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(54) A DISPENSING INSTRUMENT

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

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

According to the present invention there is provided an instrument for dispensing fluid material into the Fallopian tubes of a female body, comprising an elongate member having at or near one end thereof an expandable member and at least one outlet for fluid materials, said expandable member and the or each outlet being positionable within a uterine cavity, and a dispensing unit coupled to said elongate member at a position remote from said one end, the dispensing unit having means for expanding said expandable member, dispensing means for dispensing fluid material through the or each outlet, and a single actuator for operating both said means for expanding said expandable member and said dispensing means.

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 further embodiment of the dispensing instrument;

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

Figure 8 is a top plan view of a further embodiment of a dispensing instrument of the invention;

Figure 9 is an enlarged sectional view taken along the line 9—9 of Figure 8;

Figure 10 is a sectional view taken along the line 10—10 of Figure 9;

Figure 11 is an enlarged sectional view taken along the line 11—11 of Figure 9;

Figure 12 is a view similar to Figure 11 showing the movable member in the second position; and

Figure 13 is an enlarged sectional view of the fluid container assembly taken along the line 13—13 of Figure 9.

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 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 Fallopain 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 allows the sleeve member 444 to be readily expanded by relatively low fluid pressure to occupy the uterine cavity 432 and conform to the shape of the uterine cavity without applying extreme pressure to localized portions of the uterus walls 437 and 438. 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 drum 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 cylinder 459 can flow via the passage 442 into the

chamber 449 of the balloon assembly and thereby expand the sleeve member 444. The opposite end of the cylinder 459 is closed by a piston 463 to enclose the fluid in a chamber 464 within the cylinder 459. The cylinder 459 has a hole 466 adjacent the piston 463 which, in the inoperative position shown in Figure 2, is aligned with a hole 466' in the body 457 to allow air and sterilizing gases to flow in 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 the 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 extend 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 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 material 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 in 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 material through the Fallopain tubes in 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 co-ordinated 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 co-ordination 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, silicone 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 container 657. In a similar manner, a piston 662 is slidably located in the container 659. The plunger 514 of the second drive assembly 479 has a bifurcated end forming a pair of fingers 663 and 664. The finger 663 is positioned in the container 657 and engages the piston 661. The finger 664 is located in the container 659 and engages the piston 662. The tubes 653 and 654 extend into the housing 457 and terminate in needles 666 and 667. The needles 666 and 667 are in alignment with the pierceable end portions of the containers 657 and 659.

On actuation of the single actuator 468 the first drive assembly 467 will operate to initially expand the sleeve member 444 to fill and seal the lower portion of the uterine cavity 432 as described above with reference to Figures 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 per cent 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 material 668 flows in opposite directions in substantially equal amounts. The flow is continuous until the plunger 514 has reached the end of its stroke. At this time, the continuous movement of the actuator 468 further expands the sleeve member 444 forcing the mixed fluid material into the canals 433 and 434 of the Fallopian tubes.

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

Figures 8, 9, 10 and 11 show a further embodiment of a dispenser instrument indicated generally at 300 for dispensing fluid materials, as drugs or tissue adhesives into the uterine cavity. The dispenser instrument 300 has a dispensing unit 301 and an elongated tubular catheter 302. The dispensing unit 301 has a body 303 attached to an elongated tube 304 of the catheter 302. The tube 304 can be releasably connected or permanently fixed to the body 303. Mounted on the free end of the tube 304 is an expandable sleeve member or balloon 305. Bands 306 clamp the ends of the sleeve member 305 to the tube 304. The sleeve member 305 is made from a sheet of a soft and relaxed, flexible, elastic material such as rubber or plastics material. When the sleeve member 305 is expanded in the uterine cavity, it applies uniform outward pressure on the uterine wall. The expanded sleeve member 305 prevents the fluid materials dispensed into the uterine cavity from contacting substantial portions of the uterine wall and flowing out of the uterine cavity. Holes 307 in the end of the tube 304 provide the passageway for the fluid, as water, from within the tube 304 into the sleeve member 305 to expand the sleeve member 305. An elongated tube 308 of smaller diameter is located within the tube 304 and has a discharge outlet 309 at the free end of the tube 304.

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

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

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

Referring to Figures 11 and 12, the head 324 has a passage 326 extending longitudinally with respect to the body 303 for accommodating the rod 319. A bore 327 is provided in the head 324 which extends transversely of and opens into the passage 326. A pin 328 is slidably disposed in the bore 327. The pin 328 has a reduced diameter neck 329 attached to a head 331. A spring 332 engages the head 331 and a plug 333, closing the end of the bore 327. The spring 332 biases the pin 328 into the passage 326. The rod 317 has a finger 334 projecting from the end thereof remote from the chamber 311. When the rod 317 is in the cocked position, the finger 334 is located in the neck 329 of the pin 328 and functions as a stop to prevent movement of the pin 328 into the passage 326.

Returning to Figure 9, the rod 317 has a

notch or slot 336 in one surface thereof. The slot 336 co-operates with a lock 337 to hold rod 317 in a forward or dispensing position. The lock 337 comprises a movable pin 338 located in a passage in the body 303 surrounded by a boss 339. The pin 338 has a head 341 located outside body 303 so that it can be gripped to release the lock. The innermost portion of the pin 338 carries a C-ring or clamp ring 342 providing a stop for a spring 343. The spring 343 is located concentrically around the pin 338 and engages a portion of the body 303 to bias the pin 338 towards the rod 317. When the rod 317 has been moved to its forward position, the pin 338 will be biased into the slot 336, thereby holding the rod 317 in the forward position. The rod 319 has a slot 344. A lock 346 (Figure 8) on the body 303 holds the rod 319 in its forward position. The lock 346 is identical to the lock 337.

Figures 9 and 10 show the dispensing unit 301 with the rods 317 and 319 in their rear or cocked position. In use, the catheter 302 is positioned so that the free end thereof together with the expandable member 305 is positioned in a uterine cavity. The lever 321 of the trigger assembly 320 is then actuated by squeezing it towards the handle 323 so that it pivots about pivot pin 322. The head 324 of the lever 321 is thus moved forwardly into engagement with the end of rod 317 and moves the rod 317 into its forward position. The rod 317 is held in its forward position by the lock 337. The rod 319 is not similarly moved to its forward position as the head 324 moves relative to the rod 319 as the rod 319 moves through the passageway 326. The lever 321 is then released so that the head 324 thereof is returned to its initial rearward position by means of the spring 325. However, as the rod 317 is now held in its forward position the return of the head 324 to its rearward position moves the projecting finger 334 of the rod 317 out of the neck 329 of the pin 328. The pin 328 is thus moved by the spring 332 into the passageway 326. Thus, if the lever 321 is then actuated again, forward movement of the head 324 will move the rod 319 to its forward position and the rod 319 will be held in its forward position by the lock 346.

Referring to Figure 10, a first container or ampulla indicated generally at 350 is located in the chamber 311. A needle 351 which extends longitudinally with respect to the body 303 is mounted on a transverse base 352 and is located at the forward end of the chamber 311. The needle 351 is a hollow tubular member in fluid communication with the passage 313.

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

The container 350 is shown in more detail in Figure 13, and has a cylinder 361 for storing a fluid 362, as air or water, for expanding the expandable member 305. The forward end of the cylinder 361 has a head 363 having a passage closed with a plug 364. The other end of the cylinder 361 is closed with a plunger 366 carrying a piston 367. The rear portion of the plunger 366 has an outwardly directed flange 368 engageable with a spring 369. The forward end of the spring 369 engages an annular seat 371 on the cylinder 361 to bias the plunger 366 in an outward direction or out of cylinder 361. The plunger 366 has a central longitudinal bore 372 slidably accommodating an actuator rod 373. The rod 373 has an axial bore accommodating a compression spring 374 which extends into the bore 372 and bears against the inner end of the plunger 366 to provide a yieldable link between the rod 373 and the plunger 366.

The plunger 316 attached to the rod 317 engages the end of the rod 373. Movement of the rod 317 and hence of the plunger 316 in the forward direction initially compresses the spring 374 which applies a uniform pressure on the plunger 366. The cylinder 361 will be moved in a forward direction by the plunger 366 and the needle 351 will pierce the plug 364, thereby providing fluid communication between the container 350 and the passage 313. The continued forward movement of the plunger 316 will drive the piston 367 towards the plug 364, thereby dispensing the fluid from the cylinder 361. The

dispensed fluid will flow through tube 304 and into sleeve member 305 via holes 307 to expand the sleeve member 305, as shown in broken lines in Figure 10. The sleeve member 305 will expand with a uniform pressure so as to fill the uterine cavity and exert uniform pressure on the inside wall of the cavity. The pressure of sleeve member 305 on the cavity wall will be uniform regardless of the size of the uterine cavity.

The body 303 has doors or closure members closing openings into the chambers 311 and 312 whereby the containers 350 and 353 can be removed and replaced. Other types of containers as described in our copending application No. 10593/74 can be inserted into the chambers 311 and 312.

The dispenser instrument 300 can be used to introduce a fluid material, such as a drug, tissue adhesive, or a contraceptive gel, into the canals of the Fallopian tubes. The elongated catheter 302, with the sleeve member 305 in its contracted position, is introduced through the cervical opening into the uterine cavity. The sleeve member 305 is then expanded with fluid under pressure to fill the uterine cavity and apply uniform pressure on the inside of the uterine wall. The fluid under pressure is delivered to the sleeve member 305 via the passage in the tube 304. The head 324 of the actuator lever 321 is moved in the forward direction to force plunger 316 in a direction to move the container 350 into operative engagement with the needle 351. The needle 351 will puncture the plug 364, whereby the fluid 362 will flow via the passage in tube 304 to expand the sleeve member 305. The sleeve member, being made of flexible, elastic rubber or similar material, has a low modulus of elasticity and applies a uniform pressure to the inside of the uterine wall. This effects a relatively tight seal and fit, enabling the same catheter construction to be used on all types of primate female, regardless of the size of the uterine cavity.

Material under pressure is then dispensed from the container 353 into the uterine cavity by way of the tube 308 between the expanded sleeve member and the fundus of the uterus. The material, being under pressure, moves toward and into the canals of the Fallopian tubes. The expanded sleeve member, being located against the fundus wall, aids the movement of the material toward the canals of the Fallopian tubes. The material can be a fluid tissue adhesive which will flow into the canals. The moisture in the tissue of the canals will polymerise or set the tissue adhesive and thereby block or occlude the canals. The fluid confined by the sleeve member is then drained to contract the sleeve member by releasing the lock 337 of the rod 317 manually. The plunger 366 is then moved out of the cylinder 361 by the spring 369 so that the fluid is drawn into the cylinder 361. The catheter is then withdrawn from the uterine cavity.

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 fertilisation 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 instrument of the invention is usable to deliver sperm into the uterine cavity and canals of the Fallopian tubes to enhance conception.

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

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

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

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

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

It will be seen that the instruments described above have a single dispensing unit having a single actuator operable both

to expand the expandable member and to dispense material into 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 from which the present application is divided.

In addition, a method of dispensing fluid material into the Fallopian tubes 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 body of the female are described and claimed in our copending application No. 49023/76 (Serial No. 1,470,573) which is also divided from parent application No. 10593/74 (Serial No. 1,470,571).

WHAT WE CLAIM IS:—

1. An instrument for dispensing fluid material into the Fallopian tubes of a female body, comprising an elongate member having at or near one end thereof an expandable member and at least one outlet for fluid material, said expandable member and the or each outlet being positionable within a uterine cavity, and a dispensing unit coupled to said elongate member at a position remote from said one end, the dispensing unit having means for expanding said expandable member, dispensing means for dispensing fluid material through the or each outlet, and a single actuator for operating both said means for expanding said expandable member and said dispensing means.

2. An instrument as claimed in Claim 1, wherein said means for expanding said expandable member comprises means for applying a fluid under pressure to said expandable member, and wherein said dispensing unit further comprises means to prevent an increase in the fluid pressure applied to the expandable member above a predetermined pressure.

3. An instrument as claimed in Claim 1 or 2, wherein said actuator is operable to operate said means for expanding said expandable member and said dispensing means sequentially.

4. An instrument as claimed in Claim 3, wherein said actuator is operable to first operate said means for expanding said expandable member to partly expand said expandable member, then to operate said dispensing means, and then to operate said means for expanding said expandable member to further expand said expandable member to force dispensed material from the uterine cavity into the Fallopian tubes.

5. An instrument as claimed in Claim 4, wherein a single operation of said actuator is arranged to perform said sequential operations of said means for expanding said expandable member and said dispensing means.

6. An instrument as claimed in Claim 4 to 5, wherein a single operation of said actuator is arranged to perform said sequential operations of said means for expanding said expandable member and said dispensing means in continuous sequence.

7. An instrument as claimed in any preceding claim, wherein the dispensing unit comprises a housing having a first chamber and a second chamber, a container for storing a fluid for expanding said expandable member being located in the first chamber, a container for storing a fluid material to be dispensed being located in the second chamber, and wherein the elongate member has a passage for fluid coupled to said fluid storage container, and a passage for fluid material coupled to said material storage container the dispensing unit further comprising first movable means operable to move fluid through the fluid passage to the expandable member, and second movable means operable to move material through the material passage to the or each said outlet, said actuator being operable to sequentially move both the first movable means and the second movable means.

8. An instrument as claimed in Claim 7 when appended to any of Claims 1 to 3, wherein said first movable means comprises a first plunger slidable within said fluid storage container and a first drive assembly in the form of a first rod operably connected between said actuator and said first plunger and movable in response to movement of the actuator to move said first plunger, and wherein said second movable means comprises a second plunger slidable within said material storage container and a second drive assembly in the form of a second rod operably connected between said actuator and said second plunger and movable in response to movement of the actuator to move said second plunger, and wherein said first and second chambers are arranged in side by side relationship in a substantially common plane, and said first and second rods extend within said housing substantially parallel with respect to one another.

9. An instrument as claimed in Claim 8, wherein said actuator comprises a pivotable lever having a head on one end thereof adapted to engage the free ends of said first and second rods.

to expand the expandable member and to dispense material into 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 from which the present application is divided.

In addition, a method of dispensing fluid material into the Fallopian tubes 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 body of the female are described and claimed in our copending application No. 49023/76 (Serial No. 1,470,573) which is also divided from parent application No. 10593/74 (Serial No. 1,470,571).

WHAT WE CLAIM IS:—

1. An instrument for dispensing fluid material into the Fallopian tubes of a female body, comprising an elongate member having at or near one end thereof an expandable member and at least one outlet for fluid material, said expandable member and the or each outlet being positionable within a uterine cavity, and a dispensing unit coupled to said elongate member at a position remote from said one end, the dispensing unit having means for expanding said expandable member, dispensing means for dispensing fluid material through the or each outlet, and a single actuator for operating both said means for expanding said expandable member and said dispensing means.

2. An instrument as claimed in Claim 1, wherein said means for expanding said expandable member comprises means for applying a fluid under pressure to said expandable member, and wherein said dispensing unit further comprises means to prevent an increase in the fluid pressure applied to the expandable member above a predetermined pressure.

3. An instrument as claimed in Claim 1 or 2, wherein said actuator is operable to operate said means for expanding said expandable member and said dispensing means sequentially.

4. An instrument as claimed in Claim 3, wherein said actuator is operable to first operate said means for expanding said expandable member to partly expand said expandable member, then to operate said dispensing means, and then to operate said means for expanding said expandable member to further expand said expandable member to force dispensed material from the uterine cavity into the Fallopian tubes.

5. An instrument as claimed in Claim 4, wherein a single operation of said actuator is arranged to perform said sequential operations of said means for expanding said expandable member and said dispensing means.

6. An instrument as claimed in Claim 4 to 5, wherein a single operation of said actuator is arranged to perform said sequential operations of said means for expanding said expandable member and said dispensing means in continuous sequence.

7. An instrument as claimed in any preceding claim, wherein the dispensing unit comprises a housing having a first chamber and a second chamber, a container for storing a fluid for expanding said expandable member being located in the first chamber, a container for storing a fluid material to be dispensed being located in the second chamber, and wherein the elongate member has a passage for fluid coupled to said fluid storage container, and a passage for fluid material coupled to said material storage container the dispensing unit further comprising first movable means operable to move fluid through the fluid passage to the expandable member, and second movable means operable to move material through the material passage to the or each said outlet, said actuator being operable to sequentially move both the first movable means and the second movable means.

8. An instrument as claimed in Claim 7 when appended to any of Claims 1 to 3, wherein said first movable means comprises a first plunger slidable within said fluid storage container and a first drive assembly in the form of a first rod operably connected between said actuator and said first plunger and movable in response to movement of the actuator to move said first plunger, and wherein said second movable means comprises a second plunger slidable within said material storage container and a second drive assembly in the form of a second rod operably connected between said actuator and said second plunger and movable in response to movement of the actuator to move said second plunger, and wherein said first and second chambers are arranged in side by side relationship in a substantially common plane, and said first and second rods extend within said housing substantially parallel with respect to one another.

9. An instrument as claimed in Claim 8, wherein said actuator comprises a pivotable lever having a head on one end thereof adapted to engage the free ends of said first and second rods.

10. An instrument as claimed in Claim 9, wherein said head has a passage therethrough arranged to accommodate said second rod whereby movement of said head can be arranged to move only said first rod and hence said first plunger relative to said first chamber.

11. An instrument as claimed in Claim 10, wherein said head includes a bore extending transversely of said passage and having a pin slidably disposed therein, the pin being resiliently biased into said passage to block said passage.

12. An instrument as claimed in Claim 11, wherein said pin is arranged to be retained in said bore by said first rod whereby upon movement of said first rod by said head said pin is biased into said passage.

13. An instrument as claimed in Claim 7, wherein said first movable means comprises a first plunger slidable within said fluid storage container and a first drive assembly operably connected between said actuator and said first plunger and movable in response to movement of the actuator to move said first plunger, and wherein said second movable means comprises a second plunger slidable within said material storage container and a second drive assembly operably connected between said actuator and said second plunger and movable in response to movement of the actuator to move said second plunger.

14. An instrument as claimed in Claim 13, further comprising first releasable means to drivably connect said actuator with said first drive assembly and second releasable means to drivably connect said actuator with said second drive assembly.

15. An instrument as claimed in Claim 13 or 14, further comprising lock means associated with said first drive assembly to stop movement of said first drive assembly when a predetermined fluid pressure is present in the expandable member.

16. An instrument as claimed in Claim 15, wherein said housing has a plurality of teeth facing said first drive assembly, and said lock means are engageable with one of the teeth to stop movement of the first drive assembly when a predetermined fluid pressure is present in said expandable member.

17. An instrument as claimed in Claim 16, wherein said lock means includes a body having a projection, and biasing means for moving the projection between adjacent teeth when the predetermined pressure is attained.

18. An instrument as claimed in any of Claims 7 to 17, wherein said fluid passage is coupled to said fluid storage container by way of a first needle and said first movable means is operable to cause the first needle to pierce a portion of said fluid storage container.

19. An instrument as claimed in Claim 18, wherein said first needle is connected to said fluid passage externally of said fluid storage container and said first movable means is operable to move said fluid storage container relative to said first chamber into contact with said first needle to cause the first needle to pierce a portion of said fluid storage container.

20. An instrument as claimed in Claim 18 or 19, wherein said first needle is an elongate tubular member having a passage extending therethrough and having a pointed end portion adapted to pierce a portion of said fluid storage container.

21. An instrument as claimed in any of Claims 7 to 20, wherein said material passage is coupled to said material storage container by way of a second needle and said second movable means is operable to cause the second needle to pierce a portion of said material storage container.

22. An instrument as claimed in Claim 21, wherein said second needle is connected to said material passage externally of said material storage container and said second movable means is operable to move said material storage container relative to said second chamber into contact with said second needle to cause the second needle to pierce a portion of said material storage container.

23. An instrument as claimed in Claim 21 or 22, wherein said second needle is an elongate tubular member having a passage extending therethrough and having a pointed end portion adapted to pierce a portion of said fluid storage container.

24. An instrument as claimed in any of Claims 7 to 23, wherein a further chamber is provided in said housing and a further container for storing a fluid material to be dispensed is located in said further chamber, and further movable means operable by said actuator for moving said material out of said further container are provided.

25. An instrument as claimed in Claim 24, wherein said further container is coupled to a further passage for fluid material of said elongate member.

26. An instrument as claimed in any preceding claim, further comprising a head located on said elongate member adjacent the expandable member, said head having a material receiving passage.

27. An instrument as claimed in any preceding claim, wherein the expandable member comprises a balloon of flexible, elastic material.

28. An instrument for dispensing fluid material into the Fallopian tubes of a female body substantially as hereinbefore

described with reference to Figures 1 to 5 of the accompanying drawings.

29. An instrument for dispensing fluid material into the Fallopian tubes of a female body substantially as hereinbefore described with reference to Figures 6 and 7 of the accompanying drawings.

30. An instrument for dispensing fluid material into the Fallopian tubes of a female body substantially as hereinbefore described with reference to Figures 8 to 13 of the accompanying drawings.

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