

[54] **INTRAUTERINE DEVICE**

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[51] Int. Cl. **A61f 5/46**

[58] Field of Search..... **128/127, 128, 129, 128/130, 118**

[56]

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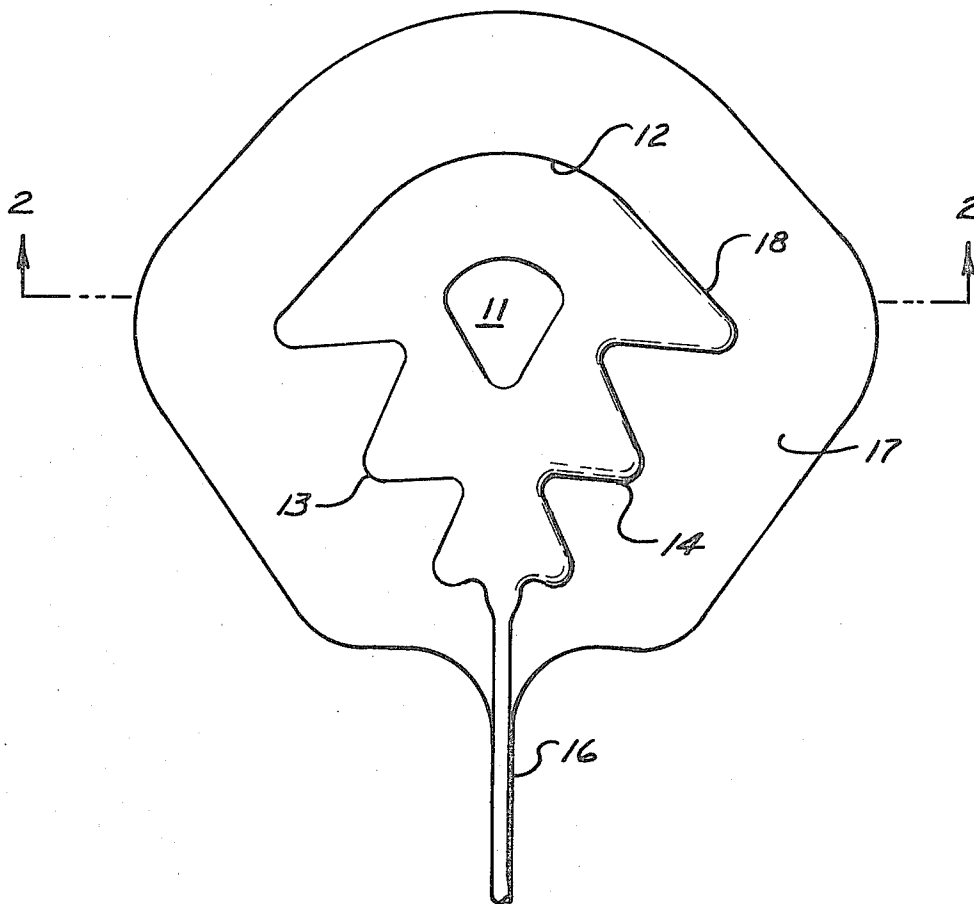
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ABSTRACT

An intrauterine device has an inflatable envelope of thin, flexible, substantially non-stretchable material. A skirt of a single thickness of thin, flexible material extends outwardly from the periphery of the envelope for from one-half to one centimeter and substantially all around the envelope.

4 Claims, 2 Drawing Figures



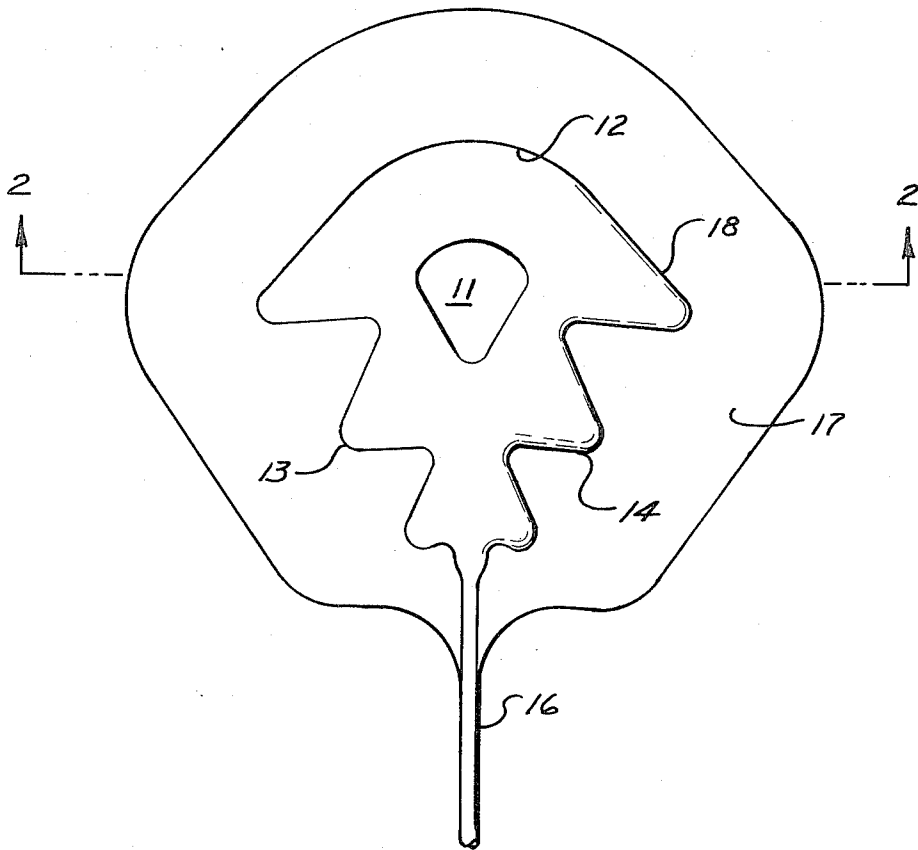


FIG. 1

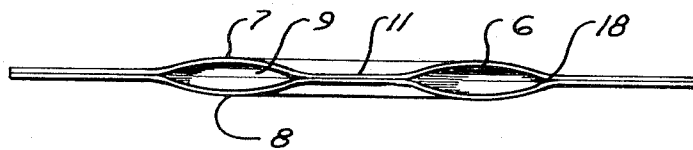


FIG. 2.

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INTRAUTERINE DEVICE

A device related to the present disclosure is shown in the once co-pending now abandoned application of Bartosik, Robinson and Kitrilakis entitled "Intrauterine Device" filed Feb. 2, 1971 with Ser. No. 111,943.

In that patent application there is shown an intrauterine device having a flexible envelope such as an inflatable body of relatively soft material confined to a particular, approximate size therein stated as 20 to 28 millimeters in maximum width, about 22 millimeters in maximum length and when distended about 2 to 3 millimeters thick. An attached tube allows inflation material such as a liquid to be introduced into or released from the envelope. The inflated envelope is generally pillow-like and disposed within a triangular outline, although its peripheral contour departs from strict geometrical regularity.

It has been found that the size of an intrauterine device, although generally confined within predetermined limits, can readily be established by the inflation technique disclosed to afford a comfortable and appropriate device. Even so, it is sometimes the case that the device, when inflated, does not occupy all of the uterine cavity. It is not desirable to overinflate the device nor to have it expand beyond its predetermined size. This is to avoid any undue pressure, internal abrasion, discomfort or other deleterious effects.

It has likewise been ascertained that the effectiveness of an intrauterine device is at least in part contingent upon the amount of uterine surface that is physically contacted or covered by the device. There is thus a requirement for maximum physical contact with the uterine wall by the device yet an equally cogent opposite requirement that the intrauterine device be kept relatively small and as soft and cushion-like as possible.

It is therefore an object of the invention to provide an intraterine device that fulfills the requirements for a relatively small, soft and compliant structure yet one which affords more than the usual ability to contact or abut the uterine wall surface.

Another object of the invention is to provide an intrauterine device that will afford adequate and augmented wall contact without irritation, mechanical abrasion or undue pressure.

Another object of the invention is to provide an improved intrauterine device that can be handled by means of the techniques set forth in the above-identified patent application.

A further object of the invention is to provide an improved intrauterine device without substantial increase in cost or complexity and with satisfactory longevity.

A further object of the invention is in general to provide an improved intrauterine device.

Other objects together with the foregoing are attained in the embodiment of the invention described in the accompanying description and illustrated in the accompanying drawing, in which:

FIG. 1 is a plan view of an intrauterine device constructed pursuant to the invention, a portion thereof being broken away to reduce the size of the figure; and

FIG. 2 is a cross section, the plane of which is indicated by the line 2—2 of FIG. 1.

In a preferred form of the device there is provided an envelope 6 of thin, flexible, substantially nonstretchable and, usually, substantially liquid impervious materials that are extremely soft to the touch yet able

to confine an inflating medium without difficulty. As disclosed in the above-mentioned application, the envelope in plan, to a rough approximation, is contained in a triangular configuration of the order of 28 millimeters in width and of the order of 22 millimeters in length, the thickness being somewhat variable. The envelope is conveniently fabricated of one or more sheets of the chosen material. When two sheets are used, an upper sheet 7 and a lower sheet 8 are in some areas unconnected or spaced apart to enclose an interior volume 9. The interior volume may be somewhat annular in form surrounding a central connected area. In this area the sheets are secured together to provide a double wall 11 without any intervening space.

The marginal configuration in plan is roughly that of an envelope having a rather flat arcuate margin 12 and a pair of converging undulatory margins 13 and 14. The interior volume 9 is in communication with the interior of a tube 16 merging with the envelope and extending to a point of attachment to an inflating device, not shown. The inflating device usually is a capsule containing a measured amount of inflating liquid.

Upon installation of the completely collapsed device, the capsule is discharged to transfer the inflating liquid through the tube 16. This expands the volume 9 to an appropriate amount resulting in an envelope usually having a thickness of from two or three centimeters. In this inflated condition the envelope occupies a large part but not all of the uterine cavity.

Pursuant to the invention, I do not materially alter the envelope 6 as shown in the above-mentioned application insofar as its general dimensions, materials, contour or outline are concerned but I do add thereto an extension or skirt 17. This usually is a single thickness of the same material from which the envelope itself is made, although it can be of double thickness and of any material which is thin, flexible, non-toxic and non-allergenic and easily conformable to the surrounding tissues without any substantial stiffness or roughness. Many of the presently available polymers or plastics are suitable for this use.

In providing the added skirt 17 I preferably do so either by extending one of the original sheets 7 or 8 beyond the normal peripheral junction seam 18 or fold which establishes the margin of the envelope of the intrauterine device itself or I attach a separate sheet or skirt to the intrauterine device envelope all around the peripheral fold or seam thereof except at the zone of attachment of the tube 16. The skirt 17 can be attached to a portion of the tube as well or can be cut away slightly so that the tube 16 is not at all restricted in any of its possible movements. The skirt 17 can be of various dimensions depending somewhat on the dimensions of the envelope but preferably extends out from the seam 18 or fold margin envelope periphery a distance of from about ½ centimeter to a distance of about 1 centimeter measured approximately radially. The periphery or free edge of the skirt 17 is carefully fabricated so that it does not have any discernable irregularities in it. It is free and flexible enough so that it can partially fold or conform or bend to good contact with the immediately adjacent surface of the uterus.

The peripheral extent of the skirt and its radial dimension and flexibility are such that there is a substantial addition to the area of contact between the device and the uterine surface since both sides of the skirt 17 are available for this purpose.

3

The installation and purposeful withdrawal of the device, and the general use and function of the augmented device, are as disclosed in the above-mentioned application which states that the tube and the envelope when collapsed have an approximately circular-cylindrical configuration less than about 3 millimeters in diameter.

What is claimed is:

1. An intrauterine device consisting of thin, flexible substantially non-stretchable material formed in the shape of an envelope having a boundary and of a size to contact a large part but not all of a uterine cavity, a flexible tube communicating with the interior of said envelope and united with said envelope for conducting liquid to the interior of said envelope, and a skirt of material of a comparable kind extending outwardly from said boundary to an extent to cover a remaining part of said uterine cavity, said envelope being a maximum of 28 millimeters wide, a maximum of 22 millimeters long and when inflated about 2 to 3 millimeters thick, and

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said skirt extending from about ½ centimeter to about 1 centimeter from said boundary.

2. A device as in claim 1 in which said skirt is a single thickness of material.

3. A device as in claim 1 in which said envelope and said skirt when collapsed and folded can fit into a circular-cylindrical configuration less than about three millimeters in diameter.

4. An intrauterine device consisting of a body having a wall structure arranged to define a hollow, flexible envelope of such a side as to fit within and contact a large part but not all of a uterine cavity and having a periphery of a predetermined shape in plan, means for conducting liquid to the interior of said envelope, and a thin, flexible skirt integral with and extending outwardly from said envelope all around the periphery thereof and having a width outwardly of said envelope about equal to that of said envelope.

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