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(54) A METHOD OF DISPENSING FLUID MATERIAL INTO THE FALLOPIAN TUBES OF A FEMALE BODY

(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 a method of dispensing fluid material into the Fallopian tubes of a female body.

According to a first 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 dispensing fluid material into the uterine cavity and subsequently moving the dispensed material from the uterine cavity into the Fallopian tubes.

According to a 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 body of the female comprising the steps of dispensing fluid material into the uterine cavity and subsequently moving the dispensed material from the uterine cavity into the Fallopian tubes.

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

Figure 2 is a longitudinal sectional view of the dispensing unit of the instrument of Figure 1;

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

Figure 4 is a 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 material in the uterine cavity;

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

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

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

Figure 1 shows 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 joined 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 a 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 a 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 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 the mucosal lining.

The uterus 422 has a top wall or 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 elongated 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 allow 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. When the cavity 432 is substantially completely filled by the expanded sleeve member 444, as shown in Figure 5, the sleeve member 444 is in engagement with the inside lining 439. 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 a 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 2, 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 cylidner 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 2, 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 rearwardly 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 1. 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 a 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 a 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 2.

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 2. 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 2, 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 a 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 2, 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 1, 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 4, 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 4, 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 5, 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 4 to the position shown in Figure 5, 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 5. This locates the fluid material in the Fallopian tubes as the pumping force applied to the material by the expandable 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 lining 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 1 to 5 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 1 to 5 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 - amyl cyanoacrylates, 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 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, silicon elastomers or formaldehyde-type materials.

Referring to Figures 6 and 7, 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 1 to 5 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 containter 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 1 to 5. 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 6, 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 6, 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 nals 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 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 described above is also 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 materials 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.

The instruments described above have a single dispensing unit which automatically performs the steps of the method of the invention upon operation of the single actuator. However, it is possible to connect an expansion unit to the passage, as passage 442, in communication with the expandable member to supply expansion fluid thereto, and to connect a dispensing unit to the or each delivery tube within the tubular member to dispense material through the tube(s) to the exit(s).

It is not necessary to provide a transverse passage, as 452, to divide the dispensed material into two streams. If required, the dispensed material can be divided into two streams by expanding the expandable member into engagement with the fundus of the uterine cavity.

If required, a second material could be dispensed into the uterine cavity as the originally dispensed material is being moved into the Fallopian tubes.

It has been found that with the method of the invention a minimal predetermined amount of material can be efficiently and rapidly be moved into the canals of the Fallopian tubes and that there is little residue left in the uterine cavity.

An instrument for dispensing fluid material into the Fallopian tubes of a female body, a method of dispensing fluid material into the Fallopian tubes of the body of a non-human female primate, and a 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. 10593/74 (Serial No. 1,470,571), from which the present application is divided.

In addition, the dispensing instrument described herein is described and claimed in our copending application No. 49022/76 (Serial No. 1,470,572), which is also divided from parent application No. 10593/74, (Serial No. 1,470,571).

WHAT WE CLAIM IS:—

1. A method of dispensing fluid material into the Fallopian tubes of the body of a non-human female primate comprising the steps of dispensing fluid material into the uterine cavity and subsequently moving the dispensed material from the uterine cavity into the Fallopian tubes.

2. A method as claimed in claim 1, wherein said material is a medicinal drug or a mixture of medicinal drugs.

3. A method as claimed in claim 1, wherein said material is a diagnostic radiopaque dye or a mixture of such dyes.

4. A method as claimed in claim 1, wherein said material is an anesthetic or a mixture of anesthetics.

5. A method of controlling conception in a human female by dispensing fluid material into the Fallopian tubes of the body of the female comprising the steps of dispensing fluid material into the uterine cavity and subsequently moving the dispensed material from the uterine cavity into the Fallopian tubes.

6. A method as claimed in claim 1 or claim 5, wherein said material is a contraceptive drug agent or a mixture of such drug agents.

7. A method as claimed in claim 1 or claim 5, 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.

8. A method as claimed in claim 1 or claim 5, wherein said material is a drug or mixture of drugs for in situ enhancement of the fertility of the female.

9. A method as claimed in any preceding claim, wherein the moving step further comprises the step of substantially completely filling the uterine cavity with an expandable member making firm engagement with the inner wall of the uterine cavity including the fundus and the corneal areas.

10. A method as claimed in claim 9, further comprising the steps of introducing the expandable member through the cervical opening into the uterine cavity, partly expanding the expandable member to engage the inside walls of the uterus near the cervical opening to partly fill the uterine cavity, dispensing the material between the expandable member and the fundus of the uterine cavity, and further expanding the expandable member to substantially complete fill the uterine cavity and to force the dispensed material from the uterine cavity into the Fallopian tubes.

11. A method as claimed in claim 10 wherein the expandable member is part expanded, the material is dispensed into the uterine cavity, and the expandable member is further expanded in a single continuous operation.

12. A method as claimed in claim 9, 10, or 11, further comprising the steps of contracting the expandable member and withdrawing the expandable member through the cervical opening after the dispensed materials have been moved into the Fallopian tubes.

13. A method as claimed in any of claims 9 to 12, 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.

14. A method as claimed in claim 13, wherein an increase in the fluid pressure applied to the expandable member above a predetermined pressure is prevented.

15. A method as claimed in any preceding claim, comprising the further step of dividing the material into two portions, and the step of moving the material further comprises forcing one portion of the material into one canal and the other portion into the other canal of the Fallopian tubes.

16. A method as claimed in any preceding claim, 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.

17. A method of dispensing fluid material into the Fallopian tubes of the body of a non-human female primate substantially as hereinbefore described with reference to the accompanying drawings.

18. A method of controlling conception in a human female by dispensing fluid material into the Fallopian tubes of the body substantially as hereinbefore described with reference to the accompanying drawings.

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