

[72] Inventors **Robert D. Fannon, Jr.**
Columbus;
Brenton R. Lower, Columbus, Ohio;
Leonard E. Laufe, 1206 Inverness Ave.,
Pittsburgh, Pa. 15207

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[73] Assignee **said Laufe, by said Fannon and said Lower**

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Primary Examiner—Lawrence Charles
Attorney—Parmelee, Utzler & Welsh

[54] **INTRAUTERINE CONTRACEPTIVE DEVICE**
8 Claims, 8 Drawing Figs.

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

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

[50] Field of Search **128/127-131**
260

ABSTRACT: An intrauterine contraceptive device formed, in part at least, of a nickel-titanium alloy which has a mechanical memory. The device is formed initially in the desired free shape it will take in the uterine cavity, heat-treated with the free shape being mechanically constrained, and then plastically deformed to a compact, elongated shape for easy insertion through a cervical canal into a uterine cavity. The device will gradually resume its free shape as it is heated to temperature near the human body temperature.

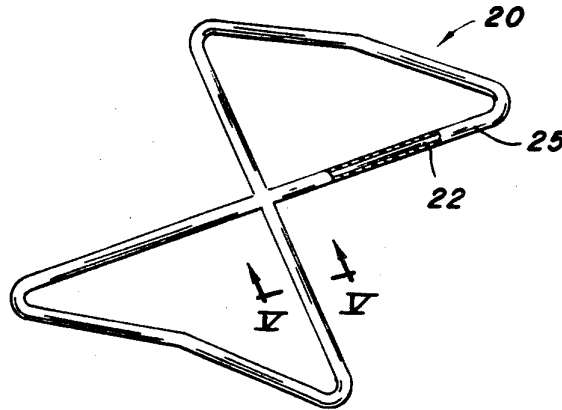


FIG. 1

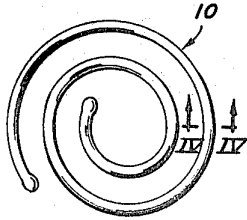


FIG. 2

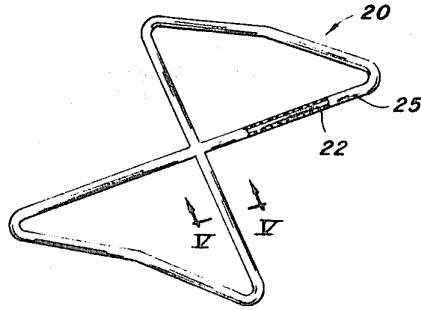


FIG. 3

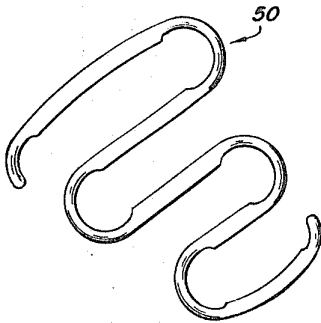


FIG. 4



FIG. 5

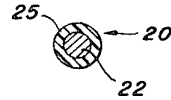


FIG. 6

FIG. 6

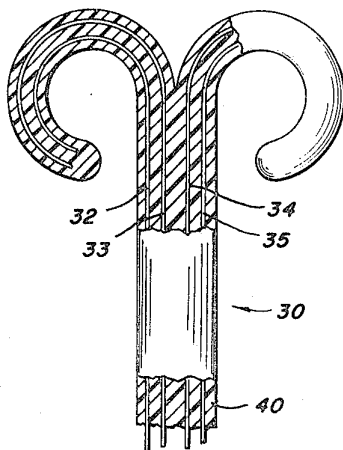
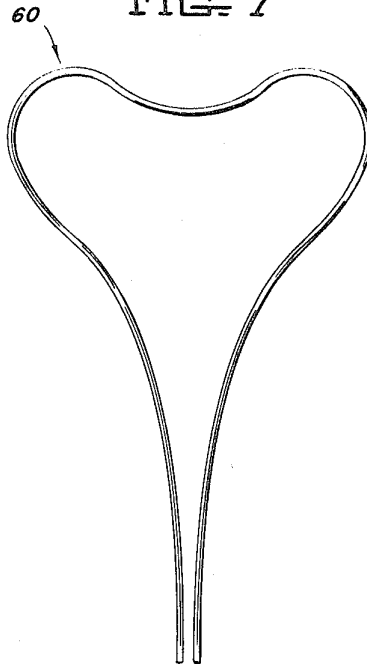


FIG. 7



INVENTORS
LEONARD E. LAUFE,
ROBERT D. FANNON, JR. & BRENTON R. LOWER
By *Parmelee, Utzler & Welsh*
Attorneys

INTRAUTERINE CONTRACEPTIVE DEVICE

This invention relates to intrauterine contraceptive devices formed from material having a mechanical memory, whereby the device is plastically deformed from its free shape to a compact shape for easy and painless insertion through a cervical canal into a uterine cavity and is gradually restored to its free shape as the device heats up to around body temperature.

Intrauterine contraceptive devices of various shapes have become known in recent years and their use is becoming increasingly widespread. The more popular devices are ring or loop shaped, and are formed usually of a plastic material. These devices have proved to be effective in preventing conception, with the reason for their effectiveness not being conclusively understood. The most commonly accepted theory is that the device irritates the interoceptors in the endometrium of the uterus and thereby prevents a fertilized ovum from adhering to the lining of the uterus. Placement of the devices in the uterus is often accomplished by use of a cannula which is simply a thin elongated tube having an internal plunger. The contraceptive devices are flexible enough so that they can be either straightened to a strand or compressed to a compact shape and then placed in the cannula. The cannula is then inserted through the cervical canal into the uterus where the device is pushed out of the cannula. The device will immediately spring into its original shape.

The commonly used intrauterine devices are not without their problems. Some of the devices have been found to display a high-ejection rate where the device is ejected from the uterus. This may lead to pregnancy when the woman is unaware of the ejection and falsely relies on its presence. Another serious problem is uterine perforation and infection when an end of the device penetrates the uterine wall. Both the ejection and the perforation problems are felt to be attributable to the material used in fabricating the devices. It is considered that most materials used are not stiff enough and that when pulsations of the uterus wall occur, as during the menstrual periods, the pulsation waves cause the device to flex to an extent where it is pushed downwards and in many cases expelled. In the case of uterus perforation, it has been observed that some materials used for the device have a steady creep and in time will grow to a point where a free end, if not properly placed, will penetrate the wall of the uterus.

Another problem in the commonly used devices is the need to remove and replace them because of premature malformation or breakage. The material again is the cause of this problem. Most often the material is not strong enough and will exhibit stress relaxation or stress cracking which will lead to the malformation and breakage.

The most common material used for intrauterine devices is polyethylene, which is flexible enough so that the device may be straightened or compressed for inclusion within a cannula. Other plastics may also be used, such as polypropylene, polytetrafluoroethylene, polyethylene glycol terephthalate, trifluorochloroethylene, polyvinyls and others. All of these plastics also exhibit the proper elasticity to reform when the device is inserted from the cannula into the uterus. However, all of the plastics have an innate characteristic to creep, and all, to a certain degree, will develop stress relaxation and stress cracking while in a uterus. In addition, some of the plastics will not provide the necessary stiffness to the device to avoid ejection from the uterus.

We overcome the aforementioned problems by providing an intrauterine device formed basically of a material which is stronger, stiffer, and has a lower creep rate than any of the materials currently being used. In addition, our intrauterine device has a mechanical memory which is characterized by a return by the device to a preformed shape after the device is plastically deformed as when it is straightened or compressed to fit in a cannula. Moreover, our device will gradually reform within the uterus as the material is heated therein, rather than reform abruptly with force as is the case with polyethylene-type devices which are not plastically deformed but are elastically deformed. More specifically, we provide an intrauterine device which comprises an elongated strand shaped in a con-

figuration lying substantially in one plane to fit within a uterine cavity; the strand being composed of at least partially throughout the length thereof of an alloy comprising 53.5-56.5 weight percent nickel, the remainder being essentially titanium. The desired shape of the device is first formed and the device then heat-treated while the shape is mechanically constrained. After heat treating, the device may be plastically deformed to a compact shape. The nature of the alloy used is such that the original shape will be restored when the alloy is heated to a temperature below the heat-treating temperature and in our application that temperature would be somewhere near human body temperature. Thus, our device has a mechanical memory.

Other details and advantages of this invention will become apparent as the following description proceeds.

In the accompanying drawings we illustrate various intrauterine devices formed in accordance with this invention, in which:

FIGS. 1 through 3 illustrate intrauterine devices of well-known shape fabricated in accordance with the present invention;

FIG. 4 is a sectional view along the line 4-4 of FIG. 1 and illustrating a solid nickel-titanium alloy construction of the device;

FIG. 5 is a sectional view along the line 5-5 of FIG. 2 and illustrates a solid core of nickel-titanium alloy surrounded by a plastic sheath construction of the device;

FIG. 6 is a view partly in section of an intrauterine device showing a wire core surrounded by plastic construction;

FIG. 7 is a view of yet another intrauterine device of the present invention as initially formed; and

FIG. 8 is the same device as illustrated in FIG. 7 but plastically deformed in a compact elongated form and surrounded by a gelatinous jacket.

This invention is illustrated in the drawings as having several alternative forms. It should be understood that the intrauterine devices shown are merely examples of many shapes which can be taken by the device of this invention.

The intrauterine devices shown in the drawings are all shaped in familiar configurations for placement within a uterine cavity. Each of the devices includes an elongated strand having a generally circular cross section. The devices are all formed with their strands composed entirely or partly of an alloy comprising 53.5-56.5 weight percent nickel and the remainder essentially titanium. The device 10 of FIG. 1 is composed entirely of the alloy; the device 20 of FIG. 2 has a solid core 22 of the alloy surrounded by a sheath 25 of molded plastic material such as polyethylene; and the device 30 of FIG. 6 has four wires 32-35 formed from the alloy with the wires being embedded in a sheath 40 of molded plastic material, such as polyethylene.

The nickel-titanium alloys used in this invention are unique among engineering alloys in that they have mechanical memories. When items formed from these alloys are heat-treated above a certain temperature while mechanically constrained in a particular shape, they will return to that shape even after the item is permanently plastically deformed. The return to the original shape is brought about by heating the item to a temperature well below the heat-treating temperature. Thus, the device 10 shown in FIG. 1 would be initially formed at room temperature. The sheathed devices 20 and 30 would have the core 22 and wires 32-35, formed initially in the configuration shown. All of the preformed parts would then be placed in a constraining device for mechanically holding the shape, heated to around 900° F., held at that temperature for a few minutes, and then cooled by quenching in water. When the parts are sufficiently cooled, the sheaths 25 and 40 may be molded onto core 22 and wires 32-35, respectively. All of the devices 10, 20 and 30 may now be plastically deformed to whatever configuration desired. For example, device 10 could be deformed to an elongated straight strand. Similarly, the device 50 of FIG. 3 could be deformed to a straight strand. The device 20 of FIG. 2 could be deformed into an elongated

compact fold configuration. The device 60 of FIG. 7 is shown in FIG. 8 in a deformed compact fold configuration. Any of the devices in their deformed configurations may be inserted into cannulas for insertion through cervical canals into uterine cavities. In the case of device 60, a gelatinous wax sheath 70 is molded around the deformed compact configuration. The wax sheath will serve to retard the reforming of the device 60 to its free shape when the device is inserted into the uterus. The wax sheath will slough away due to the heat in the uterus, after which the device 60 itself will begin heating and gradually will reform to its original shape. The device 60 is illustrated as being formed entirely of the nickel-titanium alloy, as is device 50 of FIG. 3, but both may be made with a solid or wire core surrounded by plastic sheaths. Similarly, devices 20 and 30 could be formed entirely from the nickel-titanium alloy.

The particular composition of nickel-titanium alloy selected to use in forming the intrauterine devices will result in a reforming of initial free shape of the devices at around 98° F. with this temperature being called the transition temperature. That is, the devices will reform when they reach a temperature around body temperature. Also, the alloy will begin reforming at around 70° F. Thus, it would be important to keep the device always below 70° F. before insertion into a uterus, or alternatively to keep the device in a container which will hold the deformed shape. It would be particularly desirable to place the deformed devices in metal shipping containers to hold the deformed shape during transport through temperature environments above 70° F. Otherwise, inadvertent shape recovery would result.

In addition to exhibiting the mechanical memory characteristic, the nickel-titanium alloy is stronger, stiffer, and less creep prone than the plastics commonly used in forming intrauterine devices. The details of the nickel-titanium alloys, including their physical properties are set forth in U.S. Pat. Nos. 3,174,851 and 3,351,463. The particular range of alloys used in this invention are described in the latter mentioned patent. Because of the favorable physical properties, namely stiffness and strength, of the nickel-titanium alloy, the intrauterine devices will not exhibit the high-ejection rate inherent with plastic devices. Also, the low creep rate of the alloys will minimize, if not totally eliminate, uterine perforation. The alloy is also corrosion resistant and therefore useable in the highly corrosive uterine cavity without any special chemical treatments. Finally, the alloy is not subject to the high incidence of stress relaxation and stress cracking found in the plastics commonly used with intrauterine devices, and, accordingly, will result in having devices which will retain their true shape for long periods of time. Thus, removal and replacement of devices for reasons of malformation or breakage will be greatly reduced.

In the device 30 of FIG. 6, the wires 33 and 34 in the inside portion would have the same nickel-titanium alloy composition with a transition temperature at approximately body temperature. The wires 32 and 35 in the outside portion of the device would have the same nickel-titanium alloy composition with a transition temperature much higher than that of wires 33 and 34. Wires 33 and 34 would be given a memory for the coiled portion of the device while wires 32 and 35 would be given a memory for the straight portion of the device. The coiled portion would be straightened by plastic deformation prior to insertion of the device into a uterus. Upon insertion, wires 33 and 34 would heat up to body temperature and would coil. Since wires 32 and 35 would be below their transition temperature the yield strength would be low enough so that

they would coil along with wires 33 and 34. When the device 30 was to be removed, wires 32 and 35 could be subjected to a low voltage to heat the wires to their transition temperature at which point the device would straighten and could then be easily removed. The resistance by wires 33 and 34 to straightening could be easily overcome by making the wires 32 and 35 larger in diameter.

It is emphasized here that when the intrauterine devices are reformed to their initial shape they have the same physical properties as when they were initially formed. In other words, the nickel-titanium alloys reform at their transition temperature from a pliable, reduced yield strength stage to a stiff and high yield strength stage.

While we have particularly shown and described particular embodiments of this invention, it is to be distinctly understood that the invention is not limited thereto, but that modifications may be made within the scope of the invention, and such variations as are covered by the scope of the appended claims.

We claim:

1. An intrauterine contraceptive device, comprising an elongated strand, shaped in a configuration lying substantially in one plane to fit within a uterine cavity; said strand being composed at least partially through the length thereof of an alloy comprising 53.5-56.5 weight percent nickel, the remainder being essentially titanium; and said strand being heat-treated while the configuration thereof is mechanically constrained.

2. The contraceptive device as set forth in claim 1 including a sheath surrounding the strand and composed of a material which will slough away upon insertion of the strand into a uterine cavity.

3. The contraceptive device as set forth in claim 1 wherein said strand is composed of a continuous core of said alloy throughout the length thereof and a continuous sheath of molded plastic material surrounding said core.

4. The contraceptive device as set forth in claim 1 wherein the alloy is characterized by being restored to its initial shape, after plastic deformation thereof, above human body temperature.

5. The contraceptive device as set forth in claim 1 wherein said strand is shaped and then heat-treated to about 900° F. while the shape thereof is mechanically constrained.

6. The contraceptive device as set forth in claim 1 wherein said strand is composed of a plurality of wires of said alloy extending throughout the length thereof and a continuous sheath of molded plastic material surrounding the wires.

7. An intrauterine contraceptive device comprising an elongated strand shaped in a compact configuration to fit in a cervical canal for insertion into a uterine cavity; said strand being composed at least partially through the length thereof of an alloy comprising 53.5-56.5 weight percent nickel, the remainder being essentially titanium; said strand being first formed with a free shape in substantially one plane to fit within a uterine cavity, and then heat-treated while the free shape is mechanically constrained, and finally plastically deformed into said compact configuration; and said alloy being characterized as being restored to said free shape when said strand in the compact configuration is heated to a temperature above body temperature.

8. The contraceptive device as set forth in claim 7 including a sheath of material surrounding said strand when in said compact configuration, and composed of a material which will slough away upon insertion of the strand into a uterine cavity.

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