# United States Patent [19]

**Ansari**

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[54] **INTRAUTERINE DEVICE AND MEANS FOR INSERTING AND REMOVING THE SAME**


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

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

[58] **Field of Search** ..... 128/127, 128, 129, 130, 128/260



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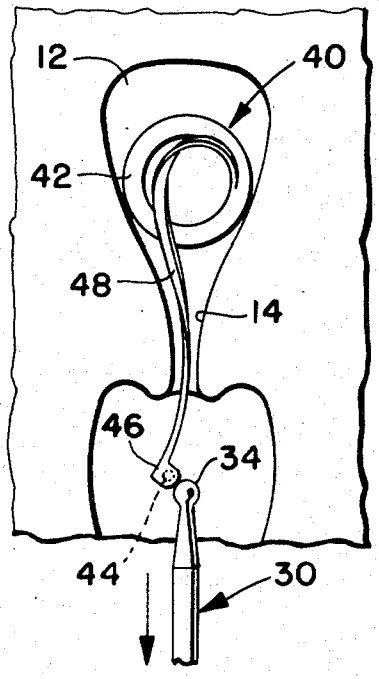
*Attorney, Agent, or Firm*—Donnelly, Maky, Renner & Otto



[57] **ABSTRACT**

An intrauterine device comprising a generally circular ring formed of elastic, inert plastic material. The material is elastically deformed during insertion into the uterine cavity by a specially formed applicator, and magnetic means are imbedded in or associated with the ring for subsequent removal by magnetic extractor means.


**6 Claims, 9 Drawing Figures**



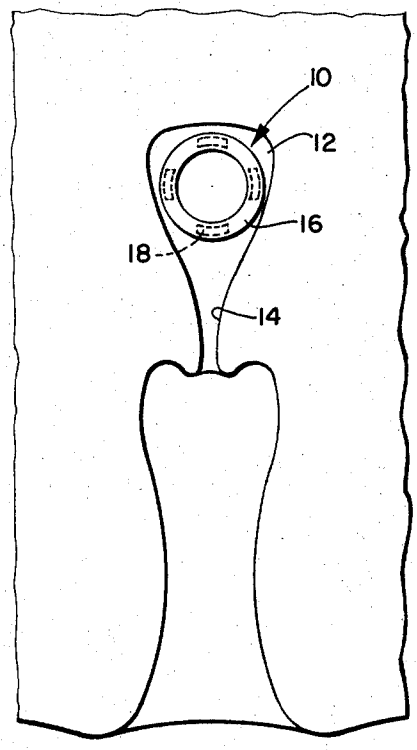



Fig. 1

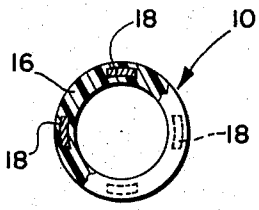



Fig. 2

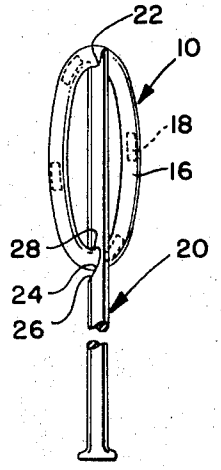



Fig. 3

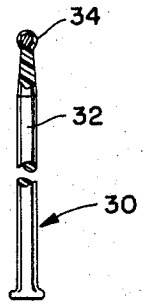



Fig. 4

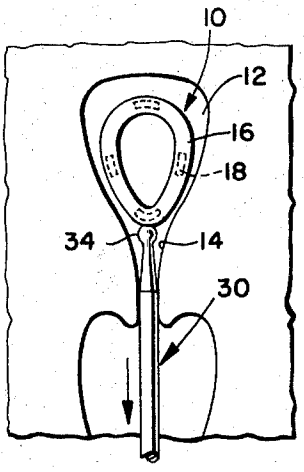



Fig. 5

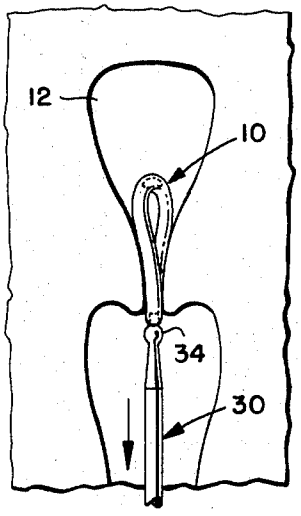



Fig. 6

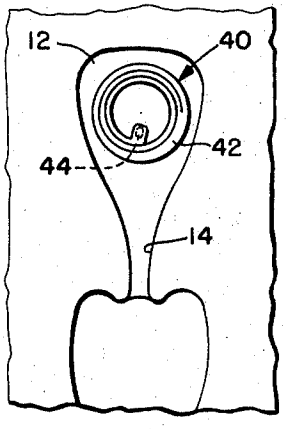



Fig. 7

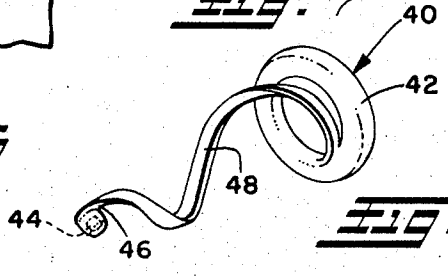



Fig. 8

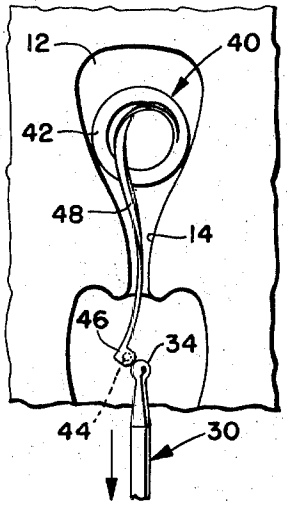



Fig. 9

# INTRAUTERINE DEVICE AND MEANS FOR INSERTING AND REMOVING THE SAME

## BACKGROUND OF THE INVENTION

The present invention relates as indicated to an intrauterine device and novel means for inserting and removing the device from the uterine cavity. The use of intrauterine devices for conception prevention has long been established, with early efforts in this field dating back at least 60 years. For one reason or another, these early developments did not produce an intrauterine device generally acceptable to the medical profession, and the concept until recently did not enjoy widespread use for conception prevention purposes.

In recent years, there has been significant interest in the use of these devices, and substantial development has taken place in an effort to provide a safe and effective intrauterine device. Although in developments to date, the shape of the device and the method of inserting and removing the same have widely differed, there are certain common characteristics. The devices are shaped to fit the uterine cavity and to be retained in position within the cavity. A string or tail is commonly carried by the device and protruding from the external cervical os for convenient removal of the device from the cavity. Recent developments in this field have also extensively relied upon the use of inert plastic material or similarly inert metals, or combinations of these materials.

Despite the recent sophistication in the materials employed in manufacturing the devices, and the techniques and methodology employed in inserting and removing the same from the uterine cavity, the use of presently available intrauterine devices have been attended by certain disadvantages and complications. Some of the more common complications associated with use of the devices are pelvic infection, chronic cervicitis, excessive uterine bleeding, spontaneous expulsion, abdominal cramping, and irregular bleeding. It is understandable that the presence of one or more of these complications frequently leads to the request from the patient that the device be temporarily or permanently removed.

My personal experience with presently available intrauterine devices over the past several years leads to the conclusion that the primary difficulties are to a great extent due to the attached string or tail carried by the device for removable purposes, and the use of materials which result in the above noted complications.

Certain of the problems resulting from the presence of a string or tail carried by the intrauterine device include local irritation of the cervix and vagina which can ultimately lead to cervico-vaginitis, ascending infection with ultimate development of pelvic inflammatory diseases, and the ability to provide directional guidance of the device toward the vagina thereby resulting in spontaneous expulsion of the device.

As above indicated, it is extremely important that the material employed for the device be environmentally compatible, that is, that the material of the device does not adversely affect the surrounding environment, or does not suffer significant deterioration because of such environment, keeping in mind that the device is continually exposed to body temperatures. Where improper materials are employed, local irritation may result causing lower abdominal cramping and discomfort, and even possibly leading to the development of endometritis. The foreign nature of the material may also cause excessive uterine bleeding, and may cause involuntary expulsion of the device due to excessive uterine contractions. A further cause for concern in regard to the materials employed is the long term affects the use of such materials may have on the uterine cavity.



## SUMMARY OF THE INVENTION

With the above in mind, a primary object of the present invention is to provide an intrauterine device the shape and material of which substantially eliminates the problems above mentioned.

A more specific object of the present invention is to provide such a device in which an inert plastic material is employed, in the form of a ring which is totally free of a string or tail of the type referred to above.

A still further object of the present invention is to provide an intrauterine device which can be deformed to the desired shape to facilitate insertion of the device into the uterine cavity, and which is provided with means for locating and removing the device from the cavity. In accordance with the present invention, means in the form of a magnetic member or members are associated with the ring thereby facilitating location thereof in the uterine cavity by a removal tool comprising a magnetic probe by means of which contact can be established with the magnetic members carried by the device and the latter withdrawn from the uterine cavity.

Still another object of the present invention is to provide a novel circular intrauterine device in which is embedded at least one magnetic member and which can readily be deformed and inserted into the uterine cavity with a conventional applicator of the type capable of deforming the device to facilitate passage of the same through the cervical canal.

Yet another object of the present invention is to provide means in the form of a magnetic probe for removing the device from the uterine cavity, with the probe, as above described serving to locate the device in the cavity and being magnetically coupled thereto for removal of the device from the cavity.

These and other objects of the invention will become apparent as the following description proceeds in particular reference to the application drawings.

## BRIEF DESCRIPTION OF THE APPLICATION DRAWING

FIG. 1 comprises a fragmentary view showing the intrauterine device of the present invention positioned within the uterine cavity;

FIG. 2 is a view of the device by itself, with the device being partially sectioned to more clearly illustrate the imbedded magnetic rings;

FIG. 3 is a perspective view of the device constructed in accordance with the present invention, shown positioned on a conventional applicator;

FIG. 4 is a side elevational view, partially sectioned, of the magnetic probe employed for removing the device from the uterine cavity;

FIG. 5 is a view generally similar to FIG. 1, showing the manner in which the magnetic probe functions to remove the device from the uterine cavity, with the device being illustrated in the initial stages of withdrawal;

FIG. 6 is a view similar to FIG. 5, showing the device being withdrawn from the uterine cavity through the cervical canal;

FIG. 7 is a fragmentary view similar to FIG. 1 showing a modified form of intrauterine device in accordance with the present invention;

FIG. 8 is a perspective view of the modified form of FIG. 7, with a normally coiled tab shown extending from the main body of the device, a position which the tab assumes when the device is removed from the uterine cavity, and

FIG. 9 is a view generally similar to FIG. 5, showing the removal of the modified form of the invention from the uterine cavity.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now in more detail to the application drawing, wherein like parts are indicated by like reference numerals, the intrauterine device in accordance with the form thereof illustrated in FIGS. 1–6 of the application drawings is generally indicated at **10** and is shown in FIG. 1 upwardly positioned fully within the uterine cavity **12**, after passing through the cervical canal **14** in a manner to be described hereinbelow.

Referring to FIG. 2, the device **10** is in the form of a ring and is preferably made of an inert plastic material. The material must not only be inert in order to provide the necessary compatibility, as above noted, but must also be elastically deformable to enhance insertion and removal of the device from the uterine cavity. Although any material possessing these characteristics may be employed, a particularly suitable material is silico-organic rubber, which is commercially available in one form under the trademark "SILASTIC," manufactured by the Dow Corning Company.

In the FIGS. 1–6 form of the invention, there is molded in the body **16** of the device a plurality of magnetic ring segments commonly designated at **18**, there being four such ring segments shown, equally spaced circumferentially around the ring. The segments **18** can be made of any suitable magnetic material, such as stainless steel. It will be understood that the magnetic segments could be more or less in number, and differently spaced within the device. The critical aspect of the invention is that the segments are spaced sufficiently far apart, with sufficient intervening silico-organic rubber material, to render the device readily deformable. Alternatively, the segments or embedded magnetic material can be flexible in nature, for instance in the form of coiled wire or granular magnetic material embedded in the rubber.

There is illustrated in FIG. 3 an applicator generally indicated at **20** for inserting the device **10** into the uterine cavity **12**. The applicator **20** is preferably formed of inert plastic material having a sufficient rigidity to perform the inserting function. A notch **22** is formed at the top of the applicator and is shaped to receive and cradle the ring body as clearly shown in FIG. 3. A second notch **24** is formed in the applicator approximately intermediate the ends thereof, with the notch including a relatively shallow entrance portion **26** and a retaining tip **28** which functions to retain the ring when positioned in the notch.

The spacing between the notches **22** and **24** is greater than the normal diameter of the device. As a result, when the device is applied to the applicator as shown in FIG. 3, the device is radially deformed to a generally elliptical shape, carried on the applicator at the notches **22** and **24**.

To insert the device into the uterine cavity, the applicator with the device mounted thereon is inserted upwardly through the cervical canal, with the radial deformation of the device facilitating such passage. When the device is wholly within the uterine cavity, the applicator **20** is slightly rotated thereby freeing the applicator from the device, after which the device gradually regains its circular form. The applicator is then withdrawn and the device is left in place until voluntarily removed.

A removing tool generally indicated at **30** is preferably provided for removing the device from the cavity, and comprises in the form shown a plastic rod-like body **32** and a magnetic probe **34** at one end thereof. When the device **10** is to be removed from the uterine cavity, the tool **30** is inserted upwardly into the uterine cavity and contact is made with the device. The magnetic probe **34** is then moved along the circumference of the device until it is at or adjacent one of the magnetic segments **18** whereupon the device is magnetically coupled to the tool **30** for removal from the uterine cavity. The removal of the device is shown in sequence in FIGS. 5 and 6 of the application drawing, with FIG. 5 illustrating the initial step of removal, with the ring slightly deformed. The elasticity of the inert plastic material permits the deformation thereof as shown in FIG. 6 whereby the device can be removed from the uterine cavity without discomfort.

A modified form of intrauterine device in accordance with the present invention is illustrated in FIGS. 7–9. The modified device is generally indicated at **40** and comprises a ring shaped body **42** similar in size and shape to that above described, and preferably made of the same inert plastic material, silico-organic rubber. However, in this form of the invention the magnetic inserts **18** are not imbedded in the body **42**. Rather a member **44** of magnetic material is carried at the free end **46** of a resilient tab **48** the opposite end of which is integrally attached to the body **42** of the device. The tab **48** is molded or otherwise formed so that it is normally coiled and nested within the body ring, as best shown in FIG. 7. The device **40** is inserted into the uterine cavity with the tab coiled, preferably by the applicator shown above in FIG. 3. In the same manner as above described, the elasticity of the material employed permits radial distortion of the device to facilitate passage of the same through the cervical canal **14** into the uterine cavity.

As shown in FIG. 9, the device **40** can be removed from the uterine cavity by the tool **30** of FIG. 4 in generally the same manner previously described. The tool **30** is inserted into the uterine cavity until the magnetic probe **34** contacts the free end **46** of the tab **48** which carries the magnetic member **44**. The tool is then withdrawn, carrying the tab **48**, as shown in FIG. 9. Thereafter, the tab can be physically grasped for removal of the body **42** of the device. As previously described, the elasticity of the device permits deformation thereof while passing through the lower part of the uterine cavity and the cervical canal so as not to cause discomfort.

Whereas the tab **48** functions as the conventional tail or string with regard to facilitating removal of the device, the tab's natural resiliency causes it to remain in

a nested position within the body **42** while the latter is in the uterine cavity. In this way, the usual irritation and side affects associated with the presence of a string or tail are avoided.

Manufacture of the modified form of the intrauterine device can be by several means. The tab in coiled shape can be molded simultaneously with the body **42.** Alternatively, a member can be molded from which the tab and body are formed as by cutting the member to the configuration desired.

The advantages of the present invention should be apparent from the above description. The material employed for the device is totally inert and relatively soft and flexible, thereby eliminating the heretofore existing problem of infection, bleeding, and discomforts associated with devices of this general type. The shape of the device and the relative flexibility thereof functions to prevent the spontaneous expulsion of the device from the uterine cavity. The elasticity of the device also permits the same to be readily inserted in or removed from the uterine cavity without encountering difficulties normally associated with intrauterine devices currently available.

An additional, significant advantage of the present invention is the total absence of a string or tail attached to the device as in most currently available forms. The need for a sting or tail is removed by the incorporation into the device of magnetic means which can be coupled to the magnetic probe of the removal tool for withdrawing the device from the uterine cavity. The irritation and associated side affects due to the presence of a string or tail are therefore eliminated in accordance with the present invention.

Whereas the invention has been described with reference to a circular ring-shaped intrauterine device, principles of the invention can be applied to devices of other shapes. In particular, the relationship of embedded magnetic material to molded rubber material is such that at least a portion of the device regardless of the shape is sufficiently easily deformed that it can be readily removed from the uterine cavity with a magnetic probe. However, the natural resiliency of that portion is such that it resumes a natural shape, when in the uterine cavity, by which irritation and side affects are avoided.

I claim:

**1.** An intrauterine device adapted to be inserted in the female uterine cavity comprising a generally ring-shape member made of elastic, inert plastic material, and means formed of magnetic material carried by said member, said device being capable of deformation for insertion through the cervical canal into said cavity, where it regains its original form when released therein, and of removal by magnetic coupling with magnetic extractor means, a tab integrally joined at one end thereof to said member and normally coiled therewithin, with said magnetic material being carried by the free end of said tab for extension of the tab and removal of the member by the extractor means.

**2.** The device of claim **1,** wherein said magnetic material comprises a plurality of circumferentially spaced members imbedded in said plastic material.

**3.** The device of claim **1,** wherein said elastic, inert plastic material is silico-organic rubber.

**4.** The device of claim **1** in combination with an applicator means for inserting said device in said cavity, said applicator means comprising a rod formed at one end thereof with a notch for receiving a first segment of the ring, and a second spaced notch for receiving a second segment of the ring generally diametrically opposed to said first segment, the spacing of said notches being greater than the normal diameter of said ring so as to effect the radial deformation thereof to generally elliptical shape to facilitate insertion of the ring into the cavity, with rotation of the applicator means releasing the ring therein.

**5.** The device of claim **1,** in combination with extractor means in the form of a probe having magnetic material at one end to effect said magnetic coupling with the ring for removal of the latter.

**6.** An intrauterine device adapted to be inserted in the female uterine cavity comprising a body made of an elastic, inert plastic material; magnetic material embedded within at least a portion of said plastic material; said portion being sufficiently deformable that it is readily removable from the uterine cavity by engagement of the magnetic material with a magnetic probe; said portion having sufficient resiliency that it assumes a natural shape when in the uterine cavity by which irritation and side effects are avoided; a normally coiled resilient tab, one end of which is integral with said main body, the tab having a free end, and the magnetic material being at said tab free end.

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