United States Patent [19]

Bolduc et al.

[11] **3,871,374**

[45] **Mar. 18, 1975**

[54] **DISPENSING INSTRUMENT**

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[73] Assignee: **Population Research Incorporated,** Minneapolis, Minn.

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[21] Appl. No.: **394,727**

[52] **U.S. Cl.** ..... **128/235,** 128/1 R

[51] **Int. Cl.** **A61m 1/00**

[58] **Field of Search** ..... 128/235, 349, 234, 224, 128/246, 127, 129, 126, 1 R, 216, 260, 240, 241, 341, 232, 2 A

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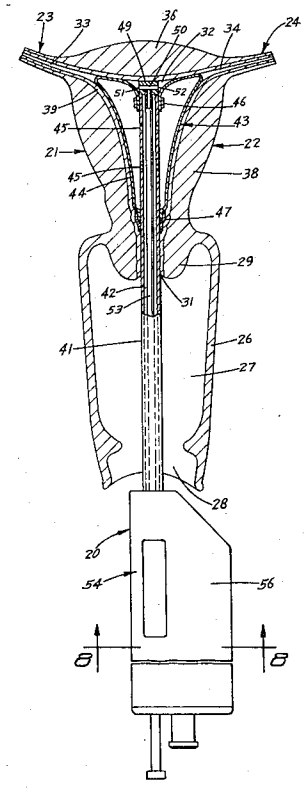
[57] **ABSTRACT**

A fluid dispensing instrument and method for introducing a fluid, as a drug material, into the canals of the Fallopian tubes of a primate female. The dispensing instrument has a tubular member carrying an expandable balloon assembly. The balloon assembly has a sleeve member which is initially expanded by operating an actuator assembly to substantially displace the entire uterine cavity and moniter the integrity of the walls of the uterus. The sleeve member is partially contracted by releasing the actuator assembly. A control mechanism cooperates with the actuator assembly to limit the fluid pressure on the sleeve member to a perdetermined pressure. Drug material is introduced into the upper portion of the uterine cavity above the partially expanded balloon assembly by operating a plunger which drives a container storing the drug material onto a needle. The balloon assembly is then fully expanded by operation of the actuator assembly to force the drug material from the upper portion of the uterine cavity into the canals of the Fallopian tubes. The expanding sleeve member forces the drug material into both canals.

28 Claims, 12 Drawing Figures



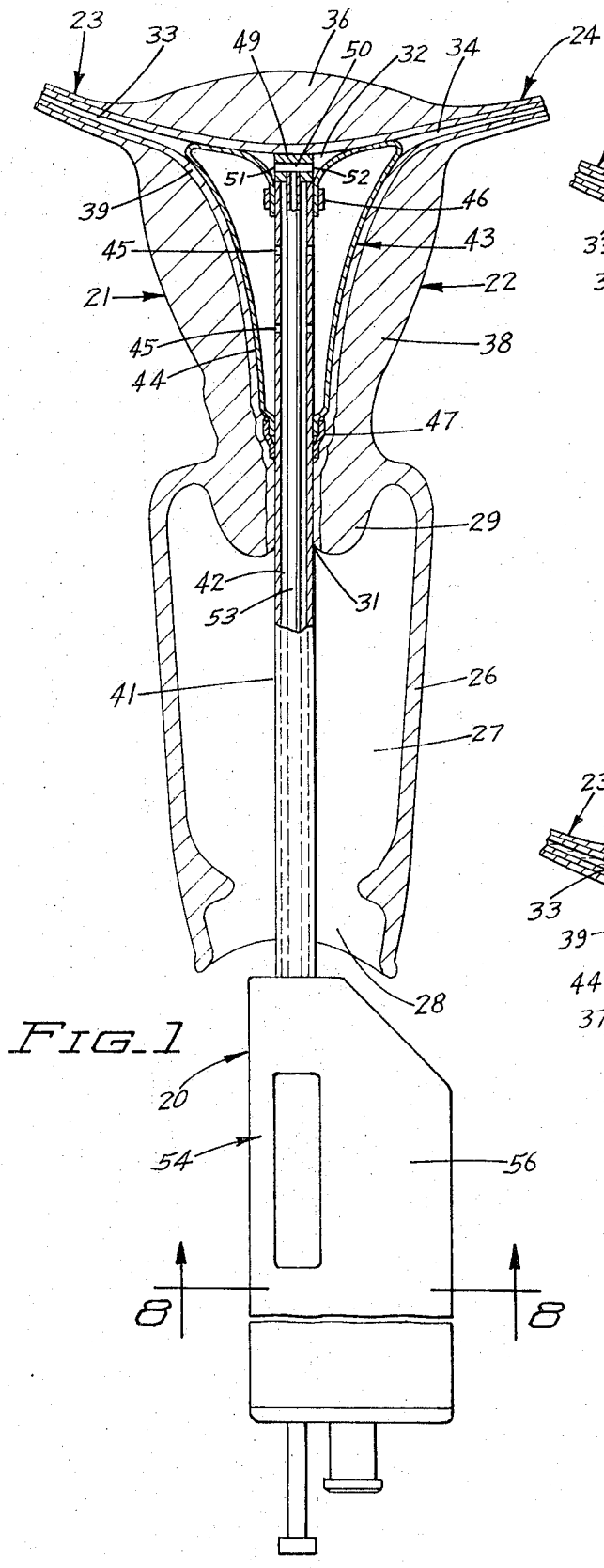


FIG. 1

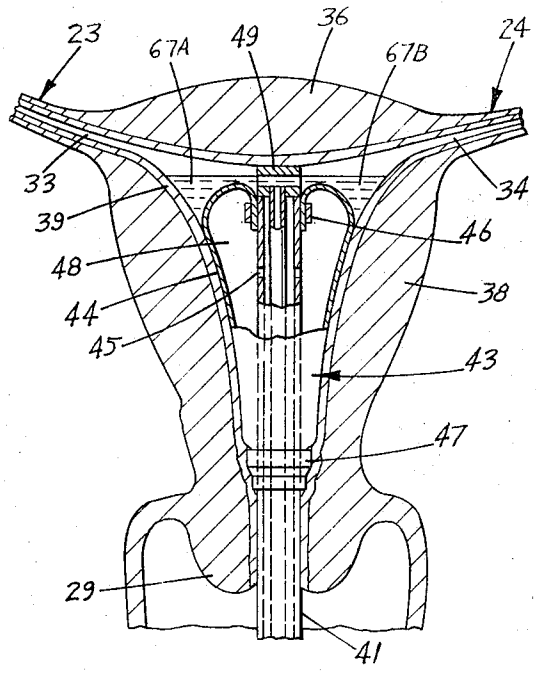


FIG. 2

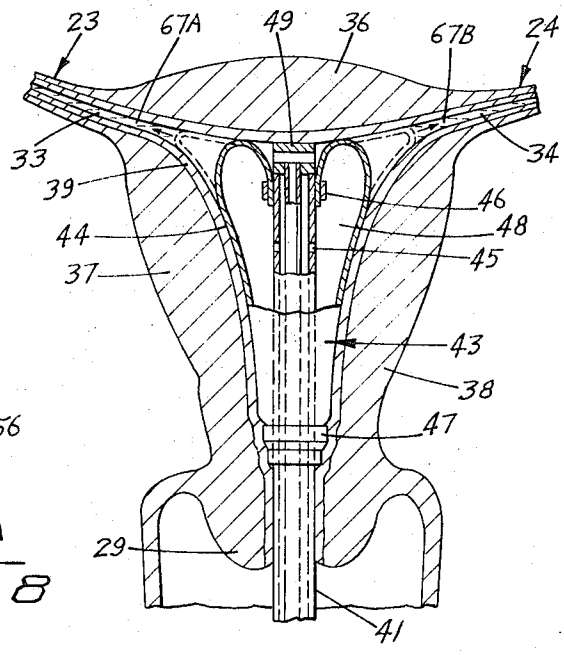


FIG. 3

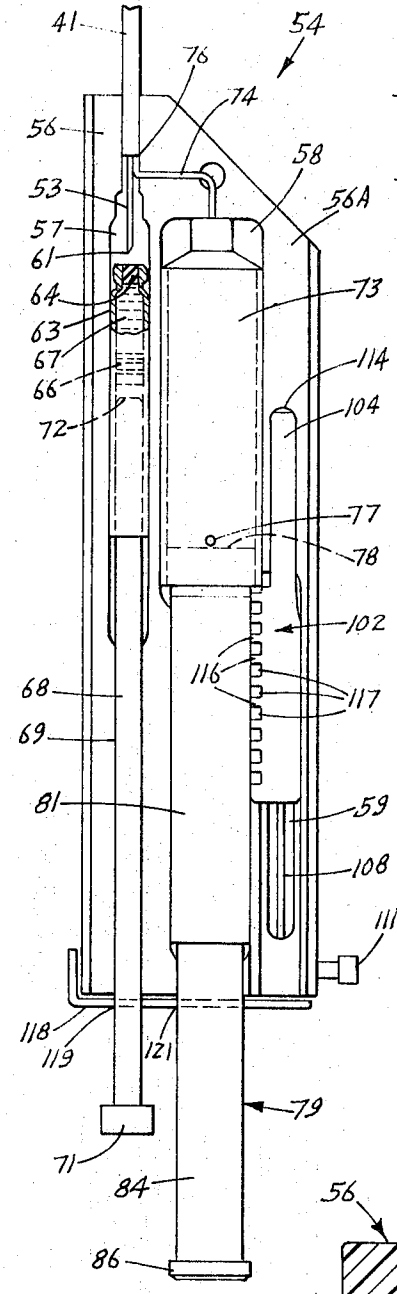


FIG_4

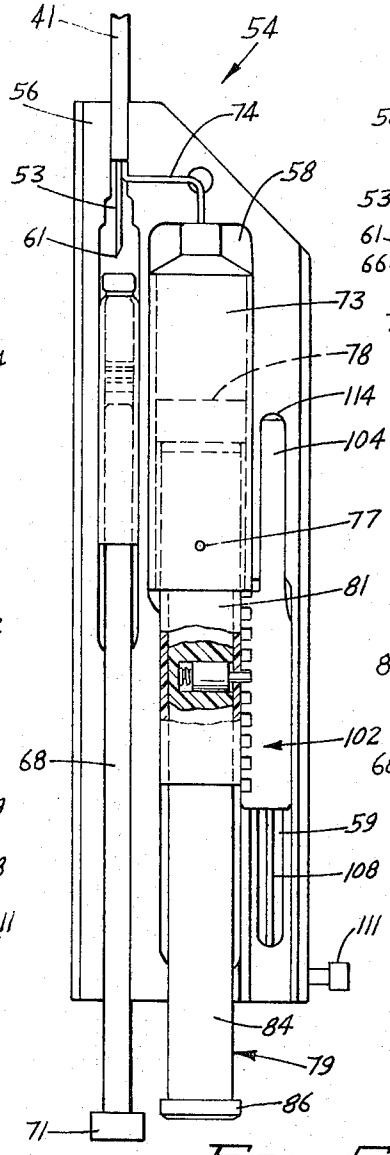


FIG_5

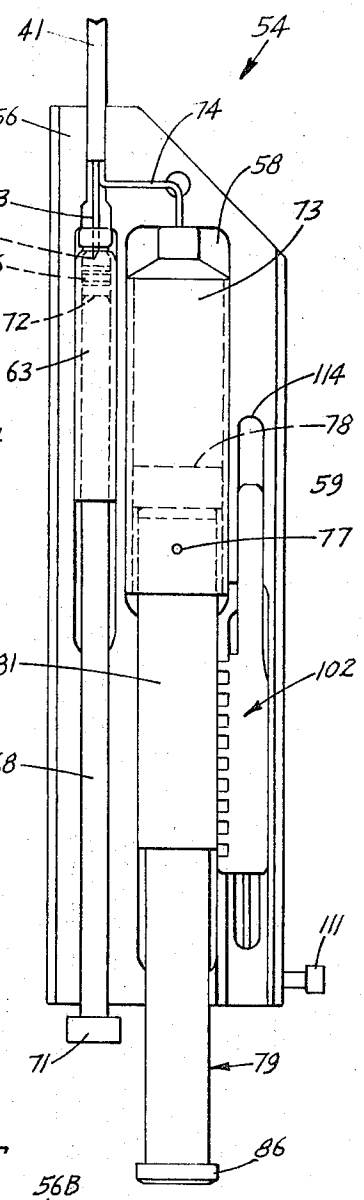


FIG_6

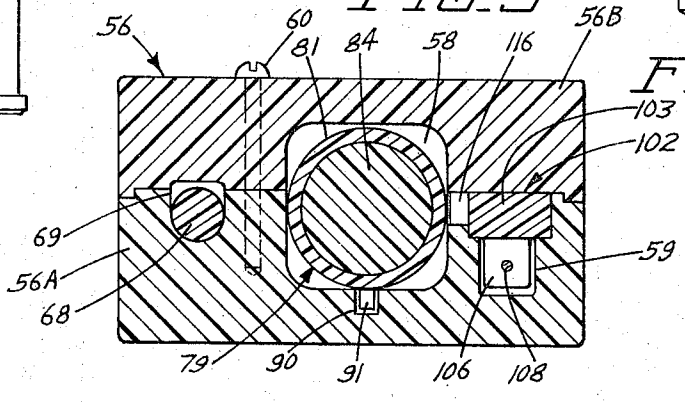


FIG_8

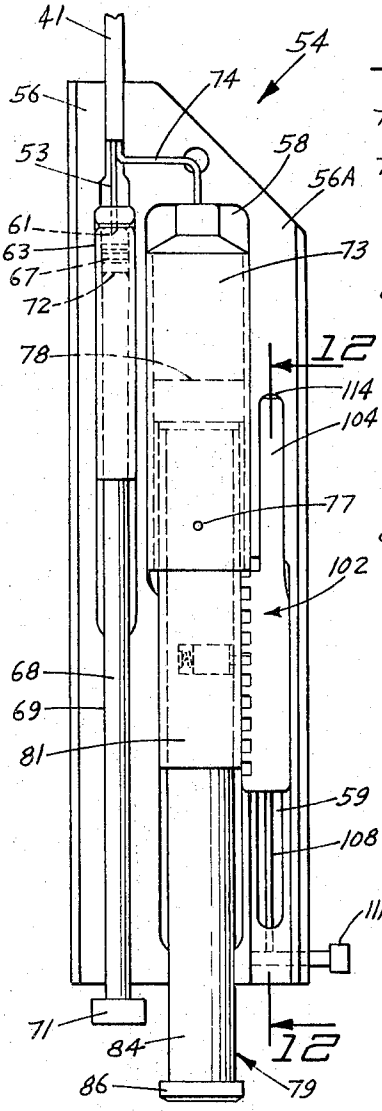
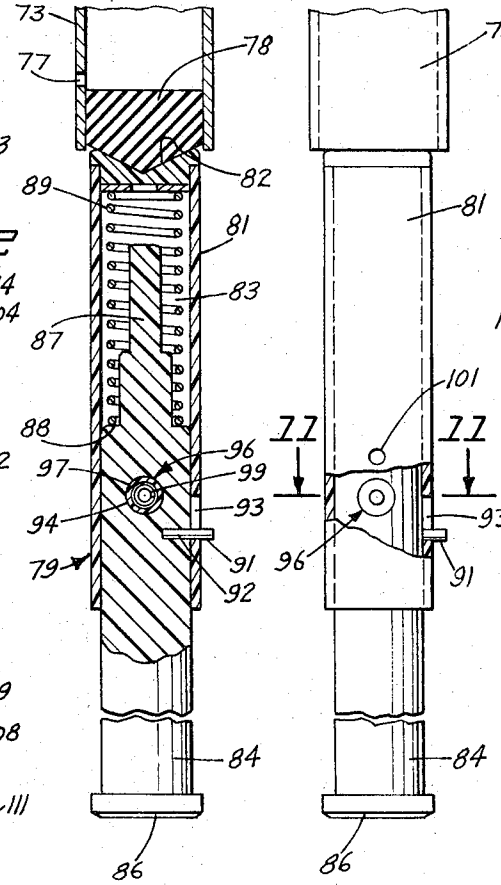


FIG_7

FIG_10 FIG_9



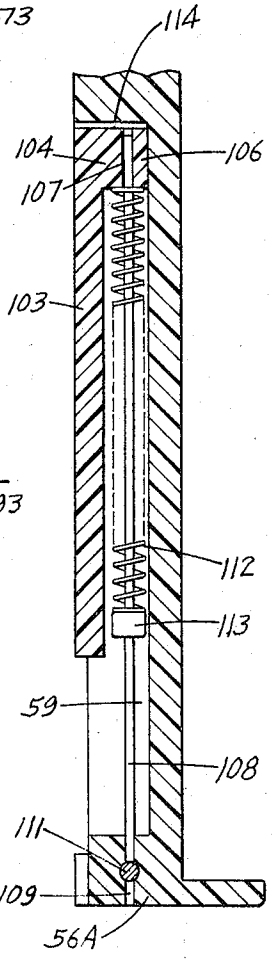


FIG_12

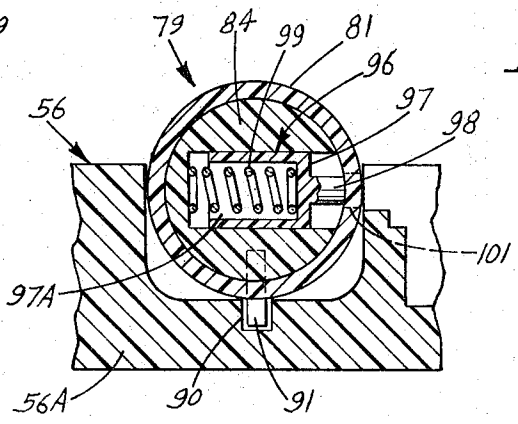


FIG_11

DISPENSING INSTRUMENT

BACKGROUND OF THE INVENTION

Bilateral disection of the Fallopian tubes is a common surgical procedure used to sterilize a female. This procedure involves severing and tying the Fallopian tubes. Intrauterine devices, as plugs and wires, are used to temporarily sterilize a female. These devices include plugs which are inserted into the canals of the Fallopian tubes to prevent ova from passing into the uterus. Smith in **1849** described a method of treating sterility by passing whale bone splints into the canals. These devices do not insure that the ova cannot flow through the canals into the uterus. The devices can be dislodged and lost without the female being aware of it. There is no assurance that the devices are effective. Climber in U.S. Pat. Nos. 3,675,693 and 3,680,245 discloses plugs attached to the uterine wall to block the entrance of ova into the uterus from the Fallopian canals and the exit of sperm from the uterine cavity into the Fallopian canals. These plugs are designed to effect temporary sterilization in that they can be removed and do not permanently block the canals of the Fallopian tubes. Plug contraceptive devices are not entirely effective in that it is possible for ova to by-pass the plugs and enter the uterus.

Liquid tissue adhesives have been developed which polymerize when applied to moist living tissue. These adhesives have been used for various surgical procedures. When the tissue adhesives are used, the cells adjacent the tissue are damaged and eventually replaced with a fibrous tissue. A liquid tissue adhesive has been injected into the uterine cavity with a catheter to occlude the canals of the Fallopian tubes. Studies have been conducted into silver nitrate, zinc chloride and methyl cyanoacrylate to occlude the canals of the Fallopian tubes. These materials have been introduced into the uterine cavity with balloon catheters in an effort to place the materials in the canals of the Fallopian tubes. These catheters are not designed to accommodate the different sizes, shapes and characteristics of uteri and do not insure that the materials are placed in each canaal of the Fallopian tubes. Also, these catheters may direct all of the material into one canal so that the material is forced through the canal into the body cavity.

SUMMARY OF THE INVENTION

The invention is directed to an instrument and method for monitering the integrity of the uterus and for dispensing a fluid, as a drug material, into both canals of the Fallopian tubes of a female. More specifically, the invention is directed to an instrument for introducing a predetermined minimum amount of tissue adhesive into both canals of the Fallopian tubes. The instrument has an elongated tubular member having a forward end attached to an expandable balloon assembly. A dispenser connected to the tubular member operates to initially expand the balloon assembly to displace substantially the entire uterine cavity.

The ballon assembly has a soft, relaxed sleeve member that is expanded to a predetermined pressure to substantially fully displace the uterine cavity. The pressure within the chamber surrounded by the sleeve member will not be attained if the walls of the uterus are weak, diseased or ruptured or if there is a leak in the fluid system for the sleeve member. The expanded sleeve assembly checks the integrity of the uterus independently of the size of the uterine cavity. A dispenser having an actuator assembly is operable to supply fluid under pressure to the chamber within the sleeve member. When a predetermined fluid pressure is attained, the actuator assembly is locked into a control mechanism which prevents further movement of the actuator assembly to build up additional fluid pressure in the chamber. The predetermined pressure is the maximum fluid pressure applied to the sleeve member thereby minimizing over-expansion of the uterus. When the force applied by the operator on the actuator assembly is released, the fluid pressure acting on the sleeve member is relieved whereby the sleeve member contracts or reduces in size but still maintains a low pressure seal with the inner wall of the lower part of the uterus.

The dispenser has a plunger for forcing drug material from a container into the uterine cavity above the partially expanded sleeve member. The actuator assembly is then operated to reexpand the sleeve member to displace the space of the uterine cavity. This expansion of the sleeve member forces the drug material in the uterine cavity into the separate canals of the Fallopian tubes. Substantially all of the drug material introduced into the uterine cavity is moved into the canals of the Fallopian tubes on expansion of the sleeve member. When a tissue adhesive is placed into the canals it reacts with the moisture in the tissue of the Fallopian tubes to polymerize the adhesive and thereby occlude the canals. The tissue adhesive is eventually replaced with scar tissue which permanently occludes the canals. The sleeve member is contracted whereby it can be readily removed from the uterine cavity.

An object of the invention is to provide an instrument and method of introducing a predetermined minimum amount of drug material into both canals of the Fallopian tubes from the uterine cavity. A further object of the invention is to provide an instrument for and method of monitoring the integrity of the walls of the uterus and fluid pressure system of the instrument before the material is introduced into the uterine cavity. Another object of the invention is to provide a method and instrument for introducing a controlled amount of drug material into the canals of the Fallopian tubes under low pressure, whereby the drug material does not flow through the Fallopian tubes into the body cavity. A still further object of the invention is to provide a method and instrument 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 which can accommodate different sizes, shapes and characteristics of uteri. Yet another object of the invention is to provide a method and instrument for introducing a material into both canals of the Fallopian tubes which is not position sensitive and does not apply substantial pressures to the material whereby the material is not forced into the blood stream.

IN THE DRAWINGS

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

FIG. 2 is a sectional view of the uterus of FIG. 1 showing the sleeve member in a partially expanded position;

FIG. 3 is a sectional view similar to FIG. 2 showing the expansion of the sleeve member to force the drug material into both canals of the Fallopian tubes;

FIG. 4 is a top plan view of the dispenser with the top section or cover removed showing the actuator assembly and plunger in the inoperative position;

FIG. 5 is a view similar to FIG. 4 showing the actuator assembly in the position to fully expand the sleeve member and locked into the control mechanism;

FIG. 6 is a view similar to FIG. 4 showing the actuator assembly in the position to partially expand the sleeve member and the plunger in the drug material dispensed position;

FIG. 7 is a view similar to FIG. 4 showing the actuator assembly in the position to fully expand the sleeve member;

FIG. 8 is an enlarged sectional view taken along the line 8—8 of FIG. 1;

FIG. 9 is a side elevational view, partly sectioned, of the actuator assembly;

FIG. 10 is a longitudinal sectional view of the actuator assembly;

FIG. 11 is an enlarged sectional view taken along the line 11—11 of FIG. 9; and

FIG. 12 is an enlarged sectional view taken along the line 12—12 of FIG. 7.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawing, there is shown in FIG. 1 a dispensing instrument indicated generally at **20** in operative relation with a female reproductive system, indicated generally at **21**. Reproductive system **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 cavity **27** having an opening or entrance **28**. The opposite end of vaginal cavity **27** is in communication with a cervix **29**. Cervix **29** has an opening **31** providing a passage from the vaginal cavity **27** to the uterine cavity **32**. Fallopian tubes **23** open or exit to opposite sides of the upper part of the uterine cavity **32**.

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 thicknesses, strength and sensitivity to pain vary from female to female. The inner wall of the uterus may contain lymph nodes and vary in size and configuration. The uterine cavities also vary in size and shape. Some uteri have strong walls while others have weak and relatively elastic walls. Diseased uteri generally have weak walls. The uterine cavity **32** is generally flattened and triangular in shape. The uterine cavity may have other shapes.

Fallopian tubes **23** and **24** are paired, trumpet-shaped, muscular linear members which extend from the superior angle of the uterine cavity **32** to the ovaries (not shown). Fallopian tubes of an adult female are musculo-membranous structures about 12 cm. in length. The outlet of the canals of the Fallopian tubes can vary in position relative to the uterine cavity. For example, the outlets can be symmetrically opposite each other, as shown in FIG. **1** of the drawing, or can be relatively close to each other. Also, the size of the canals **33** and **34** varies 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**. The intramural sections of the Fallopian tubes traverse the uterine wall in more or less straight fashion. It has an ampulla-like dilation just before it communicates with the uterine cavity. The walls of the Fallopian tubes consist of three layers; the serosal layer, the muscular layer and the mucosal lining. The muscular layer includes longitudinal muscle fibers which, when contracted, bring the outer ends of the Fallopian tubes into close contact with the surfaces of the ovaries. Blood vessels are abundant in the muscular layers where they form with the muscular bundles a kind of erectile tissue which, if engorged with blood, move the Fallopian tubes to sweep over the surfaces of the ovaries. This movement of the Fallopian tubes is impaired when the tubes are severed and tied. The occluding of the canals **33** and **34** with drug material according to the invention does not interfere with the erectile action and movement of the Fallopian tubes relative to the ovaries.

Uterus **22** has a top wall or fundus **36** and side walls **37** and **38** surrounding uterine cavity **32**. The inside of the top wall **36** and the inside of the 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**. Member **41** has a passage **42** and a length sufficient to pass through the vaginal cavity **27** and into the uterine cavity **32**. A balloon assembly indicated generally at **43** is mountd on the upper or outer end of the tubular member **41**. The balloon assembly has a sleeve member **44**. The upper or outer end of sleeve member **44** is attached to tubular member **41** with an annular fastener **46**, as a collar or threads. A similar annular fastener **47** secures the inner end of the sleeve member **44** around the tubular member **41** forming therewith a chamber **48**. A plurality of openings **45** in the tubular member **41** provide passages between the passageway **42** of the tubular member **41** and the chamber **48**.

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 of surface tension. For example, thin latex rubber having low surface tension, whereby the rubber uniformly expands with a relatively low pressure, is suitable material for sleeve member **44**. The material of sleeve member **44** readily expands to displace the uterine cavity **32** by conforming to the shape of the cavity without applying extreme pressure to localized portions of the uterus wall. When the cavity **32** is fully displaced with the sleeve member **44**, as shown in FIG. **1**, sleeve member **44** is in uniform surface engagement with the inside wall **39**. Conventional balloon catheters, being of hard, relatively non-elastic material, do not assume the configuration of the uterine cavity when expanded under low pressure.

The upper or outer end of probe **41** is closed with a head **49**. Head **49** has a transverse passage **50** having diametrically opposite open discharge ends **51** and **52**. The head **49** is secured to an elongated tube **53** extended concentrically through the tubular member **41**.

Tubular member **41** is attached to a dispenser indicated generally at **54**. Referring to FIGS. **4–8**, dispenser **54** operates to control the inflation of the balloon assembly **43** and the discharge of drug material into the uterine cavity **32**. The dispenser **54** has a housing **56** comprising a lower section or part **56A** and an upper

section or cover part 56B. A plurality of fasteners 60, as screws, hold the parts 56A and 56B together. Each part 56A and 56B has a lateral flange 55 at the rear end of the part to facilitate handling of the instrument. Housing 56 has three longitudinal cavities 57, 58 and 59 to accommodate the dispensing and control mechanism of the dispenser. The cavity 57 is in longitudinal alignment with tubular member 41. The tube 53 extends into the forward end of cavity 57 and terminates in a point 61, thereby forming a tubular needle.

As shown in FIG. 1, the housing 56 has a top opening 62 in communication with the cavity 57. The opening 62 has a longitudinal length and width sufficient to permit a container or ampulla 63 to be inserted into the cavity 67. The container 63 is an elongated cylindrical member of plastic or glass having a forward end closed with a rubber or resilient plug 64. Plug 64 is in longitudinal alignment with the point 61 of tube 53. The opposite end of container 63 is closed with a piston 66. Drug material 67 is stored in the container 63. An elongated longitudinal rod or plunger 68 is slidably located in longitudinal bore 69 in the rear portion of housing 56. The bore 69 is open to cavity 57 and aligned with the open end of the container 63. The plunger 68 has an outside head 71 adapted to be engaged by the operator of the instrument. The opposite end of plunger 68 is a forward end 72 in engagement with the piston 66.

An elongated cylinder 73 is located in the second cavity 58. The forward end of cylinder 73 is attached to a tube 74 leading to the tubular member 41. Tube 74 opens to the passage 42 of the tubular member 41 whereby the fluid, as air, in the cylinder 73 is discharged into the passage 42 to expand the sleeve member 44. The tube 74 and tube 53 are joined to the end of probe 41 with a seal structure 76, as solder, weld or the like. The open portion of cylinder 73 has a hole 77 to permit air to flow into the chamber formed by cylinder 73. The open end of cylinder 73 is closed with a piston 78. In the initial position, as shown in FIG. 4, the piston 78 is located rearwardly of the hole 77 whereby air can flow into the chamber of cylinder 73.

Located behind and in longitudinal alignment with the cylinder 73 is an actuator assembly indicated generally at 79 operable to move the piston 78 into the cylinder 73 and thereby force air through tube 74 into passage 73 to expand the sleeve member 44. The actuator assembly 79 functions to apply a predetermined fluid pressure to the sleeve member to substantially displace the uterine cavity with the sleeve member and initially monitor the integrity of the uterus. Preferably, the fluid pressure is from 7 psi to 7½ psi. The pressure applied to the sleeve member 44 will increase if the walls of the uterus have sufficient strength to resist expansion of the sleeve member 44. Weak, diseased or ruptured uterus walls and enlarged uteri are detected by the instrument as the sleeve member 44 will not be subjected to the predetermined fluid pressure since these uterus walls cannot contain the sleeve member. This checking or monitoring of the integrity of the uterus walls is done before the drug material is introduced into the uterine cavity.

Referring to FIGS. 9–11, actuator assembly 79 has a first cylindrical member 81. The forward or front end of member 81 has a cone-shaped recess 82 to accommodate the cone-shaped end of piston 78. The member 81 has a longitudinal or axial bore 83 accommodating a second cylindrical member 84. The member 84 is telescoped into the bore 83. The outer end of member 84 has a head 86 having an outer surface adapted to be engaged by the operator of the instrument. The forward or front end of member 84 has a forwardly directed projection 87 and an annular shoulder 88. A compression spring 89 located in bore 83 engages the shoulder 88 and the bottom of the bore 83, thereby biasing the first member 81 and the second member 84 away from each other or to an expanded position. The members 81 and 84 are held in assembled relation with a stop pin 91. Pin 91 is anchored in a hole 92 in member 84 and extends through a longitudinal slot 93 in member 81. The slot 93 permits limited relative movement between the members 84 and 81 against the compression force of the spring 89. The spring 89 has a calibrated force, preferably 7 to 7½ psi, whereby the fluid pressure in the system including the expandable sleeve member 44 is limited to 7 to 7½ psi. As shown in FIGS. 8 and 11, pin 91 extends downwardly into a longitudinal groove 90 in the lower section 56A of the housing. The pin 91 located in groove 90 prevents rotation of the actuator assembly 79 in the housing 56.

As shown in FIG. 11, the member 84 has a transverse hole 94 in the forward section thereof accommodating a lock means indicated generally at 96. Lock means 96 comprises a cylindrical body 97 having an outwardly directed pin or projection 98. The body 97 has a bore 97A accommodating a compression spring 99. The spring 99 biases the body 97 and projection 98 in an outward transverse or lateral direction forcing the outer end of projection 98 into engagement with the inner wall of the member 81. As shown in FIG. 9, the member 81 has a hole 101 in longitudinal alignment with the lock means 96. When the member 84 is moved into member 81 a distance to align or register the pin 98 with hole 101, the spring 99 will force the projection 98 through hole 101 into operative engagement with a control mechanism indicated generally at 102.

Referring to FIGS. 8 and 12, control mechanism 102 comprises an elongated body 103 slidably disposed in longitudinal cavity 59. Body 103 has an elongated head 104 positioned in the forward end of cavity 59. The forward end of head 104 has a downwardly projected ear 106. Ear 106 has a longitudinal hole 107 accommodating a guide rod 108. Rod 108 extends linearly the full length of cavity 59 and has a rear portion located in a hole 109 in body 56A. A removable transverse pin or stop member 111 extends transversely through the body intersecting the hole 109, thereby holding the rod 108 in assembled relation with body 56. A compression spring 112 is concentrically positioned about the forward end of rod 108. The forward end of spring 112 engages the ear 106. The rear end of spring 112 engages a stop collar 113 secured to rod 108. Spring 112 biases the body 103 in a forward direction to a stop position and yieldably holds the forward end of the head 104 in engagement with the end wall 114 of cavity 59.

The side of body 103 facing the actuator assembly 79 has a plurality of linearly spaced fingers or teeth 116. Spaces 117 separate the fingers 116 from each other. The spaces 116 have a width to accommodate the end of pin 98 to lock the actuator assembly 79 to the body 103, as shown in FIG. 5, when the actuator assembly is in its contracted position.

Referring to FIG. 4, the plunger 68 and actuator assembly 79 are held in an inoperative position by a transverse locking rod or pin 118. The pin 118 extends

through a transverse hole **119** in plunger **68** and a transverse hole **121** in plunger assembly **79.** The pin engages the back end wall of housing **56** to prevent both the plunger **68** and actuator assembly **79** from being inadvertently pushed into the body **56.**

In use, the entire instrument is sterilized with the cylinder **63** loaded in cavity **57.** The expandable balloon assembly **43** is in a deflated condition and inserted into the uterine cavity **32** via the vaginal cavity **27** and cervical passage **31.** The ballon assembly **43** is moved up into the uterine cavity **32** until the head **49** is adjacent the top wall or fundus **36.** The pin **118** is removed so that the actuator assembly **79** can be operated to monitor the integrity of the walls of the uterus.

The actuator assembly **79** is moved into the body **56.** This moves the piston **78** into the cylinder **73.** The fluid, as air, in cylinder **73** flows via tube **74** and passage **43** in tube **41** into the chamber **48** surrounded by sleeve member **44.** As shown in FIG. **1,** the sleeve member **44** is expanded until it fills the entire uterine cavity **32.** Portions of the sleeve member **44** expand upwardly to the exit portions of the Fallopian tube canals **33** and **34.** The material of sleeve member **44,** being of soft, relaxed, elastic material, conforms to the shape of the uterine cavity and readily expands to fill the uterine cavity. The member **84** of actuator **79** is continuously moved into body **56** to increase the pressure of the fluid in the fluid system for the balloon assembly. When the pressure is at the desired level, i.e., 7 to 7½ psi, the member **84** will move from its extended position into the member **81** to a contracted or "in" position. This movement will align pin **98** with hole **101.** Spring **99** will force pin **98** through hole **101** into one of the spaces **117** of the body **103** of the control mechanism **102.** The pin **98** will engage an adjacent finger **116** to thereby prevent further movement of the actuator assembly **79** into the cylinder **73.** This limits the pressure of the fluid in sleeve assembly **44** to the pressure as determined by the compression characteristics of the spring **89** in the actuator assembly **79.**

In the event that there is a leak in the fluid system of the sleeve member **44** or that the walls of the uterus are weak, diseased or ruptured they will not have sufficient strength to confine the sleeve member **44,** the actuator assembly **79** will not lock into the control mechanism **102.** The impaired uterus will not develop a reaction pressure that will establish a pressure of the fluid in chamber **48** sufficient to overcome the compression characteristics of spring **89.** Accordingly, pin **98** will not move into registration with hole **101.** When the operator releases the pressure on the actuator assembly **79,** the actuator assembly **79** will move back to its initial position, as shown in FIG. **4,** and thereby provide an indication of deficiency in the strength of the uterine wall. If there is a leak in the fluid system of sleeve member **44,** the actuator assembly **79** will not return to its initial position as the pressure in the system is lost. The actuator assembly **79** can be moved into body **56** until its head **86** abuts against the end of the body **56.** This is the maximum movement of the actuator assembly **79** which limits enlargement or expansion of sleeve member **44.**

In the event the uterine walls have sufficient strength, the member **84** will move relative to member **81** of the actuator assembly **79** and pin **98** will move into registration with the hole **101.** Pin **98** is driven by spring **99** into the body **103,** producing an audio click. This sound signals the operator that the uterus has a size and strength to accommodate the fully expanded sleeve member **44.** If the uterus walls are weak or if there is a leak in the fluid system, the pin **98** will not lock into body **103.** Accordingly, the audio click is not produced. Pin **98** locks the actuator assembly **79** to the body **103,** preventing further movement of actuator assembly **79** into cylinder **73.** The operator will then release the pressure on the actuator assembly **79.** The actuator assembly **79,** along with piston **78** and body **103,** will move in a rearward direction against the compression force of the spring **112.** Spring **112** has a compression force charactistic of preferably 2½ to 3 psi. In other words, when the force on actuator assembly **79** has been released, the pressure in chamber **48** will drop to 2½ to 3 psi. As shown in FIG. **2,** the sleeve member **44** will contract to fill the lower portion of the uterine cavity. The pressure in chamber **48** is suffcient to maintain the sleeve member **44** in continuous and firm engagement with the side walls **37** and **38** of the uterus.

As shown in FIG. **6,** the plunger **68** is moved into body **56.** The plunger **68** forces the plug **64** into engagement with point **61,** moving the point through plug **64.** The plunger **68,** being in engagement with piston **66,** forces the drug material **67** through the passage of tube **53.** As shown in FIG. **2,** the material is dispensed in two positions **67A** and **67B** in opposite directions through the passage **50** of head **49** to opposite sides of the uterine cavity **32** above the partially expanded sleeve member **44.**

Referring to FIG. **7,** as soon as the dispensing of the drug material **67** from the container **63** is completed, the operator applies a force to the actuator assembly **79** to progressively expand the sleeve member **44.** As shown in FIG. **3,** sleeve member **44** moves outward to fill the entire uterine cavity. As the sleeve member **44** expands, it forces or pushes the drug material up into the canals **33** and **34** of the Fallopian tubes **23** and **24,** respectively. The sleeve member **44** is expanded to its initial expanded position, as shown in FIG. **1.** The actuator **79,** being locked to the control mechanism by the pin **98,** limits the movement of the actuator into the cylinder **73.** The forward end of head **104** will abut against end **114** to stop the actuator at its initial position. In this position, the pressure in the chamber **48** expanding the sleeve member **44,** will return to its initial pressure, i.e. 7 to 7½ psi. The sleeve member **44** expands to fully displace the uterine cavity and move the drug materials **67A** and **67B** into the canals of the Fallopian tubes. In other words, the expanding sleeve member **44** functions as an expanding diaphragm pump to force and move the drug materials **67A** and **67B** into the respective canals. Sleeve member **44,** being in firm engagement with the inside walls **39,** prevents the drug material **67A** and **67B** from remaining in uterine cavity **32.** As the sleeve member **44** expands, it does not block or hold the drug material, as it pushes the drug material into the canals.

When drug materials of the tissue adhesive type are used, canals **33** and **34** will be permanently occluded. Tissue adhesives, as the cyanoacrylate type, cause fibroplastic proliferation which in time will hystologically close the canals **33** and **34.** The tissue adhesives polymerize when subjected to moist, living tissue. The cells adjacent the tissue are damaged and eventually replaced with fibrous tissue.

The removal of balloon assembly **43** from the uterine cavity is accomplished by removing the pin **111.** This releases rod **108** allowing the body **103** to move outwardly. This permits the actuator assembly **79** to move outwardly, releasing or relieving the pressure of the fluid in cylinder **73.** This allows the sleeve member **44** to contract to its initial position whereby the balloon assembly can be removed from the patient via the cervical opening **31** and vaginal cavity **29.**

The drug material can be one of a number of fluids or semifluids 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, cyanoacrylate type materials or like materials 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-cyanoacryate, 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 be of the type that will temporarily block or occlude the canals of the Fallopian tubes. After a period of time, the canals will reopen to resume their normal function. Examples of other drug materials are contraceptive gels, water, silicone elastomers and like materials.

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. An instrument for placing material into both canals of Fallopian tubes open to a uterine cavity comprising: a ballon assembly having an expandable sleeve member surrounding a chamber, means supporting the balloon assembly, dispensing means connected to said means supporting the balloon assembly operable to expand the sleeve member and discharge material into the uterine cavity, said dispensing means including first means fluidly connected to said chamber to supply fluid under pressure thereto, actuator means cooperating with said first means to supply a predetermined fluid pressure to said chamber to expand the sleeve member to fully displace the uterine cavity, control means cooperating with said actuator means when said predetermined pressure is attained to stop further expansion of the sleeve member, said control means allowing partial contraction of the sleeve member when the actuator means is released, and second means operable to discharge material into the uterine cavity, said actuator means operable to re-expand said sleeve member by subjecting the sleeve member to said predetermined pressure whereby said material in the uterine cavity is forced into the canals of the Fallopian tubes by the expanding sleeve member.

2. The instrument of claim **1** wherein: the first means includes a cylinder and a piston movable within said cylinder to force fluid from said cylinder into the chamber, said actuator means engageable with said piston to move said piston relative to said cylinder.

3. The instrument of claim **1** wherein: the actuator means includes a first member, a second member movable relative to said first member from an extended position to a contracted position, said contracted position being attained when the predetermined fluid pressure is present in the chamber, biasing means yieldably holding the second member in its extended position, and lock means engageable with the control means when the second member is in the contracted position.

4. The instrument of claim **3** wherein: the control means includes a movable member having a plurality of spaced fingers selectively engageable with the lock means, biasing means holding the movable member in a stop position and allowing movement away from the stop position on release of the actuator means whereby the sleeve member is partially contracted.

5. The instrument of claim **4** wherein: the lock means includes a body having a projection, and biasing means for moving the projection between adjacent fingers when said predetermined pressure is attained.

6. The instrument of claim **1** wherein: the sleeve member is made of expandable tubular sheet material having low surface tension properties.

7. The instrument of claim **1** wherein: the elongated means is a tubular member having a passage open to a chamber surrounded by the sleeve member, said first means being fluidly connected to said passage, said second means including a tube extended longitudinally through said passage, said tube having an exit opening means adjacent the sleeve member, container means carrying the material connectable to said tube, and means operable to couple the container means to the tube and drive the material from the container means through the tube and into the uterine cavity.

8. The instrument of claim **7** wherein: the exit opening means has a first opening for directing material in one direction in the uterine cavity and a second opening for directing material in another direction in the uterine cavity.

9. The instrument of claim **1** wherein: the second means includes a tube having exit opening means adjacent the sleeve member to direct material into the uterine cavity, said exit opening means having a first opening for directing material in one direction and a second opening for directing material in another direction.

10. An instrument for placing material into both canals of Fallopian tubes of a uterine cavity comprising: expandable sleeve means surrounding a chamber for displacing the uterine cavity, dispenser means connected to said sleeve means operable to expand the sleeve means and discharge material into the uterine cavity, said dispenser means including a first means to supply a predetermined fluid pressure to said chamber to expand the sleeve means to fully displace the uterine cavity, control means cooperating with said first means when said predetermined pressure is attained to stop further expansion of the sleeve means, said control means allowing partial contraction of the sleeve means when the first means is released, and second means operable to discharge material into the uterine cavity, said first means operable to re-expand said sleeve means by subjecting the sleeve means to said predetermined pressure whereby said material in the uterine cavity is forced into the canals of the Fallopian tubes by the expanding sleeve means.

11. The instrument of claim 10 wherein: said first means includes a cylinder and a piston movable within said cylinder to force fluid from said cylinder into the chamber surrounded by the sleeve means, and actuator means engageable with said piston to move said piston relative to said cylinder.

12. The instrument of claim 11 wherein: the actuator means includes a first member, a second member movable relative to the first member from an extended position to a contracted position, said contracted position being attained when the predetermined fluid pressure is present in the chamber, biasing means yieldably holding the second member in its extended position, and lock means engageable with the control means when the second member is in the contracted position.

13. The instrument of claim 12 wherein: the control means includes a movable member having a plurality of spaced fingers selectively engageable with the lock means, biasing means holding the movable member in a stop position and allowing movement away from the stop position on release of the actuator means whereby the sleeve member is partially contracted.

14. The instrument of claim 13 wherein: the lock means includes a body having a projection, and biasing means for moving the projection between adjacent fingers when said predetermined pressure is attained.

15. The instrument of claim 10 wherein: the sleeve means is made of expandable tubular sheet material having low surface tension properties.

16. An instrument for placing material in both canals of Fallopian tubes open to the uterine cavity comprising: a balloon assembly having an expandable sleeve member, first means operable to expand the sleeve member into engagement with the inside walls of the uterus to fully displace the uterine cavity and then partially contract the sleeve member, second means for discharging material into the uterine cavity between the partially contracted sleeve member and the inside top wall of the uterus, said first means being operable to re-expand the sleeve member to fully displace the uterine cavity whereby the material in the uterine cavity is forced into the canals of the Fallopian tubes by the re-expanding sleeve member.

17. The instrument of claim 16 including: elongated tubular means for supporting the balloon assembly connected to the first means and the second means.

18. The instrument of claim 16 wherein: the first means includes an actuator assembly operable to supply predetermined fluid pressure to a chamber surrounded by the sleeve means, and control means cooperating with said actuator assembly when said predetermined pressure is attained to stop further expansion of the sleeve member, said control means allowing partial contraction of the sleeve member when the actuator assembly is released.

19. The instrument of claim 18 wherein: the actuator means includes a first member, a second member movable relative to the first member from an extended position to a contracted position, said contracted position being attained when the predetermined fluid pressure is present in the chamber, biasing means yieldably holding the second member in its extended position, and lock means engageable with the control means when the second member is in the contracted position.

20. The instrument of claim 19 wherein: the control means includes a movable member having a plurality of spaced fingers selectively engageable with the lock means, biasing means holding the movable member in a stop position and allowing movement away from the stop position on release of the actuator means whereby the sleeve member is partially contracted.

21. The instrument of claim 20 wherein: the lock means includes a body having a projection, and biasing means for moving the projection between adjacent fingers when said predetermined pressure is attained.

22. The instrument of claim 16 wherein: the sleeve means is made of expandable tubular sheet material having low surface tension properties.

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