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Soichet

[11] **3,923,051**

[45] **Dec. 2, 1975**

[54] **INFLATABLE INTRAUTERINE CONTRACEPTIVE DEVICE FOR POSTPARTUM USE**

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[52] **U.S. Cl.** **128/130**

[51] **Int. Cl.²** **A61F 5/46**

[58] **Field of Search** 128/127, 128, 129, 130, 128/131

[56] **References Cited**

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Primary Examiner—Lawrence W. Trapp

Attorney, Agent, or Firm—Ostrolenk, Faber, Gerb & Soffen

[57] **ABSTRACT**

A Y-shaped IUD with an inflatable balloon between its two arms; the IUD is to be inserted into the uterus shortly after childbirth or abortion when the uterus is enlarged; after insertion into the uterus, the IUD is inflated through a check valve; another check valve permits the inflated IUD to shrink by leaking out of fluid as the enlarged uterus goes through postpartum or postabortion involution; inlet and outlet of inflation fluid is through tube means in which are located the check valves; the inflation tube can be separable from the IUD after inflation, leaving only an outlet tube.

21 Claims, 11 Drawing Figures

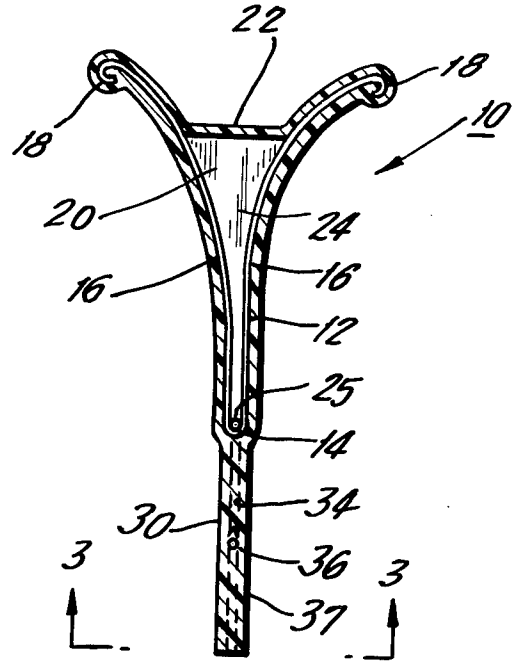


FIG. 1

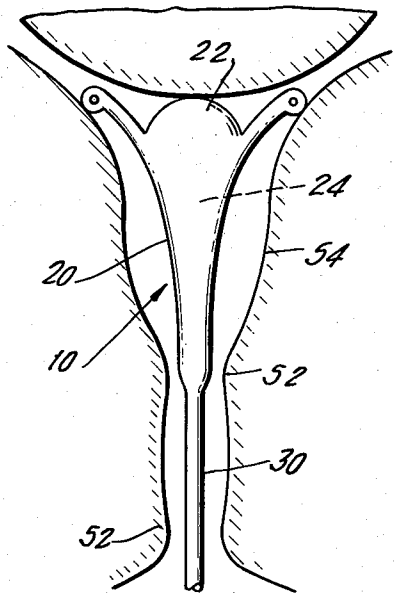


FIG. 2

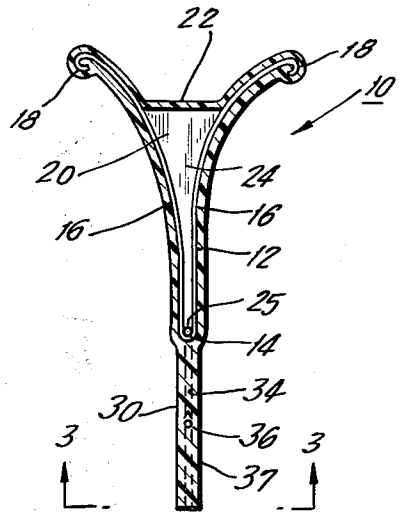


FIG. 3

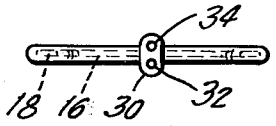


FIG. 4

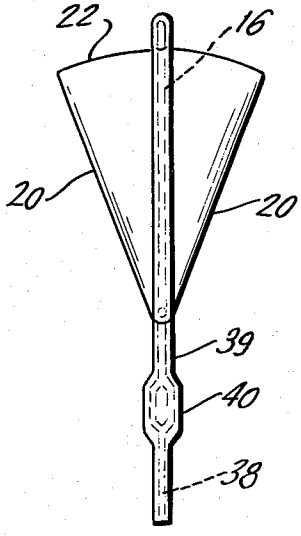


FIG. 5

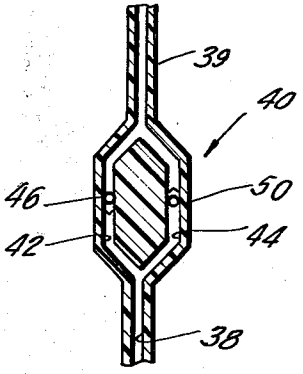


FIG. 9.

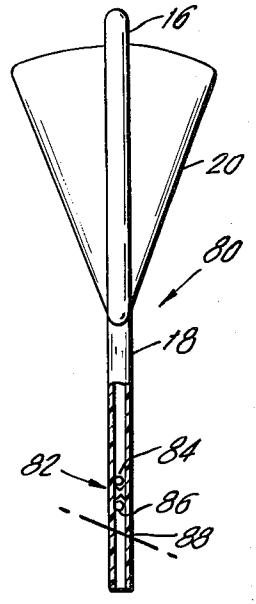


FIG. 6.

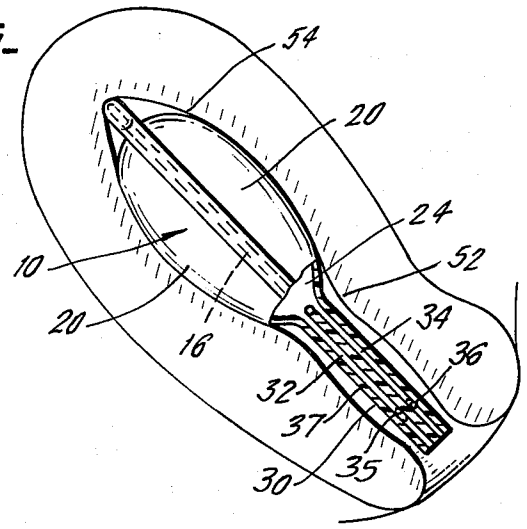
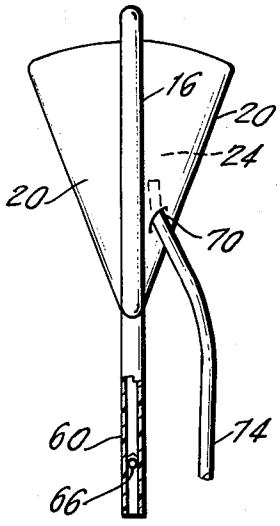


FIG. 10.



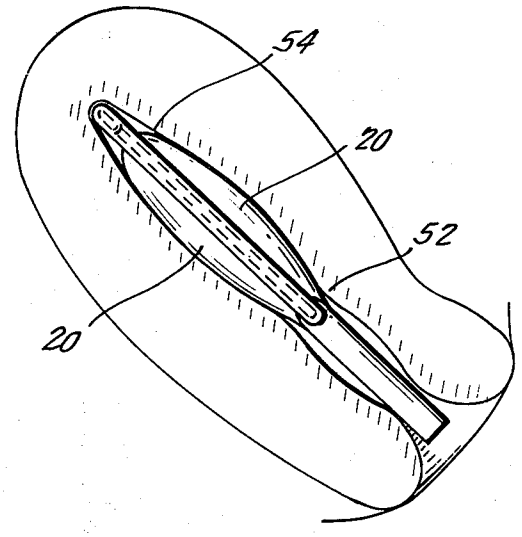
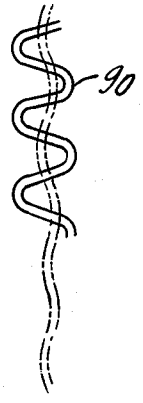


FIG. 7.

FIG. 11.



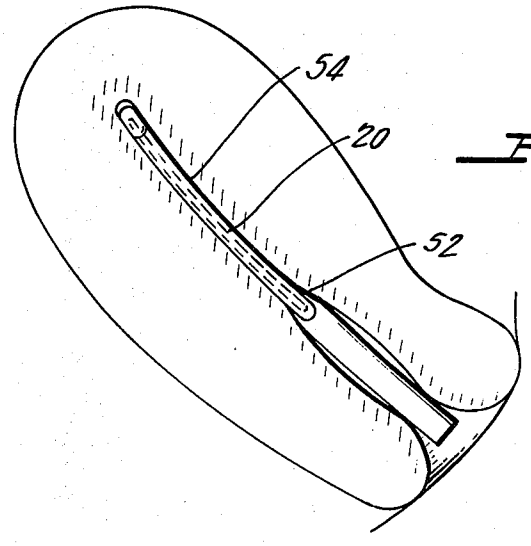


FIG. 8.

INFLATABLE INTRAUTERINE CONTRACEPTIVE DEVICE FOR POSTPARTUM USE

BACKGROUND OF THE INVENTION AND DESCRIPTION OF THE PRIOR ART

This is an improvement over my prior U.S. Pat. No. **3,811,435** issued May **21, 1974,** which discloses a novel intrauterine contraceptive device (IUD) that is shaped to enable it to remain within the uterus and is designed to prevent perforation of the uterus. An excellent time for emplacing an IUD is shortly after childbirth or abortion while the woman is still confined at a medical facility and the vagina, cervix and uterus are enlarged, which eases emplacement. However, a normal size IUD would not be securely held in the enlarged uterus and would fall out through the enlarged cervix. An IUD large enough to be securely held without falling out would cause damage to the uterus and/or cervix during uterine postpartum or postabortion involution unless the IUD were periodically replaced with a smaller size IUD.

There is another problem with a multipara female whose uterus has gone through postpartum or postabortion involution. The uterus is permanently somewhat enlarged, and conventional IUDs may not be securely held in place. Thus, an IUD that can be enlarged sufficiently to contact the walls of an enlarged uterus of a multipara female is desirable.

One solution to the problem of providing an IUD for postpartum or postabortion use is the collapsible ring shown in U.S. Pat. No. **3,659,597,** or relatively higher force exerting collapsible arm IUD as shown in U.S. Pat. No. **3,511,231.** However, both of these normally outwardly biased means may exert a too great force once the uterus has gone through postpartum or postabortion involution. Furthermore, the outward force exerted by these means is only in its plane of orientation.

Another highly relevant form of IUD, having the purpose of maximizing the surface area contact between the uterine walls and the surfaces of the IUD, is the inflatable IUD, as shown in U.S. Pat. Nos. **3,779,241** and **3,401,689.** Both of these IUDs are inserted into the uterus in an uninflated condition and are inflated after insertion to maximize contact with the uterine walls. However, both of these inflatable IUDs are useful only where the uterus and cervix are stable in size. If either were inserted in a postpartum or postabortion involuting uterus, a physician would be required to periodically bleed inflation fluid from the IUD in order to prevent it from exerting unnecessary pressure on the walls of the postpartum or postabortion involuting uterus.

SUMMARY OF THE INVENTION

The invention provides an inflatable IUD adapted for emplacement immediately following childbirth or abortion. The IUD includes means for permitting periodic, automatic release of inflation fluid from the inflated IUD during uterine postpartum or postabortion involution. Thus, an IUD inserted immediately following childbirth or abortion need not be frequently checked, replaced, corrected or deflated by a physician. The natural tendency of a patient to avoid visiting her physician following childbirth or abortion and the attendant reduction in expense to a patient as a result of not having to make frequent visits makes the invention valuable to patients.

Hereinafter, only the after childbirth or postpartum condition will be mentioned. It should be understood that the postabortion condition is also being discussed.

In accordance with the invention, the inflation chamber of the IUD communicates externally of the uterus through a normally closed, pressure responsive, one way check valve, which opens to permit release of fluid from the inflation chamber upon increase of pressure in the IUD due to uterine postpartum involution. The outlet valve may be in an outlet tube communicating with the inflation chamber.

In addition, because the IUD shrinks with the uterus, removal of the partially inflated IUD from the uterus would be no more difficult than removal of any uninflated IUD.

In another development of the invention, the inlet to the inflation chamber of the IUD is also through a pressure responsive, one-way check valve. The physician inflates the IUD by pressurizing a tube leading to the IUD. The pressurization can be by hypodermic needle and syringe. This pressurization opens the inlet valve and permits entrance of fluid into the IUD. The one-way inlet valve precludes undesired return of fluid. In one arrangement, the inlet valve is a check valve spaced away from the inflation chamber in a tube communicating with that chamber. In another arrangement, the inlet valve is a resilient flap normally closing an opening in the inflation chamber wall. This flap can be opened by inlet pressure and it returns to closed condition upon pressure discontinuance. Alternatively, the inlet tube can be passed through this flap and to reclose that valve, the inlet tube is merely withdrawn.

According to a further development of the invention, there is an elongated tube means communicating from the inflation chamber of the IUD, which is of sufficient length to be grasped by the physician while the IUD is emplaced. At least one or both of inlet and outlet of inflation fluid is through this tube means. Corresponding with outlet and/or inlet being through this tube means, the appropriate ones of the outlet valve and the inlet valve are also in this tube means. The tube means may comprise a single tube, serving for both inlet and outlet, with both valves in that tube. There may be only a single valve in the single tube which serves for valving both inlet and outlet flow. The tube means may comprise separate inlet and outlet tubes each containing the respective valve. The inlet tube may be separate from the inflation chamber and may be removable after inflation.

In accordance with a further development of the tube means, it is made of an appropriate inert, resilient plastic material. The tube means, or at least one tube thereof, has a normal sinusoidal curvature. Its normal elasticity causes the tube means to return to its curved condition, and in returning, the tube means is drawn upwardly in the vagina so that it would be out of the way.

The IUD of the invention would have the same plastic coated wire construction as that taught in my prior U.S. Pat. No. **3,811,435.**

Stretched between and supported on the resilient arms of the IUD is a flexible, thin walled, hollow chamber which is made of appropriate stretchable inert plastic material, e.g. silicone rubber and which, when inflated, expands upwardly, slightly sidewardly and also forwardly and rearwardly of the arms. Thus, the IUD is

expansible both in the plane of the arms and forward and rearward of that plane.

The filler fluid for the IUD could be air, water, saline solution or other biologically inert liquid.

Accordingly, it is the primary object of the present invention to provide an effective IUD.

It is another object of the present invention to provide an effective IUD for use in a multipara female.

It is a further object of the present invention to provide an effective IUD for use shortly after childbirth or abortion.

It is another object of the present invention to provide an IUD that will not exit through a temporarily wide open cervix or an enlarged cervix.

It is another object of the present invention to provide such an IUD, which will not exert undue pressure on the uterine walls as the uterus involutes after childbirth.

It is yet another object of the present invention to provide such an IUD, which can be used after childbirth during uterine postpartum involution without the patient having to frequently visit a physician.

It is another object of the present invention to provide such an IUD, which is inflatable and which will deflate during uterine postpartum involution.

It is a further object of the present invention to provide such an IUD with an improved deflation means.

It is another object of the present invention to provide such an IUD with an improved inflation means.

It is a further object of the invention to provide such an IUD with an appropriate means for inflation and/or deflation of the IUD, wherein such means naturally shifts to a more convenient position when not in use.

These and other objects of the present invention will become apparent from the following description of the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a diagrammatic front elevational view in cross-section of a uterus after childbirth showing an inflated IUD in accordance with the invention in position in the uterus;

FIG. **2** is an elevational view in cross-section of the IUD shown in FIG. **1** in uninflated condition;

FIG. **3** is a view along the line of and in the direction of arrows **3** in FIG. **2**;

FIG. **4** is a side elevational view of an alternate arrangement of an IUD in accordance with the invention, in the inflated condition;

FIG. **5** is an enlarged fragmentary view of a valve assembly for the arrangement of FIG. **4**;

FIG. **6** is a diagrammatic side elevational view of an enlarged postpartum uterus showing the IUD of FIG. **2** in position and inflated;

FIG. **7** is the same view as FIG. **6** after a period of time and after the uterus has partially involuted postpartum;

FIG. **8** is the same view as FIGS. **6** and **7** after the uterus has fully postpartum involuted;

FIG. **9** shows still another variation of the valving and the tube means of the invention;

FIG. **10** shows yet another variation of the valving in accordance with the invention; and

FIG. **11** is a schematic view of the tube means of the IUD in accordance with a further development of the invention.

DETAILED DESCRIPTION OF THE INVENTION

Turning to FIG. **2**, the IUD **10** of the invention is formed with a metal or plastic backbone **12** contoured substantially into a Y shape. The backbone in this embodiment is a single strip of resilient stainless steel which is folded at **14** to form the arms **16.**

At the free end of each arm **16** is a rounded promontory **18.** Backbone **12** is coated with silicone rubber, with a rubber having the trademark "SILASTIC" or with other suitable biologically inert thermoplastic material.

Serving as a web joining arms **16** and integrally formed with the rubber coating on arms **16** is the double layer web wall structure **20** which is sealed around arms **16** and is sealed at the top wall **22** and at its base **25** to define an enclosed inflation chamber **24** between walls **20, 22.** The material of chamber walls **20, 22** is the same as that coating backbone **12** and is flexible and elastic so that it can contact and assume the shape of the walls of the uterus and so that it can be inflated, as in FIGS. **1** and **4** and deflated, as shown in the sequence of FIGS. **6–8.** The arms **16** prevent any significant sideward expansion, as viewed in FIGS. **1** and **2,** of walls **20.** There is some minor expansion of arms **16** to ensure that the promontories **18** maintain engagement with the uterine wall. However, virtually all of the inflation expansion is against the forward and backward walls of the uterus and some is upwardly, as shown in FIGS. **1, 4** and **6.**

Depending beneath joint **14** of the Y-shaped IUD is a tail **30,** which is of sufficient strength to serve as the conventional means for removing the IUD from the uterus by drawing upon the tail. However, tail **30** is also involved in inflation and deflation of chamber **24.** As shown in the embodiment of FIGS. **3** and **6,** tail **30** is formed of two parallel tubes **32, 34** carried in an exterior layer **37** of biologically inert material, with tube **32** being for inlet of inflation fluid into chamber **24** and tube **34** being for outlet therefrom. Both of tubes **32,** 34 communicate into chamber **24.** To enable the inleting and outleting of fluid from chamber **24,** appropriate inlet valve **35** in tube **32** and outlet valve **36** in tube **34** are provided. Inlet valve **35** is a one-way check valve which is normally spring biased closed but which opens upon a physician injecting a fluid into passage **32** under sufficient pressure to open check valve **35.** The inflowing fluid then moves into and inflates chamber **24** to the required extent. Upon discontinuance of fluid injection through passage **32,** check valve **35** recloses and inflation chamber **24** is then sealed at the appropriate inflation level.

Outlet check valve **36** is in tube **34** and is spring biased closed with a spring force sufficient to ensure that chamber **24** remains properly inflated. Both of check valves **35** and **36** remain closed to prevent any leakage or undesired exit of fluid from chamber **24.** However, the spring force holding valve **36** closed is selected so that when a predetermined level of pressure in chamber **24** is exceeded due to force exerted by the uterine walls during postpartum involution, the pressure in chamber **24** and thus in tube **34** above valve **36** increases sufficiently to open check valve **36** and permit slow leakage therethrough of enough of the fluid that was in chamber **24** to reduce the pressure therein. Eventually, sufficient fluid exits past valve **36** to reduce the pressure behind that valve enough to cause the

valve to reclose and seal the chamber **24** at lesser inflation and smaller size.

FIGS. **4** and **5** show a modification of the plural tube arrangement of FIG. **3**, but in other respects, the IUD of FIG. **4** corresponds to that of FIGS. **1** and **2**. In FIGS. **4** and **5**, there is but a single tube **38** passing through tail **39**. To enable the inleting and outleting of fluid from chamber **24**, valve chamber **40** is included in tail **39**. Valve chamber **40** is divided into inlet passage **42** and outlet passage **44**. In inlet passage **42** is one-way inlet valve **46**, which is normally spring biased closed but which opens upon a physician injecting a fluid into passage **38** under sufficient pressure to open check valve **46**. The inflowing fluid then moves into and inflates chamber **24** to the required extent. Upon discontinuance of fluid injection through passage **38**, check valve **46** recloses and inflation chamber **24** is then sealed at the appropriate inflation level.

Outlet check valve **50** is spring biased closed with a spring force sufficient to ensure that chamber **24** remains properly inflated. Both of check valves **46** and **50** remain closed to prevent any leakage or undesired exit of fluid from chamber **24**. However, the spring force holding valve **50** closed is selected so that when a predetermined level of pressure in chamber **24** is exceeded due to force exerted by the uterine walls during postpartum involution, the pressure in chamber **24** and thus in passage **38** above valve housing **40** increases sufficiently to open check valve **50** and permit slow leakage therethrough of enough of the fluid that was in chamber **24** to reduce the pressure therein. Eventually, sufficient fluid exits past valve **50** to reduce the pressure behind that valve enough to cause the valve to reclose and reseal chamber **24** at lesser inflation and smaller size.

Because of valves **35, 36** and of two-way valve **40**, which preclude any undesired leakage of fluid into or out of chamber **24**, the free ends of tails **30, 39** can be opened. However, to prevent the build-up of contaminants within tubes **32, 34, 38**, the valves would be close to the open ends of the tubes.

After childbirth, the IUD is inserted in its uninflated condition suggested in FIGS. **2** and **8** through the enlarged and flaccid cervix **52** of FIGS. **1** and **6** into the enlarged uterus **54** of the female. As shown in FIG. **6**, because the uterus and cervix are so enlarged, IUD **10** would fall out through the cervix unless it were held there by some appropriate means. Thus, by the means described, inflation chamber **24** is inflated and fills the uterus **54**, walls **20** contact the front and back walls of the uterus and the IUD also is enlarged sufficiently so as to no longer easily fit through the enlarged cervix **52**.

After childbirth, the uterus goes through postpartum involution and the cervix shrinks to normal size. In FIG. **7**, an intermediate postpartum involuted condition is illustrated. The inflated IUD has partially deflated as a result of the pressure exerted by the uterine walls due to postpartum involution. Valve **36** permits the leakage of fluid from chamber **24** and permits the deflation.

Eventually, the uterus contracts to its normal size for a multipara female, as shown in FIG. **8**, and the inflation chamber of the IUD correspondingly deflates to match the normal shape of the uterus. The now normal size cervix holds the shrunken IUD in the uterus as with other IUDs known in the art. However, any permanent enlargement of the uterus, which resulted from childbirth, is filled by the partially enlarged IUD, which will shrink in size no more than necessary to relieve the uterine wall pressure exerted thereon, whereby the IUD will be aided in staying in the uterus by that slight degree of inflation which holds the inflation chamber exterior surfaces of the IUD against the walls of the uterus. Also, such placement and holding of the IUD inflation chamber walls against the walls of the uterus greatly aids in contraception, which the invention is intended to foster.

FIG. **9** shows yet another variation of tube means **80** for both inflating and deflating inflation chamber **24**. Tube means **80** is a permanent tail having the characteristics of tube means **39**. However, instead of dividing flow through a separating valve chamber, like **40**, tube means **80** is a single tube with only a single valve means **82** therein. Valve means **82** is comprised of an inlet valve **84**, which functions like valve **46**, and an outlet valve **86**, which functions like valve **50**. Valves **84, 86** are schematically shown. They may be integrated into a single element or assembly, e.g. a resilient flapper plate which flexes to open the tube for desired flow upon the desired pressure level being exceeded on either side of it.

It is desirable that tube means **80** not be visible after insertion of the IUD and inflation thereof. Yet, for ease of handling during inflation, the tube means should be quite long. But, a long tube means will not be invisible after inflation. Quite long tube means **80** has its valve means **82** quite near IUD walls **20**. After inflation, tube means **80** is cut off at **88**, just below valve **82**. The outlet valve **86** is still controlling exit leakage, but the tube means **80** itself can now be quite short and therefore invisible. Tube means **80** would be the tail by which the IUD can be later withdrawn through the cervix.

FIG. **10** shows yet another variation of tube means for inflation chamber **24**. The permanent tail **60** only includes the outlet tube and its corresponding outlet check valve **66**.

Inlet to chamber **24** is through normally closed slit opening **70** which comprises a check valve that is comprised of resilient plastic material. Elongated, open inlet tube **74** is passed through opening **70** into chamber **24**. The size of tube **74** matches that of opening **70** so that inserted tube **74** sealingly passes through the opening. The chamber is inflated with fluid through tube **74**. When inflation is completed, tube **74** is withdrawn from opening **70** and is then withdrawn from the body. Valve opening **70** recloses and seals chamber **24**.

In a variation of the above arrangement, the outlet end of tube **74** is placed against, but not through, opening **70**, and the inflation pressure of fluid in tube **74** opens opening **70**.

With this arrangement, inlet tube **74** can be quite long to enable a physician to easily work with it outside the body for inflating chamber **24**. At the same time, outlet tube **60** can be quite short in length so as always to be within the vagina and out of the way.

Turning to FIG. **11**, a variation **90** of either of tails **30, 39** or **80** is shown, wherein the plastic material of which tail **90** is comprised is given a natural sinusoidal curvature, as shown in solid lines. When a physician wishes to inflate the IUD, he draws the curved IUD into a more straightened condition, illustrated in broken lines. After he has inflated the IUD, the physician releases tail **90** and it draws up into the vagina, assumes the sinusoidal shape and is out of the way. It is apparent that outlet tube **60** could also have the characteristics of tail **90** although there would be no need to draw out

the tube during its normal use. It is apparent also that tube **80** need not have the shape of tail **90** if tube **80** is cut off at **88** at a location well up into the vagina.

There has just been described a novel IUD that is particularly useful for females shortly after childbirth or abortion at which times the uterus and cervix are temporarily enlarged. The IUD includes an inflation chamber, which is inflated to conform to the enlarged shape of the uterus, and it further includes a valve system, which at the least comprises a normally biased closed outlet valve, which permits gradual squeezed outlet of inflation fluid from the inflation chamber during uterine postpartum or postabortion involution, and may also include an inlet valve, which enables injection of fluid into the inflation chamber but otherwise seals that chamber against inlet or outlet of fluid.

Although the present invention has been described in connection with preferred embodiments thereof, many variations and modifications will now become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

I claim:

1. An intrauterine contraceptive device, comprising:

a hollow inflatable member defining a chamber therein, said member being of a size sufficiently small when it is deflated to permit insertion of said member through the cervix and of a size sufficiently large to prevent passage through the cervix when such member is substantially inflated;

outlet means communicating with said chamber for permitting exit of inflation fluid from such chamber; pressure responsive means in said outlet means, said pressure responsive means including means normally sealing said outlet means against fluid exit therethrough and being responsive to pressure in said chamber that is above a predetermined level to open said outlet means until pressure in said chamber decreases below said predetermined level and said pressure responsive means then reclosing said outlet means at pressure below said predetermined level.

2. The intrauterine contraceptive device of claim **1,** wherein said outlet means comprises a tube means communicating with said chamber, said means for sealing said outlet means comprises a one-way check valve, including means which gives that check valve said predetermined opening pressure.

3. The intrauterine contraceptive device of claim **1,** further comprising:

inlet means communicating with said chamber and adapted to permit introduction of fluid into said chamber; pressure responsive means in said inlet means, said pressure responsive means including means normally sealing said inlet means against fluid entering past that means and being responsive to pressure outside said chamber to open said inlet means and permit inflation of said chamber.

4. The intrauterine contraceptive device of claim **3,** wherein said outlet means is comprised of a tube means communicating with said chamber; said means for sealing said outlet means comprises a one-way check valve including means which gives that check valve said predetermined opening pressure.

5. The intrauterine contraceptive device of claim **4,** wherein said inlet means is also comprised of said tube means; said means for sealing said inlet means comprises a second oneway check valve.

6. The intrauterine contraceptive device of claim **5,** wherein said tube means is comprised of a resilient, flexible material and is given a normally sinusoidal curvature, so that said tube means can be drawn straighter and when drawing force is removed therefrom, said tube means returns to its sinusoidally curved condition.

7. The intrauterine contraceptive device of claim **5,** wherein the device further comprises a pair of spaced arms; said inflatable member is attached to and extends between said arms.

8. The intrauterine contraceptive device of claim **7,** wherein said tube means defines a tail depending from said inflatable member; said tail being of sufficient strength to be grasped and to draw said intrauterine contraceptive device from the uterus.

9. The intrauterine contraceptive device of claim **5,** wherein said tube means comprises an outlet means tube and an inlet means tube; said outlet means tube and said inlet means tube are separate elements and are secured together and form a tail depending from said inflatable member; said tail being of sufficient strength to be grasped and to draw said intrauterine contraceptive device from the uterus.

10. The intrauterine contraceptive device of claim **9,** wherein said tail is comprised of a resilient, flexible material and is given a normally sinusoidal curvature, so that said tail can be drawn straighter and when drawing force is removed therefrom, said tail returns to its sinusoidally curved condition.

11. The intrauterine contraceptive device of claim **5,** wherein said tube means comprises an outlet means tube and an inlet means tube; said outlet means tube and said inlet means tube being integrated into a single tube in which are located both said inlet means check valve and said outlet means check valve.

12. The intrauterine contraceptive device of claim **11,** wherein said single tube has a valve chamber therein with separate inlet and outlet passages therethrough, with said inlet means check valve being in said inlet passage and said outlet means check valve being in said outlet passage.

13. The intrauterine contraceptive device of claim **11,** wherein said inlet means check valve and said outlet means check valve are integrated into a single valve.

14. The intrauterine contraceptive device of claim **11,** wherein said tube is relatively long and is long enough to normally hang out of the vagina when said device is in the uterus and said inlet means check valve and said outlet means check valve are relatively near said inflatable member such that if said tube is cut off below said check valves, the tube is within the vagina and does not hang out.

15. The intrauterine contraceptive device of claim **11,** wherein said single tube is of sufficient strength to be grasped and to draw said intrauterine contraceptive device from the uterus.

16. The intrauterine contraceptive device of claim **11,** wherein said single tube is comprised of a resilient flexible material and is given a normally sinusoidal curvature, so that said single tube can be drawn straighter and when drawing force is removed therefrom, said single tube returns to its sinusoidally curved condition.

17. The intrauterine contraceptive device of claim **5,** wherein said tube means comprises an outlet means

tube and an inlet means tube; said outlet means tube and said inlet means tube are separate elements;

said inflatable member having walls defining said chamber; said inlet means one-way check valve being in a said chamber wall; said inlet means tube being removable from said contraceptive device and being positionable at said inlet means check valve to cause same to open.

18. The intrauterine contraceptive device of claim **17,** wherein said inlet means check valve comprises a resilient slit opening normally biased to close that opening through said chamber wall and openable upon pressure being exerted thereupon.

19. The intrauterine contraceptive device of claim **18,** wherein said inlet means tube is passed through said inlet means check valve wall opening and opens said inlet means check valve.

20. The intrauterine contraceptive device of claim **18,** wherein said outlet means tube is comprised of a resilient, flexible material and is given a normally sinusoidal curvature, so that said outlet means tube can be drawn straighter and when drawing force is removed therefrom, said outlet means tube returns to its sinusoidally curved condition.

21. The intrauterine contraceptive device of claim **18,** wherein said inlet means tube is longer than said outlet means tube.

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