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(54) DISPENSING INSTRUMENT AND METHOD

(71) We, POPULATION RESEARCH INCORPORATED, a corporation organised and existing under the laws of the State of Minnesota, United States of America of 7875 Beech Street N.E., Minneapolis, Minnesota 55432, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to an instrument and a method for dispensing fluid material into the Fallopian tubes of a female body.

According to a first aspect of the invention there is provided an instrument for dispensing fluid material into the Fallopian tubes of a female body comprising an elongate tubular member having an expandable member at or near one end thereof positionable in a uterine cavity, said expandable member being made from a soft and relaxed, flexible and elastic material having a low modulus of elasticity as hereinafter defined, and said expandable member being of sufficient size relative to the dimensions of the tubular member to expand longitudinally of the tubular member at least as far as the said one end thereof, whereby the expandable member can be expanded to substantially completely fill the uterine cavity and conform to the shape thereof.

According to a further aspect of the invention there is provided a method of dispensing fluid material into the Fallopian tubes of the body of a non-human female primate comprising the steps of inserting the elongate tubular member of the dispensing instrument hereinabove defined into the uterine cavity of the female body so that said expandable member is positioned within the uterine cavity, dispensing the material through the tubular member into the uterine cavity, and expanding the expandable member, either before or after the material is dispensed into the uterine cavity, so that it substantially completely fills the uterine cavity and conforms to the shape thereof and moves the dispensed material from the uterine cavity into the Fallopian tubes.

According to a still further aspect of the invention there is provided a method of controlling conception in a human female by dispensing fluid material into the Fallopian tubes of the female body, comprising the steps of inserting the elongate tubular member of the dispensing instrument as hereinabove defined into the uterine cavity of the femal body so that said expandable member is positioned within the uterine cavity, dispensing the material through the tubular member into the uterine cavity, and expanding the expandable member, either before or after the material is dispensed into the uterine cavity, so that it substantially completely fills the uterine cavity and conforms to the shape thereof and moves the dispensed material from the uterine cavity into the Fallopian tubes.

The value of the "low modulus of elasticity" of the material of the expandable member is such that when an expandable member made from material having such a low modulus of elasticity is expanded within a uterine cavity to substantially completely fill the cavity, the member will be confined by and substantially conform to the shape of the uterine cavity.

Embodiments of the present invention will hereinafter be described, by way of example, with reference to the accompanying drawings, in which:—

Figure 1 is a longitudinal sectional view of the genital system of a female primate with an embodiment of a dispensing instrument extended into the uterine cavity;

Figure 2 is a top elevational view of a dispensing unit of the instrument;

Figure 3 is an enlarged sectional view taken along the line 3—3 of Figure 1;

Figure 4 is an enlarged section view taken along the line 4—4 of Figure 3;

Figure 5 is a section view taken along the line 5—5 of Figure 4;

Figure 6 is a sectional view similar to Figure 4 showing the dispensing unit actuated to discharge fluid therefrom;

Figure 7 is a cross sectional view of a further embodiment of a dispensing unit for the dispensing instrument;

Figure 8 is a sectional view taken along the line 8—8 of Figure 7;

Figure 9 is a sectional view similar to Figure 7 showing the dispensing unit in the discharge position;

Figure 10 is a diagrammatic view of a further embodiment of the dispensing unit in a non-dispensing position;

Figure 11 is a sectional view similar to Figure 10 showing the dispensing unit in the discharge position;

Figure 12 is a longitudinal sectional view of a further embodiment of a dispensing unit in the non-dispensing position;

Figure 13 is a view similar to Figure 12 showing the dispensing unit in the discharge position;

Figure 14 is a side elevational view of a container spaced from a needle adapted to carry fluid from the container;

Figure 15 is an end elevational view of the sealed end of the container of Figure 14;

Figure 16 is a longitudinal sectional view taken along the line 16—16 of Figure 15;

Figure 17 is an enlarged sectional view of the sealed end of the container;

Figure 18 is a sectional view taken along the line 18—18 of Figure 14;

Figure 19 is a sectional view similar to Figure 16 showing the container in assembled relation with the needle;

Figure 20 is a top plan view of a further enbodiment of a dispensing instrument of the invention;

Figure 21 is an enlarged sectional view taken along the line 21—21 of Figure 20;

Figure 22 is a sectional view taken along the line 22—22 of Figure 21;

Figure 23 is an enlarged sectional view taken along the line 23—23 of Figure 20;

Figure 24 is a sectional view similar to Figure 23 showing the lock in the release position;

Figure 25 is a sectional view similar to Figure 23 showing a modification of the lock;

Figure 26 is a top plan view of another embodiment of a dispensing instrument of the invention;

Figure 27 is an enlarged sectional view taken along the line 27—27 of Figure 26;

Figure 28 is a sectional view taken along the line 28—28 of Figure 27;

Figure 29 is an enlarged sectional view taken along the line 29—29 of Figure 27;

Figure 30 is a view similar to Figure 29 showing the movable member in the second position;

Figure 31 is an enlarged sectional view of the fluid container assembly used in the dispensing instrument;

Figure 32 is a sectional view of a reproductive system of a female accommodating a dispensing instrument of the invention for locating fluid material in both canals of the Fallopian tubes;

Figure 33 is a longitudinal sectional view of the dispensing assembly shown in Figure 32;

Figure 34 is a sectional view taken along the line 34—34 of Figure 33;

Figure 35 is a sectional view of a female reproductive system accommodating the dispensing instrument shown in Figure 32 in section with the balloon assembly partially inflated in the uterine cavity and fluid material in the uterine cavity;

Figure 36 is a sectional view similar to Figure 35 showing the balloon assembly fully expanded in the uterine cavity;

Figure 37 is a plan view, partly sectioned, similar to Figure 35, of an embodiment of the dispensing instrument; and

Figure 38 is an enlarged sectional view of the discharge end of the dispensing instrument of Figure 37.

Referring to the drawing, there is shown in Figure 1 a diagrammatic female genital system indicated generally at 20. An intrauterine catheter indicated generally at 21 is located in the genital system to direct a fluid material, as a drug or tissue adhesive into the canals of the Fallopian tubes. The tissue adhesive can be isobutyl 2 - cyanoacrylate monomer, silver nitrate or quinacrine materials. The cyanoacrylate monomer is a liquid plastics which sets up or polymerizes in response to moisture and thereby functions to occlude the canals of the Fallopian tubes. The fluid material can be of the type that temporarily block or occlude the canals of the Fallopian tubes. After a period of time the canals will reopen to resume their normal function.

The genital system 20 has an elongated vagina 22 defined by the cylindrical vaginal wall 23. The vagina 22 opens into the vestibule 24. The opposite end of the vagina is attached to the uterus, indicated generally at 26. Uterus 26 is a pear-shaped, thick walled, hollow organ situated between the bladder and rectum. Uterus 26 has a uterine cavity 27 which is flattened and triangular in shape. The size of the uterine cavity varies from female to female. The top or fundus 28 of uterus 26 is joined

to the uterus body 29. The lower end of the body contains the cervix 31 which separates the vagina 22 from the uterine cavity 27. The uterine wall is composed of an outer serosal layer, or peritoneum; a firm, thick, intermediate coat of smooth muscle tissue, or myometrium; and an inner mucosal lining, or endometrium 32.

Leading to the upper part of opposite sides of the uterus 26 are Fallopian tubes 33 and 34. The Fallopian tubes are paired, trumpet-shaped, muscular members which extend from the superior angles of the uterine cavity to the ovaries (not shown). The ovaries are solid, slightly irregular shaped bodies situated on either side of the uterus behind and below the Fallopian tubes.

Fallopian tubes 33 and 34 each have a canal or aqueduct 36 and 37 respectively. The Fallopian tubes are musculomembranous structures and in human females are about 12 cm. in length. They are commonly divided into isthmus, intramural and ampullary sections. The canals 36 and 37 provide passages for the movement of ova from the ovaries into the uterine cavity. The intramural section of each Fallopian tube traverses the uterine wall generally in a more or less straight fashion, but its course may be tortuous in some females. It has an ampulla-like dilation just before it communicates with the uterine cavity 27. The canals 36 and 37 are narrowest at the intramural sections. The walls of the Fallopian tubes consist of three layers; a serosal layer, a muscular layer and a mucosal lining. The muscular layer includes longitudinal muscle fibres which, when contracted, bring the ends of the Fallopian tubes in close contact with the surface of the ovaries. Blood vessels are abundant in the muscular layer where they form with the muscle bundles a kind of erectile tissue which, if engorged, moves the Fallopian tubes to sweep over the surface of the ovaries. This movement of the Fallopian tubes is impaired when the tubes are severed and tied. Occluding the canals 36 and 37 with drug material does not interefere with the erectile action and movement of the Fallopian tubes.

The catheter 21 has an elongated first tube 38 having a length sufficient to extend through the vagina and into the uterine cavity 27. An expandable sleeve member 39, as a balloon or the like, is secured to the upper end of the tube 38 with bands 40. The outer end of the sleeve member 39 terminates at the outer end of the tube 38. The sleeve member 39 is made from a soft and relaxed, flexible and elastic material having a low modulus of elasticity for example, the sleeve member could be made from rubber. The sleeve member expands uniformly when expanded by fluid pressure. The sleeve member 39 can be expanded to completely fill the uterine cavity regardless of the size of the uterine cavity. This enables the same catheter construction to be used on all types of primate females. The expanded sleeve member 39 has a generally pear-shaped chamber 41 filled with a fluid, as water or air. The sleeve member 39 is of a sufficient size relative to the dimensions of the tube 38 to expand longitudinally with respect thereto so that the expanded sleeve member contacts the fundus 28 of the uterine cavity. The tube 38 has a plurality of holes 42 connecting the passage of the tube 38 with the chamber 41. The upper end of the tube 38 is closed with a plug 43.

The end of the tube 38, remains projecting from the vestibule 24, and is attached to a fluid dispensing unit indicated generally at 44. The tube 38 can be releasably attached to the dispensing unit 44 or fixed to the dispensing unit 44. The dispensing unit has a body 46 carrying a movable plunger 47. When the plunger 47 is moved in the direction of arrow 48, a fluid, preferably water, is forced from the dispensing unit 44 into the expandable sleeve member 39 to expand the sleeve member 39 to fill the uterine cavity 27.

Located within the tube 38 are a pair of smaller tubes 49 and 52 for carrying fluid materials into the uterine cavity 27. The tube 49 has a portion extended outwardly from the tube 38 and attached to a dispensing unit 51. The tube 52 is attached to a dispensing unit 53. The dispensing units 51 and 53 are preferably identical in construction and can be used to dispense the same fluid materials or different fluid materials at separate time intervals. One of the dispensing units can dispense a neutralizer fluid into the uterine cavity. The following description describes the construction of the dispensing unit 51 but each of the dispensing units 44 and 53 can be similarly constructed.

Referring to Figures 2 to 5, the dispensing unit 51 has a body or housing 57 comprising a cylindrical side wall 58 and an end wall 59. The housing 57 has a chamber 61 and outwardly directed ears 62 and 63. The ears 62 and 63 extend in diametrically opposite directions from opposite sides of the open end of body 57 and the cylindrical side wall 58. A collapsible container or ampulla indicated generally at 64 is located in chamber 61. The container holds a fluid material such as a material for treating and/or occluding the canals of the Fallopian tubes. The container 64 has an accordion pleated cylindrical side wall 66 secured to a transverse generally flat bottom wall 67. The center portion of the bottom wall 67 has a longitudinal tubular

member 68. The member 68 has an outwardly projecting portion 68A and an inwardly directed portion 68B. The outwardly projecting portion 68A is attached to the tube 49 of the catheter 21, and this attachment can be either permanent or releasable. The tubular member 68 is closed with a transverse diaphragm 69. The diaphragm 69 is a relatively thin disc member located in the transverse plane of bottom wall 67. The opposite end of the container 64 is closed with a transverse seal 71.

The container 64 is preferably made of a deformable lead alloy having good moisture and vapor barrier properties. Other deformable materials having good moisture and vapor barrier properties can be used to fabricate the container. These properties are important to prevent moisture and vapor sensitive material from polymerizing or setting during storage periods. The material of the container is also chemically inert to the fluid material stored in the container.

Located within the container 64 is a longitudinal needle 73. The needle 73 is a hollow member terminating in a bevelled end having a point 74 located adjacent the inner surface of the diaphragm 69. The opposite end of the needle 73 is attached to a circular head 76. As shown in Figures 4 and 5, the needle 73 has a longitudinal passage 77 extending through the pointed end of the needle, and the side wall of the needle 73 has a hole 78 communicating the longitudinal passage 77 with the interior of the container 64. Fluid material from the container can thus flow through the hole 78 and along the passage 77 of the needle 73 to the pointed end thereof. A plurality of holes or an elongated slot could be provided in the needle 73 to provide communication between the passge 77 of the needle and the container.

The chamber 61 is closed with a plunger or movable member 79. A portion of the movable member fits into the chamber and has outwardly directed ribs 81 and 82 extending into longitudinal grooves 83 and 84 in the inside portions of the cylindrical side wall 58. The ribs 81 and 82 hold the plunger 79 in assembled relation with the body 57 and guide the plunger linearly into the chamber 61. The plunger 79 has an inwardly open recess 86 for accommodating the outer end of the container 64. The bottom central portion of the recess 86 has a cavity 87 providing a space for the seal 71. The plunger 79 can be removed from the side wall 58, enabling the container 64 to be removed from the chamber and replaced with a new container.

Referring to Figure 6, the dispensing unit 51 is operated by moving the plunger 79 into the chamber 61. This is accomplished by applying a force on the outer end of the plunger 79 in the direction of arrow 88. An operator places his first and second fingers under the ears 62 and 63 and uses his thumb to apply force to the plunger 79. The needle 73 will be moved through the diaphragm 69. The fluid material within container 64 will be placed under pressure and forced through the hole 78 along passage 77 in the needle and into the tube 49. The tube 49 carries the fluid material up into uterine cavity 27. The fluid material is discharged from an end 54 of the tube 49 and flows along the inner wall of the fundus into the canals 36 and 37 of the Fallopian tubes. Pressure is applied to plunger 79 until all of the fluid material in the container 64 is dispensed therefrom. The sleeve member 39, being in engagement with the inner wall of the fundus, limits the amount of fluid material that can collect on the inner wall.

The dispensing unit 51 is a disposable item that contains a single dosage or unit of fluid material.

Referring to Figures 7, 8 and 9, there is shown a further embodiment of a dispensing unit, indicated generally at 100, connected to discharge fluid, for example, a drug, or water, under pressure into a tube 101 of the catheter. Dispensing unit 100 has a body or housing 102 comprising a cylindrical side wall 103 joined to a flat end wall 104. The side wall 103 surrounds a cylindrical chamber 106 having an open end opposite to the end wall 104. Oppositely directed ears 107 and 108 are secured to the open end of the side wall 103.

Located within the chamber 106 is a container or ampulla indicated generally at 109 for storing fluid, for example, drugs, tissue adhesive, water, air or gas. The container 109 is a collapsible structure having a cylindrical side wall 111 and an end wall 112. The end wall 112 is located in flat surface engagement with the inside surface of the end wall 104 of the body 102. The center portion of the end wall 112 carries a longitudinal tubular member 113. A portion of the tubular member 113 extends through a hole 114 in the end wall 112. The tubular member 113 has an outwardly projecting portion 113A and an inwardly directed portion 113B. The tube 101 of the catheter is connected to the portion 113A either permanently or releasably. The mid portion of the tubular member 113 has a transverse diaphragm or disc 116 closing the passage through the tubular member 113. The end of the container 109 remote from the end wall 112 is closed by a folded seal 117. A

longitudinal needle 118 is located in the container 109. The needle 118 has a point 119 located within the inwardly directed portion 113B of the tubular member 113. The end of the needle 118 remote from the point 119 is attached to a transverse head 121. The head 121 is located adjacent the inside surface of the wall of the container 109 remote from the end wall 112. As shown in Figure 8, the needle 118 has a generally U-shaped cross-section. One side of the needle is open to the fluid in the container. This allows the fluid to flow longitudinally along the container past the point 119 when the point pierces the diaphragm 116. The needle can be a longitudinal tubular member having one or more holes providing access to the passage in the needle, as shown by needle 73 in Figure 6.

A plunger 122 closes the open end of the housing 102. Plunger 122 has a pair of diametrically opposite ribs or projections 123 and 124. The ribs 123 and 124 are located in longitudinally extending groove 126 and 127 in the inside of the side wall 103 of the housing to guide the longitudinal movement of the plunger into the housing. The inner face of plunger 122 has an annular recess 128 to accommodate portions of the container when the plunger 122 is moved into the chamber 106. The center portion of the plunger 122 has a cavity 129 for accommodating the seal 117 of the container.

In use, referring to Figure 9, force is applied to the plunger 122 in the direction of arrow 131. This moves the plunger 122 into the chamber 106. The plunger 122 collapses the container 109 and moves the needle through the diaphragm 116. As soon as the point 119 of the needle penetrates the diaphragm 116, the fluid within container 109 can flow through the needle 118 into the tube 101. Fluid will continue to flow through the needle 118 as long as force is applied to the plunger 122. The plunger 122 can be moved into the chamber 106 until the head 121 abuts against the inner portion 113B of the tubular member 113.

Figures 10 and 11 show a modification of the needle and container arrangement. A container 132 has a generally flat end wall 133, the midportion of the end wall 133 having a longitudinal tubular member 134. The tubular member 134 has an outwardly directed outer portion 134A and an inwardly projected inner portion 134B. The midportion of the tubular member 134, in general alignment with the end wall 133, has a diaphagm or disc 136. A needle indicated generally at 137 is longitudinally aligned with the passage in the tubular member 134. The needle 137 has a cone-shaped head 138 terminating in a point. The head 138 is connected to an elongated shank 139. As shown in Figure 11, when the needle 137 is moved in the direction of arrow 141, the head 138 punctures the diaphgram 136. The hole in the diaphragm 136 is larger than the shank 139, allowing the fluid in the container to flow past the diaphragm 136 into the discharge portion of the tubular member 134. The outer portion 134A the tubular member has threads 142 adapted to receive a female threaded member, as a nut or sleeve. Other types of connections can be used to couple the tubular member 134 to the delivery tube.

Referring to Figures 12 and 13, there is shown a fluid dispensing container or ampulla indicated generally at 143. The container has a cylindrical side wall 144 surrounding a chamber 145 for storing fluid, for example, drugs, tissue adhesive, water or gas. The wall 144 is made of non-collapsible material. A generally flat transverse end wall 146 is integral with one end of side wall 144. The center portion of the end wall 146 has an elongated longitudinal tubular member 147. The tubular member 147 has an outer portion 147A extending outwardly from the end wall 146 and an inner portion 147B projecting into the chamber 145. The midportion of the tubular member 147 is closed with a diaphragm 148. The diaphragm 148 is located in transverse alignment with the end wall 146 and is of a material that can be pierced by a needle.

An elongated longitudinal needle 149 is located within chamber 145. One end of the needle 149 is located within the passage of inner portion 147B and terminates in a point 151. The other end of the needle 149 is attached to a transverse head 152. The head 152 has an annular outer peripheral surface which forms a seal 153 with the adjacent inner wall of side wall 144 so as to prevent moisture, air or other substances from entering chamber 145. The needle 149 has a generally U-shaped cross section as shown by the needle 118 in Figure 8. Alternatively, the needle 149 can be a tubular member having one or more holes to provide a passage for the movement of fluid in chamber 146 out of the end of the needle 149. The needle 149 can also have the shape of the needle 137, as shown in Figures 10 and 11. Other shapes and structures can be used to permit the flow of fluid along the needle through the diaphragm once the diaphragm has been pierced by the point of the needle.

In use, the head 152 is moved into the chamber 145 in the direction of arrow 154 shown in Figure 13. The point 151 of the needle will penetrate and pierce the diaphragm 148. The fluid in chamber 145 is forced along the needle through the pierced

diaphragm and discharged via the outer portion 147A of the tubular member.

Referring to Figures 14 and 19, there is shown a container or ampulla indicated generally at 160 for storing a fluid, for example, a drug, liquid tissue adhesive, semi-liquid material or a gas. The container 160 is located in longitudinal alignment with a tubular needle 161. The needle 161 is secured to a generally transverse base 162 and has a point or sharp edge 163 at one end. The base 162 is mounted in a housing (not shown) to fix the position of the needle 161.

The container 160 is a one-piece body having a continuous side wall 164. The side wall 164 has an accordion-pleated shape and is of a cylindrical configuration and surrounds a chamber 166 for storing the fluid. One end of the container 160 is closed with a diaphragm or cylindrical disc member comprising an end wall 167. An outwardly directed longitudinal sleeve 168 is attached to the outer peripheral edge of the end wall 167 and forms an extension of the container. A disc or pad 169 of resilient material, for example, sponge rubber or plastics foam, is located within the sleeve 168 and covers the end wall 167. The sleeve 168 has a rolled outer edge or bead 171 holding the pad within the sleeve 168.

The other end of the container 160 is closed by an end wall 172. The end wall 172 has a transverse seam 173 closed to moisture and vapor to seal the container. As shown in Figure 17, the seam 173 has lapped and inturned edges that are sealed together. The container is made of a material having moisture and vapor impervious properties. Preferably the material is a deformable lead alloy which is chemically inert to the fluid stored in the container. Other deformable materials having good moisture and vapor barrier properties can be used to form the container. These properties are essential to prevent moisture and vapor sensitive materials from setting or polymerizing during lengthy storage periods. For example, the cyanoacrylate monomer is extremely sensitive to moisture and vapor. It must be stored in a sealed container which does not allow ingress of moisture and vapor. The monomer will set in a short period of time when exposed to moisture, including the moisture of tissues.

In use, force is applied to the end wall 172 in the direction of arrow 174. This force moves the container 160 into operative engagement with the needle 161. The force will also collapse the side wall 164 and apply sufficient force to the container whereby the needle 161 will cut through or pierce both the pad 169 and the end wall 167. The pad 169, being made of resilient elastic material, will be formed with a hole 176 in tight sealing engagement with the outer peripheral surface of the needle 161. The needle 161 will also make a hole 177 in the end wall 167. The needle 161, being a hollow tubular member, provides a passage for the flow of fluid from the chamber 166 into a tube of catheter.

Each dispensing unit described above and as illustrated in Figures 2 to 19 can be connected to any one of the tubes of the catheter to supply fluid thereto. Figures 20 to 24 illustrate a single dispensing unit which can be connected to the catheter to supply fluid to all of the tubes thereof.

Referring to Figure 20, there is shown a dispensing unit indicated generally at 200 attached to a further embodiment of the dispensing instrument which comprises an elongated balloon catheter 202. The dispensing unit has a body or housing 201 attached to an elongated linear tube 203 of the catheter. Tube 203 can be an integral extension of the body or releasably connected to the body 201. The outer end of the catheter has an expandable sleeve member or balloon 204 of soft and relaxed, flexible and elastic material having a low modulus of elasticity, the balloon 204 being adapted to confine fluid, as water or gas, to enlarge the expandable balloon 204. As shown in Figure 22, a second smaller tube 206 is located within the tube 203. The tube 206 extends the entire length of the tube 203 and has an outlet opening 205 at the outer end whereby fluid material can be discharged from the catheter. The outer end of tube 203 can be recessed to ensure the flow of fluid from outlet opening 205. The balloon 204 is of sufficient size relative to the dimensions of the tube 206 to expand at least as far as the outer end of the tube 206 to thereby contact the fundus of the uterine cavity in which it is inserted.

The body 201, as shown in Figure 22, houses a pair of longitudinally extending chambers 207 and 208. The chambers 207 and 208 are located side-by-side substantially in the same plane. A passage 209 connects the chamber 207 with the passageway of the tube 203. A similar passage 211 connects the chamber 208 with the passage in the tube 206. A short tubular needle 212 extends longitudinally into the chamber 207. The needle 212 is attached to a transverse base 213 positioned at the end of the chamber 207 adjacent to the passage 209. The outer peripheral edge of the base 213 is located in a groove in the housing to fix the position of the base 213 and the needle 212 relative to the chamber 207. The needle 212 has a passage extending therethrough in communication with the passage 209 so that fluid can flow through the needle into the passage 209.

A second tubular needle 214 extends longitudinally into the chamber 208. The needle 214 is attached to a base 216 located at the end of the chamber 208 adjacent to the passage 211. The outer peripheral edge of the base 216 is located in a groove in the housing 201 to fix the position of the base and the needle relative to the chamber 208. The needle 214 has a passage extending therethrough which communicates with the passage 211 so that the fluid can flow through the needle and into the passage 211.

A container or ampulla 217 having a chamber 218 for fluid, for example, water or air, is located in the chamber 207. The container 217 has at its end facing the needle 212 a diaphragm 219. A pad 221 of resilient cushioning material is located between the diaphragm 219 and the pointed end of the needle 212. A plunger 222 is attached to the opposite end of the container 217. A suitable dovetail slot or groove 237 can be used to connect the container to the plunger. Other types of connections can be used to attach the container to the plunger. A longitudinal rod 223 is connected to plunger 222 and extends into a bore 224 in the housing 201. A coil spring 226 is positioned around the rod 223 within the chamber 207 and engages the housing 201 and the plunger 222 to bias the plunger towards the needle 212.

A releasable lock 227 engages the rod 223 to hold the plunger 222 in a cocked position in which the diaphragm 219 is held from the needle 212. Referring to Figures 23 and 24, releasable lock 227 comprises a cylindrical member or body 228 extending into a hole 229 in the housing 201 through a cutout or groove 230 in the rod 223. The body 228 has a semi-circular cutout 231 in alignment with the rod 223. The exposed end of the body 228 has a handle 232. The handle 232 is movable in the direction of arrow 233 shown in Figure 20 to move the cutout 231 into registration with rod 223. When the cutout 231 is in registration with rod 223, as shown in Figure 24, the rod is free to move. The spring 226 will bias the plunger 222 towards the needle 212. The pointed end of container 217 and the diaphragm 219 towarfs the needle 212. The pointed end of the needle will pass through the pad 221 and puncture the diaphragm 219. The needle 212 will form a seal with the diaphragm 219 whereby the fluid in the chamber 218 will flow through the needle, passage 209 and into the passage of catheter tube 203. The fluid in the tube 203 will expand the balloon 204 of the catheter. The biasing force of the spring 226 will force substantially all of the fluid in chamber 218 through needle 212.

An outwardly projecting finger 234, shown in Figure 21 is attached to the plunger 222. The finger 234 extends through a longitudinal slot 236 in the housing 201. The free end of the finger 234 is enlarged so that it can be gripped. The plunger 222 and the container 217 have cooperating connections such as the dovetail connection 237, shown in Figure 22. When force is applied to the finger 234, the plunger 222 can be moved in a reverse direction, expanding the container 217. This withdraws the fluid from the catheter, decreasing the size of the balloon 204. The plunger 222 can be moved until lock 227 can be moved to fix the position of the plunger 222 in the housing. Other types of retraction structure can be used to expand the container 217 to relieve the fluid from the balloon 204.

A container or ampulla 238 is located in the chamber 208 adjacent the needle 214. The container 238 has a chamber 239 for storing fluid material as drugs or tissue adhesives. The container 238 has a diaphragm 241 at one end thereof, the diaphragm being spaced from the pointed end of the needle 214 by a resilient pad 242. Some fluid materials that are moisture and vapor sensitive require a container made of material having good moisture and vapor barrier properties. Preferably a deformable lead alloy is used to make this type of container. These properties are important to prevent moisture and vapor sensitive fluid materials from polymerizing or setting during storage periods. The material of the container is also chemically inert to the fluid material stored in the container. Located adjacent the opposite end of the container 238 is a plunger 243. A longitudinal rod 244 attached to the plunger 243 extends into a bore 246 in the housing 201. A spring 247 located in chamber 208 engages the housing 201 and the plunger 243 to bias the plunger towards the needle 214. The rod 244 is held by a releasable lock 248 which is identical to the lock 227. It is operated by moving the handle of the lock to the dotted line position, as shown in Figure 20. This releases the rod 214 whereby the spring 247 will move the plunger to move the diaphragm 241 towards the needle 214. The pointed end of the needle 214 will pierce diaphragm 241, thereby providing a fluid connection between the chamber and the passage 211 leading to the tube 206. The diaphragm will be located in sealing relation with respect to the needle whereby the fluid material in chamber 239 of the container 238 will be forced by the biasing action of the spring 247 through the needle 214, the passage 211 and the passage of the tube 206.

Body 201 has doors or closure members closing openings into the chambers 207 and

208 whereby the containers 217 and 238 can be removed and replaced. Other types of containers as herein disclosed can be inserted into the chambers.

Figure 25 shows a further form of a releasable lock 250 for the plunger 222. A similar lock may also be provided for the plunger 243. The lock 250 has a body or rod 251 having a semi-circular cutout 252. The rod 223 attached to the plunger has a similar cutout. A spring 253 is located in the base of the bore 229 receiving the rod 251. The spring 253 biases the rod 251 to a position in which the cutouts of the rod 223 and the rod 251 are out of alignment. The free end of the rod 251 is attached to a head 254.

In the position of the rod 251 shown in Figure 25, the rod 223 and hence the plunger 222 are held in the cocked position as shown in Figure 22. The rod 223 is released by pushing head 254 in the direction indicated by arrow 256, until the cutout 252 is aligned with the cutout of the rod 223. This releases the holding action on the rod 223 whereby the spring 226 can move the rod to force the diaphragm 219 into engagement with the needle 212.

Figures 26, 27, 28 and 29 show a further embodiment of a dispenser instrument indicated generally at 300 for discharging fluid material, as drugs or tissue adhesives into the uterine cavity. The dispenser instrument 300 has a dispensing unit 301 and an elongated tubular catheter 302. The dispensing unit 301 has a body 303 attached to an elongated tube 304 of the catheter 302. The tube 304 can be releasably connected or permanently fixed to the body 303. Mounted on the free end of the tube 304 is an expandable sleeve member or balloon 305. Bands 306 clamp the ends of the sleeve member 305 to the tube 304. The sleeve member 305 is made from a sheet of a soft and relaxed, flexible, elastic material such as rubber or plastics material having a low modulus of elasticity. The sleeve member 305 is of sufficient size relative to the tube 304 to expand longitudinally of the tube 304 as far as the free end thereof. When expanded in the uterine cavity the sleeve member 305 substantially completely fills the uterine cavity and applies uniform outward pressure on the uterine wall. The expanded sleeve member 305 prevents the fluid materials dispensed into the uterine cavity from contacting substantial portions of the uterine wall and flowing out of the uterine cavity. Holes 307 in the end of the tube 304 provide the passageway for the fluid, as water, from within the tube 304 into the sleeve member 305 to expand the sleeve member 305. An elongated tube 308 of smaller diameter is located within the tube 304 and has a discharge outlet 309 at the free end of the tube 304.

The body 303 has a pair of side-by-side chambers 311 and 312 which extend longitudinally with respect to the body 303 and are located substantially in a common plane. A passage 313 connects the front end of chamber 311 with the tube 304. In a similar manner, a passage 314 connects the front end of chamber 312 with the tube 308.

A first plunger 316 is movably positioned within the first chamber 311. A rod 317 is attached to the plunger 316 and extends rearwardly away from the chamber 311. A second plunger 318 is movably located within the second chamber 312. A rod 319 is secured to the plunger 318 and extends rearwardly away from the chamber 312 substantially parallel to the rod 317. A trigger assembly or actuator indicated generally at 320 is mounted on the rear portion of the body 303 adjacent the end of rods 317 and 319 remote from the chambers 311 and 312.

The trigger assembly 320 has a lever 321. The mid-portion of the lever 321 has a hole accommodating a transverse pivot pin 322. Pivot pin 322 is anchored in a handle or piston grip 323 secured to the rear portion of the body 303. The lever 321 has a head 324 extending transversely of the body 303. A spring 325 engages the body 303 and the end of the lever 321 adjacent the head 324 to bias the lever to a rear or cocked position. The head 324 may be slidably engaged with the ends of rods 317 and 319.

Referring to Figures 29 and 30, the head 324 has a passage 326 extending longitudinally with respect to the body 303 for accommodating the rod 319. A bore 327 is provided in the head 324 which extends transversely of and opens into the passage 326. A pin 328 is slidably disposed in the bore 327. The pin 328 has a reduced diameter neck 329 attached to a head 331. A spring 332 engages the head 331 and a plug 333, closing the end of the bore 327. The spring 332 biases the pin 328 into the passage 326. The rod 317 has a finger 334 projecting from the end thereof remote from the chamber 311. When the rod 317 is in the cocked position, the finger 334 is located in the neck 329 of the pin 328 and functions as a stop to prevent movement of the pin 328 into the passage 326.

Returning to Figure 27, the rod 317 has a notch or slot 336 in one surface thereof. The slot 336 cooperates with a lock 337 to hold rod 317 in a forward or dispensing position. The lock 337 comprises a movable pin 338 located in a passage in the body 303 surrounded by a boss 339. The pin 338 has a head 341 located outside body 303 so that it can be gripped to release the lock. The inner-most portion of the pin 338 carries a

C-ring or clamp ring 342 providing a stop for a spring 343. The spring 343 is located concentrically around the pin 338 and engages a portion of the body 303 to bias the pin 338 towards the rod 317. When the rod 317 has been moved to its forward position, the pin 338 will be biased into the slot 336, thereby holding the rod 317 in the forward position. The rod 319 has a slot 344. A lock 346 (Figure 26) on the body 303 holds the rod 319 in its forward position. The lock 346 is identical to the lock 337.

Figures 27 and 28 show the dispensing unit 301 with the rods 317 and 319 in their rear or cocked position. In use, the catheter 302 is positioned so that the free end thereof together with the expandable member 305 is positioned in a uterine cavity. The lever 321 of the trigger assembly 320 is then actuated by squeezing it towards the handle 323 so that it pivots about pivot pin 322. The head 324 of the lever 321 is thus moved forwardly into engagement with the end of rod 317 and moves the rod 317 into its forward position. The rod 317 is held in its forward position by the lock 337. The rod 319 is not similarly moved to its forward position as the head 324 moves relative to the rod 319 as the rod 319 moves through the passageway 326. The lever 321 is then released so that the head 324 thereof is returned to its initial rearward position by means of the spring 325. However, as the rod 317 is now held in its forward position the return of the head 324 to its rearward position moves the projecting finger 334 of the rod 317 out of the neck 329 of the pin 328. The pin 328 is thus moved by the spring 332 into the passageway 326. Thus, if the lever 321 is then actuated again, forward movement of the head 324 will move the rod 319 to its forward position and the rod 319 will be held in its forward position by the lock 346.

Referring to Figure 28, a first container or ampulla indicated generally at 350 is located in the chamber 311. A needle 351 which extends longitudinally with respect to the body 303 is mounted on a transverse base 352 and is located at the forward end of the chamber 311. The needle 351 is a hollow tubular member in fluid communication with the passage 313.

A second container or ampulla, indicated generally at 353, is located in the chamber 312. The forward end of the chamber 312 has a needle 354 extending longitudinally with respect to the body 303 mounted on a transverse base 356. The needle 354 is a hollow tubular member having a passage in fluid communication with the passage 314 of the tube 308. The container 353 is an elongated cylindrical member of glass, plastics or the like having a head 357. The head has a rubber plug (not shown) in alignment with the needle 354. Slidably positioned within the container is the plunger 318 which is engageable with a piston 358 confining fluid material 359 in the container. The plunger 318 is moved in the forward direction by movement of the rod 319 to its forward position. On movement of the plunger 318 in the forward direction, the head 357 will be pierced by the needle 354, thereby providing a fluid communication between the container 353 and the passage 314. The piston 358 will be moved in a forward direction to drive the fluid material from the container. The fluid material can be a drug, tissue adhesive, or semifluid material for treating or occluding the canals of the Fallopian tubes.

The container 350 is shown in more detail in Figure 31, and has a cylinder 361 for storing a fluid 362, as air or water, for expanding the expandable member 305. The forward end of the cylinder 361 has a head 363 having a passage closed with a plug 364. The other end of the cylinder 361 is closed with a plunger 366 carrying a piston 367. The rear portion of the plunger 366 has an outwardly directed flange 368 engageable with a spring 369. The forward end of the spring 369 engages an annular seat 371 on the cylinder 361 to bias the plunger 366 in an outward direction or out of cylinder 361. The plunger 366 has a central longitudinal bore 372 slidably accommodating an actuator rod 373. The rod 373 has an axial bore accommodating a compression spring 374 which extends into the bores 372 and bears against the inner end of the plunger 366 to provide a yieldable link between the rod 373 and the plunger 366.

The plunger 316 attached to the rod 317 engages the end of the rod 373. Movement of the rod 317 and hence of the plunger 316 in the forward direction initially compresses the spring 374 which applies a uniform pressure on the plunger 366. The cylinder 361 will be moved in a forward direction by the plunger 366 and the needle 351 will pierce the plug 364, thereby providing fluid communication between the container 350 and the passage 313. The continued forward movement of the plunger 316 will drive the piston 367 towards the plug 364, thereby dispensing the fluid from the cylinder 361. The dispensed fluid will flow through tube 304 and into sleeve member 305 via holes 307 to expand the sleeve member 305, as shown in broken lines in Figure 28. The sleeve member 305 will expand so as to fill the uterine cavity and conform to the shape thereof and exert uniform pressure on the inside wall of the cavity. The pressure of sleeve member 305

on the cavity wall will be uniform regardless of the size of the uterine cavity.

The body 303 has doors or closure members closing openings into the chambers 311 and 312 whereby the containers 350 and 353 can be removed and replaced. Other types of containers, as disclosed herein, can be inserted into the chambers.

The dispenser instrument 300 can be used to introduce a fluid material, such as a drug, a tissue adhesive, or a contraceptive gel, into the canals of the Fallopian tubes. The elongated catheter 302, with the sleeve member 305 in its contracted position, is introduced through the cervical opening into the uterine cavity. The sleeve member 305 is then expanded with fluid under pressure to fill the uterine cavity and apply uniform pressure on the inside of the uterine wall. The fluid under pressure is delivered to the sleeve member 305 via the passage in the tube 304. The head 324 of the actuator lever 321 is moved in the forward direction to force plunger 316 in a direction to move the container 350 into operative engagement with the needle 351. The needle 351 will puncture the plug 364, whereby the fluid 362 will flow via the passage in tube 304 to expand the sleeve member 305. The sleeve member, being made of a soft and relaxed, flexible and elastic material, as rubber, having a low modulus of elasticity applies a uniform pressure to the inside of the uterine wall. This effects a relatively tight seal and fit, enabling the same catheter construction to be used on all types of primate female, regardless of the size of the uterine cavity. Material under pressure is then dispensed from the container 353 into the uterine cavity by way of the tube 308 between the expanded sleeve member and the fundus of the uterus. The material, being under pressure, moves toward and into the canals of the Fallopian tubes. The expanded sleeve member, being located against the fundus wall, aids the movement of the material toward the canals of the Fallopian tubes. The material can be a fluid tissue adhesive which will flow into the canals. The moisture in the tissue of the canals will polymerize or set the tissue adhesive and thereby block or occlude the canals. The fluid confined by the sleeve member is then drained to contract the sleeve member by releasing the lock 337 of the rod 317 manually. The plunger 366 is then moved out of the cylinder 361 by the spring 369 so that fluid is drawn into the cylinder 361. The catheter is then withdrawn from the uterine cavity.

Referring to Figure 32, there is shown a further embodiment of a dispenser instrument indicated generally at 420 having an elongated tubular catheter located in a uterine cavity of a female reproductive system shown generally at 421. The female reproductive system has a uterus 422 jointed to a pair of Fallopian tubes 423 and 424. The lower part of the uterus 422 is integral with an elongated vagina 426. The vagina 426 has vaginal cavity 427 having an opening or entrance 428. The opposite end of the vaginal cavity 427 is in communication with the cervix 429. The cervix 429 has a cervical opening 431 providing a passage from the vaginal cavity 427 to the uterine cavity 432. Fallopian tubes 423 and 424 have exits 433A and 434A at opposite sides of the upper part of the uterine cavity 432.

The uterus 422 is usually pear-shaped, thick walled, hollow organ situated between the bladder and rectum. The uteri of females vary in size and shape. Wall thickness, wall strength and sensitivity to pain may vary from female to female. The size and configuration of the uterine cavities can vary. The uterine cavity 432 is generally flattened and triangular in shape. Some uteri have cavities that have other shapes.

The Fallopian tubes 423 and 424 are trumpet-shaped muscular members, which are about 12 cm. in length in human females, and which extend from the superior angles of the uterine cavity 432 to the ovaries (not shown). The outlets 433A and 434A of the canals 433 and 434, respectively, can vary in position relative to the uterine cavity and relative to each other. Outlets 433A and 434A are usually symmetrically opposite each other, as shown in Figure 32, and their position and proximity are principally related to the uterine size and configuration. Also, the size of the canals 433 and 434 and the size of the outlets 433A and 434A vary from female to female.

The Fallopian tubes are commonly divided into isthmus, intramural and ampullary sections. The canals 433 and 434 provide passages for the movement of ova from the ovaries to the uterine cavity 432 as well as the movement of sperm from the uterine cavity toward the ovaries. The intramural sections of the Fallopian tubes traverse the uterine wall generally in a more or less straight fashion, but their course may be tortuous in some females. The walls of the Fallopian tubes consist of three layers; the serosal layer, the muscular layer and mucosal lining.

The uterus 422 has a top wall of fundus 436 and side walls 437 and 438 which surround the uterine cavity 432. The inside of the top wall 436 and the insides of side walls 437 and 438 have an inside lining or membrane 439 which is periodically

sloughed off in the normal cycle of the female.

The dispenser instrument 420 has an elongate tubular catheter having a tubular member 441 of sufficient length to pass through the vaginal cavity 427 and into the uterine cavity 432. The tubular member 441 has a longitudinal passage 442 extending throughout its length. A balloon assembly indicated generally at 443 is mounted on the upper or outer end of the tubular member 441. Balloon assembly 443 has a flexible and expandable sleeve member 444 surrounding the upper end of the tubular member 441. A fastener 446, such as a collar or thread, attaches the upper end of the sleeve 444 to the tubular member 441. A similar fastener 447 attaches the opposite end of the sleeve 444 to the tubular member 441. The tubular member 441 has a plurality of openings 448 which provide communication between the passage 442 and a chamber 449 within the sleeve member 444.

Sleeve member 444 is formed from a sheet member made of soft and relaxed, flexible and elastic material, such as rubber or plastics which expands uniformly. For example, thin latex rubber having a low modulus of elasticity is a suitable material for the sleeve member 444. The low modulus of elasticity of the rubber allows the sleeve member 444 to be readily expanded by relatively low fluid pressure to occupy the uterine cavity 432 and conform to the shape of the uterine cavity without applying extreme pressure to localized portions of the uterus walls 437 and 438. The sleeve member 444 is of sufficient size relative to the tubular member 441 to expand longitudinally of the tubular member as far as the outer end of a head 451 on the outer end of the tubular member 441. Thus, when the cavity 432 is substantially completely filled by the expanded sleeve member 444, as shown in Figure 36, the sleeve member 444 is in engagement with the inside lining 439 of both the side walls 437 and 438 and the top wall 436 of the uterine cavity. Conventional balloon catheters, being of hard, relatively non-elastic material, do not assume the configuration of the uterine cavity when expanded.

The upper or outer end of the tubular member 441 is closed by the head 451. The head 451 has a transverse passage 452 open to opposite sides of the head 451. An elongated tube 453 is secured to the head 451 and extends in the longitudinal passage 442 of the tubular member 441 over the length of the tubular member 441. The tube 453 has a passage 452 for carrying a fluid material, such as a drug material, to the transverse passage 452 of the head 451. The transverse passage 452 directs the fluid material in opposite directions in two portions into the upper section of the uterine cavity 432. The head 451 has a cap 456 having a surface or wall adapted to engage the inner wall of the fundus 436. The cap 456 spaces the passage 452 from the inner wall of the fundus 436.

Referring to Figure 33, the instrument 420 has a dispensing unit having an elongated housing or body 457 attached to the end of the tubular member 441. The body 457 has a first chamber 458 accommodating an elongated cylinder 459. The cylinder 459 has a forwardly directed neck 461 connected to a tube 462. The tube 462 has a passage which is in communication with the passage 442 of the tubular member 441 so that fluid, such as air, in the cylinder 459 can flow via the passage 442 into the chamber 449 of the balloon assembly and thereby expand the sleeve member 444. The opposite end of the cylinder 459 is closed by a piston 463 to enclose the fluid in a chamber 464 within the cylinder 459. The cylinder 459 has a hole 466 adjacent the piston 463 which, in the inoperative position shown in Figure 33, is aligned with a hole 466' in the body 457 to allow air and sterilizing gases to flow into the chamber 464.

Located rearwardly of the piston 463 is a first drive assembly indicated generally at 467 operable to move the piston 463 into the cylinder 459. The first drive assembly 467 is connected to an actuator 468 projecting rearwardy from the body 457.

The body 457 has a second chamber 469 located adjacent one side of the first chamber 458. A tube 471 is mounted in the body 457 to connect the tube 453 to the chamber 469. Tube 471 has a needle 472 at one end thereof which projects longitudinally into the chamber 469. The opposite end of the tube 471 is mounted in a plug 473 closing the end of the tubular member 441 and connected to the tube 453 which leads to the head 451. The chamber 469 has an elongated shape and is open to the top of body 457, as shown in Figure 32. A cylindrical container or ampulla 474 is located in chamber 469 in alignment with the needle 472. The forward end of the container 474 has a pierceable plug 476 aligned with the needle 472. The open end of the container 474 is closed by a slidable piston 477 to enclose fluid material 478 within the container 474.

A second drive assembly indicated generally at 479 extends rearwardly from the container 474 and is drivably connected to the actuator 468. The actuator 468 is operable to complete the entire dispensing of fluid material into the canals of the Fallopian tubes in a single stroke. The rear

portion of the body 457 has outwardly and oppositely directed flanges 481 and 482 which serve as finger grips during actuation of the actuator 468. The actuator 468 has a hole 483 for accommodating a pin 483A to hold the actuator 468 in the inoperative position. The pin 483A prevents accidental actuation of the dispensing instrument.

The first drive assembly 467 is a force-transmitting mechanism operable to move the piston 463 into the cylinder 459 and thereby increase the pressure in the fluid system for the balloon assembly 443 and expand the sleeve member 444. The first drive assembly 467 has a cylinder or sleeve 484 slidably carrying body 486 at its rearward end. The opposite or forward end of the sleeve 484 is attached to a head 487. The head 487 has a central hole 488 which provides access into the sleeve 484. The rearward end of the piston 463 has a cone-shaped portion 489 to accommodate the forward end of the head 487 which is cone-shaped. The hole 488 is aligned with an adjusting screw 491 threaded into body 486. The position of the screw 491 relative to the body 486 can be changed by the use of a tool such as screw-driver, inserted through the hole 488 before assembly of the piston 463 in the chamber 464. A pair of springs 492 and 493 bias the head 487 and the body 486 in opposite directions whereby the first drive assembly 467 is biased into a rearward, inoperative position. The spring 492 abuts against the head 487. The spring 493 rests on the screw 491. Adjusting the position of the screw 491 adjusts the tension or force of the spring 493. The screw 491 performs a fine adjustment of the spring force to accommodate variations in the spring 493 and to provide for desired fluid pressure in the chamber 449 of the sleeve member 444. A washer 494 having a central hole aligned with the hole 488 in the head 487 is located between the springs 492 and 493. The washer 494 is a cylindrical sleeve slidably received within the sleeve 484. The spring 492 is a light or weak spring as compared to the spring 493. The weak spring 492 will compress under a light load, for example 2—3 psi, into the washer 494 and the forward end of the washer 494 will abut against the head 487. This ensures the partial expansion of the sleeve member 444 at a low predetermined pressure. A predetermined maximum pressure is determined by the compression force characteristics of the spring 493 and permits the instrument to be used with all shapes and sizes of uteri.

The sleeve 484 and the body 486 are held in assembled relation by a pin 496 carried by the body 486. The pin 496 extends through an elongated longitudinal slot 497 in the sleeve 484. The slot 497 permits the sleeve 484 to move relative to the body 486 as the springs 492 and 493 are compressed. The pin 496 projects through the slot 497 into an elongated linear groove 498 in the housing 457 and thereby prevents rotational movement of the first drive assembly 467 relative to the housing 457.

The body 486 has a transverse passage 499 accommodating a drive link 501. The drive link 501 is a transverse member or tube having spherical members at its opposite ends. The first end of the drive link 501 is located in a recess 502 in the side of the actuator 468. The actuator 468 also has a second recess 503 for accommodating the first end of the link 501. Located rearwardly of the second recess 503 is a shoulder 504 adapted to engage the rearward end of the body 486 when the first end of the link 501 is in the recess 503. The housing 457 has a recess 506 adapted to accommodate the opposite end of the drive link 501. The recess 506 is positioned in front of the drive link 501 in the inoperative position of the drive assembly 467 as shown in Figure 33.

A lock unit indicated generally at 507 is movably located in a transverse bore 508 in the body 486. The lock unit 507 has a plunger 509 carrying a finger or projection 510 extending transversely of the body 486. The finger 510 is adapted to engage one of a plurality of teeth 511 located in the housing 457. The teeth 511 face the drive assembly 467. The teeth 511 are ratchet teeth which allow only reverse movement of the drive assembly when the finger 510 of the lock unit 507 is in engagement with one of the teeth 511. The plunger 509 is biased in an outward direction by way of a spring 512 located at the closed end of the bore 508. The sleeve 484 has a hole 513 spaced forwardly from the finger 510 in the inoperative position of the drive assembly 467 shown in Figure 33. Upon compression of the springs 492 and 493, the body 486 moves relative to the sleeve 484 until the finger 510 is aligned with the hole 513, at which time the spring 512 will bias the finger 510 through the hole 513 into engagement with one of the teeth 511. This prevents further movement of the drive assembly 467 in a forward direction and limits the pressure of the fluid in the chamber 449 of sleeve 444.

The second drive assembly 479 is operable to drive the container 474 towards the needle 472 so that the plug 476 is pierced by the needle 472. In addition, the second drive assembly 479 forces the piston 477 into the container 474 to thereby drive the material 478 through the needle 472 into the tube 453. The tube 453 carries the

fluid to the head 451 where it is discharged in opposite directions into the upper portion of the uterine cavity 432. As is shown in Figure 33, the second drive assembly 479 has an elongated linear plunger 514 slidably located in a longitudinal passage 515 in the housing 457. The plunger 514 has a forward end 516 adapted to engage the piston 477. The opposite end of the plunger 514 has a transverse passage 517. A movable drive link 518 is located in the passage 517. The link 518 comprises a rigid member such as tube having spherical ends. One end of the drive link 518 is located in a semi-spherical recess 519 located in the side of the actuator 468. The opposite end of the drive link 518 rides on the side wall of the housing 457 forming part of the passage 515, thereby retaining the link in the recess 519. The housing 457 has a recess 521 which, in the inoperative position of the drive assembly 479 shown in Figure 33, is forward of the link 518 so that the link 518 will remain in driving relationship with the actuator 468 until the link is aligned with recess 521. At this time the link 518 will be forced into the recess 521 whereby the actuator 468 will be able to move in a forward direction and the plunger 514 will remain stationary.

In use, the dispensing instrument 420 is packaged with the container 474 located in the chamber 469. The actuator 468 is locked in its inoperative position with the pin 483A extending through the hole 483. The pin 483A engages the end of the housing 457 to prevent the actuator 468 from moving into the housing. The entire dispensing instrument is sterilized before it is used.

The tubular member 441 is inserted through the vaginal cavity 427, and the cervical opening 431 into uterine cavity 432 so that the balloon assembly 443 is positioned in the uterine cavity 432 as shown in Figure 1. The sleeve member 444 is in the collapsed condition during insertion so that the balloon assembly can be readily positioned in the uterine cavity. The tubular member 441 is moved into the uterine cavity until head 451 engages the fundus 436. It is known that uteri can vary in size, shape and position so that the balloon assembly may or may not be symmetrically located relative to the Fallopian tubes 423 and 424. As shown in Figure 32, the balloon assembly 443 is centrally located in the uterine cavity 432. In some cases, the longitudinal axis of the balloon assembly may be angularly positioned in the uterine cavity adjacent one side of the cavity. The dispensing instrument 420 is effective in placing fluid material into both canals of the Fallopian tubes regardless of the position of the balloon assembly in the uterine cavity 432.

The pin 483A is then removed from the hole 483, so that the actuator 468 can then be moved into the housing 457 to inflate the expandable sleeve member 444 and dispense fluid material into the uterine cavity 432 and then fully expand the sleeve member 444 to pump or force the fluid material into the canals of the Fallopian tubes. The operator uses flanges 481 and 482 as finger rests so that a forwardly directed force can be applied to the actuator 468. As shown in Figure 35, the actuator 468 is first moved into the housing 457 a short distance so that the first drive assembly 467 moves the piston 463 into the cylinder 459. This expands the sleeve member 444 so that it forms a plug or seal in the lower portion of the uterine cavity 432. The sleeve member 444 is expanded into firm engagement with the inside lining or membrane 439. The drive link 501 couples the actuator 468 to the first drive assembly 467 to transmit the motion of the actuator 468 to the first drive assembly 467. This moves the piston 463 into the chamber 464. The drive link 518 couples the plunger 514 with the actuator 468 so that the forward end 516 of the plunger 514 engages the piston 477 in the container 474. This moves the entire container 474 in the forward direction. The needle 472 pierces the plug 476, thereby moving the needle through the plug 476 and into the chamber containing the fluid material 478. The drive link 501 is then aligned with the recess 506 in the housing 457, and moves to the right, as shown in Figure 35, releasing the drive link 501 from the actuator 468. The continued forward movement of the actuator 468 applies force to the plunger 514 which moves the piston 477 into the container 474. Fluid material 478 is forced via the tubes 471 and 453 to the head 451. The fluid material is discharged in opposite directions via the transverse passage 452 into the upper part of the uterine cavity 432.

As shown in Figure 36, the continued forward movement of the actuator 468 places the shoulder 504 of the actuator 468 in engagement with the bottom of the body 486. At the same time the drive link 501 moves into the recess 503, thereby releasing the drive link 501 from the recess 506. As the actuator 468 continues to be moved into the housing 457 the pressure in the chamber 464 is increased and this further expands the sleeve member 444. The expanding sleeve member 444 drives the fluid material from the upper portion of the uterine cavity through the outlets 433A and 434A of the canals 433 and 434 of the Fallopian tubes. The sleeve member 444 continues to expand until the fluid pressure in the system

containing the sleeve member chamber 449 and the chamber 464 is approximately 8 psi. Other pressures can be selected as the upper pressure limit. This upper pressure limit is determined by the compression characteristics of the springs 492 and 493. The compression of springs 492 and 493 permits the body 486 to move in the sleeve 484. This movement continues until the finger 510 is aligned with the opening 513. When the finger 510 and the hole 513 are aligned, the spring 512 forces the finger 510 through the hole 513 and into the space between adjacent teeth 511. The finger 510 anchors on a forward tooth, thereby preventing further movement of the actuator 468 into the housing 457. Since the actuator 468 is prevented from moving into the housing 457 by the lock unit 507, the pressure in the balloon chamber 449 is limited to a selected maximum pressure, depending upon the compression characteristics of the springs 492 and 493.

As the actuator 468 is moved into the housing 457 from the position shown in Figure 35 to the position shown in Figure 36, the drive link 518 moves from the recess 519 into the recess 521. This terminates the forward motion of the plunger 514 to stop dispensing the fluid material into the uterine cavity 432. The continued movement of the actuator 468 increases the fluid pressure in the chamber 449, thereby expanding the sleeve member 444 to pump or push the fluid material from the uterine cavity 432 into the canals 433 and 434 of the Fallopian tubes. The pumping action ceases when the sleeve member 444 is fully expanded, as shown in Figure 36. This locates the fluid material in the Fallopian tubes as the pumping force applied to the drug material by the expanding sleeve member 444 is insufficient to move the fluid material through the Fallopian tubes into the body cavity.

The actuator 468 is then retracted. The drive link 501, being located in the recess 503, provides a drive connection between the body 486 and the actuator 468. The finger 510 of the lock unit 507 slips over the teeth 511. This retracts the piston 463 in the chamber 464. The fluid in the chamber 449 of the sleeve member 444 flows back into the chamber 464 thereby contracting the sleeve member 444. This releases the sleeve member 444 from engagement with the line 439 and enables the balloon assembly 443 and hence the tubular member 441 to be withdrawn from the uterus of the patient.

From the foregoing description of the operation of the dispensing instrument shown in Figures 32 to 36 it will be appreciated that, once the tubular member 441 has been inserted in position, an operator only needs to move the single actuator 468 forward in a continuous movement to dispense a predetermined amount of material from the container 474 into the canals of the Fallopian tubes. It will be seen that the first drive assembly 467 and the second drive assembly 479 are coordinated to sequentially operate to partially expand the sleeve member 444, to dispense the material from the container 474 into the uterine cavity and then to fully expand the sleeve member 444 to push the dispensed material into the canals of the Fallopian tubes. Thus coordination is achieved by the relative positions of the recesses 506 and 521 in the housing 457. Thus, in the embodiment shown in Figures 32 to 36 the recess 506 is positioned a distance in front of the initial, inoperative position of the drive link 501 which ensures that the actuation of the drive assembly 467 is temporarily halted or interrupted until the bottom of the body 486 engages the shoulder 504 of the actuator 468, at which time the movement of the drive assembly 467 is continued. However, if required, the positions of the recesses 506 and 521 can be arranged relative to one another so that the discharge of the fluid material is commenced during the initial expansion of the sleeve member 444, and that the continued expansion of the sleeve member 444 commences during the discharge of the fluid material. If required, the expansion of the sleeve member 444 could be continuous and the fluid material discharged during the expansion. The expansion of the sleeve member 444 is of course stopped when a predetermined pressure has been attained.

The fluid material dispensed into the canals of the Fallopian tubes can be one of a number of fluids or semi-fluids used to test, treat or occlude the canals of the Fallopian tubes. For example, the fluid material can be a tissue adhesive. The tissue adhesive can be a cyanoacrylate type material. Cyanoacrylate is a liquid plastics material which polymerizes or sets when exposed to a hydroxyl ion source, such as water, and therefore occludes the canals of the Fallopian tubes. The body cells adjacent to the adhesive are damaged and are eventually replaced by fibrous tissue so that the occlusion of the canals is permanent. The cyanoacrylates include, but are not limited to, methyl cyanoacrylate, methyl - 2 - cyanoacrylate, ethyl cyanoacrylates, n - propyl cyanoacrylates, n - butyl cyanoacrylates, n - amylcyanoacrylates, n - hexyl cyanoacrylates, n - heptyl cyanoacrylates, isobutyl - 2 - cyanoacrylates and n - octyl cyanoacrylates. The fluid material can also be of a type that sets in response to body heat or other stimuli. It may be a type which produces permanent occlusion or of a type

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which will temporarily block or occlude the canals of the Fallopian tubes, after which the canals will be reopened and resume their normal function. Examples of other types of fluid materials are contraceptive gels, water, silicone elastomers or formaldehyde-type materials.

Referring to Figures 37 and 38, there is shown a further embodiment of a dispensing instrument indicated generally at 420A. The dispensing instrument 420A is similar to the dispensing instrument 420 shown in Figures 32—36 and like parts of the instrument and of the female reproductive system associated therewith have been accorded the same reference numerals. The operation of the dispensing instrument 420A is also similar to that of the instrument 420.

Dispensing instrument 420A uses a two-part fluid material which is mixed at the end of the tubular member 441 as it is forced into the upper part of the uterine cavity 432. The mixed fluid material is pushed into the canals 433 and 434 of the Fallopian tubes 423 and 424 by the expansion of the sleeve member 444.

A head 651 is mounted on the free end of the tubular member 441. The head 651 has a transverse passage 652 having oppositely directed discharge openings for directing the fluid material in two parts into the upper part of the uterine cavity 432. A first tube 653 and a second tube 654 extend within the bore of the tubular member 441 and are connected to the head 651. The head has a mixing chamber or passage 655 in fluid communication with the passages of the tubes 653 and 654 and the transverse passage 652. The fluid materials flow through the tubes 653 and 654 and are mixed in chamber 655. The mixing continues as the fluid materials are divided into two streams and forced in opposite directions in passage 652, as indicated by the arrows.

The housing 457 has a pair of chambers 656 located adjacent chamber 458 for accommodating a pair of ampullae or containers 657 and 659. One container 657 stores a first fluid material 658, whilst the second container 659 stores a second fluid material 660. A first piston 661 is slidably located in the container 657. In a similar manner, a piston 662 is slidably located in the container 659. The plunger 514 of the second drive assembly 479 has a bifurcated end forming a pair of fingers 663 and 664. The finger 663 is positioned in the container 657 and engages the piston 661. The finger 664 is located in the container 659 and engages the piston 662. The tubes 653 and 654 extend into the housing 457 and terminate in needles 666 and 667. The needles 666 and 667 are in alignment with the pierceable end portions of the containers 657 and 659.

On actuation of the single actuator 468 the first drive assembly 467 will operate to initially expand the sleeve member 444 to fill and seal the lower portion of the uterine cavity 432 as described above with reference to Figures 32 to 36. Continued movement of the actuator 468 will engage the second drive assembly 479 to move the fingers 663 and 664 in the forward direction. The plunger 514 moves in the forward direction, as shown in Figure 37, to drive the containers 657 and 659 onto the needles 666 and 667, respectively. The fingers 663 and 664, being in engagement with the pistons 661 and 662, simultaneously force the fluid materials 658 and 660 through the tubes 654 and 653. The fluid materials are simultaneously discharged into the mixing chamber 655. Substantially the same amounts of fluid materials are introduced into the mixing chamber 655 so that the mixture of fluid materials contains about 50 per cent of the first material and 50 percent of the second material. The mixed material, indicated at 668 in Figure 37, is introduced into the upper part of uterine cavity 432. The mixed drug material 668 flows in opposite directions in substantially equal amounts. The flow is continuous until the plunger 514 has reached the end of its stroke. At this time, the continuous movement of the actuator 468 further expands the sleeve member 444 forcing the mixed fluid material into the canals 433 and 434 of the Fallopian tubes.

The materials 658 and 660 can be of the type which when mixed will set to form a semi-rigid plastics material. The mixture can be responsive to moisture in the tissues to set or responsive to body heat or other factors to set. The mixture has a reaction time such that it can be introduced into the canals 433 and 434 before it will set. For example, the two-part fluid material may be two-part epoxy resins, two-part tissue adhesives, silicone RTV, or a polymer consisting of Dow Corning Silastic (Registered Trade Mark) 382 Medical Elastomer and 360 Medical Fluid. It is understood that other types of fluid materials which will set when mixed can be used. Furthermore, the ratio of the fluid material can be varied by increasing the size of one of the containers. For example, two parts of the first material can be mixed with one part of the second material by using the appropriate size containers in the housing 457.

The fluid material dispensed into the canals of the Fallopian tubes by any of the instruments described above can be of the type which treats the canals and uterus to

enhance the flow of ova and sperm in the canals and uterus. The material can include material which expands or opens the canals or passages of the Fallopian tubes to enhance fertilization or conception. At the present time there are several materials or chemicals which are used to treat the canals of the Fallopian tubes to enhance fertilization or conception.

It is believed that in some of the infertility cases the sperm are blocked or unable to transport themselves across the cervix and endometrial cavity. The apparatus and method of the invention is usable to deliver sperm into the uterine cavity and canals of the Fallopian tubes to enhance conception.

Alternatively, the material dispensed into the Fallopian tubes can be a contraceptive drug for local action in the Fallopian tubes and uterus. For example bioabsorbable microspherules containing contraceptive agents as progestins can be delivered to the canals of the Fallopian tubes; such microspherules break down over a period of time, e.g. one year, thereby inhibiting conception during this period. Alternatively, material to permanently occlude the Fallopian tubes could be dispensed therein to thereby sterilize the female.

Materials such as fibrinolytic enzymes can be introduced into the canals of the Fallopian tubes and uterine cavity to treat the tissues, e.g. to treat inflammation and/or prevent adhesions from forming around the ends of the Fallopian tubes.

Diagnostic materials can be introduced into the canals of the Fallopian tubes with the apparatus and method of the invention. These material include oil base and aqueous base X-ray dyes and color indicator dyes such as methylene blue and indigo carmine and the like.

Anaesthetic materials can be introduced into the canals of the Fallopian tubes with the apparatus of the invention.

Anti-inflammatory agents such as corticoids can be used locally to treat inflammation. Antibiotics can also be used for local treatment of the Fallopian tubes.

It will be seen that all of the embodiments of the dispensing instrument described above are capable of introducing material into both canals of the Fallopian tubes of a female from the uterine cavity. It has been found that the instrument efficiently directs the materials into the canals and that therefore only a minimum amount of material is required. This, together with the fact that it is not necessary for the expandable member to apply such a substantial pressure on the material ensures that the material is not forced into the blood stream or body cavity. The instrument can be provided with means preventing the application of pressure above a predetermined value to the expandable member and this ensures that the uterus is not over-expanded.

The dispensing instrument described above is simple to operate and can be used with a minimum of manipulative delay. It places a minimum amount of force on the walls of the uterus and can be used successfully with uteri of different sizes, shapes and characteristics.

A dispensing instrument as shown in Figures 26 to 38 of this application is described and claimed in our copending application No. 49022/76 (Serial No. 1,470,572), divided out of the present application. In addition, the method of dispensing fluid material into the Fallopian tubes of the body of a non-human female primate and the method of controlling conception in a human female by dispensing fluid material into the Fallopian tubes of the female body are described and claimed in our copending application No. 49023/76, (Serial No. 1,470,573, divided out of the present application.

WHAT WE CLAIM IS:—

1. An instrument for dispensing fluid material into the Fallopian tubes of a female body comprising an elongate tubular member having an expandable member at or near one end thereof positionable in a uterine cavity, said expandable member being made from a soft and relaxed, flexible and elastic material having a low modulus of elasticity as hereinbefore defined, and said expandable member being of sufficient size relative to the dimensions of the tubular member to expand longitudinally of the tubular member at least as far as the said one end thereof, whereby the expandable member can be expanded to substantially completely fill the uterine cavity and conform to the shape thereof.

2. An instrument as claimed in claim 1, wherein said expandable member is made from a sheet of said elastic material formed into a balloon.

3. An instrument as claimed in claim 1 or 2, wherein the elastic material forming the expandable member is latex rubber.

4. An instrument as claimed in claim 1 or 2, wherein the elastic material forming the expandable member is plastics material.

5. An instrument as claimed in any preceding claim, wherein said elongate tubular member is an elongate tubular catheter having a first passage extending therethrough, said first passage being in communication with said expandable member, and wherein at least one passage for fluid material extends through said

enhance the flow of ova and sperm in the canals and uterus. The material can include material which expands or opens the canals or passages of the Fallopian tubes to enhance fertilization or conception. At the present time there are several materials or chemicals which are used to treat the canals of the Fallopian tubes to enhance fertilization or conception.

It is believed that in some of the infertility cases the sperm are blocked or unable to transport themselves across the cervix and endometrial cavity. The apparatus and method of the invention is usable to deliver sperm into the uterine cavity and canals of the Fallopian tubes to enhance conception.

Alternatively, the material dispensed into the Fallopian tubes can be a contraceptive drug for local action in the Fallopian tubes and uterus. For example bioabsorbable microspherules containing contraceptive agents as progestins can be delivered to the canals of the Fallopian tubes; such microspherules break down over a period of time, e.g. one year, thereby inhibiting conception during this period. Alternatively, material to permanently occlude the Fallopian tubes could be dispensed therein to thereby sterilize the female.

Materials such as fibrinolytic enzymes can be introduced into the canals of the Fallopian tubes and uterine cavity to treat the tissues, e.g. to treat inflammation and/or prevent adhesions from forming around the ends of the Fallopian tubes.

Diagnostic materials can be introduced into the canals of the Fallopian tubes with the apparatus and method of the invention. These material include oil base and aqueous base X-ray dyes and color indicator dyes such as methylene blue and indigo carmine and the like.

Anaesthetic materials can be introduced into the canals of the Fallopian tubes with the apparatus of the invention.

Anti-inflammatory agents such as corticoids can be used locally to treat inflammation. Antibiotics can also be used for local treatment of the Fallopian tubes.

It will be seen that all of the embodiments of the dispensing instrument described above are capable of introducing material into both canals of the Fallopian tubes of a female from the uterine cavity. It has been found that the instrument efficiently directs the materials into the canals and that therefore only a minimum amount of material is required. This, together with the fact that it is not necessary for the expandable member to apply such a substantial pressure on the material ensures that the material is not forced into the blood stream or body cavity. The instrument can be provided with means preventing the application of pressure above a predetermined value to the expandable member and this ensures that the uterus is not over-expanded.

The dispensing instrument described above is simple to operate and can be used with a minimum of manipulative delay. It places a minimum amount of force on the walls of the uterus and can be used successfully with uteri of different sizes, shapes and characteristics.

A dispensing instrument as shown in Figures 26 to 38 of this application is described and claimed in our copending application No. 49022/76 (Serial No. 1,470,572), divided out of the present application. In addition, the method of dispensing fluid material into the Fallopian tubes of the body of a non-human female primate and the method of controlling conception in a human female by dispensing fluid material into the Fallopian tubes of the female body are described and claimed in our copending application No. 49023/76, (Serial No. 1,470,573, divided out of the present application.

WHAT WE CLAIM IS:—

1. An instrument for dispensing fluid material into the Fallopian tubes of a female body comprising an elongate tubular member having an expandable member at or near one end thereof positionable in a uterine cavity, said expandable member being made from a soft and relaxed, flexible and elastic material having a low modulus of elasticity as hereinbefore defined, and said expandable member being of sufficient size relative to the dimensions of the tubular member to expand longitudinally of the tubular member at least as far as the said one end thereof, whereby the expandable member can be expanded to substantially completely fill the uterine cavity and conform to the shape thereof.

2. An instrument as claimed in claim 1, wherein said expandable member is made from a sheet of said elastic material formed into a balloon.

3. An instrument as claimed in claim 1 or 2, wherein the elastic material forming the expandable member is latex rubber.

4. An instrument as claimed in claim 1 or 2, wherein the elastic material forming the expandable member is plastics material.

5. An instrument as claimed in any preceding claim, wherein said elongate tubular member is an elongate tubular catheter having a first passage extending therethrough, said first passage being in communication with said expandable member, and wherein at least one passage for fluid material extends through said

catheter, the or each material passage terminating at or near said one end of the catheter with an outlet for material positionable within the uterine cavity.

6. An instrument as claimed in claim 5, further comprising a head located on said one end of said catheter and having side discharge outlets to divide and direct material into the uterine cavity.

7. An instrument as claimed in claim 6, wherein said head includes an enlarged portion adapted to contact the fundus and space the discharge outlets from the fundus.

8. An instrument as claimed in claim 6 or 7, wherein at least two material passages extend through said catheter and said head has a transvere passage in communication with said material passages whereby material from said further passages is received and mixed in said transverse passage and discharged into the uterine cavity.

9. An instrument as claimed in any of claims 5 to 8, further comprising dispensing means coupled to the or each material passage and operable to dispense material therethrough to the or each outlet, said dispensing means comprising at least one container for material to be dispensed and means for moving the material from the or each container through the or each material passage.

10. An instrument as claimed in claim 9, wherein the or each container is collapsible and has a hollow needle supported therein in alignment with the respective material passage, and wherein a movable plunger is arranged with respect to the or each container so that movement of the plunger collapses said container and causes the needle to pierce said container.

11. An instrument as claimed in claim 9, wherein the or each container is connected to the end of a respective material passage, a hollow needle extends longitudinally within the end of the or each material passage, and a movable plunger is arranged with respect to the or each container so that movement of the plunger moves the respective container into contact with the needle and causes the needle to pierce said container.

12. An instrument as claimed in any of claims 5 to 11, further comprising means coupled to said first passage and operable to expand the expandable member, said means comprising a container for a fluid and means for moving the fluid from the fluid container through said first passage to the expandable member.

13. An instrument as claimed in claim 12, wherein the container of the means for expanding the expandable member is collapsible and has a hollow needle supported therein in alignment with said first passage, and wherein a movable plunger is arranged with respect to the container so that movement of the plunger collapses the container and causes the needle to pierce said container.

14. An instrument as claimed in claim 12, wherein the container is connected to the end of said first passage, a hollow needle extends longitudinally within the end of the first passage, and a movable plunger is arranged with respect to the container so that movement of the plunger moves the container into contact with the needle and causes the needle to pierce the container.

15. An instrument as claimed in any of claims 5 to 8, further comprising a dispensing unit, said dispensing unit comprising a housing having a first chamber and a second chamber, a first container for fluid for expanding the expandable member being located in the first chamber, a second container for fluid material to be dispensed being located in the second chamber, a first needle operable to puncture said first container, a second needle operable to puncture said second container, wherein said first passage is coupled to said first needle, and said material passage is coupled to said second needle, first movable means operable to cause the first needle to pierce a portion of said fluid container whereby fluid moves through the first passage to the expandable member, and second movable means operable to cause the second needle to pierce a portion of said second container whereby material moves through the further passage to said outlet.

16. An instrument as claimed in claim 15, wherein said dispensing unit further comprises an actuator operable to sequentially move the first movable means and the second movable means.

17. An instrument as claimed in claim 16, wherein said dispensing unit further comprises a first drive assembly operably coupled to said actuator and movable in response to movement of said actuator to supply fluid under pressure through said first passage to said expandable member to thereby expand said expandable member.

18. An instrument as claimed in claim 17, further comprising lock means associated with said first drive assembly for stopping movement of the first drive assembly when a predetermined fluid pressure is present in said expandable member.

19. An instrument as claimed in claim 18, wherein the housing of said dispensing unit has a plurality of teeth facing said first drive assembly, and said lock means are engageable with one of the teeth to stop movement of the first drive assembly when

a predetermined fluid pressure is present in said expandable member.

20. An instrument as claimed in claim 19, wherein said lock means includes a body having a projection, and biasing means for moving the projection between adjacent teeth when the predetermined pressure is attained.

21. An instrument as claimed in any of claims 16 to 20, wherein said dispensing unit further comprises a second drive assembly operably coupled to said actuator and movable in response to movement of the actuator to supply material through said material passage to said outlet.

22. An instrument as claimed in claim 21 comprising first releasable means to drivably connect said actuator with said first drive assembly, and second releasable means to drivably connect said drive assembly to said actuator.

23. An instrument as claimed in any of claims 9 to 11, or 15 to 22, wherein the fluid material to be dispensed is stored in said container therefor, and wherein said material is a medicinal drug.

24. An instrument as claimed in any of claims 9 to 11, or 15 to 22, wherein the fluid material to be dispensed is stored in said container therefor, and wherein said material is a contraceptive drug agent.

25. An instrument as claimed in any of claims 9 to 11, or 15 to 22, wherein the fluid material to be dispensed is stored in said container therefor, and wherein said material is a tissue adhesive.

26. An instrument as claimed in any of claims 9 to 11, or 15 to 22, wherein the fluid material to be dispensed is stored in said container therefor, and wherein said material is a diagnostic radiopaque dye.

27. An instrument as claimed in any of claims 9 to 11, or 15 to 22, wherein the fluid material to be dispensed is stored in said container therefor, and wherein said material is an anesthetic.

28. An instrument as claimed in any of claims 9 to 11, or 15 to 22, wherein the fluid material to be dispensed is stored in said container therefor, and wherein said material is a drug for enhancement of the fertility of the female.

29. An instrument for dispensing fluid material into the Fallopian tubes of a female body substantially as hereinbefore described with reference to and as illustrated in Figures 1 to 6 of the accompanying drawings.

30. An instrument for dispensing fluid material into the Fallopian tubes of a female body substantially as hereinbefore described with reference to and as illustrated in Figure 1 modified as shown in Figures 7 to 9 of the accompanying drawings.

31. An instrument for dispensing fluid material into the Fallopian tubes of a female body substantially as hereinbefore described with reference to and as illustrated in Figure 1 modified as shown in Figures 10 and 11 of the accompanying drawings.

32. An instrument for dispensing fluid material into the Fallopian tubes of a female body substantially as hereinbefore described with reference to and as illustrated in Figure 1 modified as shown in Figures 12 and 13 of the accompanying drawings.

33. An instrument for dispensing fluid material into the Fallopian tubes of a female body substantially as hereinbefore described with reference to and as illustrated in Figure 1 modified as shown in Figures 14 to 19 of the accompanying drawings.

34. An instrument for dispensing fluid material into the Fallopian tubes of a female body substantially as hereinbefore described with reference to and as illustrated in Figures 20 to 24 of the accompanying drawings.

35. A method of dispensing fluid material into the Fallopian tubes of the body of a non-human female primate comprising the steps of inserting the elongate tubular member of the dispensing instrument claimed in claim 1 into the uterine cavity of the female body so that said expandable member is positioned within the uterine cavity, dispensing the material through the tubular member into the uterine cavity, and expanding the expandable member, either before or after the material is dispensed into the uterine cavity, so that it substantially completely fills the uterine cavity and conforms to the shape thereof and moves the dispensed material from the uterine cavity into the Fallopian tubes.

36. A method as claimed claim 35, wherein said material is a medicinal drug or a mixture of medicinal drugs.

37. A method as claimed in claim 35, wherein said material is a diagnostic radiopaque dye or a mixture of such dyes.

38. A method as claimed in claim 35, wherein said material is an anesthetic or a mixture of anesthetics.

39. A method of controlling conception in a human female by dispensing fluid material into the Fallopian tubes of the female body, comprising the steps of inserting the elongate tubular member of the dispensing instrument claimed in claim 1 into the uterine cavity of the female body so that said expandable member is positioned within the uterine cavity, dispensing the material through the tubular member into the uterine cavity, and expanding the expandable member, either

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40. A method as claimed in claim 35 or claim 39, wherein said material is a contraceptive drug agent or a mixture of such drug agents.

41. A method as claimed in claim 35 or claim 39, wherein said material is a tissue adhesive or a mixture of such adhesives for effecting the closure of the Fallopian tubes to the passage of ova, thereby effecting sterilization of the female.

42. A method as claimed in claim 35 or claim 49, wherein said material is a drug or a mixture of drugs for in situ enhancement of the fertility of the female.

43. A method as claimed in any of claims 35 to 42, wherein the step of expanding the expandable member further comprises expanding said expandable member with a fluid under pressure to apply uniform pressure on the inside walls and fundus of the uterine cavity.

44. A method as claimed in claim 43, wherein an increase in the fluid pressure applied to the expandable member over a predetermined pressure is prevented.

45. A method as claimed in any of claims 35 to 44, wherein the material is dispensed into the uterine cavity after said expandable member has been expanded to substantially completely fill the uterine cavity.

46. A method as claimed in any of claims 35 to 44, further comprising the steps of partly expanding the expandable member to engage the inside walls of the uterus near the cervical opening to partly fill the uterine cavity, then dispensing the material between the expandable member and the fundus of the uterine cavity, and then further expanding the expandable member to substantially completely fill the uterine cavity to force the dispensed material from the uterine cavity into the Fallopian tubes.

47. A method as claimed in claim 46, wherein the expandable member is partly expanded, the material is dispensed into the uterine cavity, and the expandable member is further expanded in a single continuous operation.

48. A method as claimed in any of claims 35 to 47, further comprising the steps of contracting the expandable member and withdrawing the expandable member after the dispensed material has been moved into the Fallopian tubes.

49. A method as claimed in any of claims 35 to 48, comprising the further step of dividing the material into two portions, and the step of expanding the expandable member acting to force one portion of the material into one canal and the other portion into the other canal of the Fallopian tubes.

50. A method as claimed in any of claims 35 to 49, wherein said fluid material comprises a first material and a second material, said first and second materials being mixed together before the materials are dispensed into the uterine cavity.

51. A method of dispensing fluid material into the Fallopian tubes of the body of a non-human femal primate using the dispensing instrument claimed in claim 1, substantially as hereinbefore described with reference to Figures 1 to 5 of the accompanying drawings.

52. A method of controlling conception in a human female by dispensing fluid material into the Fallopian tubes of the female body using the dispensing instrument claimed in claim 1, substantially as hereinbefore described with reference to Figures 1 to 5 of the accompanying drawings.

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