Aug. 17, 1965 L. MARGULIES 3,200,815

COIL SPRING INTRA-UTERINE CONTRACEPTIVE DEVICE AND METHOD OF USING

Filed April 24, 1962 2 Sheets-Sheet 1

FIG. 1

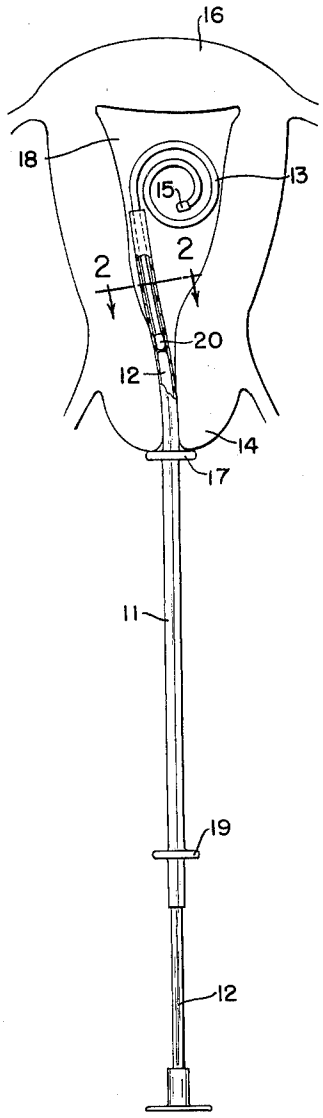


FIG. 2

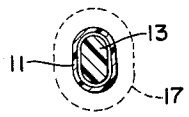


FIG. 3

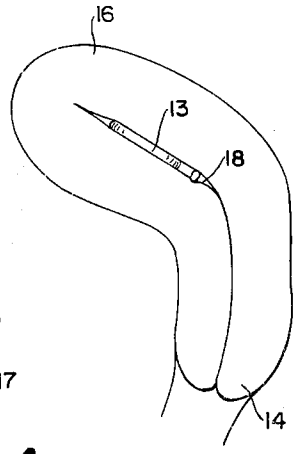


FIG. 4

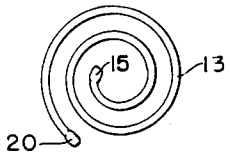


FIG. 5

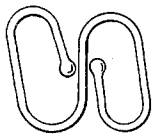


FIG. 6

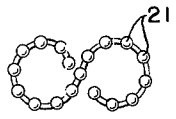


FIG. 7

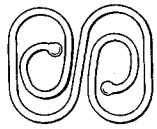
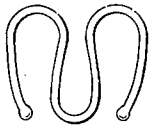


FIG. 8



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Filed April 24, 1962 2 Sheets-Sheet 2

Fig. 10.

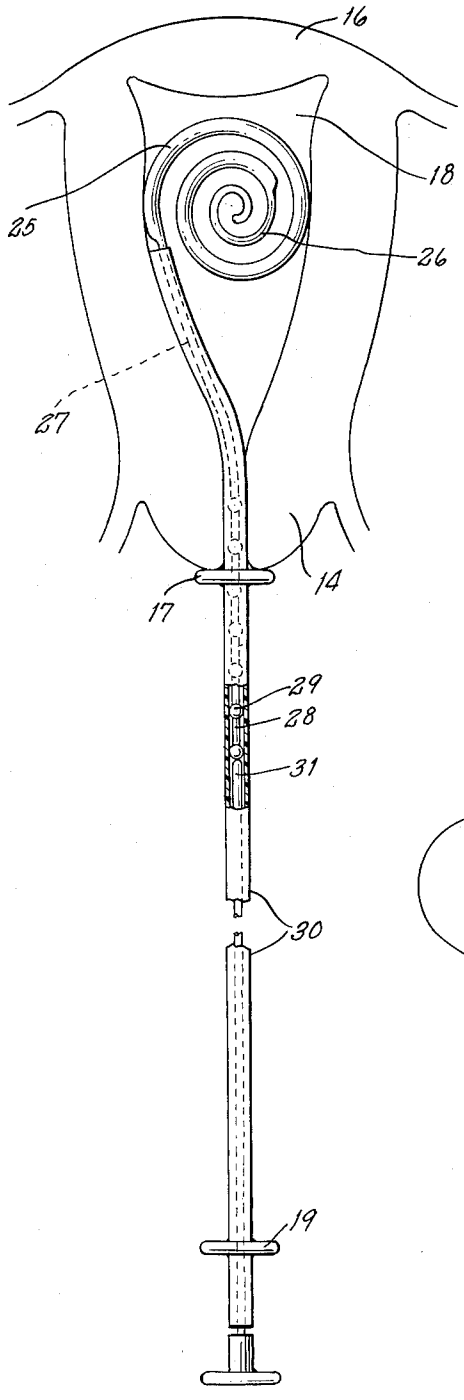
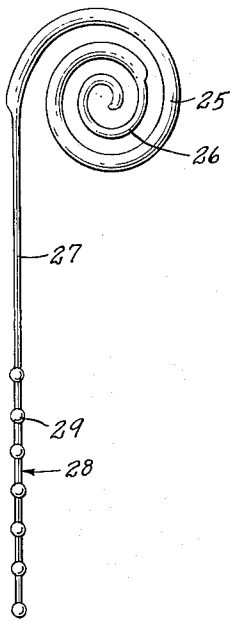


Fig. 9.



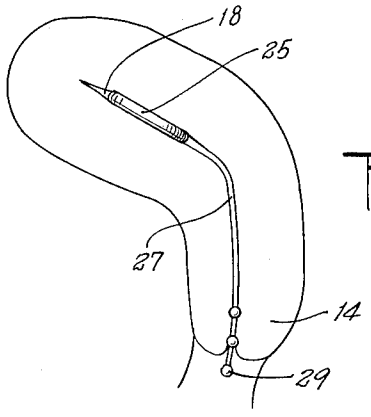


Fig. 11.

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3,200,815

COIL SPRING INTRA-UTERINE CONTRACEPTIVE DEVICE AND METHOD OF USING

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Filed Apr. 24, 1962, Ser. No. 191,674
23 Claims. (Cl. 128—130)

This invention relates to new and useful improvements in intra-uterine birth control devices and more particularly relates to a painless method and object that may be introduced through the cervix although having a diameter in situ considerably larger than the normal cervical canal with the presence and relative position of the object within the uterus being readily and easily determinable at all times.

Birth control or contraception has been practiced by innumerable methods to various degrees of effectiveness for centuries and in modern times has become the subject of organized study and even actively encouraged by certain governments in the world. However, no fully satisfactory method of preventing pregnancy has been developed, it being desirable that a method be effective, safe, cheap, simple, physically and psychologically acceptable and permanently applicable without repeated regimen but subject to cancellation at will.

In 1929 Graefenberg reported on the celebrated ring which bears his name and which became the subject of dispute among gynecologists all over the world. This ring was about one inch in diameter, flexible and formed of silver originally and subsequently of other metals that are presumably inert. It required dilation of the cervix to about 10 mm. to permit passage of the ring when folded which was extremely painful unless anaesthesia were utilized. Ota in Japan added a central element to the ring and formed it of gold, gilt silver or polyethylene with a nylon coil around the outer circle, to overcome certain objections that had been raised but the dilation of the cervical canal remained a disadvantage as before. A report (10 Yokohama Medical Bulletin 89–105 1959) on the Ota device describes almost 20,00 cases having a frequency of conception of about 2.2% in two years. The rate of conception of a portion of the cases were determined by the Stix-Notestein method and showed 96.5% effectiveness, this being equivalent to one pregnancy in 40 years of exposure.

A silkworm gut ring had also been developed which is preferred by some writers because of the insertion difficulty of the Graefenberg ring. As described by Oppenheimer, this is a ring formed of three or four intertwined threads of silkworm gut, each about 14 cm. long with a knot at each end. These threads and the resultant ring are very stiff and must be dipped into hot water to avoid cracking of the threads and permit knotting of the ends so that the end points or cracked threads will not pierce the uterine wall. Furthermore, this ring must be formed just before use, as otherwise it will lose its elasticity properties which are essential. A report (78 Am. J. Obst. & Gynec. 446–454 1959) primarily on the silkworm gut ring describes over 1,000 insertions (a few were the Graefenberg silver ring) on 329 patients with an effectiveness of about one pregnancy in 40 years of exposure. This report points out that rings are 25 times as effective as rubber caps (diaphragms). Diaphragms, although having certain psychological disadvantages and being inconvenient, are generally considered the most effective method in general use in the United States.

Halton also coiled silkworm gut in individual pieces and placed two or three in the uterus via capsules but they caused considerable uterine disturbances.

The Graefenberg rings were involved in heated controversy when first reported which apparently precluded any substantial use of the devices at that time. However, the two aforementioned reports, based on over 20,000 cases, show the devices to be effective and safe, and particularly when inert materials are used.

Thus the intra-uterine rings already meet several of the criteria for an ideal contraceptive as they are (1) by far the most effective, (2) cheap to manufacture, (3) permanently applicable but subject to removal at any time, (4) offer no physical or psychological interference with intercourse, and (5) safe to use. However, the plastic or metal rings are either very painful to insert and remove or must be transferred with anaesthesia and the silkworm gut ring must be formed immediately before insertion and must be critically treated with hot water to avoid cracking and subsequent piercing of the uterine wall, all of which are time consuming and detract from the universal acceptance of intra-uterine rings, particularly on a mass basis as is desired in certain over-populated areas of the world.

Therefore, it is an object of this invention to provide an ideal intra-uterine device for contraceptive purposes.

It is also an object of this invention to provide an intra-uterine coil that may be cheaply fabricated in mass quantities prior to the time for inserting same.

It is an additional object of this invention to provide such an intra-uterine coil (and method) that may be painlessly and simply inserted and removed through the normal cervical canal without dilation.

It is a further object of this invention to provide an intra-uterine coil and method of placing same that permits placement within the frontal plane of the uterus to avoid any discomfort from the device.

It is another object of this invention to provide such an intra-uterine coil, the presence and relative position of which can be easily and immediately determined by the particular subject or the doctor.

I have found that an ideal intra-uterine device may be provided by taking an elongated flexible element with two free ends having a transverse diameter or largest dimension not greater than about 4 mm. but which is coiled, curved or otherwise formed to define a substantial area in one plane. The device is flexible enough so that it can be straightened to a strand by slight force but is rigid enough to immediately return to its original shape when the force is removed, i.e., it exhibits perfect elasticity. This permits the painless insertion of the device through the cervical canal through a cannula into the uterus where it will immediately regain its original shape on being pushed out of the cannula. The device may be provided with an integral follower which will extend through the cervical canal and into the vagina for a short distance where it may be sensed with the fingers through the vagina, the position determined and the entire unit easily removed if desired.

With the above objects and features in view, the nature of which will be more apparent, the invention will be more fully understood by reference to the drawings, the accompanying detailed description and the appended claims.

In the drawings:

FIG. 1 is a frontal section through the uterus showing an intra-uterine coil being placed in the uterine cavity;

FIG. 2 is a section through line 2—2 of FIG. 1;

FIG. 3 is a sagittal section through the uterus after placement of the coil of FIG. 1;

FIG. 4 is a perspective view of the coil of FIGS. 1 to 3;

FIGS. 5 to 8 are perspective views of modified intra-uterine devices in accordance with this invention;

FIG. 9 is a perspective view of a coil with a sensing follower;

FIG. 10 is a frontal section through the uterus showing the coil of FIG. 9 being placed; and

FIG. 11 is a sagittal section through the uterus after placement of the coil of FIG. 9.

This invention as illustrated in the drawings shows several alternative modified forms or shapes and the placement of such coils in the uterus, although in every form the contraceptive has two free ends which may be pulled apart to form an elongated strand.

The various coils shown in FIGS. 4 to 9 all have two free ends, are made of flexible material and thus may be lengthened into a straight strand by application of slight force. Moreover, many other shapes can be made having the same properties, it being within the scope of this invention to have a shape which is deformable to an elongated straight strand but when free returns to define a shape in substantially one plane and of substantial area relative to the cross-section of the strand and preferably in which the total curvature is more than 360°, the curvature being all in one direction as in coils **13** and **25**, FIGS. 4 and 9, in two directions as in FIGS. 5, 6 and 7 or in several directions as in FIG. 8.

These coils may be formed of any inert material which exhibits the proper elasticity to reform the coil from a straight strand and is sufficiently inert to be considered safe for intra-uterine application. It is preferred to use plastics that have been tested and found inert to the human body such as polyethylene, polypropylene, polyethylene glycol terephthalate ("Dacron"), polytetrafluoroethylene ("Teflon"), polyvinyls, silicones, etc. Metals coated with plastics or otherwise inert may also be used. I prefer to use polyethylene and have found an excellent formulation to be 80% polyethylene and 20% barium sulfate which are mixed as powders and then molded into any of the various shapes by injection molding under pressure. The barium sulfate is desirable, but not necessary, so that the position and presence of the coil may be noted at any time by radiology. Other radio opaque materials can, of course, be used. The coil of FIG. 9 will seldom, if ever, require radiology, and thus is less concerned with a radio opaque material.

As pointed out before, the placement of the Graefenberg ring and other devices have created a difficult problem in the past. As will be appreciated from FIGS. 3 and 11, the uterine cavity is largely a potential cavity but does not exist as an actual cavity until and unless there is something within the uterus. Therefore, to avoid irritation and other inconveniences, it is essential that the primary plane of the coil lie within the frontal plane of the uterus as is shown in FIGS. 1, 3, 10 and 11. Thus, the placement of the coil assumes importance.

The placement of these coils is accomplished through a cannula **11** provided with an internal plunger **12**, such cannulas generally having a diameter of less than 4.5 mm. if they are to be inserted painlessly through the cervical canal without dilation. Any of the coils of FIGS. 4 to 8 (FIG. 4 as shown) are inserted into the cannula **11**, and the end of the cannula then passed through the cervix **14** of the uterus **16** until the inner oval flange **17** contacts the cervix. This flange which is approximately 2 inches from the end of the cannula, is not necessary, of course, but serves as a convenient measurement to insure that the end of the cannula has passed sufficiently high into the uterine cavity **18** to permit discharge of the coil and also to indicate the plane of the coil to the operator.

The cannula, if metal, will generally be slightly curved in the sagittal plane for ease and convenience of insertion and if made of plastic will also be slightly forced into this position by the tendency of the coil to return to its curved shape and by the natural curve of the uterus and cervix. In any event, the coil will be ready to curve itself on release in the same plane as the curvature of the cannula and since it is highly desirable that the coil lie in the frontal plane, the cannula should be rotated 90° and then the plunger **12** placed in position (if not before) and pushed to force out the coil **13** which will then take the position shown in FIGS. 1 and 3. It is also preferred that inner end **15** of the coil enter the cavity first (and outer end **20** last) because the free inner end makes little movement, whereas if outer end **20** enters first, there is relatively extensive movement of free end **20** which may rub against the cavity wall. Outer oval flange **19** is preferably provided near the exterior end of the cannula to also aid the operator to determine the plane of the cannula at any time, but the inner flange **17** is far more important for this purpose. If the flanges were circular, they could be marked to indicate the cannula plane but the oval shape is convenient for both visual and tactile sensing.

For convenience in placement of the coil in a specific plane, it has been found desirable that the cannula and coil have an oval (or rounded rectangular) cross-section (see FIG. 2) rather than a circular one as the latter would permit rotation of the coil within the cannula and the operator would not know in which plane he was placing the coil. Thus if the long dimension shown in FIG. 2 is in the frontal plane on the original insertion of the cannula the operator by a mere 90° rotation, which will be obvious from observing flange **17** or **19**, will be in a position to discharge the coil into the frontal plane in the manner shown in FIGS. 1 and 3. In addition, the oval cross-section helps retain the curvature in the plane transverse to the shorter dimension.

The preferred embodiment of the invention is shown in FIGS. 9, 10 and 11, coil **25** being similar to coil **13** of FIG. 4, except that the leading end **26** of coil **25** is of a slightly reduced diameter and the trailing end has attached thereto follower **27** which has a plurality of enlarged areas or beads **29** spaced along its trailing end zone **28**. The reduced diameter of leading end **26** aids the unit to start curling immediately on its release from the cannula.

As shown in FIG. 10, cannula **30** is longer and plunger **31** about the same length as the corresponding elements **11** and **12** in FIG. 1. The longer cannula **30** is required to house the additional length of follower **27** therein. The leading end of cannula **30** is placed similar to **11** and the plunger **31** pushed to its limit as shown, at which point coil **25** is within the uterine cavity **18** but the follower **27** remains in the cannula. The cannula is then removed and follower **27** and beads **29** (both of less diameter than the trailing portion of coil **25**) assume the position in the cervical canal with the beads extending partly out into the vagina. The extra beads are severed to leave the placement of the unit as shown in FIG. 11.

As shown in FIG. 11, when coil **25** is in position in the uterus, the coil portion occupies the same position as coil **13** in FIG. 3 but the follower **27** extends through the cervical canal of the uterus with the beads or thickened areas **29** being positioned near the opening of the cervix. In fact, since the cervical canal is of variable length in different patients, the coil of FIG. 9 has an elongated zone **28** of spaced beads **29** but after positioning of the coil in the uterus, the extra length of beads may be severed so that only one or two beads are extending into the vagina, the follower being pliable and harmless to any object found in the vagina.

This follower serves three functions, the first and more important being that the presence and relative position of the coil within the uterus may readily be determined with the fingers by merely feeling for and counting the beads. This is important because the primary fault of coil **13** has been its passage from the uterus on a few occasions without the knowledge of the patient.

The second important reason is the fact that the entire coil can be readily removed by merely grasping beads **29** and pulling the coil from the uterus by hand and thus avoiding the insertion of a hooked device into the uterus as is required with coil **13**.

A further advantage of the follower is the fact that the unthickened portion of the follower is not round but

is oval or flat-shaped and thus by feeling the follower the doctor will immediately know whether the coil **25** is laying in the proper plane as shown in FIG. 11 or whether it may be lying at an angle to that plane which would tend to irritate the uterine walls.

Atlhough coil **13** of FIG. 4 and the other coils of FIGS. 5 through 8 have been found to give excellent results as a contraceptive as long as they remain in position, they may be lost without the knowledge of the patient, are more difficult to remove than coil **25** and cannot be observed in position without radiology and accordingly coil **25** is to be preferred.

The following data has been accumulated on different sizes and modifications of the coils:

Fig.	Diameter, mm.	Patients	Ejections, percent	Months Exposure	
				Total	Per Pregnancy
4	23	49	23	330	80
4	27	58	23	840	130
4	30	156	10	1,200	200
4	33	106	6.5	550	finite
9	33	264	2.2	1,050	finite

Thus the larger size coils are preferred as they reduce both the ejections and pregnancies, there having been no pregnancies with the 33 mm. coils. Ejection may lead readily to pregnancies when the woman is unaware of the ejection and is falsely relying on its presence.

In view of the fact that the largest cannulas for cervical insertion without dilation are not more than 4.5 mm. in their longest transverse dimension, the coil's longest transverse dimension should not be more than 4 mm. and I have found, in fact, that a preferred dimension is about 2 by 3 mm. and 16 cm. long, the follower of FIG. 9 being an additional 10 cm., including the distal 5 cm. having beads **29**. The preferred diameter, i.e. largest dimension, across the coil per se is about 3.3 cm., the range being 2 to 4 cm. The smaller sizes are, of course, ejected more but some women with a small uterus cannot receive a 3.3 cm. coil so that a 2.5 cm. coil is generally provided for them.

One of the advantages of coils **13** and **25** of FIGS. 4 and 9 is the fact that they are very adept at being positioned in the frontal plane, inasmuch as the direction of curvature never changes while the coil is being discharged. However, the other patterns shown do change direction of curvature which means rotation of the entire unit discharged prior to the change. Thus these patterns are more apt to become caught in the uterine walls on discharge from the cannula without taking up the desirable frontal plane and this may thereafter cause irritation for the patient. Thus the simple coils **13** and **25** have been found highly satisfactory for easy insertion into the uterus.

As will be noted, the coil of FIG. 6 is provided with thickened areas which aid the elastic properties of the coil. All of the coils are preferably provided with thick ends (**15** and **20** on FIG. 4) to prevent piercing or irritation of the uterine wall.

These various designs shown in FIGS. 4 to 9 have shown no side effects, except for slight cramps and spotting in a few women for a few days after insertion and occasionally some pre- and post-menstrual staining for a few months. The preferred time for insertion is the end of the second week of the menstrual cycle, i.e., around ovulation time and not sooner than two cycles after a delivery or abortion.

The coils of FIGS. 4 to 8 are easily and painlessly removed by inserting a hook through the cervix, securing the coil and pulling it back through the cervix, whereas the coil of FIG. 9 is merely pulled out. The coils can be left in the uterus for several years and should be removed only if there is a disturbance in the uterus, after menopause, or a decision to resume exposure to pregnancy.

When the word "coil" is used in the specification or claims, it is intended to cover any device such as shown in FIGS. 4 to 9 which are formed from a strand having two free ends but is curved more or less continually in one or more directions.

I claim:

1. An intra-uterine contraceptive comprising an elongated strand having two free ends and a free shape in substantially one plane that includes a coil adapted to lie within the uterine cavity connected to a substantially straight follower adapted to extend through the cervical canal, said strand being readily deformable to a straight line by application of force and always returning to said coil shape when free of said force, said strand in its free shape or deformed to a straight line presenting a continuous smooth surface along its longitudinal extent.

2. The contraceptive of claim **1** wherein the curvature of said coil exceeds 360°.

3. The contraceptive of claim **1** wherein said strand is made of molded plastic.

4. The contraceptive of claim **1** wherein said strand is made of molded polyethylene.

5. The contraceptive of claim **1** wherein said coil is curved in one direction only.

6. The contraceptive of claim **1** wherein said coil is curved in one direction only for at least about 720°.

7. The contraceptive of claim **1** wherein the transverse section of said coil has one dimension greater than the other.

8. The contraceptive of claim **1** wherein the free end of said follower includes spaced beads.

9. The contraceptive of claim **1** wherein the transverse section of said follower has one dimension greater than the other.

10. A method of preventing pregnancy comprising placing an elongated strand within a cannula passable through the cervical canal without dilation, said strand having two free ends and a free shape as a coil in substantially one plane, said strand being readily deformable to a straight line by application of force and always returning to said coil shape when free of said force, said coil and said strand presenting a continuous smooth surface along their longitudinal extents, inserting one end of said cannula through said cervical canal and into the uterine cavity, forcing said strand with a plunger through said cannula into said uterine cavity without contact between said strand and said cervical canal, whereby said strand regains said free coil shape within said uterine cavity.

11. The method of claim **10** wherein said cannula and said strand are positioned relative to said uterus so that said strand emerges from said cannula and regains said free coil shape with said coil plane being in the frontal plane of said uterus.

12. The method of claim **10** wherein said elongated strand in free shape includes said coil and a substantially straight follower and said follower is positioned to extend through said cervical canal with its free end in the vagina.

13. The method of claim **12** wherein said free end of said follower is provided with spaced sensing beads.

14. The method of claim **12** wherein the transverse section of said follower has one dimension greater than the other.

15. The method of claim **11** wherein said coil is curved in one direction only.

16. The method of claim **15** wherein the inner end of said coil passes first from said cannula into said uterus.

17. The method of claim **11** wherein said cannula is slightly curved, said cannula curve is in the sagittal plane of said uterus on insertion, and before said forcing of said strand, said cannula is rotated 90° so that said cannula curve is in the frontal plane of said uterus during said forcing step.

18. The method of claim 11 wherein the transverse sections of said strand and said cannula are oval and the primary plane of said coil is parallel to the lesser dimension of said oval.

19. The contraceptive of claim 1 wherein said follower strand has a lesser diameter than said coil strand.

20. A method of preventing pregnancy comprising insertion within a uterine cavity of a contraceptive comprising an elongated straight strand having two free ends and a free shape as a coil in substantially one plane, said strand being readily deformable to a straight line by application of force and always returning to said coil shape when free of said force, said coil and said strand presenting a continuous smooth surface along their longitudinal extents.

21. The method of claim 20 wherein said one plane lies in the frontal plane of said uterus.

22. A method of preventing pregnancy comprising insertion within a uterine cavity of a contraceptive comprising an elongated straight strand having two free ends and a free shape as a coil in substantially one plane adapted to lie within the uterine cavity and a substantially straight follower adapted to extend through the cervical canal, said strand being readily deformable to a straight

line by application of force and always returning to said coil shape when free of said force, said strand, coil and follower presenting a continuous unbroken surface along their longitudinal extents.

23. The method of claim 22 wherein said follower strand has a lesser diameter than said coil strand.

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RICHARD A. GAUDET, *Primary Examiner.*

RICHARD J. HOFFMAN, *Examiner.*

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,200,815 August 17, 1965

Lazar Margulies

It is hereby certified that error appears in the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

Column 1, before line 10, insert the following paragraph:

> This application is a continuation-in-part application of my copending application Serial No. 68,088, filed November 8, 1960, now abandoned.

Signed and sealed this 26th day of October 1965.

(SEAL)
Attest:

ERNEST W. SWIDER
Attesting Officer

EDWARD J. BRENNER
Commissioner of Patents