are present.

In many cases the menstrual flow is accompanied with much irritation of the vagina and more or less suffering, resulting in part at least from improper drainage. This is frequently the case where there is any displacement of the uterus or other organ. Furthermore, the walls of the vagina are extensible and full of creases and folds into which the secretions and other matter enter, and which for obvious sanitary reasons, it is important to sterilize and disinfect. Most commonly it is attempted to secure this result by douches, in which not infrequently there is used, particularly by the unadvised or poorly advised, harsh chemicals, many of which

are on the market advertised for this purpose, and which may cause serious injury to the delicate membranes. Even douches are frequently omitted on account of the difficulty or lack of opportunity of taking the same, with extremely unfortunate results. In lieu of douches, suppositories of various types are coming into increasing use. These sterilize the vagina to some extent but have no capacity either of protecting the vagina from matter flowing from the uterus of sealing the cervix against the entry into the uterus of undesired matter, both of which my invention may provide.

My device moreover is more satisfactory than douches in that there is no heat or cold to af- 15 fect the patient. My pessary or like device may be made of soluble, partly soluble, or insoluble material. If of soluble material, the same is molded in desired form and, because of the medicament contained therein, its contact with 20 all adjacent members is disinfecting, sterilizing, medicative and deodorizing in nature. results increase as the device dissolves, but it is designed to melt so slowly that before it has melted to the extent that its isolating and hold- 25ing capacities are ended, its sterilizing action is complete or well advanced. Such substances as gelatine, glycerine, or paraffin are satisfactory in use, though I prefer to use a material which upon dissolution will be absorbed by the body tissues 30 so that no residue is left to collect in the vagina. The fact that nothing remains to be removed is an important advantage of the soluble form of my invention.

If made of partially soluble material, the pessary retains its sealing and holding characteristics throughout its period of use, while the soluble portions thereof melt and sterilize surrounding bodies and regions and entrapped matter. It may be retained for any desired period but 40 usually by the time all the soluble material has melted, the period of danger has passed.

If of insoluble material, the device may be retained as long as desired, and extraneous disinfecting or sterilizing matter carried or in- 45 jected into the vagina.

If my device is used to receive or to drain off menstrual flow, ordinarily the insoluble or partially soluble forms are used. In such case, the same may be packed with gauze or other material to absorb the moisture if desired. If used to protect the uterus from the entry of undesired matter and to sterilize such matter, preferably the entirely soluble form is used, although if it is desired at the same time to support the uterus 55

or distend the walls of the vagina, the partially soluble form may be employed to great advantage.

The partially soluble embodiment may comprise a flexible or inflexible body of desired contour, which may be entirely coated, internally and externally, with a material which dissolves slowly at body temperatures, such as certain gelatine. Instead of coating the same, if preferred, my pessary may be made with pockets in its surfaces filled with medicated substances which dissolve or are freed at body temperatures. These pockets may be inside or outside or both. As the pessary substantially fills the vaginal passage, pockets in the outside of the same are likely to entrap any matter which may escape past the edges of the pessary.

Depending upon its use, my pessary may be so constructed as to provide an isolating or seal20 ing member adapted to shut off the cervix to surrounding areas, or it may be constructed so as to connect the cervix with the mouth of the vagina and shut off the vagina. In this latter use, its bottom may be closed, and the device collect the menstrual flow. In this case it may be desirable to make some portion of my device of extensible material so that in cases where it may be inconvenient to remove the same, the device will expand to receive additional amounts of secretions.

As a further modification my device may be made of textile gauze or other fibrous material treated with medicament and coated with soluble gelatine or the like, and molded to desired form. Upon the melting of the gelatine the gauze, or if desired a sponge-like material, is freed and absorbs the moisture. In this case, as the device must be removed, a cord, tape or strip of gauze may be incorporated in the device to extend through the entrance to the vagina and by which the device may be removed if and when this is desired.

In all cases, my device tends to distend the walls of the vagina, relieving pressure against the cervix, reduces nervous tension and causes a re45 laxed condition. If desired, it may contain drugs to alleviate pain. The gelatinous or other soluble material acts as a lubricant and allays inflammation. If extension of the vagina is particularly desired, some sponge-like material or a soluble gelatinizing material such as tapioca or sago may be incorporated in my device and the same when released will expand or swell and distend the walls of the vagina. The metal and hard rubber bogies sometimes used for this purpose frequently cause inflammation and have been known to cause peritonitis.

Another field of usefulness of my device lies in the case of operations or treatment of some single part or area either within the vagina, uterus or 60 other organ. My device may be constructed with openings to any desired area and, particularly in the soluble or partially soluble forms will disinfect and protect surrounding areas so that no infection will spread and the treated area will be 65 protected from dangerous matter which otherwise might reach the same. The yielding nature, flaccidity and creases and folds in the vagina make it difficult to get access to diseased parts and thus handicap accurate incisions. By insert-70 ing my device, which may be made in suitable shapes for treatment of cervix, cervical canal and uterus, also for protecting the vagina and cervical canal while treating the uterus, the organs may be distended, supported and disinfected, 75 and if of hollow construction, a predetermined opening may be made in the same, permitting ready access to the part to be treated and insertion of instruments, acids, drugs, etc. Also, medicine or cauterizing and strong solutions, powders, gas, may be included in the suppository in cells formed in the suppository or otherwise as desired, with soothing, coating and counter irritants in remaining parts. My pessary may be used to promote healing and prevent infection after operations, etc., and may also be 10 used to drain certain parts while protecting other parts from irritation and infection.

If desired, the insoluble form of my device may be filled with ice and used as an ice bag, in which case, it may be open at top and closed at 15 bottom, or if of type usually open at bottom, the bottom may be plugged, or the device may be filled with a fluid which produces effect of ice or heat, or the whole pessary made of such material.

To adapt the pessaries to the individual patient as well as to certain uses, in certain types of the same, usually of permanent nature, certain portions may be made extensible or compressible, provided there be some definite rigid 25 members about which or upon which the more variable parts may be supported. If desired it may be air-cushioned in part, or air may be incorporated in the sponge-like texture of the whole if such material is used. It may also be constructed so as to permit ready insertion and expansion once in position as by fluting the same in whole or in part.

My suppository is capable of a great variety of uses and may be made of almost any shape 35 and material desired, provided the main objectives of my invention be retained, that is, the isolation, sterilization and protection of one organ or a portion thereof, and the sterilization of surrounding organs and or regions of undesired 40 matter.

In the drawing I have illustrated and in the specification disclosed several practical embodiments of my invention. In the drawing:

Fig. 1 is a sectional view of one of my com- 45 pletely soluble pessaries.

Fig. 2 is a similar view of a pessary which is partially soluble.

Fig. 3 shows a wholly insoluble pessary with a packing.

Fig. 4 shows a partially soluble pessary with its lower end closed.

Fig. 5 is a view of a pessary having an extensible portion and provided with moisture entrapping pockets.

Fig. 6 is a closed end pessary having a packing. Fig. 7 is a view of a pessary showing in dotted lines alternate constructions for different uses.

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Fig. 8 shows a pessary having a passage throughout.

Fig. 9 shows a pessary having an opening to a part to be treated.

Fig. 10 shows a pessary having a fluted extensible cylinder.

Fig. 11 shows a pessary having a plurality of 65 circumferential flanges.

My pessary comprises a head portion of generally spherical contour provided with a cupshaped recess or recess 2 on the upper portion substantially diagonally of the pessary or an-70 gularly of the longitudinal axis thereof, which recess is adapted to receive the cervix or other organ, and above which extends a tangential portion or horn 3 adapted to fill the furnix or similar passage so as to prevent the entrance 75

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thereinto of matter from the cervix or vagina. The cup 2 may be round or oval, centered or non-centered, as desired.

Integral with the head portion 1 is a cylindrical or tubular portion 4. This member 4 may be closed to the cup 2 and open at its opposite end 4' as in Figs. 1, 2 and 3, or may be open to the cup 2 and closed at its lower end 4² as in Figs. 4, 5 and 6. Or the cup 2 and cylinder 4 may both have communicating recesses as in Figs. 8 and 9, or the cylinder may be solid as in Figs. 7 and 11.

In the first case, the device is intended to isolate the cervix by enclosing the same with the 15 cup 2, and to entrap matter present in the vagina with the recess in the cylinder 4, in which the same is retained until the pessary has either in whole or in part dissolved. The gradual melting of the soluble medicated material of which 20 my pessary is in whole or in part composed sterilizes all surfaces with which the same comes in contact, and the dissolved substance enters all regions adjacent the organ to be protected and sterilizes all matter within the same, as well as 25 any matter which may have entered the recess in the cylinder 4, and this sterilizing continues until the walls of the device collapse if the same is of entirely soluble nature, or until the soluble portion thereof dissolves.

of durable material, such as rubber, aluminum or the like, completely covered or partially covered with a layer S of medicated soluble material, the foreign matter entrapped in the cylinder 4 is never released in the vagina, and any such matter as may have found its way past the cylinder wall which substantially fills the vagina, has been subjected to the sterilizing effect of the freed medicament contained in the layer S of soluble material on the outer surface of the cylinder 4.

If the wholly insoluble type is used, sterilizing matter may be inserted by douche or suppository and because of the substantially complete isolation of the cervix by reason of the portions 2 and 3, there is but slight danger of any undesired matter reaching the cervix. However as the pessary of Fig. 1 entirely dissolves and is absorbed by the tissues of the vagina and other organs, whereas the insoluble portions of Figs. 2 and 3 have to be removed, the form of Fig. 1 is generally preferred. There are uses however, for example, where continued support for the uterus or expansion of the vagina walls are involved when the insoluble forms are more desirable.

In case my device is designed as in Figs. 4, 5 and 6 to entrap and collect menstrual flow and to prevent the same from entering the vagina 60 and filling the creases and folds in the walls thereof, the wall, 5 separating the cup 2 from the hollow cylinder 4 is omitted and the outer end of the cylinder closed as at 42. In such case, I prefer to use the only partially soluble or in-65 soluble construction. Furthermore, in such cases, it is of advantage to make the portion 2 of extensible material to receive increasing quantities of secretion as of rubber as indicated in Fig. 5. Similarly the portion 4 may be made ex-70 tensible if desired. This characteristic however need not prevent the device from being covered with the soluble medicated substance S, which as it melts will disinfect and sterilize the regions adjacent the cervix and in the interior 75 of the vagina.

It is possible however to use the wholly soluble form successfully for such purpose, particularly if there be sealed therein a sponge, gauze or other absorbent material 6 as shown in Fig. 6, in which case, there may be incorporated in the pessary a tape or strip of gauze 7 by which the sponge or other body may be removed.

It will be understood that also in the forms of Figs. 1, 2 and 3, or any other form capable of receiving the same, packings of gauze or like absorbent material 6 may be inserted, or any of my devices may be made of gauze or similar material, saturated with sterilizing matter, and moulded to desired form with or without a covering layer of glycerine or gelatin S.

The wholly soluble pessary may be satisfactorily made of gelatin, glycerine or like substances slowly melting at body temperatures. The partially soluble forms may be completely covered with such material or may be constructed 20 with pockets or cells filled with such material as shown at 9, Fig. 5, which material will be released as the seal of gelatin or other substance melts. The medicament or drug may be mixed into the body of glycerine or gelatin, or may be contained only in certain portions thereof as in cavities or cells in the body of the walls. This is all incidental to the principal invention and improvements as herein set forth.

All of my devices may be provided with reinforcing positioning flanges 10 as shown in Fig.
5, or the surfaces of the devices may be concaved or hollowed as at 11 in Fig. 7 to receive
portions of the vagina walls whereby the device
is held in position.

The device of Fig. 8 is hollow throughout and the opening in its upper end affords access to the cervix. It will be understood that there may be an opening at any predetermined point. By means of such a device an instrument may be 40 inserted or drugs or swabs applied to isolated parts as to the vagina wall through the opening 12 in Fig. 9. Meanwhile the rest of the vagina or other organ is protected and simultaneously sterilized or otherwise treated with material as 45 desired. Such a device may also be used to sterilize the vagina when it is not desired to isolate the cervix.

If it is desired only to sterilize the vagina the pessary may be made of solid soluble material, 50 formed only with the cup shaped recess 2, the horn 3 and cylinder 4. If in addition, it is desired to use the same as a receptacle, one or the other end of the cylinder must be open, and the passages therethrough closed or otherwise to 55 adapt it to its use.

It is possible to incorporate directly in the pessary some particular drug intended for some particular organ or portion of organ. I have shown such a construction in Fig. 7 wherein there is provided in the cup 2 a raised portion 13 which may be a cell containing medicine or drug for the mouth of the uterus or cervix. In dotted lines I have shown an alternative portion 14 intended to enter the cervical canal, and at 15 a longer portion intended to enter the uterus. In each case the drug will be delivered in the organ for which it is intended. To properly insert these types, a physician's services may be necessary.

Instead of the hollow cylinder of Figs. 1, 2, and 3, the same may be made of solid material, and a plurality of downwardly flaring flanges 16 extend from its periphery as shown in Fig. 11, 75

and which prevent the passages of any substance ordinarily entering the hollow cylinder 4.

If desired the device may be air cushioned in whole or in part. This may be done by providing double walls or double bottoms or sides only. If desired the device may be reinforced by rings or ribs both outside and in and these also aid in positioning the device. The cylinder may be of any length or shape to adapt it to its use, and if 10 of removable type may have tapes, strings or gauze incorporated therein to aid in its removal.

What I therefore claim and desire to secure by Letters Patent is:

- 1. A device of the class described comprising 15 a one-piece member including a head portion having a continuously convex side wall and a concave recess in the upper portion of said head at a point secant to the vertical axis thereof and adapted to encircle the os cervix to isolate the 20 same from the vagina, and an integral elongated hollow cylindrical member of lesser diameter than said head member and extending downwardly therefrom, said convex head member being designed to be engaged and closely held by the 25 vagina walls to hold said recess about the cervix and to retain said cylindrical member wholly within the vagina, said device comprising a consumable material soluble at body temperatures and including a suitable sterilizing medicament 30 freed to all surrounding areas as said material dissolves.
- 2. A device of the class described comprising a one-piece member including a head portion having a continuously convex side wall and a con-35 cave recess in the upper portion of said head at a point secant to the vertical axis thereof and adapted to encircle the os cervix to isolate the same from the vagina, a horn extending tangentially from the highest point of the rim of said 40 recess and adapted to enter and fill the furnix, and an integral elongated hollow cylindrical member of lesser diameter than said head member, said convex head being designed to be engaged and closely held by the vagina walls to 45 hold said recess about the cervix and said horn in the furnix, and to retain said cylindrical member wholly within the vagina, said device comprising a consumable material soluble at body temperatures and including a suitable sterilizing 50 medicament freed to all surrounding areas as said material dissolves.
- 3. A device of the class described comprising a one-piece member including a head portion having a continuously convex side wall and a 55 concave recess in the upper portion of said head at a point secant to the vertical axis thereof and adapted to encircle the os cervix to isolate the same from the vagina, and an integral elongated hollow cylindrical member of lesser diameter 60 than said head member, said convex head member being designed to be engaged and closely held by the vagina walls to hold said recess about the cervix and to retain said cylindrical member within the vagina, said device consisting of con-65 sumable material soluble at body temperatures and including a suitable sterilizing medicament free to all surrounding areas as said device dissolves.
- 4. A device as defined in claim 1 consisting of 70 a frame member having on all its surfaces a coating of said consumable soluble medicated material and including a suitable sterilizing medicament freed to all surrounding areas as said coating dissolves.

- 5. A device as defined in claim 3 in which a naturally expansible consumable packing is disposed within said device and which is freed within the vagina when the device dissolves and swells therein and supports the vagina walls until absorbed by the same.
- 6. A device as defined in claim 3 in which an absorbent packing is disposed within said device to be freed in the vagina upon solution of the soluble member and means for removing said 10 packing from the vagina.
- 7. A device as defined in claim 3 in which a member of predetermined design and of consumable medicated material extends from the inner wall of said recess and is adapted to be 15 positioned within the os cervix.
- 8. A device as defined in claim 3 in which means are provided on the outer wall of the member for entrapping and retaining matter within the vagina until the same is sterilized by 20 the medicament freed as said device dissolves.
- 9. A device as defined in claim 3 in which there is a continuous passage through said device from said cylindrical member to some predetermined point to permit treatment thereof while other 25 portions of the vagina are protected by the walls of said device.
- 10. The device claimed in claim 1, in which a member of predetermined design extends from said inner wall of said recess and is adapted to 30 be positioned within the os cervix.
- 11. The device claimed in claim 1 in which means are provided on the outer wall thereof for entrapping and retaining matter within the vagina until the same is sterilized by the medica- 35 ment freed as said material dissolves.
- 12. The device claimed in claim 1 in which there is a continuous passage through said device from said cylindrical member to some predetermined point to permit treatment at such 40 point while other portions of the vagina are protected by the walls of said device.
- 13. A device of the class described comprising a one-piece member including a head portion and an integral open ended elongated hollow cy-45 lindrical member, said device comprising a consumable material soluble at body temperatures and including a suitable sterilizing medicament freed to all surrounding areas as said material dissolves, there being a continuous passage 50 through said device from said cylindrical member to some predetermined point to permit treatment at such point while surrounding areas are protected by the walls of said device.
- 14. A device of the class described comprising 55 a one-piece member including a head portion having a continuously convex side wall and a concave recess in the upper portion of said head adapted to encircle the os cervix to isolate the same from the vagina, and an integral elongated 60 hollow cylindrical member of lesser diameter than said head member and extending downwardly therefrom and communicating with said head portion and closed at its bottom, said device comprising a consumable material soluble 65 at body temperatures and including a suitable sterilizing medicament freed to all surrounding areas as said material dissolves.
- 15. The device of claim 14 which consists of a frame having a coating of said consumable solution medicated material.
- 16. The device of claim 14 in which either the head or cylinder portion is extensible.

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