

[54] SINGLE STROKE DISPENSING METHOD

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[51] Int. Cl. A61m 1/00

[58] Field of Search 128/235, 1 R, 232, 303, 128/240, 241, 260, 349, 246, 224, 127-130

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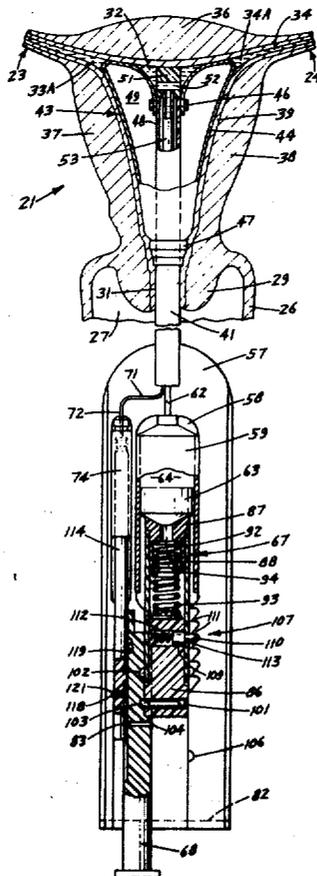
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[57] ABSTRACT

A fluid dispensing instrument and method for placing a drug material in the uterine cavity and moving the drug material from the uterine cavity to the canals of the Fallopian tubes of a female primate. The instrument has an elongated probe carrying an expandable sleeve. A housing connected to the probe has piston and cylinder structure connected with a first drive linkage to a movable actuator. A container storing the drug material is located in the housing. A second drive linkage connects the actuator with a plunger operable to move the container onto a needle and force the drug material through the probe and into the uterine cavity. The actuator is continuously moved into the housing to initially partially expand the sleeve member to displace part of the uterine cavity. Further movement of the actuator dispenses the drug material from the probe into the uterine cavity. Continued movement of the actuator fully expands the sleeve member to displace the entire uterine cavity and pump the drug material into the canals of the Fallopian tubes. After the sleeve member is contracted by releasing the fluid pressure applied thereto, the probe is removed from the uterine cavity.

20 Claims, 7 Drawing Figures



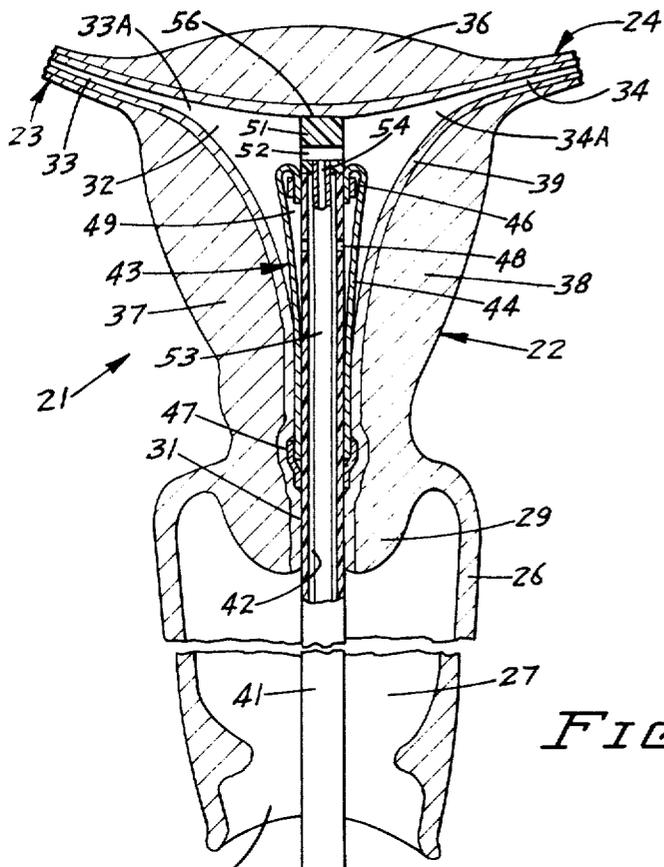


FIG. 2

FIG. 1

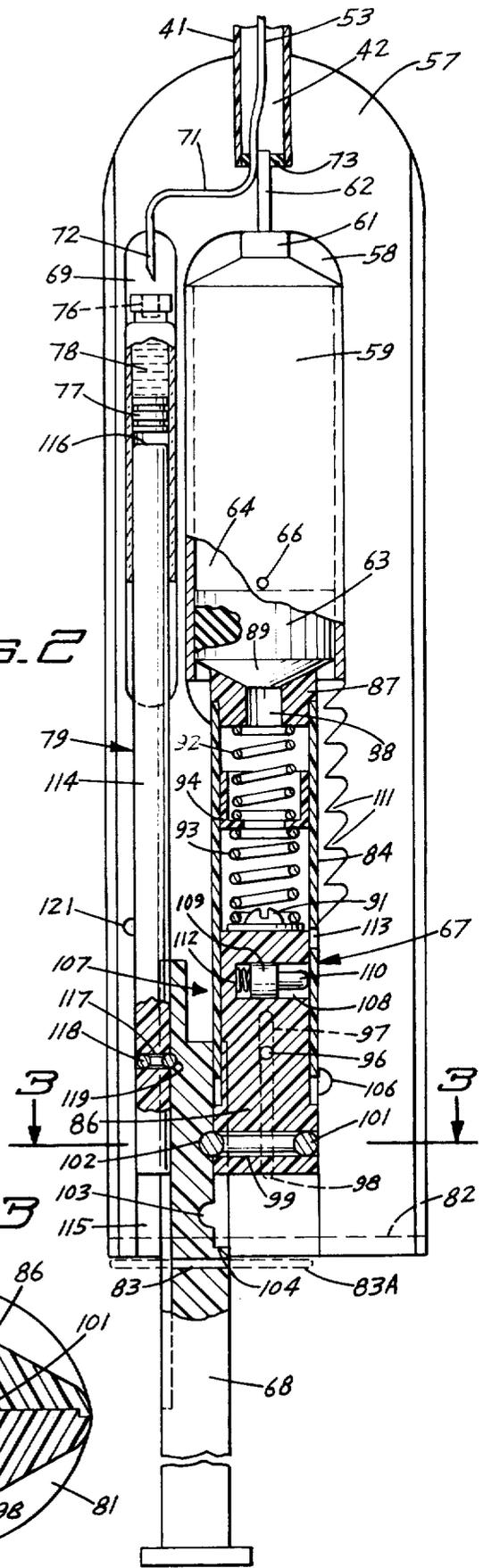


FIG. 3

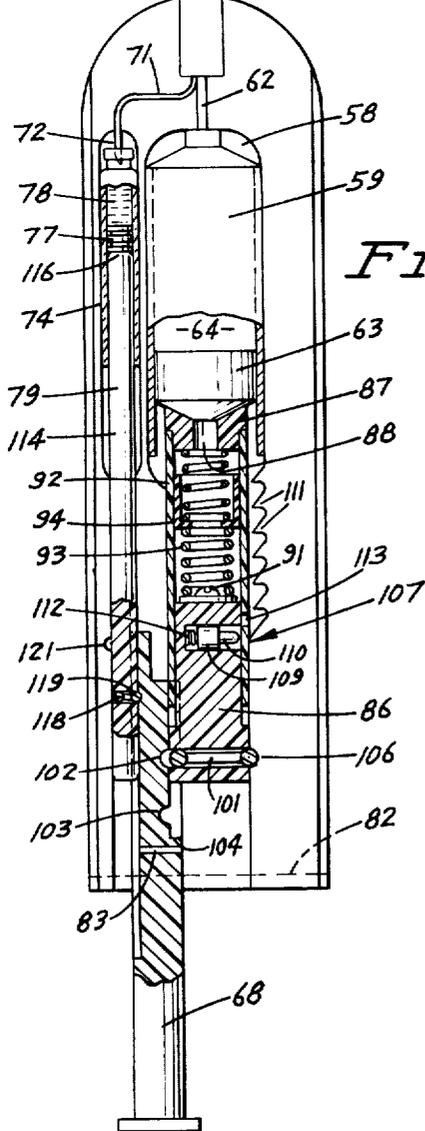
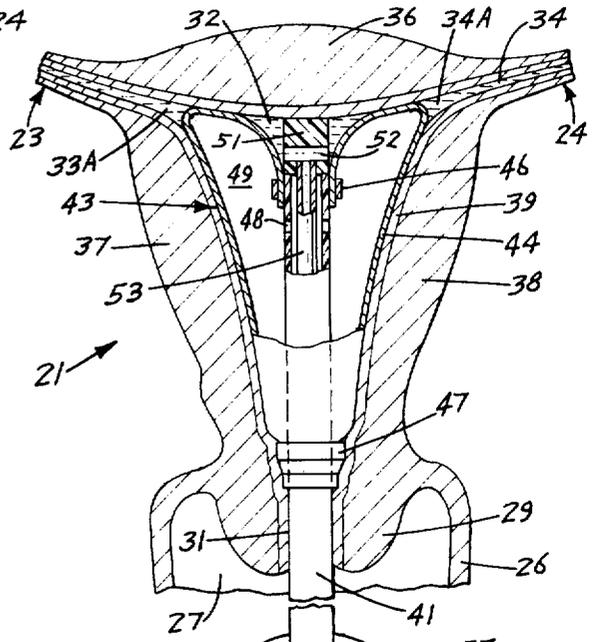
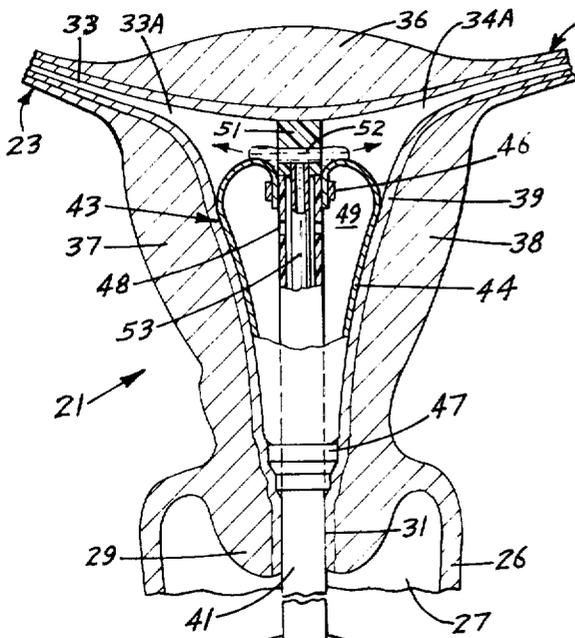


FIG. 4

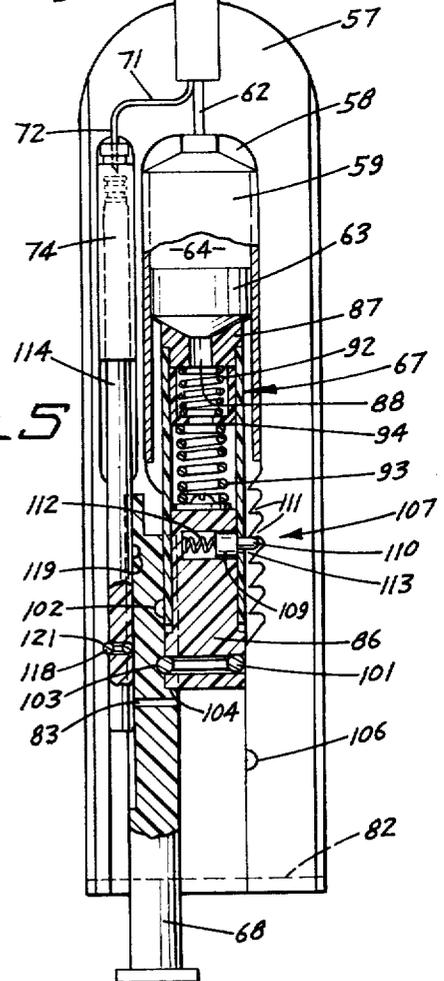


FIG. 5

SINGLE STROKE DISPENSING METHOD

BACKGROUND OF INVENTION

Liquid tissue adhesives or glues have been developed which polymerize when applied to moist living tissue. These adhesives have been used for various surgical procedures, both internally and externally. When the tissue adhesives are used, the cells adjacent the adhesives are damaged and eventually replaced with fibrous tissue. Liquid tissue adhesives have been injected into the uterine cavity of a female with a catheter in an effort to occlude the canals of the Fallopian tubes. The tissue adhesives, being sensitive to moisture, will set up in the uterine cavity if it is not quickly placed into the canals of the Fallopian tubes. Extreme pressures cannot be used to rapidly inject the tissue adhesive to the canals as the adhesives may be forced through the canals into the body cavity. The catheters and procedures used with the catheters are not designed to handle the liquid tissue adhesives and place these adhesives into the canals of the Fallopian tubes. Also, the catheters do not accommodate different sizes, shapes and characteristics of uteri and do not insure that the adhesives are placed in each canal of the Fallopian tubes. Also, the catheters may direct all of the material into one canal so that the excess material is forced through the canal and into the body cavity.

SUMMARY OF INVENTION

The invention is directed to an apparatus and method for dispensing a fluid, as a drug material, into both canals of the Fallopian tubes of a female primate. More specifically, the invention is directed to a method and apparatus for introducing a predetermined amount of tissue adhesive into the canals of the Fallopian tubes of a female from the uterine cavity. The apparatus has an elongated probe having a forward end carrying an expandable balloon assembly. A dispensing housing having a single actuator is used to expand the balloon assembly and discharge drug material into the uterine cavity. The dispenser has a first drive assembly operable to initially partially expand the balloon assembly to form a seal and holding structure in the lower portion of the uterine cavity. Continued movement of the actuator discharges the drug material into the uterine cavity above the partially expanded balloon assembly. Further continued movement of the actuator continues the expansion of the balloon assembly to displace the remaining space in the uterine cavity. The balloon assembly expands and forces the drug material into both canals of the Fallopian tubes. Substantially all of the drug material introduced into the uterine cavity is moved by the expanding balloon assembly into the canals of the Fallopian tubes in a short period of time. When a tissue adhesive is placed in the canals, it reacts with the tissue to polymerize the adhesive and thereby occlude the canals. The tissue adhesive is eventually replaced with scar tissue which permanently occludes the canals. The balloon assembly is contracted whereby it can be readily removed from the uterine cavity by withdrawing the actuator from the housing.

The drug material can be a mixture of materials which set up after they are mixed. Separate drug materials are moved to the discharge end of the dispenser and mixed at the end. The mixture of drug materials is directed into the uterine cavity. The expansion of the

balloon assembly forces the mixture of drug materials into the canals of the Fallopian tubes.

An object of the invention is to provide an apparatus and method of introducing a predetermined minimum amount of drug material into both canals of the Fallopian tubes of a female from the uterine cavity. Another object of the invention is to provide a dispensing apparatus and method which has an actuator movable to discharge tissue adhesives into the uterine cavity and move the tissue adhesives from the uterine cavity into the canals of the Fallopian tubes of a female before the adhesives can set up in the uterine cavity. Another object of the invention is to provide an apparatus for introducing in a short period of time a controlled amount of drug material into the canals of the Fallopian tubes under low pressure with a single and continuous action on the part of the operator. A further object of the invention is to provide an apparatus for introducing drug material into the canals of the Fallopian tubes which places a minimum amount of force on the walls of the uterus and can accommodate different sizes, shapes and characteristics of uteri. A further object of the invention is to provide an apparatus and method for introducing drug material into both canals of the Fallopian tubes which is not position sensitive and does not apply substantial pressure to the fluid material, whereby the fluid material is not forced into the blood stream or body cavity. Yet another object of the invention is to provide an apparatus and method of introducing material into both canals of the Fallopian tubes with the balloon assembly subjected to a maximum predetermined pressure to eliminate any over-expansion of the uterus. A still further object of the invention is to provide an apparatus for placing drug materials into the canals of the Fallopian tubes which is simple to operate and is used with a minimum of operator manipulative delay. Another object of the invention is to provide an apparatus and method for mixing separate drug materials, directing the mixed drug materials into the uterine cavity and forcing the mixed drug materials in the uterine cavity into the canals of the Fallopian tubes. Other objects and advantages of the apparatus and method of the invention are set out in the following specification and accompanying drawings.

IN THE DRAWINGS

FIG. 1 is a foreshortened sectional view of a reproductive system of a female primate accommodating a dispensing instrument of the invention for locating drug material in both canals of the Fallopian tubes;

FIG. 2 is a longitudinal sectional view of the dispensing assembly of the instrument of the invention;

FIG. 3 is a sectional view taken along the line 3—3 of FIG. 2;

FIG. 4 is a foreshortened sectional view of the female reproductive system accommodating the dispensing instrument shown in section with the balloon assembly partially inflated in the uterine cavity and drug material in the uterine cavity;

FIG. 5 is a foreshortened sectional view similar to FIG. 4 showing the balloon assembly fully expanded in the uterine cavity;

FIG. 6 is a foreshortened plan view, partly sectioned similar to FIG. 4, of a modification of the dispensing instrument; and

FIG. 7 is an enlarged sectional view of the discharge end of the dispensing instrument of FIG. 6.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawing, there is shown in FIG. 1 the dispensing instrument of the invention indicated generally at 20 with the probe located in the uterine cavity of a female primate. The female primate reproductive system shown generally at 21 has a uterus 22 joined to a pair of Fallopian tubes 23 and 24. The lower part of uterus 22 is integral with an elongated vagina 26. Vagina 26 has a vaginal cavity 27 having an opening or entrance 28. The opposite end of vaginal cavity 27 is in communication with the cervix 29. Cervix 29 has a cervical opening 31 providing a passage from the vaginal cavity 27 to the uterine cavity 32. Fallopian tubes 23 and 24 open, or have exits 33A and 34A, to opposite sides of the upper part of the uterine cavity 32.

The female primate uterus 22 is a generally pear-shaped, thick walled, hollow organ situated between the bladder and rectum. The uteri of female primates 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 32 is generally flattened and triangular in shape. Some uteri have cavities that have other shapes.

The Fallopian tubes 23 and 24 are paired, trumpet-shaped, muscular members about 12 cm in length which extend from the superior angles of the uterine cavity 32 to the ovaries (not shown). The outlets 33A and 34A of the canals 33 and 34 respectively can vary in position relative to the uterine cavity and relative to each other. The outlets 33A and 34A are usually symmetrically opposite each other, as shown in FIG. 1, and their position and proximity are principally related to the uterine size and configuration. Also, the size of the canals 33 and 34 and the size of the outlets 33A and 34A vary from female to female.

Fallopian tubes are commonly divided into isthmus, intramural and ampullary sections. Canals 33 and 34 provide passages for the movement of ova from the ovaries to the uterine cavity 32, 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 the mucosal lining.

Uterus 22 has a top wall or fundus 36 and side walls 37 and 38 which surround the uterine cavity 32. The inside of top wall 36 and the insides of side walls 37 and 38 have an inside lining or membrane 39 which is periodically sloughed off in the normal cycle of the female.

Dispensing instrument 20 has an elongated probe or tubular member 41 having a length sufficient to pass through the vaginal cavity 27 and into uterine cavity 32. Member 41 has a longitudinal passage 42 extended throughout its length. A balloon assembly indicated generally at 43 is mounted on the upper or outer end of tubular member 41. Balloon assembly 43 has a flexible and expandable sleeve member 44 surrounding the upper end of probe 41. A fastener 46, as a collar or thread, attaches the upper end of sleeve 44 to the probe 41. A similar fastener 47 attaches the opposite end of sleeve 44 to the probe 41. Probe 41 has a plurality of openings 48 which provide communication between

the passage 42 and a chamber 49 within sleeve member 44.

Sleeve member 44 is a tubular sheet member of soft and relaxed, flexible and elastic material, as rubber or plastic, which expands with a minimum tension. For example, thin latex rubber having low surface tension is suitable material for sleeve member 44. The low surface tension of the rubber allows the rubber to uniformly expand with relatively low pressure. The material of sleeve member 44 readily expands to displace uterine cavity 32 by conforming to the shape of the uterine cavity without applying extreme pressure to localized portions of the uterus walls 37 and 38. When cavity 32 is fully displaced with sleeve member 44, as shown in FIG. 5, sleeve member 44 is in uniform surface engagement with the inside lining 39. 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 probe 41 is closed with a head 51. Head 51 has a transverse passage 52 open to opposite sides of head 51. An elongated tube 53 is secured to the head 51. Tube 53 extends the length of probe 41 and has a passage 54 for carrying a drug material to the transverse passage 52 which directs the drug material in opposite directions in two portions into the upper section of the uterine cavity 32. Head 51 has a longitudinal section or cap 56 having a top surface or wall adapted to engage the inner wall of fundus 36. The cap 56 spaces the passage 52 from the inner wall of fundus 36.

Referring to FIG. 2, dispensing instrument 20 has an elongated housing or body 57 attached to the end of probe 41. Body 57 has a first chamber 58 accommodating an elongated cylinder 59. Cylinder 59 has a forwardly directed neck 61 connected to a tube 62. Tube 62 has a passage which is in communication with passage 42 of the probe 41 so that fluid, as air, in cylinder 59 can flow via passage 42 into chamber 49 of the balloon assembly and thereby expand the sleeve member 44. The open end of cylinder 59 is closed with a piston 63 to trap the fluid in chamber 64. The cylinder 59 has a hole 66 adjacent the piston 63 to allow air and sterilizing gases to flow into the chamber 64.

Located rearwardly of the piston 63 is a first drive assembly indicated generally at 67 operable to move the piston 63 into cylinder 59. The first drive assembly 67 is connected to an actuator 68 projected rearwardly from body 57.

The body 57 has a second chamber 69 located adjacent one side of the first chamber 58. A tube 71 is mounted in the body 57 to connect the tube 53 to chamber 69. Tube 71 has a longitudinally extended needle 72 projected into chamber 69. The opposite end of tube 71 is mounted in a plug 73 closing the end of probe 41 and connected to the tube 53 which leads to the head 51. Chamber 69 has an elongated shape and is open to the top of body 57, as shown in FIG. 1. A cylindrical container or ampulla 74 is located in chamber 69 in alignment with needle 72. The forward end of container 74 has a pierceable plug 76 aligned with needle 72. The open end of container 74 is closed with a slidable piston 77 to trap drug material 78 in container 74.

A second drive assembly indicated generally at 79 extends rearwardly from container 74 and is drivably connected to actuator 68. Actuator 68 is operable in a sin-

gle stroke or movement to complete the entire dispensing of drug material into the canals of the Fallopian tubes. The rear portion of housing 57 has outwardly and oppositely directed flanges 81 and 82 which serve as finger grips during actuation of actuator 68. Actuator 68 has a hole 83 for accommodating a pin 83A to hold the actuator 68 in the inoperative position. The pin 83A prevents accidental actuation of the dispensing instrument.

Drive assembly 67 is a force-transmitting mechanism operable to move piston 63 into cylinder 59 and thereby increase the pressure in the fluid system for the balloon assembly 43 and expand the sleeve member 44. The drive assembly 67 has a cylinder or sleeve 84 slidably carrying a body 86. The opposite or upper end of sleeve 84 is attached to a head 87. Head 87 has a central hole 88 which provides access into sleeve 84. The outer end of piston 63 has a cone-shaped portion 89 to accommodate the cone-shaped outer end of head 87. The hole 88 is aligned with an adjusting screw 91 threaded into body 86. The position of screw 91 relative to body 86 can be changed with the use of a tool, as a screwdriver, extended through hole 88. A pair of springs 92 and 93 bias the sleeve 84 and body 86 in opposite directions whereby the first drive assembly 67 is biased into its elongated position. Spring 92 abuts against head 87. Spring 93 rests on screw 91. Adjusting the position of screw 91 adjusts the tension or force of the spring 93 which biases the head 87 and body 86 in opposite directions. Screw 91 performs a fine adjustment of the spring force to accommodate variations in spring 93 and to provide for desired fluid pressure in chamber 49. A washer 94 having a central hole for rod 88 is located between springs 92 and 93. Spring 92 is a light or weak spring as compared to spring 93. The weak spring 92 will compress under a light load, for example 2-3 psi, whereby the washer 94 will abut against head 87. This insures the partial expansion of sleeve member 44 at low predetermined maximum pressure. The predetermined maximum pressure is determined by the compression force characteristics of spring 93 and permits the instrument to be used with all shapes and sizes of uteri, as the spring 93 adjusts for the differences in the uteri.

Sleeve 84 and body 86 are held in assembled relation with a pin 96 extended through elongated longitudinal slot 97 in sleeve 84. Slot 97 permits the sleeve 84 to move relative to body 86 as the springs 92 and 93 are compressed. Pin 96 projects through slot 97 into an elongated linear groove 98 in the housing 57 and thereby prevents rotational movement of the drive assembly 67 relative to the housing 57.

Body 86 has a transverse passage 99 accommodating a drive link 101. The drive link 101 has spherical members at its opposite ends joined with a transverse member or tube. The first end of drive link 101 is located in a recess 102 in the side of the actuator 68. Actuator 68 has a second recess 103 for accommodating the link 101. Located below recess 103 is a shoulder 104 adapted to engage the end of body 86 when link 101 is in recess 103. Housing 57 has a recess 106 adapted to accommodate the opposite or right end of drive link 101. Recess 106 is located in a forward direction from the initial position of drive link 101, as shown in FIG. 2, so that the actuation of the drive assembly 67 is temporarily halted or interrupted until the end of body 86 engages the shoulder 104, at which time the movement

of the drive assembly 67 is continued. The locations of recesses 106 and 121 in housing 57 can be coordinated with each other so that the initial expansion of sleeve member 44 overlaps the discharge of drug material into the uterine cavity and the continued expansion of sleeve member 44. In this case, the sleeve member 44 has a continuous expansion until the sleeve member 44 has been subjected to the maximum fluid pressure.

A lock unit indicated generally at 107 is movably located in a bore 108 in body 86. Lock unit 107 has a plunger 109 carrying an outwardly directed finger or projection 110. Finger 110 is adapted to engage one of a plurality of teeth 111 located in housing 57. The teeth 111 face drive assembly 67. Teeth 111 are ratchet teeth which allow only reverse movement of the drive assembly when lock unit 107 is in operative position with teeth 111. Plunger 109 is biased in an outward direction with a spring 112 located at the base of bore 108. Sleeve 84 has a hole 113 spaced forwardly from finger 110. On compression of springs 92 and 93, the body 86 moves relative to sleeve 84 until the finger 110 is aligned with hole 113, at which time spring 112 will bias finger 110 through hole 113 into engagement with one of the teeth 111. This prevents further movement of the drive assembly 67 in a forward direction and limits the pressure of the fluid in the chamber 49 of sleeve member 44.

The second drive assembly 79 is operable to drive the container 74 onto needle 72 and force the piston 77 into the container and thereby drive the drive material 78 through needle 72 into the tube 53. Tube 53 carries the fluid to head 51 where it is discharged in opposite directions into the upper portion of uterine cavity 32. Returning to FIG. 2, second drive assembly 79 has an elongated linear plunger 114 slidably located in a longitudinal passage 115 in housing 57. Plunger 114 has a forward end 116 adapted to engage piston 77. The opposite end of plunger 114 has a transverse passage 117. A movable drive link 118 is located in passage 117. Link 118 has spherical ends that are connected with a rigid member such as a tube. One end of drive link 118 is located in a semi-spherical recess 119 located in the side of actuator 68. The opposite end of drive link 118 rides on the side wall of the housing 57 forming part of passage 115, thereby retaining the link in recess 119. Housing 57 has a recess 121 forward of the link 118 so that the link 118 will remain in driving relationship with actuator 68 until the link is aligned with recess 121. At this time the link 118 will be forced into recess 121 whereby actuator 68 will continue to move in a forward direction and plunger 114 will remain stationary.

In use, the dispensing instrument 20 is packaged with container 74 located in the chamber 69. The actuator 68 is locked in an inoperative position with a pin 83A extended through hole 83. The pin 83A engages the end of the housing 57 to prevent actuator 68 from moving into the housing. The entire dispensing instrument is sterilized before it is used.

The operating procedure begins with inserting the balloon assembly 43 into the vaginal cavity 27, through cervical opening 31 and into the uterine cavity 32 shown in FIG. 1. Sleeve member 44 is in the collapsed condition so that the balloon assembly can be readily positioned in the uterine cavity. The probe 41 is moved into the uterine cavity until head 51 engages the fundus 36. 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 23 and 24. As shown in FIG. 1, balloon assembly 43 is centrally located in the uterine cavity 32. In some cases, the balloon assembly may be angularly positioned in the uterine cavity adjacent one side of the cavity. Dispensing instrument 20 is effective in placing drug material into both canals of the Fallopian tubes regardless of the position of the balloon assembly in uterine cavity 32.

Pin 83A is removed from hole 83, making plunger 68 ready to be moved into the housing 57 to inflate the expandable sleeve member 44 and dispense drug material into the uterine cavity 32 and then fully expand the sleeve member 44 to pump or force the drug material into the canals of the Fallopian tubes. The operator uses flanges 81 and 82 as finger rests so that inwardly directed force can be applied to the actuator 68. As shown in FIG. 4, the actuator 68 has been moved into housing 57 a short distance such that the first drive assembly has moved the piston 63 into the cylinder 59. This expands the sleeve member 44 so that it forms a plug or seal in the lower portion of the uterine cavity 32. The sleeve member 44 is expanded into firm engagement with the inside lining or membrane 39. Drive link 101 couples actuator 68 to the first drive assembly 67 to transmit the motion of actuator 68 to the drive assembly 67. This moves piston 63 into chamber 64. The drive link 118 couples plunger 114 with actuator 68 so that the forward 116 of the actuator engages the piston 77 in the container 74. This moves the entire container 74 in a forward direction. The needle 72 pierces plug 76, thereby moving the needle through plug 76 and into the chamber containing the drug material 78. The drive link 101 is aligned with recess 106 in the housing 57. This permits the drive link 101 to move to the right, as shown in FIG. 4, releasing the drive link from the actuator 68. The continued movement of the actuator 68 applies force to plunger 114 which moves piston 77 into container 74. Drug material 78 is forced via tubes 71 and 53 to head 51. The drug material is discharged in opposite directions via the transverse passage 52 into the upper part of uterine cavity 32.

As shown in FIG. 5, the continued movement of actuator 68 places the shoulder 104 in engagement with the bottom of the body 86. At the same time drive link 101 moves into recess 103, thereby releasing drive link 101 from recess 106. Actuator 68 is moved into housing 57, thereby increasing the pressure in the chamber 64. This further expands sleeve member 44. The expanding sleeve member 44 drives the drug material from the upper portion of the uterine cavity through exit openings 33A and 34A of the canals 33 and 34 of the Fallopian tubes. The sleeve member 44 continues to expand until the fluid pressure in the system containing the sleeve member and chambers 49 and 64 is approximately 8 psi. Other pressures can be selected as the upper pressure limit. This pressure is determined by the compression characteristics of the springs 92 and 93 and adjusting screw 91. The compression of springs 92 and 93 permits body 86 to move into the sleeve 84. This movement continues until finger 110 is aligned with opening 113. When finger 110 and hole 113 are aligned, the spring 112 forces the finger 110 through hole 113 and into the space between adjacent teeth 111. Finger 110 anchors on a forward tooth, thereby preventing further movement of the actuator 68 into

housing 57. Since actuator 68 is prevented from moving into the housing 57 by lock unit 107, the pressure in the balloon chamber 49 is limited to a selected maximum pressure, depending on the compression characteristics of the springs 92 and 93.

As the actuator 68 is moved into housing 57 from the position shown in FIG. 4 to the position shown in FIG. 5, drive link 118 moves from recess 119 into recess 121. This terminates the forward motion of plunger 114 to stop dispensing of the drug material into uterine cavity 32. The continued movement of actuator 68 increases the fluid pressure in the chamber 49, thereby expanding sleeve member 44 to pump or push the drug material from uterine cavity 32 into canals 33 and 34 of the Fallopian tubes. The pumping action ceases when the sleeve member 44 is fully expanded, as shown in FIG. 5. This locates the drug material in the Fallopian tubes as the pumping force applied to the drug material is insufficient to move the drug material through the Fallopian tubes into the body cavity.

The actuator 68 is then pulled out of housing 57. Drive link 101, being located in recess 103, provides a drive connection between body 86 and plunger 68. The finger 110 of lock unit 107 slips over the teeth 111. This pulls the piston 63 out of chamber 64. The fluid in the chamber 49 flows back into chamber 64, contracting sleeve member 44. This releases the sleeve member 44 from engagement with lining 39 and enables the balloon assembly 43 to be withdrawn from the uterus of the patient.

When drug materials of the cyanoacrylate tissue adhesive type are used canals 33 and 34 will be permanently occluded. Tissue adhesives, as the cyanoacrylate type, cause fibroblastic proliferation which in time closes the canals 33 and 34. The tissue adhesives polymerize when exposed to a hydroxyl ion source, such as water. The cells adjacent the adhesive are damaged and are eventually replaced with fibrous tissue. Certain other tissue adhesives will polymerize in response to body heat or other stimuli.

In terms of method, the dispensing instrument is used to place drug material in both canals of the Fallopian tubes via the uterine cavity. The contracted balloon assembly is initially placed in the uterine cavity, as shown in FIG. 1, by inserting the balloon assembly 43 through cervical opening 31. The actuator 68 is then released so that it can be moved into housing 57. The operator moves the single actuator 68 with a continuous movement into the housing 57 to complete the operation. The first drive assembly 67 and second drive assembly 79 are coordinated to sequentially operate to partially expand the sleeve member 44 to displace the lower portion of the uterine cavity and form a seal with the lower walls of the uterine cavity. The plunger 114 then engages the piston 77 to force the container onto needle 72 and force the drug material 78 from the container and discharge the drug material in opposite directions into the uterine cavity 32 above the partially expanded sleeve member 44. This operation is shown in FIG. 4. The continued movement of actuator 68 further expands the partially expanded sleeve member 44 to fully displace uterine cavity 32. This is done by subjecting the sleeve member 44 to fluid under pressure by moving the piston 63 into chamber 64. The actuator 68 will continue to move until lock unit 107 engages one of the teeth 111, thereby preventing further expansion of the sleeve member 44. The sleeve member 44 can

only be subjected to a maximum predetermined pressure so as not to place undue pressure on the walls of the uterus. The expanding sleeve member 44 forces or pumps the drug material that has been discharged into the uterine cavity through the openings 33A and 34A and into the canals 33 and 34 of the Fallopian tubes. The sleeve member 44 is then contracted by relieving the pressure applied thereto. This is done by pulling the actuator 68 out of the housing 57 so that the fluid can move into the container chamber 64. The instrument is then removed from the uterine cavity via the cervical opening and vaginal passage.

The drug material 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 drug material can be a tissue adhesive. The tissue adhesive can be a cyanoacrylate-type material or like material used as surgical glues. Cyanoacrylate is a liquid plastic which sets up or polymerizes in response to moisture and thereby functions to occlude the canals of the Fallopian tubes. The cyanoacrylates include, but are not limited to, methyl cyanoacrylate, methyl-2-cyanoacrylate, ethyl cyanoacrylates, n-propyl cyanoacrylates, n-butyl cyanoacrylates, n-amyl cyanoacrylates, n-hexyl cyanoacrylates, n-heptyl cyanoacrylates, isobutyl-2-cyanoacrylates and n-octyl cyanoacrylates. The drug material can also be of a type that sets up in response to body heat or other stimuli. It may be a type which produces permanent occlusion or of a type which will temporarily block or occlude the canals of the Fallopian tubes, after which the canals may be reopened to resume their normal function. Examples of other drug materials are contraceptive gels, water, silicone elastomers, formaldehyde-type materials and like materials.

Referring to FIGS. 6 and 7, there is shown a modification of the dispensing instrument indicated generally at 20A. Dispensing instrument 20A and the female reproductive system associated therewith follow the dispensing instrument shown in FIGS. 1-5. Corresponding parts of the instrument and reproductive system have the same reference numerals with the suffix A.

Dispensing instrument 20A uses a two-part drug material which is mixed at the end of the probe as it is forced into the upper part of the uterine cavity 32A. The mixed drug material of the sleeve member 44A to displace uterine cavity 32A.

Head 251 is mounted on the outer end of the probe or tubular member 41A. The head 251 has a transverse passage 252 having oppositely directed discharge openings for directing the drug material in two parts into the upper part of the uterine cavity 32A. A first tube 253 and a second tube 254 are connected to the head 251. The head has a mixing chamber or passage 255 in fluid communication with the passages of the tubes 253 and 254 and the transverse passage 252. The drug materials flow through the tubes 253 and 254 and are mixed in chamber 255. The mixing continues as the drug materials are separated and forced in opposite directions in passage 252, as indicated by the arrows.

Housing 57A has a pair of chambers 256 located adjacent chamber 58A for accommodating a pair of ampullae or containers 257 and 259. Container 257 stores a first drug material 258. Container 259 stores a second drug material 260. A first piston 261 is slidably located in container 257. In a similar manner a piston 262 is slidably located in container 259. Plunger 114A of the second drive assembly 79A has a bifurcated end form-

ing a pair of fingers 263 and 264. Finger 263 is positioned in container 257 and engages piston 261. Finger 264 is located in container 259 and engages piston 262. The tubes 253 and 254 extend into housing 57A and terminate in needles 266 and 267. Needles 266 and 267 are in alignment with the pierceable end portions of containers 257 and 259.

On actuation of the single actuator 68A, the first drive assembly 67A will operate to initially expand the sleeve member 44A to fill and seal the lower portion of the uterine cavity 32A. Continued movement of actuator 68A will engage the second drive assembly 79A to move the fingers 263 and 264. Plunger 114A moves in a forward or upward direction, as shown in FIG. 6, to drive the containers 257 and 259 onto needles 266 and 267, respectively. The fingers 263 and 264, being in engagement with the pistons 261 and 262, simultaneously force the drug materials 258 and 269 through the tubes 254 and 253. The drug materials are simultaneously discharged into the mixing chamber 255. Substantially the same amount of drug materials is introduced into the mixing chamber 255 so that the mixture of drug materials contains about 50 percent of the first drug material and 50 percent of the second drug material. The mixed drug material, indicated at 268 in FIG. 6, is introduced into the upper part of uterine cavity 32A. The mixed drug material 268 flows in opposite directions in substantially equal amounts. The flow is continuous until the plunger 14A has reached the end of its stroke. At this time the continuous movement of the actuator 68A further expands the sleeve member 44A forcing the mixed drug material into the canals 33A and 34A of the Fallopian tubes.

Drug materials 258 and 260 can be the type which when mixed will set up to form a semi-rigid plastic material. The mixture can be responsive to moisture in the tissues to set up or responsive to body heat or other factors to set up. The mixture has a reaction time such that it can be introduced into canals 33A and 34A before it will set up. The following is an example of the materials of the two-part drug material. The two-part drug materials may be two-part epoxies, two-part tissue adhesives, silicone RTV, or a polymer consisting of Dow Corning Silastic 382 Medical Elastomer and 360 Medical Fluid. It is understood that other types of drug materials that are mixed and set up can be used. Furthermore, the ratio of the drug materials can be varied by increasing the size of one of the containers. For example, two parts of the first drug material can be mixed with one part of the second drug material by using the appropriate size containers in the dispenser housing 57A.

While there have been shown and described preferred embodiments of the dispensing instrument and method of introducing materials into both canals of the Fallopian tubes of a female, it is understood that various changes in the structure and method may be made by those skilled in the art without departing from the spirit of the invention.

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

1. A method of placing material into both canals of the Fallopian tubes of a female open to the uterine cavity with an expandable sleeve means comprising: introducing the sleeve means into the uterine cavity in a contracted condition, expanding the sleeve means to

displace part of the uterine cavity by subjecting the sleeve means to a fluid pressure, discharging material into the uterine cavity above the expanded sleeve means in opposite lateral directions which separates the material into two portions, continuing the expansion of the sleeve means to fully displace the uterine cavity by subjecting the sleeve means to an increased fluid pressure thereby forcing the material in the uterine cavity into the canals of the Fallopian tubes, said continuing expansion of the sleeve means moves said two portions of the material into the canals of the Fallopian tubes, contracting the sleeve means by reducing the fluid pressure applied thereto, and removing the contracted sleeve means from the uterine cavity.

2. The method of claim 1 including: preventing an increase in the fluid pressure applied to the sleeve means when the sleeve means has been fully expanded.

3. The method of claim 1 wherein: the sleeve means is continuously expanded from the contracted condition to the fully expanded position, and the drug material is introduced into the uterine cavity after initial expansion of the sleeve means.

4. The method of claim 1 wherein: the material is a first material and a second material, said first material and second material being mixed together during the movement of the materials before the materials are discharged into the uterine cavity.

5. The method of claim 1 wherein: the sleeve means is partially expanded, the material is discharged into the uterine cavity, and the sleeve means is fully expanded by a single continuous movement of a single actuator.

6. A method of placing material into both canals of the Fallopian tubes of a female open to the uterine cavity with an expandable sleeve means comprising: introducing the sleeve means into the uterine cavity in a contracted condition, expanding the sleeve means to displace part of the uterine cavity by subjecting the sleeve means to a fluid pressure, discharging a first material and a second material into the uterine cavity above the expanded sleeve means, said first material and second material being mixed together during movement of the materials before the materials are discharged into the uterine cavity, continuing the expansion of the sleeve means to fully displace the uterine cavity by subjecting the sleeve means to increased fluid pressure thereby forcing the material in the uterine cavity into the canals of the Fallopian tubes, contracting the sleeve means by reducing the fluid pressure applied thereto, and removing the contracted sleeve means from the uterine cavity.

7. The method of claim 6 wherein: the sleeve means is partially expanded, the first material and second material are discharged into the uterine cavity, and the sleeve means is fully expanded by a single continuous movement of a single actuator.

8. The method of claim 6 including: preventing an increase in the fluid pressure applied to the sleeve means when the sleeve means has been fully expanded.

9. The method of claim 6 wherein: the sleeve means is continuously expanded from the contracted condition to fully expanded position, and the mixed first and second materials are introduced into the uterine cavity after initial expansion of the sleeve means.

10. A method of placing material into both canals of the Fallopian tubes of a female open to the uterine cavity with an expandable sleeve means comprising: intro-

ducing the sleeve means into the uterine cavity in the contracted condition, expanding the sleeve means to displace part of the uterine cavity by subjecting the sleeve means to a fluid pressure by movement of a single actuator, discharging material into the uterine cavity above the expanded sleeve means with continued movement of the single actuator, continuing the expansion of the sleeve means to fully displace the uterine cavity by subjecting the sleeve means to an increased fluid pressure by continuous movement of the single actuator thereby forcing the material in the uterine cavity into the canals of the Fallopian tubes, contracting the sleeve means by reducing the fluid pressure applied thereto, and removing the contracted sleeve means from the uterine cavity.

11. The method of claim 10 including: preventing an increase in the fluid pressure applied to the sleeve means when the sleeve means has been fully expanded.

12. The method of claim 10 wherein: the sleeve means is continuously expanded from the contracted condition to the fully expanded position and the material is introduced into the uterine cavity after the initial expansion of the sleeve means by the continuous movement of the single actuator.

13. The method of placing material into both canals of the Fallopian tubes of a female open to the uterine cavity with an expandable sleeve means comprising: introducing the sleeve means into the uterine cavity in a contracted condition, expanding the sleeve means to displace part of the uterine cavity in response to movement of a single actuator, discharging material into the uterine cavity above the expanded sleeve means in response to further movement of the single actuator, continuing the expansion of the sleeve means to fully displace the uterine cavity in response to continuing movement of the single actuator thereby forcing the material in the uterine cavity into the canals of the Fallopian tubes, contracting the sleeve means, and removing the contracted sleeve means from the uterine cavity.

14. The method of claim 13 wherein: the material is discharged into the uterine cavity in opposite lateral directions which separates the material into two portions, said continuing expansion of the sleeve means moves said two portions of the material into the canals of the Fallopian tubes.

15. The method of claim 13 including: preventing an increase of the size of the sleeve means when the sleeve means has been fully expanded.

16. The method of claim 13 wherein: the material is a first material and a second material, said first material and second material being mixed together during the movement of the materials before the materials are discharged into the uterine cavity.

17. The method of placing material into canals of tubes connected to a structure having a cavity, said canals being open to the cavity with an expandable sleeve means comprising: introducing the sleeve means into the cavity in a contracted condition, expanding the sleeve means to displace part of the cavity in response to movement of a single actuator, discharging material into the cavity above the expanded sleeve means in response to further movement of the single actuator, continuing the expansion of the sleeve means to fully displace the cavity in response to continuing movement of the single actuator thereby forcing the material in the cavity into the canals of the tubes, contracting the

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sleeve means, and removing the contracted sleeve means from the cavity.

18. The method of claim 17 wherein: the material is discharged into the cavity in opposite lateral directions which separates the material into two portions, said continuing expansion of the sleeve means moves said two portions of the material into the canals of the tubes.

19. The method of claim 17 including: preventing an

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increase of the size of the sleeve means when the sleeve means has been fully expanded.

20. The method of claim 17 wherein: the material is a first material and a second material, said first material and second material being mixed together during the movement of the materials before the materials are discharged into the cavity.

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