Concentric Loop Intrauterine Device

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Notice: The portion of the term of this patent subsequent to Apr. 23, 1991, has been disclaimed.

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Abstract
An intrauterine device comprising two concentric generally circular rings formed of elastic, inert plastic material coupled by a plurality of bridges of similar material. The material is elastically deformed during insertion into the uterine cavity by a specially formed applicator, and magnetic material is imbedded in a normally coiled tab associated with the inner of the two rings for subsequent removal by magnetic extractor means.

9 Claims, 4 Drawing Figures
CONCENTRIC LOOP INTRAUTERINE DEVICE

This application is a continuation-in-part of my co-pending patent application for Intrauterine Device and Means for Inserting and Removing the Same, Ser. No. 273,545, filed July 20, 1972, now U.S. Pat. No. 3,605,777, issued Apr. 23, 1974.

BACKGROUND OF THE INVENTION

The present invention relates as indicated to an improved two-ring intrauterine device and novel means for 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 sixty 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 is 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.

Depite 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. Another disadvantage with conventional intrauterine devices is that they may become lost within the abdominal cavity and, being normally non-metallic, such a lost device is difficult or even impossible to locate. 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 removale 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.

Moreover, it is desirable and often essential that the diameter or external periphery of an intrauterine device have a sufficiently large dimension to assure adequately accomplishing its intended function; yet the interior of such devices should preferably be open or free of material to permit otherwise normal uterine body functions. A large diameter interiorly open ring-type intrauterine device, however, is potentially hazardous if it somehow penetrates the uterine wall and enters the abdomen, for the large diameter opening thereof would be capable of bowel strangulation or the like.

As above indicated, it is extremely important that the materials 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.

Another object of the present invention is to provide such a device in which an inert plastic material is employed in the form of two concentric rings which is totally free of a string or tail of the type referred to above and which has a large amount of free or open space within the outer periphery defining the same.

A 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.

An additional object of the present invention is to provide a novel two-ring circular intrauterine device having a normally coiled tab in which is embedded at least one magnetic member and such device being adapted readily to 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.

Still another object of the invention is to provide an intrauterine device which is readily detectable in the body using magnetic or conventional x-ray techniques.

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 perspective view of the device constructed in accordance with the present invention, shown positioned on an applicator; FIG. 3 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 the withdrawal; and FIG. 4 is a plan view similar to FIG. 1 showing a modified form of intrauterine device in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now in more detail to the drawing, wherein like parts are indicated by like reference numerals, the intrauterine device in accordance with the form thereof illustrated in FIGS. 1, 2 and 3 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 hereinafter.

The intrauterine device 10 is in the form of a pair of concentric rings 10a, 10b with bridging material 15 in the form of connector bridges positioned therebetween and is preferably made of an inert plastic material. The material must not only be inert in order to provide the necessary compatibility, as noted above, 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.

The outer dimension, such as the diameter, perimeter or periphery, of the device 10 is preferably of a size which relates to that of the uterine cavity 12 so that the intrauterine device can perform its intended function. Moreover, the diameter of the inner ring 10b is preferably of a size to preclude detrimental side affects of such a device, such as, for example, bowel strangulation or the like, thus precluding entry into the device of such a body part. Moreover, the fairly large free or open spaces defined between respective rings and bridging material connecting the same as well as within the inner ring of the device 10 permits the uterus otherwise to function normally.

In the preferred form of the invention a normally coiled tab 16 is coiled within the inner ring 10b of the device for purposes described in more detail below. A member 17 of any suitable magnetic material, such as stainless steel, which provides a magnetic field that exhibits a magnetic force on another magnet or a piece of magnetically responsive material or which is not a magnet itself but is responsive to the magnetic field of another magnet, is carried at the free end 18 of the resilient tab 16, the opposite end of which is integrally attached to the inner ring 10b of the device 10. The tab 16 is molded or otherwise formed so that it is normally coiled and nested within the body ring 10b, as best shown in FIG. 1. The device 10 is inserted into the uterine cavity with the tab 16 coiled.

As shown in FIG. 2, the applicator, generally indicated at 20, for inserting the device 10 into the uterine cavity 12 is preferably formed of inert plastic material having a sufficient rigidity to perform the inserting function. A notch 22 formed at the top of the applicator is shaped to receive and cradle the inner ring 10b of the body of the device 10. Moreover, the 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 inner ring 10b of the device, although, if desired, the applicator may be designed to cooperate similarly with the outer ring 10a. As a result, when the device is applied to the applicator as shown in FIG. 2, the device is radially deformed to generally elliptical shape, carried on the applicator at the notches 22 and 24.

To insert the device 10 into the uterine cavity 12, the applicator with the device mounted thereon is inserted upwardly through the cervical canal 14, 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.

As shown in FIG. 3, the device 10 can be removed from the uterine cavity by a removing tool 30, which comprises a plastic rod-like body 32 and a magnetic probe 34 at one end thereof. The tool 30 is inserted into the uterine cavity until the magnetic probe 34 from which a magnetic field emanates contacts the free end 18 of the tab 16 which carries the magnetic member 17. The tool 30 is then withdrawn carrying the tab 16, as shown in FIG. 3. Thereafter, the tab can be physically grasped for removal of the body comprising the concentric rings and bridging material of the device 10. 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 16 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 of the device 10 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 intrauterine device illustrated in FIGS. 1, 2 and 3 can be by several means. For example, the tab end coiled shape can be molded simultaneously within the body of the device 10. Alternatively, a member can be molded from which the tab and body are formed as by cutting the member to the configuration desired.

Turning now briefly to FIG. 4, a modified form of the invention is shown comprising a main body 40 comprising outer and inner rings 40a, 40b coupled by connector bridges 41 defining the intrauterine device and molded in the outer ring 40a of the body there are a plurality of magnetic segments commonly designated at 42, there being four such segments shown, equally
The segments 42 can be made of any suitable magnetic material as described, for example, above. 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 in either embodiment can be flexible in nature, for instance in the form of coiled wire or granular magnetic material embedded in the rubber.

Insertion of the modified form of the device into the uterine cavity is similar to that described above with reference to the preferred form of the invention using the applicator shown in FIG. 2. When the device 40 of FIG. 4 is to be removed from the uterine cavity, the removal 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 till it is at or adjacent one of the magnetic segments 17 whereupon the device is magnetically coupled to the tool 30 for removal from the uterine cavity. The elasticity of the inert plastic material permits the deformation of the device 40, whereby the device can be removed from the uterine cavity without discomfort.

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 conventional string or tail is removed by the incorporation into the device of magnetic means in a normally coiled tab or in the body of the device itself 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.

A further advantage of the invention is that the two-ring arrangement provides an outer ring of sufficient diameter to perform the required function of the device while the inner ring is sufficiently small to avoid strangulation of body parts or similar detrimental effects and the relatively large open spaces within the confines of the device permit natural occurrence of normal uterine body functions. Moreover, should the device become lost in the body, it can be easily detected by x-ray equipment or by a magnetic detector, which avoids the need for exposing the patient to x-rays.

Whereas the invention has been described with reference to a circular concentric ring 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.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. An intrauterine device adapted to be inserted in the female uterine cavity comprising a member made of elastic substantially inert material, said member including generally concentric inner and outer rings coupled by a plurality of connector bridges, and means formed of magnetic material carried in said device, 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 tab is integrally joined to said inner ring.

3. The device of claim 2, wherein said tab is normally coiled within said inner ring.

4. The device of claim 1, wherein said elastic substantially inert material comprises silico-organic rubber.

5. The device of claim 1, wherein said rings comprise circular rings.

6. The device of claim 1, wherein said plurality of connector bridges comprise four connector bridges.

7. The device of claim 1, wherein said ring, connector bridges and normally coiled tab are substantially co-planar.

8. An intrauterine device adapted to be inserted in the female uterine cavity comprising a body made of an elastic substantially inert material, said body including concentric inner and outer rings coupled by a plurality of connector bridges, magnetic material embedded within at least a portion of said material, said portion being sufficiently deformable that it is readily removably 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 affects are avoided; and further comprising a normally coiled resilient tab having one end integral with one of said rings, said tab having a free end, and the magnetic material being at said tab free end.

9. The device of claim 8, wherein said elastic substantially inert material comprises silico-organic rubber.

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