Jan. 14, 1964 W. A. SNELL 3,117,573

DIAPHRAGM

Filed Dec. 1, 1961

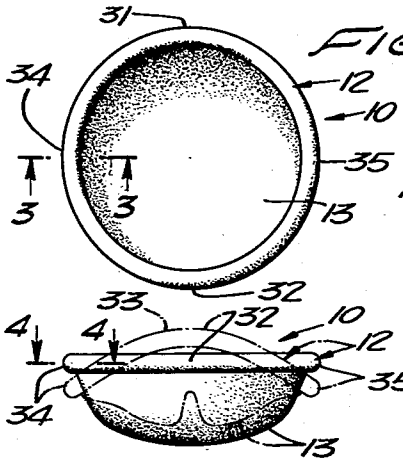


FIG. 1.

FIG. 2.

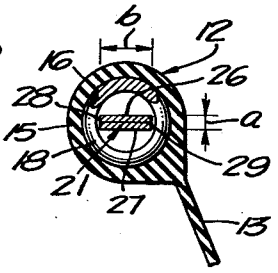


FIG. 3.

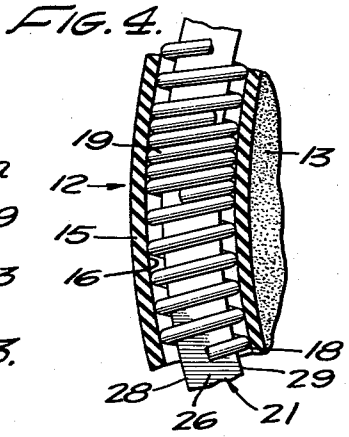


FIG. 4.

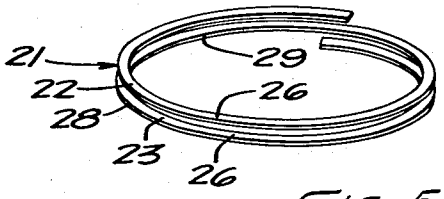


FIG. 5.

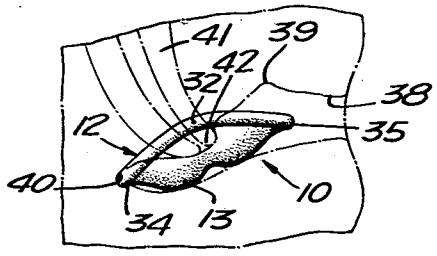


FIG. 6.

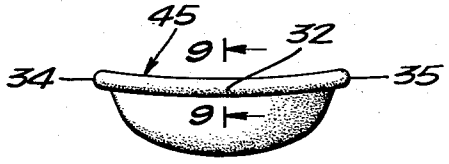


FIG. 8.

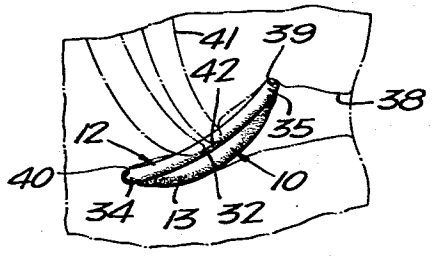


FIG. 7.

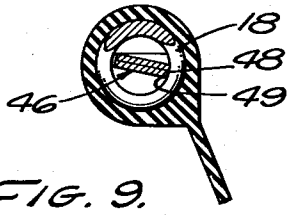


FIG. 9.

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United States Patent Office 3,117,573
Patented Jan. 14, 1964

3,117,573

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Filed Dec. 1, 1961, Ser. No. 156,230
6 Claims. (Cl. 128—127)

This invention relates generally to vaginal diaphragms and more particularly to spring means in the rim of a diaphragm.

There are diaphragms which are resiliently deformable for purposes of insertion to a planar elliptical configuration in the rim and they flex to a cylindrical arc and are supposed to seat snugly in the vaginal vault around the cervix, but they do not seat firmly enough at the posterior fornix and the pubic arch to provide adequate support and to assure a complete and reliable cervical seal.

There is a type of diaphragm having a frusto-conical rim which bows upwardly in one direction only to a saddle configuration having antipodal arcs reaching up and pressing into the vault muscles front and rear of the cervix; but this type of diaphragm has the disadvantage that when being inserted, the cervix is in the way of the leading arc, making it difficult to properly position the diaphragm encircling the cervix.

Within the past few years, another type of diaphragm has become available, it having two arcuate spring segments in its rim enabling the diaphragm rim to be bowed or arced downwardly in an inverted saddle configuration to clear the cervix during insertion with the final step of the placement operation being a bowing of the diaphragm rim in an opposite direction so that its front and rear arcs reach and press into the posterior fornix and the pubic arch respectively; but diaphragms with such segmented springs when being flexed for insertion must be pressed at those particular diametrically opposite points or regions of the midpoints of the arcuate spring segments. Also in the absences of guards or other special means the spring ends may puncture the rubber of the rim.

It is an object of this invention to provide a vaginal diaphragm which obviates the above mentioned disadvantages or difficulties and is adapted to bow in one attitude during insertion to clear the cervix and to bow in a contrary attitude in the final step of placement to provide a complete and reliable seal around the cervix.

Another object of this invention is to provide a diaphram of the above mentioned character which is normally flexed slightly in the direction of the configuration it assumes to seal the cervix.

A general object of this invention is to provide an improved easily insertable diaphragm which is simple in construction, and capable of being manufactured economically.

Further objects and advantages of the invention will appear during the course of the following part of this specification wherein the details of construction and mode of operation of two preferred embodiments are described with reference to the accompanying drawing in which:

FIGURE 1 is a plan view of a diaphragm embodying this invention;

FIGURE 2 is a side view of the diaphragm and a superimposed view in broken lines showing the diaphragm in one of its flexed positions;

FIGURE 3 is a detail section taken radially of the rim of the diaphragm along line 3—3 of FIGURE 1;

FIGURE 4 is a detail section taken circumferentially of the diaphragm along line 4—4 of FIGURE 2;

FIGURE 5 is a perspective view on an enlarged scale of the spiral spring of the diaphragm;

FIGURE 6 is a diagrammatic sagittal section illustrating how the diaphragm is flexed in one attitude for insertion;

FIGURE 7 is a view corresponding to that of FIGURE 6 but showing the diaphragm flexed in an opposite direction in the final step of its placement;

FIGURE 8 is a side view of another embodiment of this invention; and,

FIGURE 9 is a detail section taken radially of the rim of the diaphragm along line 9—9 of FIGURE 8.

Referring to FIGURES 1–7, the diaphragm shown therein is designated generally by reference numeral **10**. It comprises an annular rim **12**, and a thin sheet **13** extending across the space bounded by the rim. The rim of the illustrated diaphragm **10** is circular in plan and substantially circular in radial section, and the sheet **13** is dome-shaped, these particulars being mentioned for the purpose of making this description of the illustrated embodiment complete, they being subject to variation to accord with prescriptions by doctors, as, for example, in some instances a doctor may prefer that the sheet **13** extend flat across the rim.

Rim **12** comprises a ring **15** of elastomer, e.g., rubber, in the form of a tore, the inside space of which is designated by numeral **16**. Concentric and within the space **16** is a helical coil spring **18**, the ends of which have been interconnected at **19** (FIGURE 4) as by threading the turns or convolutions of the two ends together so as to make the coil spring **18** into a circlet. Concentric within the spring **18** is a helical spring **21**, here of two turns **22** and **23**.

For purposes of convenience in referring to the springs **18** and **21** with distinguishing terminology, the spring **18** is herein referred to as a coil spring and the spring **21** as a flat spring. The flat spring **21** is easily threaded into the coil spring before interconnecting the ends of the coil spring.

Rubber ring **15** may be formed around the coil spring **18** by dipping the coil spring into latex and rotating the convolutions of the spring. The sheet **13**, like the rubber ring **15** being preperably formed of elastomer, is then joined circumferentially of the sheet to the ring and the assembly is then cured. The flat spring **21** does not interfere with turning of the coil spring in the operation of forming the rubber ring **15**.

The use of a coil spring in the rim of a diaphragm has been recognized as providing the advantages of flexibility and smoothness of curvature of the rim to conform to the vaginal vault; however, with a coil spring alone, the diaphragm rim is subject to becoming twisted into a figure eight configuration, thus requiring the use of an intravaginal device for insertion of the diaphragm. Also a coil spring by itself is too flexible to provide optimum support and sealing pressure. A flat type spring in the rim of a diaphragm prevents twisting into a figure eight, thereby enabling insertion without the use of an intravaginal device and provides pressure of the rim against the vaginal wall. For these reasons, it is preferred to include both a coil spring and a flat spring in the rim of a diaphragm; however, I desire to make it clear that diaphragms having a flat spring of the type to which this invention relates but without a coil spring are contemplated by this invention. Also various relationships of the two springs are herein contemplated, some of which are illustrated, for example, in FIGURES 8 and 9 of the drawing of my prior Patent 2,538,478. A coil spring of smaller diameter and of smaller radial section than the illustrated coil spring **18** may be used on the inside or outside of the flat spring **21** or adjacent either of its flat sides. In the cases of no coil spring or of combinations of coil and flat springs in which the coil spring does not encircle the flat spring, the rubber ring portion **15** of the rim need not have a hollow **16**, and may be molded to adhere to all surfaces of the spring or springs.

Another facet of structural variation pertains to the

flat spring 21. The illustrated flat spring 21, as mentioned above, comprises two turns 22 and 23 formed from a single strip of spring material. The use of a flat spring of two or more turns is preferred over one of but a single turn because a flat spring of a plurality of turns has superior flexibility characteristics. In cases where a flat spring of a single turn is employed, it is preferred to bind or suitably splice the two ends of the flat spring together. It is to be noted further that the flat spring may be formed of any suitable resilient material, e.g., steel and nylon.

The feature of importance which structurally distinguishes the diaphragms of this invention over those previously used, resides in the configuration in radial section of the flat spring 21. More particularly, the spring 21, before embedment thereof and in its unflexed condition, lies in a flat plane. The spring is substantially uniform in radial section throughout its 360 degree extent. Any radial section through the spring has a shortest diameter (dimension *a* in FIGURE 3) and a longest diameter (dimension *b*), these diameters being normal to each other, and the shortest diameter *a* being perpendicular to the general plane of the flat spring 21. Each turn of the illustrated spring 21 is rectangular in radial section, the longer sides of the rectangle being designated by numerals 26 and 27, and the shorter sides by numerals 28 and 29. By way of illustration for the relative dimensions of the sides of a flat spring 21 of steel, each turn may be 0.008 inch thick (one-half dimension *a*) and 0.060 inch wide (dimension *b*).

With the longer dimension *b* of the flat spring 21 extending in the plane of the spring in its unflexed condition, the diaphragm rim may be flexed in either of two directions to resemble a hyperbolic paraboloid or saddle configuration. By pressing radially inward on the rim at any two diametrically opposite points, e.g., 31 and 32 in FIGURE 1, the diaphragm will flex either upwardly or downwardly. The broken line position 33 of the diaphragm in FIGURE 2 is the downwardly flexed position i.e., the rim 12 is flexed to a shape having two downwardly bowed arc portions, diametrically opposite each other, their medial points being designated by numerals 34 and 35 respectively, these being on a diameter which is perpendicular to the diameter defined by points 31 and 32. Also, by pressure against the diametrically opposite points 31 and 32, the rim may be flexed to bow upwardly at the diametrically opposite points 34 and 35.

The broken line position of the diaphragm in FIGURE 2 is a flexed position of the diaphragm for insertion purposes. In FIGURES 6 and 7 the diaphragm is illustrated diagrammatically within the female vaginal vault. The vault proper is designated by reference numeral 38. Numeral 39 designates the symphysis pubis or notch of the pubic arch, and numeral 40 designates the posterior fornix behind the uterus, indicated at 41, the uterus opening into the vault at the cervix indicated at 42. The diaphragm may be inserted to the position shown in FIGURE 6 with the leading arc 34 of the rim clearing the cervix. Finger tip pressure is then exerted upwardly on the underside of the rim at the point 35. Such pressure causes the diaphragm rim to flex in an opposite direction to the position shown in FIGURE 7 with the now upwardly extending arcs at points 34 and 35 pressing and seating in the posterior fornix and notch respectively, and with the now downwardly bowed arcs at medial points 31 and 32 seating against the sides of the vault. When in the FIGURE 7 position, the diaphragm rim encircles the cervix and provides support to the tissues around the cervix and assures a complete and reliable cervical seal.

Referring to FIGURES 8 and 9, the diaphragm shown therein is designated, generally by reference numeral 45, its component parts and structural details being identical to that of the diaphragm 10 with the exception that its flat spring 46, corresponding in all other respects to the flat spring 21, is of such size with respect to the coil spring 18, that it provides a normal flexure or bias to the diaphragm 45 slightly in the direction of the FIGURE 7 position of diaphragm 10. The inside diameter of the flat spring 46, measured across the space bounded by it, i.e., taken at its inside 48, before being positioned within the coil spring, is less than the small diameter of the coil spring taken at the inside 49 of the coil spring. Thus when the flat spring 46 is positioned within the coil spring 18, the flat spring will be expanded slightly radially outward, and its inside 48 will be in circumferentially continuous engagement with the inside 49 of the coil spring. Such expansion of the flat spring 46 contorts the rim 12 of diaphragm 45 to a saddle configuration (FIGURE 8) in which the pair of diametrically opposite arc portions at medial points 34 and 35, along what may appropriately be referred to as a longitudinal axis, are bowed upwardly, and the pair of diametrically opposite arcs at medial points 31 and 32, along a transverse axis, are bowed downwardly. The resulting configuration of the flat spring 46 is illustrated in FIGURE 9 by the showing of its radial section taken at point 32 at which the longer dimension of the rectangle of such radial section extends inwardly at a slight angle downward from the transverse axis. In the radial sections at the points 34 and 35 the longer dimension of the rectangle extends outwardly at a slight angle downward from the longitudinal axis.

To flex the diaphragm 45 for insertion purposes, the same is pressed inwardly at diametrically opposite points 31 and 32 along its transverse axis and the leading and trailing arc portions at points 34 and 35 along the longitudinal axis are pulled downwardly with respect to points 31 and 32 to a configuration corresponding to the broken line shape 33 of FIGURE 2 so that the leading arc 34 will clear the cervix. After being inserted to the FIGURE 6 position, the diaphragm is then flexed by finger tip pressure under the rim at trailing arc point 35 in the direction of its normal bias to seat around the cervix with the leading and trailing arcs pressing upwardly in the posterior fornix 40 and notch 39 respectively, and with the side arcs 31 and 32 bowed downwardly against the sides of vault 38.

While the particular diaphragm herein shown and disclosed in detail is fully capable of attaining the objects and providing the advantages hereinbefore stated, it is to be understood that it is merely illustrative of the presently preferred embodiments of the invention and that no limitations are intended to the details of construction or design herein shown other than as defined in the appended claims.

I claim:

1. A vaginal diaphragm comprising a composite spring assembly including an inner helical spring of large radius and greater than one full convolution in length entirely enclosed by an outer annular spring of relatively small radius, said inner spring being formed of thin strip stock wound on edge with the width thereof lying substantially in a common plane and fitting loosely within the hollow core of said outer spring, and a cup shaped thin-walled rubber diaphragm formed with a thin-walled tubular rim surrounding and supported by the exterior of said outer spring leaving a hollow annular cavity enclosing said composite spring assembly.

2. A vaginal diaphragm comprising a composite pair of helical springs the convolutions of which are of widely different diameters, the spring of larger diameter being formed of thin wide strip stock wound on edge into a helix with the width of the strip lying in a common plane normal to the axis of said helix, the spring of smaller diameter being formed of round wire and having its convolutions loosely encircling all convolutions of said edge-wound strip spring, and a thin-walled cup-shaped diaphragm of elastomeric material having a hollow tubular rim enclosing said composite pair of helical springs, said larger diameter spring being highly resistant to deformation in the plane of the strip width and being easily deformable out of said plane upon the application of forces

acting inwardly toward the axis of said flat helix from the diametrically opposed exterior sides thereof.

3. A vaginal diaphragm having a resiliently reinforced rim having a pronounced tendency to resume an annular position when free of applied external forces and characterized by its ability to bow with equal facility in either axial direction upon the application of inwardly directed forces applied from the diametrically opposed exterior points of said rim, said diaphragm having a unitary one-piece thin-walled cup-shaped main body of elastomeric material, a pair of loosely assembly helical springs enclosed in the cavity formed by said rim including an inner spring of in excess of one convolution in length formed of wide thin resilient strip material with the width thereof lying substantially parallel to a plane normal to the axis of said helix, a close-wound spring helix the convolutions of which encircle said flat spring and entirely enclose the same, the convolutions of said last mentioned spring cooperating to support said flat spring in a plane substantially coincident with the annular axis thereof.

4. A vaginal diaphragm as defined in claim 3 characterized in that the rim of said main body is hollow and sufficiently large in cross section as to enclose and surround said close-wound spring helix.

5. A vaginal diaphragm as defined in claim 3 characterized in that said flat spring is supported solely by said close-wound spring helix out of contact with said elastomeric material.

6. A vaginal diaphragm as defined in claim 3 characterized in that said spring of thin wide strip material includes at least two helical convolutions, and being further characterized in that the opposite ends of said close-wound spring helix are interleaved with one another.

References Cited in the file of this patent

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