May 10, 1966 J. LIPPES 3,250,271

INTRAUTERINE DEVICE

Filed April 29, 1963

Fig. 1.

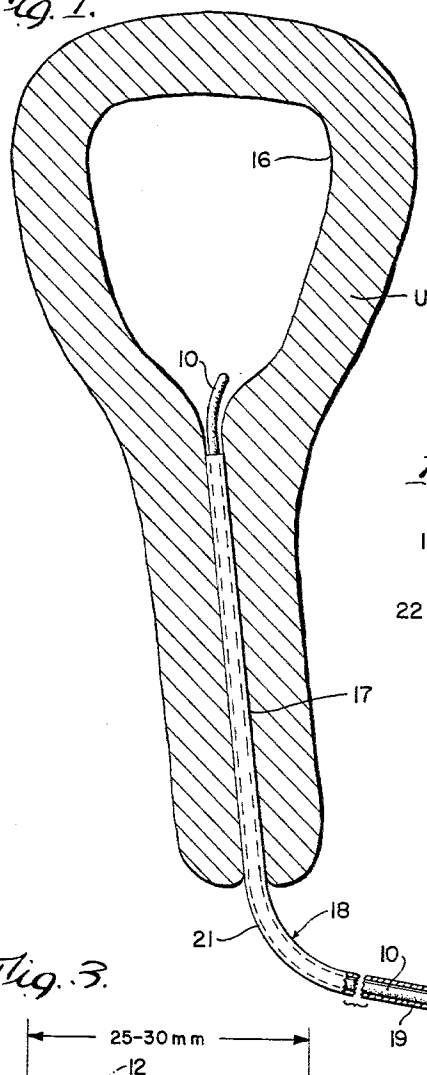


Fig. 2.

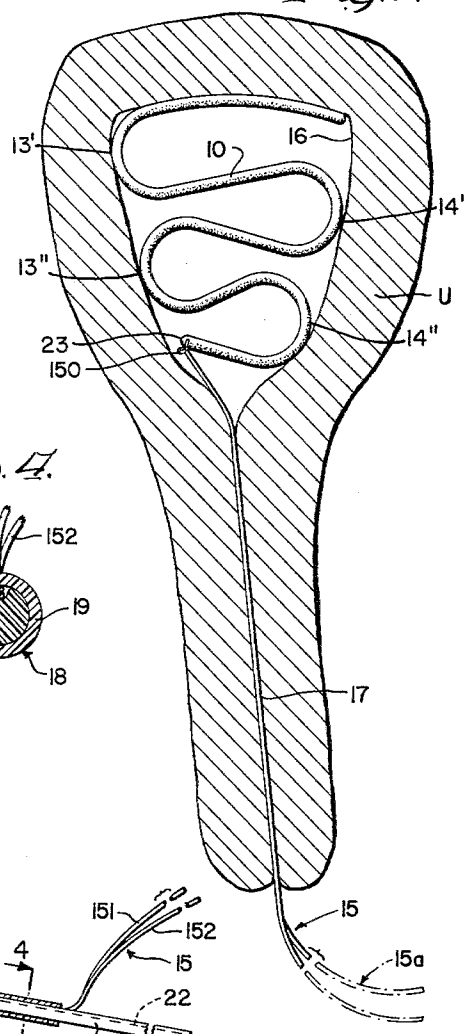
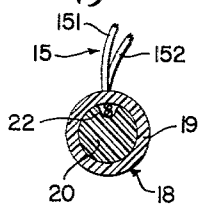


Fig. 4.



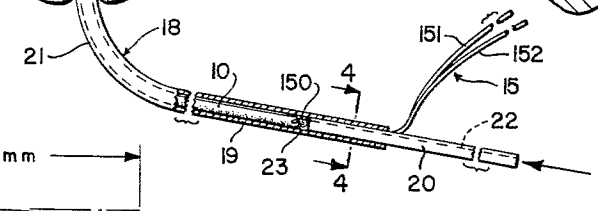
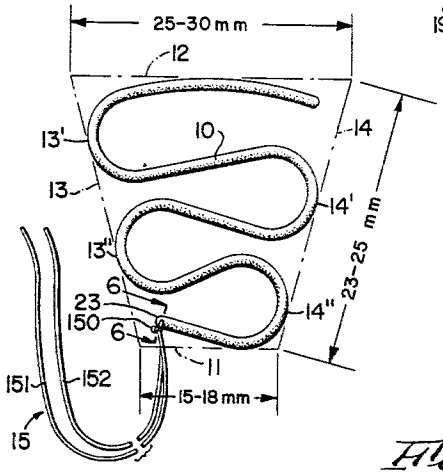


Fig. 3.



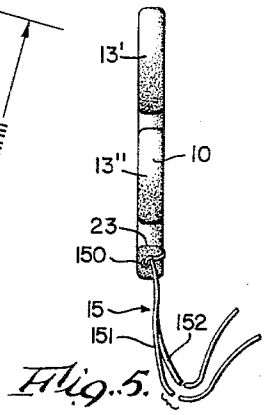
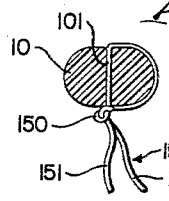


Fig. 5.

Fig. 6.



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INTRAUTERINE DEVICE

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This invention relates to an intrauterine device, and more particularly to such a device useful for contraceptive purposes.

It is a known medical fact that a foreign object in the uterus will prevent conception. Heretofore, different types of intrauterine devices for contraceptive purposes have been proposed but none has been fully satisfactory.

An important object of the present invention is to provide an intrauterine device which may be readily inserted into the uterus with the aid of a simple instrument.

Another object is to provide such an intrauterine device which may be worn with comfort for months, and even years, and thereafter simply and readily removed without discomfort to the wearer.

A further object is to provide such an intrauterine device which does not prevent or interfere with menstruation or in any other way adversely affect the well-being of the wearer.

A further object is to provide such an intrauterine device any undesired displacement of which from the uterus following proper insertion therein can be detected.

Still another object is to provide such an intrauterine device which is simple in construction, easy to manufacture and relatively inexpensive.

Other objects and advantages of the present invention will be apparent from the following detailed description of a preferred embodiment illustrated in the accompanying drawing in which:

FIG. 1 is a side elevational view, partly in section, of an instrument in operative position for inserting into a uterus the inventive intrauterine device, also shown in substantially straightened out form and arranged on the instrument.

FIG. 2 is a view similar to FIG. 1 insofar as illustration of the uterus is concerned and showing the intrauterine device in operative position therewithin following its insertion and withdrawal of the aforesaid inserting instrument, a portion of the tail forming part of the device which is cut off following insertion being illustrated in broken lines.

FIG. 3 is a side elevational view of the intrauterine device in the operative sinuous configuration which it normally assumes, and showing the critical dimensions of the isosceles trapezoid within whose imaginary boundaries the device in its normal sinuous form is confined.

FIG. 4 is an enlarged transverse sectional view of the inserting instrument with the intrauterine device arranged thereon and taken on line 4—4 of FIG. 1.

FIG. 5 is a left end elevational view of the intrauterine device shown in FIG. 3.

FIG. 6 is an enlarged sectional view thereof taken on line 6—6 of FIG. 3.

The inventive intrauterine device is shown as comprising an elongated or bar-like body **10** of flexible material arranged in sinuous or serpentine form substantially in one plane within the imaginary boundaries of an isosceles trapezoid having a short boundary side **11**, a parallel long side **12**, and a pair of non-parallel boundary sides **13** and **14** of equal length. The dimensions of such sides are critical. The short side **11** has a length falling in the range of from about 15 to about 18 millimeters. The long side **12** has a length falling in the range of from about 25 to about 30 millimeters. Each of the non-parallel sides **13** and **14** has a length falling in the range of from about 23 to about 25 millimeters. As shown, the device

has two nodes or reverse curves on each side of the body, those on the left being designed **13'** and **13"** and those on the right being designated **14'** and **14"**. Referring to FIG. 3, it will be noted that the sinuous body **10** is confined entirely within the boundary sides **11–14** of the isosceles trapezoid, the boundary side **13** being tangent to the one pair of nodes **13'** and **13"** and the boundary side **14** being tangent to the other pair of nodes **14'** and **14"**. These nodes are connected to progress from one end of the body **10** to the other end thereof successively reversing their directions of curvature. Thus, as viewed in FIG. 3, starting from the upper and large end of body **10** and moving toward the lower and small end thereof, node **13'** curves in a counterclockwise direction, node **14'** in a clockwise direction, node **13"** in a counterclockwise direction, and node **14"** in a clockwise direction. The terminal portions of bar-like body **10**, one being the body part between node **13'** and the adjacent free end and the other being the body part between node **14"** and the adjacent free end, are severally contacted by a parallel boundary sides **11** and **12**.

The body **10** may be round or non-round such as oblong in cross-section as shown in FIG. 6 and preferably has a major dimension in cross-section of about 0.080 inch, and a length when straightened out of about 4.5 inches.

The intrauterine device also comprises a thread-like tail **15** of flexible material connected at one end to that end of the body **10** at the short side **11** of the aforementioned trapezoid. Preferably, the tail **15** is provided by inserting a length of a single thread through a hole **101** in the end portion of the body **10** until about half the length of the thread has passed through the hole. Then the two thread portions are tied into a knot indicated at **150** leaving two strands **151** and **152**. However, a single strand tail may be used and it may be suitably attached to the body **10** other than by being tied thereto.

The tail **15** may be round or non-round in cross-section and is preferably smaller in cross-section than the body **10**. The length of the tail **15** is about 2.5 inches.

The intrauterine device may be made of any suitable flexible material. While the body portion **10** and the tail portion **15** may be made of different materials, it is preferred that they be made of the same material. It is preferred to make the device of polyethylene with the body portion **10** composed of low density polyethylene and the tail portion **15** composed of linear polyethylene. I have found a surgical thread having a thickness of about 0.007 inch particularly useful to provide the tail. If a single strand tail is employed it may be molded integrally with or fused to the body of the device.

Regardless of what material the device is made of, it is essential that the body **10** provides a resilient member capable of being substantially straightened out and upon release thereafter returning to its sinuous form as illustrated. In the case of polyethylene, this can be conveniently achieved by molding the body **10** in its sinuous form so that when straightened out, it has "memory" or a resistance to cold flow which causes it to return to its sinuous configuration.

Viewed in another manner, the inventive intrauterine device comprises a bar-like body of flexible material curved in a substantially flat plane in the shape of a large S continuing into a smaller S, the body being capable of being substantially straightened out and upon release tending to return to such continuous double S-curved shape.

If desired about 20% by volume of barium sulfate may be mixed with the plastic material to render devices molded therefrom visible to X-ray examination.

The reason why the aforementioned resilient characteristic of the body portion **10** of the intrauterine device

is important will now be apparent when the mode of inserting the device into an uterus is considered.

Referring to FIGS. 1 and 2, an uterus is represented at U having a cavity **16** in the inner portion or fundus of the uterus which communicates with the vagina (not shown) by a neck portion or isthmus **17**.

The inserting instrument represented generally by the numeral **18** is shown as comprising a sleeve or tube **19** and a plunger **20** freely slidably arranged therein. The sleeve or tube **19** has a gradually turning or curved inner portion as indicated at **21**, and while it may be made of a rigid material it is preferably made of a flexible plastic material such as one of the long chain fluorinated polymers of ethylene such as tetrafluoroethylene, known under one trademark as Teflon. In cross section, the sleeve or tube **19** may be round, or non-round such as being oblong.

The plunger **20** is made of a flexible material since it must follow the contour of the passage in the sleeve or tube **19**, and is also preferably made of Teflon. The cross-section of the plunger **20** corresponds generally to that of the sleeve or tube **19**, except that the plunger is provided with a longitudinal groove **22**.

In use of the instrument **18**, the sleeve or tube **19** and plunger **20** are first separated. The body portion **10** of the intrauterine device is then fed into the sleeve or tube **19**, with the free end remote from the tail portion **15** being inserted into the end of the sleeve or tube remote from the curved portion **21**. In the course of so inserting the body portion **10**, it is straightened out against its natural urging of assuming its sinuous form. When the body portion has been substantially completely inserted within the sleeve or tube **19**, the tail portion **15** is placed in the groove **22** in the plunger **20**, such groove being large enough to receive the tail portion. The end of the plunger **20** adjacent the trailing end of the straightened out body portion **10** is then inserted into the sleeve or tube **19**. Partial insertion of the tail portion within the groove **22** is depicted in FIG. 1, in which the partial insertion of the plunger **20** within the sleeve or tube **19** is also illustrated. The leading end of the plunger **20** thrustingly bears against the rearwardly facing shoulder **23** formed by the trailing end of the body portion **10** due to the difference in thickness of the tail portion **15**.

With the intrauterine device so arranged on the instrument **18**, the assembly is inserted into the vagina (not shown) and partially into the uterine cavity **16** through the isthmus **17** as illustrated in FIG. 1. Thereafter, the plunger **20** with the tail portion arranged within the groove **22**, is gradually pushed into the sleeve or tube **19**.

As the body portion **10** enters the uterine cavity **16**, it returns to its sinuous form, as shown in FIG. 2. The plunger **20**, which is longer than the sleeve or tube **19**, is continued to be pushed inwardly thereof until the entire body portion **10** is accommodated within the uterine cavity **16** and the tail portion **15** is left extending through the isthmus **17**. Thereafter the instrument **18** is withdrawn and the portion of the tail **15** extending outwardly of the isthmus **17** may be cut off. Such cut-off portion is shown at **15***a* in FIG. 2.

Instead of utilizing an inserting instrument for the intrauterine device in which the plunger has a groove such as the groove **22**, the plunger may have enough clearance between its periphery and the internal surface of the guide sleeve or tube as will accommodate the tail portion **15** of the device and still be freely slidable within the sleeve or tube.

Clinical studies have shown that the intrauterine device remains in the operative position shown in FIG. 2 and does not rotatively move within the uterine cavity so as to draw thereinto the tail **15**. The device may be left within the uterus for months or years and will remain in its operative position during such time. In case it is desired to remove the device, this is readily accomplished by grasping the free end of the tail **15** with a suitable instrument such as forceps (not shown) and thereafter gradually pulling the device outwardly of the uterus through the isthmus **17**. In being so removed, the body portion **10** straightens out substantially to pass through the isthmus **17** without discomfort.

From the foregoing, it will be seen that the embodiment of the present invention illustrated accomplishes the various objects stated and is illustrative rather than limitative of the invention, the scope of which is to be measured by the appended claims.

What is claimed is:

1. An intrauterine device, comprising an elongated body arranged in sinuous form in substantially one plane within the imaginary boundaries of an isosceles trapezoid including a pair of opposite non-parallel boundary sides and a pair of opposite parallel boundary sides, such sinuous body having a pair of nodes on each of two opposite sides thereof and a terminal portion at each end, one of said non-parallel boundary sides being tangent to one node pair and the other of said non-parallel boundary sides being tangent to the other node pair, said nodes being connected to progress from one end of said body to the other end thereof successively reversing their directions of curvature, said parallel boundary sides severally contacting said terminal portions.

2. An intrauterine device, comprising an elongated body of flexible material arranged in sinuous form in substantially one plane within the imaginary boundaries of an isosceles trapezoid including opposite parallel long and short boundary sides and a pair of opposite non-parallel boundary sides, such sinuous body having a pair of nodes at each of two opposite sides thereof and a terminal portion at each end, one of said non-parallel boundary sides being tangent to one node pair and the other of said non-parallel boundary sides being tangent to the other node pair, said nodes being connected to progress from one end of said body to the other end thereof successively reversing their directions of curvature, said parallel boundary sides severally contacting said terminal portions, and a flexible tail connected to the free end of that terminal portion of said body at said short boundary side of said trapezoid.

3. An intrauterine device, comprising an elongated body of flexible material arranged in sinuous form in substantially one plane within the imaginary boundaries of an isosceles trapezoid having short, long and non-parallel boundary sides, said short boundary side having a length falling in the range of from about 15 to about 18 millimeters, said long boundary side having a length falling in the range of from about 25 to about 30 millimeters and said non-parallel boundary sides severally having a length falling in the range of from about 23 to about 25 millimeters, such sinuous body having a pair of nodes on each of two opposite sides thereof and a terminal portion at each end, one of said non-parallel boundary sides being tangent to one node pair and the other of said non-parallel boundary sides being tangent to the other node pair, said nodes being connected to progress from one end of said body to the other end thereof successively reversing their directions of curvature, said parallel boundary sides severally contacting said terminal portions.

4. An intrauterine device, comprising an elongated body of flexible material arranged in sinuous form in substantially one plane within the imaginary boundaries of an isosceles trapezoid having short, long and non-parallel boundary sides, said short boundary side having a length falling in the range of from about 15 to about 18 millimeters, said long boundary side having a length falling in the range of from about 25 to about 30 millimeters and said non-parallel boundary sides severally having a length falling in the range of from about 23 to about 25 millimeters, such sinuous body having a pair of nodes on each of two opposite sides thereof and a terminal portion at each end, one of said non-parallel

boundary sides being tangent to the one node pair and the other of said non-parallel boundary sides being tangent to the other node pair, said nodes being connected to progress from one end of said body to the other end thereof successively reversing their directions of curvature, said parallel boundary sides severally contacting said terminal portions, and a flexible tail connected to the free end of that terminal portion of said body at said short boundary side of said trapezoid.

5. An intrauterine device, comprising a bar-like body of flexible material arranged in sinuous form in substantially one plane to provide a resilient member confined within the imaginary boundaries of an isosceles trapezoid having short, long and non-parallel boundary sides, said short boundary side having a length falling in the range of from about 15 to about 18 millimeters, said long boundary side having a length falling in the range of from about 25 to about 30 millimeters and said non-parallel boundary sides severally having a length falling in the range of from about 23 to about 25 millimeters, said member when in said sinuous form having a pair of nodes on each of two opposite sides thereof and a terminal portion at each end, one of said non-parallel boundary sides being tangent to one node pair and the other of said non-parallel boundary sides being tangent to the other node pair, said nodes being connected to progress from one end of said body to the other end thereof successively reversing their directions of curvature, said parallel boundary sides severally contacting said terminal portions, said member being capable of being substantially straightened out and upon release thereafter returning to said sinuous form on its own.

6. An intrauterine device, comprising a bar-like body of flexible material arranged in sinuous form in substantially one plane to provide a resilient member confined within the imaginady boundaries of an isosceles trapezoid having short, long and non-parallel boundary sides, said short boundary side having a length falling in the range of from about 15 to 18 millimeters, said long boundary side having a length falling in the range of from about 25 to 30 millimeters and said non-parallel boundary sides severally having a length falling in the range of from about 23 to about 25 millimeters, said member when in said sinuous form having a pair of nodes on each of two opposite sides thereof and a terminal portion at each end, one of said non-parallel boundary sides being tangent to one node pair and the other of said non-parallel boundary sides being tangent to the other node pair, said nodes being connected to progress from one end of said body to the other end thereof successively reversing their directions of curvature, said parallel boundary sides severally contacting said terminal portions, said member being capable of being substantially straightened out and upon relief thereafter returning to said sinuous form on its own, and a flexible thread-like tail connected to the free end of that terminal portion of said body at said short boundary side of said trapezoid.

7. An intrauterine device as set forth in claim 5 wherein said member when substantially straightened out has a length of about 4.5 inches.

8. An intrauterine devices, comprising a bar-like body of flexible material curved in a substantially flat plane in the shape of a large S continuing into a smaller S, said body being capable of being substantially straightened out and upon release thereafter tending to return to such continuous double S-curved shape.

9. An intrauterine device, comprising a bar-like body of flexible material curved in a substantially flat plane in the shape of a large S continuing into a smaller S, said body being capable of being substantially straightened out and upon release thereafter tending to return to such continuous double S-curved shape, said body adjacent the free end of such smaller S-shaped portion having a hole, and a thread passing through said hole and tied into a knot intermediate its ends to provide a two-strand tail.

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