

[54] **ABORTIVE DEVICE AND METHOD**

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[51] Int. Cl.**A61b 19/00, A61f 5/46**
[58] Field of Search 128/1 R, 127, 129, 130, 131,
128/344

[56] **References Cited**

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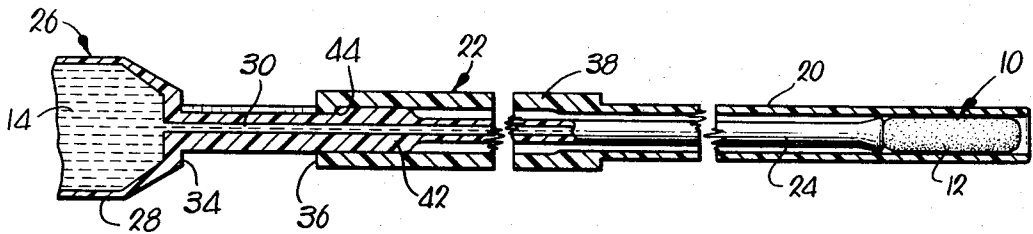
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[57] **ABSTRACT**

Premature termination of pregnancy is effected by insertion of a hollow, distensible body of elastomeric material into the uterus to stimulate muscular activity sufficiently to induce menstruation and thereby cause spontaneous expulsion of the nonviable embryo. In one form of the invention, after the body is inserted, it is filled with a substance to effect the distension thereof. In another embodiment, the body is provided with an incrustation and then charged with a pressurized substance before insertion. The incrustation dissolves in the uterus, permitting the substance to expand and distend the body to a size which precludes its expulsion until shedding of the endometrium and discharge of the implantation therewith.

9 Claims, 10 Drawing Figures



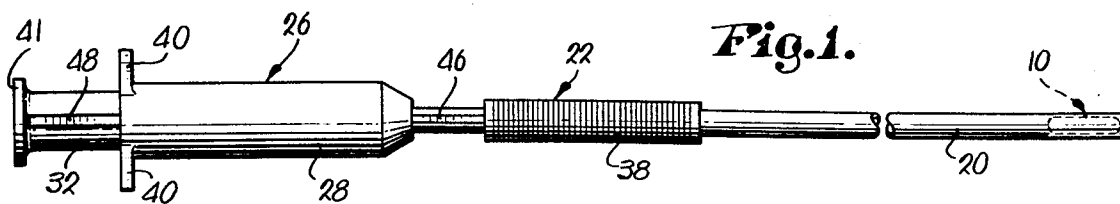


Fig. 1.

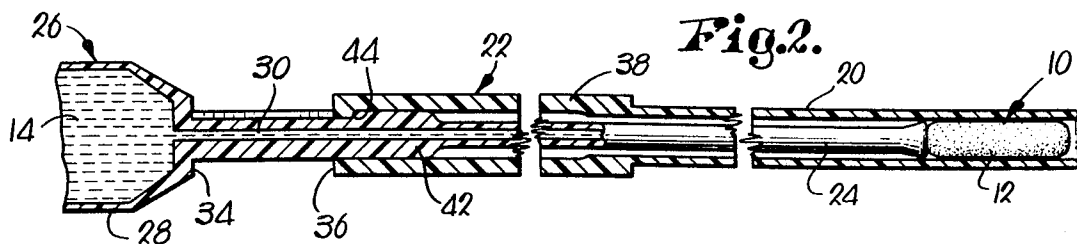


Fig. 2.

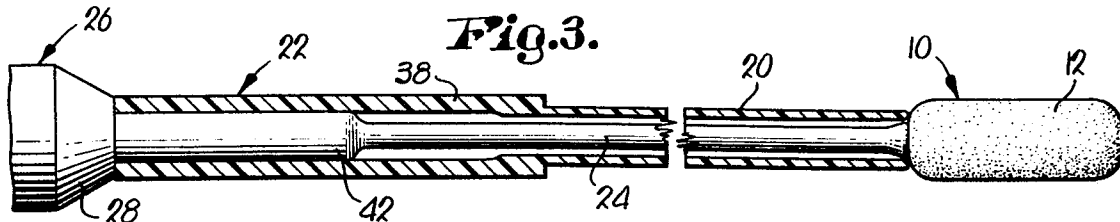


Fig. 3.

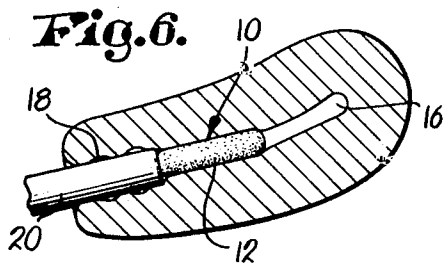


Fig. 6.

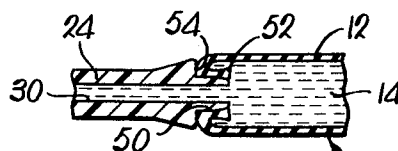


Fig. 4.

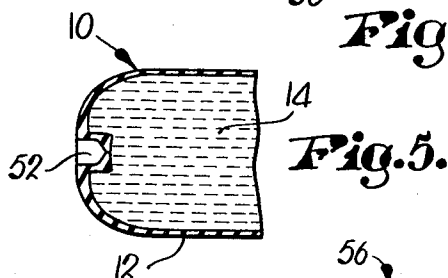


Fig. 5.

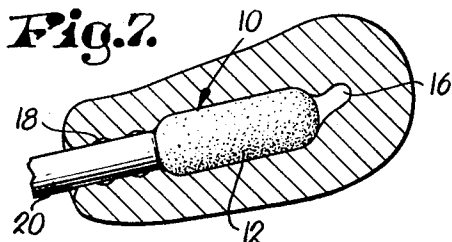


Fig. 7.

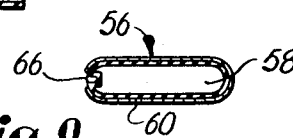


Fig. 9.

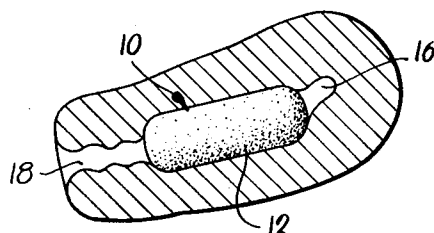


Fig. 8.

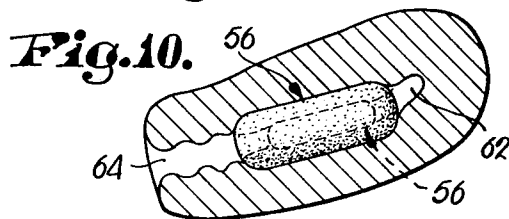


Fig. 10.

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ABORTIVE DEVICE AND METHOD

Legalized abortive methods have, for the most part, heretofore been performed by the duly authorized and properly registered physician through use of a curette or the like in the case of the nonviable embryo and other surgical instruments with respect to the viable fetus. On the other hand, miscarriages for various reasons occur quite frequently, oftentimes without knowledge by the female, particularly within a short period of time following conception. Such spontaneous expulsion may be caused by health, injury or unknown factors which induce menstruation and resultant discharge of the endometrium, together with the fertilized ovum implanted therein.

It is an important object of the instant invention, therefore, to provide the doctor with a safe and simple, yet effective means for duplicating such premature expulsion of the nonviable embryo during the early stages of pregnancy without need for the usual uterus scraping procedures or any other type of surgical techniques.

Another important object of my present invention is to cause naturopathic abortion by virtue of the fact that the uterus tends to expel foreign objects, causing miscarriage, and eliminating the need for surgical discomfort or the risk of ill after effects.

Still another object of the present invention is to provide an abortive device which may be easily and quickly inserted into the uterus by the physician, following which the fertilized ovum is expelled through natural process of muscular activity and induced menstruation.

In the drawing:

FIG. 1 is an elevational view of one type of tubular instrument which may be used to carry out one of the methods of my present invention, illustrating in phantom a first example of an abortive device which may be inserted thereby;

FIG. 2 is an enlarged, fragmentary, longitudinal cross-sectional view of the instrument and device shown in FIG. 1;

FIG. 3 is a view similar to FIG. 2, still further enlarged, showing the device projected beyond the tubular portion of the instrument;

FIG. 4 is a fragmentary cross-sectional view of a portion of the device and of the proximal end of the plunger of the instrument;

FIG. 5 is a fragmentary cross-sectional view, enlarged still further, of the device after the same is detached from the plunger;

FIGS. 6, 7 and 8 are fragmentary cross-sectional views showing the successive steps of inserting the device and its position in the uterus after withdrawal of the instrument from the cervix;

FIG. 9 is a cross-sectional view of a modified form of abortive device made pursuant to my present invention; and

FIG. 10 is an enlarged view of the device of FIG. 9 showing the same within the uterus.

In FIGS. 1-8 of the drawing there is illustrated an abortifacient (abortion inducing means) denoted by the numeral 10 in the nature of an elongated, hollow body 12 which may be made from a silicone rubber or other essentially nonporous, distensible, elastomeric material capable of preventing escape therefrom of a body-distending substance 14. While the precise shape of the body 12 is of no special importance, ease of in-

sertion into uterus 16 through the cervix 18, and proper fitting of body 12 within the uterus 16 suggests, to some extent at least, choice of the generally elliptical configuration of body 12 as illustrated. Moreover, the size of the body 12 is not particularly critical, but generally, depending somewhat on the size and condition of the uterus 16 and cervix 18, it may measure from about 1 ½ to 2 ½ inches long and from about ½ to 1 inch in diameter in the uterus 16 after expansion of body 12 by substance 14.

For insertion purpose, and by way of example, the abortive device 10 may be placed in one end of a tube 20 forming part of a manually manipulable tool 22 which is also equipped with a plunger 24. Tool 22 may be further provided with a separate or an integral syringe 26 or other apparatus that includes a cylinder 28 communicating with bore 30 in plunger 24 and having a reciprocable piston 32 used to force the substance 14 from cylinder 28 through bore 30 and into body 12 after the device 10 is disposed within the uterus 16 as shown in FIG. 6.

Shoulder 34 on cylinder 28 engages abutment 36 on enlarged portion 38 of tube 20 to indicate that the device 10 has been fully ejected from the tube 20, whereupon the doctor uses finger tabs 40 on cylinder 28 to facilitate depression of thumb piece 41 on piston 32. Boss 42 on plunger 24 engages shoulder 44 in portion 38 of tube 20 to limit the extent of retraction of plunger 24. Ribs 46 and 48 on tube 20 and piston 32 respectively slide within corresponding grooves (not shown) in portion 38 and cylinder 28 respectively to prevent relative rotation of the component parts of the tool 22. Plunger 24 terminates in a short nozzle 50 that fits within an orifice provided with a check valve or a self-sealing orifice 52 in that end of the body 12 which abuts a shoulder 54 on plunger 24.

In use, the plunger 24 is extended until shoulder 34 engages abutment 36 so as to project nozzle 50 out of the proximal end of tube 20, permitting insertion of nozzle 50 into orifice 52 as seen best in FIG. 4. Plunger 24 is then retracted to pull the device 10 into the tube 20 as shown in FIGS. 1 and 2. Piston 32 is thereupon removed, cylinder 28 is filled with the substance 14 (FIG. 2) and piston 32 is then replaced as shown in FIG. 1.

The physician thereupon inserts the tube 20 through the vagina (not shown) and into the cervix 18, following which he depresses the plunger 24 until shoulder 34 engages the abutment 36 to fully eject the device 10 into the uterus 16 as shown in FIG. 6.

The body 12 is then charged with the substance 14 by depression of plunger 24, causing the body 12 to expand as shown in FIGS. 3 and 7. The plunger 24 is then retracted until boss 42 engages shoulder 44, causing withdrawal of nozzle 50 from the orifice 52 as the enlarged device 10 is held against movement into the tube 20 by abutment against the proximal end of tube 20. Orifice 52 seals automatically (FIG. 5) trapping the substance 14 within the body 12, whereupon the tube 20 is withdrawn from the cervix 18 and the vagina, leaving the device 10 in the uterus 16 as shown in FIG. 8.

As is well known, the presence of device 10 in the uterus causes natural muscular activity in an effort to expel the device 10 from the uterus 16 through the cer-

vix 18. The size of device 10 is such that expulsion does not occur until the muscular action becomes sufficiently forceful to induce menstruation. This results in shedding of the endometrium of the uterus 16 and its discharge from the cervix 18 along with the fertilized ovum implanted therein as well as the device 10.

It follows then that the wall of body 12 should be sufficiently thin and pliable as to cause it to distend readily under the pressure of the substance 14 forced therein by use of the tool 22 in the manner above described, yet be strong and tough enough to withstand the pressure and not burst. Moreover, the material chosen for body 12 must be resistant not only to the physical forces of movement into and out of tube 20 but to the extraction of nozzle 50 from within the orifice 52. Still further, the elastomeric material from which body 12 is made must be capable of resisting all chemical reaction while subjected to the fluids within the uterus 16 and not in any manner become an irritant to the internal uterus tissues.

Consideration should also be given to proper choice of the substance 14 such that no deleterious chemical reaction will occur between the material chosen for body 12 and the substance 14 used for its distension. Many types of fluids may be used but a weak saline solution or other liquid is satisfactory because there should be no risk of injury to the patient in the event of accidental spillage by the doctor or leakage from the body 12.

The abortive device 56 illustrated in FIGS. 9 and 10 includes a body 58 which may have the same characteristics as the body 12 except that it is precoated with an incrustation 60 capable of being softened or dissolved in uterus 62 after insertion of the device 56 thereinto through cervix 64. Moreover, after body 58 is so coated and prior to insertion of device 56 into the uterus 62, body 58 is charged with a pressurized substance which will distend the body 58 after the incrustation 60 has softened or dissolved away, it being understood, of course, that incrustation 60 be capable of preventing distension of body 58 by the substance therein while the incrustation 60 remains in a hardened condition on body 58.

A check valve or self-sealing orifice 66 may be provided for the body 58 the same as in the body 12 but the plunger 24 of the insertion tool 22 need not be provided with the bore 30 or the nozzle 50, and there will be no need for syringe 26 if the body 58 is charged with a compressible fluid or the like, such as air or other elastic gas, before device 56 is loaded into the outer end of tube 20.

The pressure of the substance in body 58 should be sufficient only to balloon the body 58, after softening or dissolution of incrustation 60, to approximately the expanded size of body 12 as above specified and as shown in FIGS. 8 and 10, but device 56, prior to insertion, as shown in FIG. 9, should be about the same size as unexpanded device 10 (compare with FIG. 2) for ease of direction through cervix 64.

Proper selection of the ingredients for the incrustation 60 will assure its softening by body heat of the patient and/or dissolution by the uterus fluids, sufficient to release body 58 for expansion by the compressed substance precharged therein, all without/injury or harmful effects to the patient. Such ingredients may in-

clude an admixture of a filler, a binder for increasing the strength and cohesive properties of incrustation 60, and a disintegrating agent for increasing its speed of solution.

5 Powdered milk, powdered cocoa, or sugar (powdered or granular) may be used as the filler, whereas the binder may be selected from glucose, an acacia or gelatine solution, a heavy sugar syrup, or a starch paste. Lactose may also be used to serve both as a filler and as
10 a binder. If a disintegrating agent is believed necessary or desirable, the use of corn or potato starch will make it unnecessary to rely entirely on the heat of uterus 62 to release body 58 for expansion as shown in FIG. 10.

15 While it is not contemplated that the devices or methods above described will necessarily be satisfactory in an effort to effect miscarriage of the viable fetus beyond the first 12 to 28 weeks of gestation, its use to induce abortion of the nonviable embryo during at least the first 8 weeks of pregnancy will, in most cases, cause no ill effects and constitute a decided improvement over devices and methods heretofore used or suggested.

Having thus described the invention, what is claimed as new and desired to be secured by Letters Patent is:

- 25 1. An abortifacient comprising:
an essentially nonporous, distensible hollow body of elastomeric material insertable into the uterus through the cervix,
30 said body containing a substance when the body is in the uterus capable of distending the body to a size sufficient to induce menstruation,
said substance being expansible, said body having an incrustation normally holding the body against
35 distension by said substance, said incrustation softening in the uterus to release the body for distension by the substance.
2. An abortifacient as claimed in claim 1 wherein said substance is a compressible fluid.
- 40 3. An abortifacient as claimed in claim 1, said body being provided with a self-sealing orifice through which said substance may be directed after the incrustation is placed thereon.
4. An abortifacient as claimed in claim 1 wherein
45 said incrustation contains a binder for increasing its strength and cohesive properties.
5. An abortifacient as claimed in claim 1 wherein said incrustation contains a disintegrating agent for increasing the speed of solution.
- 50 6. An abortifacient as claimed in claim 1 wherein said incrustation comprises an admixture of a filler, a binder and a disintegrating agent.
7. A method of terminating pregnancy prematurely which comprises insertion of an essentially nonporous,
55 distensible hollow body of elastomeric material into the uterus through the cervix, said body containing a substance when the body is in the uterus capable of distending the body to a size sufficient to induce menstruation, said substance being expansible and being directed into the body under pressure before the latter is inserted into the uterus, said body prior to having the substance directed thereinto being provided with an incrustation which softens when the body is in the uterus,
60 said incrustation holding the body against distension by said substance until the incrustation softens.
8. A method of terminating pregnancy prematurely comprising the steps of:

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inserting an essentially nonporous, distensible hollow
body into the uterus through the cervix;
injecting a predetermined amount of substance into
said body when the latter is in the uterus to distend
the body to a size sufficient to induce muscular ac-
tivity of such magnitude as to cause menstruation;
and
expelling the body while still in its fully distended

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condition from the uterus through the cervix by
the force of said uterine muscular activity during
the induced menstruation.

9. The method as claimed in claim 8, wherein the
substance injected into said body is limited to an
amount which will produce a maximum of from $\frac{1}{2}$ to 1
inch in the body when the latter is fully distended.

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