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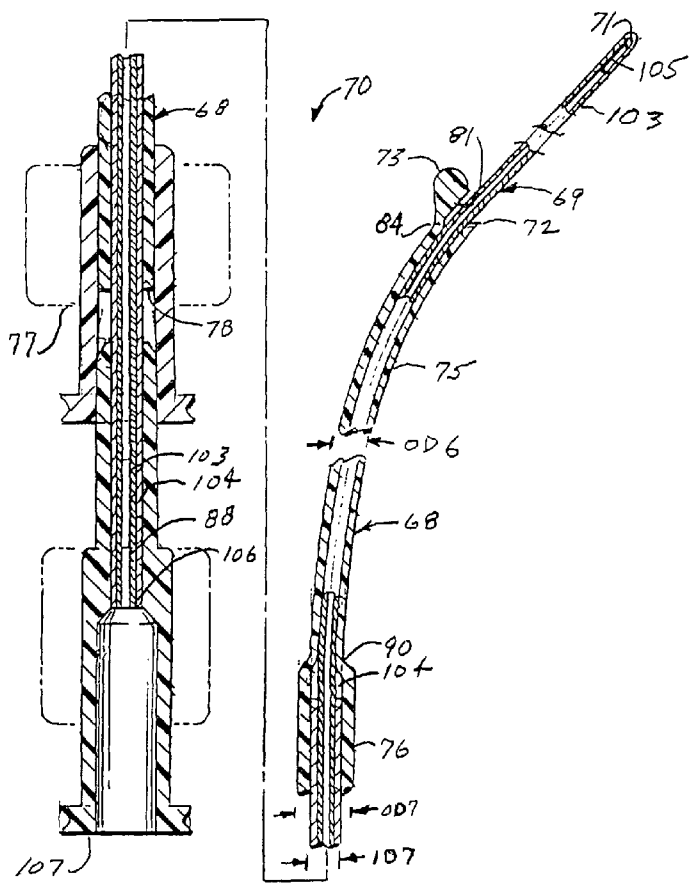
(54) **Title:** CATHETER SYSTEM FOR IMPLANTING EMBRYOS



(57) **Abstract:** Described is a catheter system for implanting embryos into a woman's uterus. The catheter system utilizes a protective catheter sleeve for introducing a catheter into the uterus without mucus contamination of an inner catheter. Once the sleeve containing the inner catheter is introduced into the uterus, the protected inner catheter, carrying the embryos, is pushed through a swivelable distal end cap on the sleeve to a desired implanting location. The distal end of the inner catheter has a protective cap and a side opening for embryo release. Also, stiffness and indicia features of the outer sleeve and inner catheter assist in the physician's handling of the catheter system and in ensuring a desired uterus location for implanting.

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CATHETER SYSTEM FOR IMPLANTING EMBRYOS

CROSS REFERENCE TO RELATED APPLICATION

The present application is related to prior U.S. application Serial No. 09/542,060 filed April 3, 2000, which is a continuation-in-part of U.S. application Serial No. 09/010,876 filed January 22, 1998, now abandoned, which application was a continuation-in-part of U.S. application Serial No. 08/638,451 filed 04/26/96, now abandoned.

BACKGROUND

The invention relates to a catheter system for implanting embryos into a woman's uterus. More particularly, this invention concerns such a catheter system utilizing a protective catheter sleeve for introducing a catheter into the uterus without mucus contamination. And it concerns an improved catheter construction for embryo protection and deposit.

Typically, in present fertility clinics, three or four embryos are placed in a tiny, flexible catheter near the opening in the depositing end (the distal end) of the catheter. The catheter is then inserted through the woman's cervix and the embryos flushed hydraulically from the catheter and, hopefully, the embryos become implanted in the uterus wall. But the small catheter required is difficult to insert and mucus from the mouth of the cervix may be caught at the mouth of the catheter and interfere with the embryos. So, a stiffer and larger sleeve catheter may be used for insertion through the cervix; and then the smaller catheter may be pushed through and out the larger sleeve catheter to implant the embryos. This sleeve use helps, but cervix mucus may still be caught in the introduction end (the distal end) of the larger catheter and then transferred to the smaller catheter, thus still possibly interfering with the embryos.

The prior art includes some catheter-type devices for use in embryo implantation. In particular, Bacich U.S. Pat. No. 5,472,419 and Fischl U.S. Pat. No. 4,790,814 both employ the use of a catheter-type device, each having distal end openings to allow passage of the embryos to the uterus. Though these devices may be used for embryo implantation, they do not adequately address the problem of preventing the accumulation of mucuslike material at the distal end opening, which may interfere with embryo implantation. Other embryo implanting devices employ the use of a catheter enclosed within an outer sleeve. For example, Wallace's GB No. 2,118,840 employs the use of an inner catheter slidable within

an outer sleeve where the distal end of the outer sleeve is open. Though this device might also be suitable for embryo implantation, it fails to teach or implement an efficient way to protect against mucus accumulation within the outer sleeve during insertion. Other medical devices in fields other than embryo implantation employ the use of a catheter enclosed within an outer sleeve. For example, Pokorney U.S. Pat. No. 5,083,572 employs the use of an inner catheter slidable within an outer sleeve for use in obtaining vaginal secretions; but the purpose and construction are to bring in secretions/mucus within the outer sleeve, not to keep them out. And Pokorney's use of side sampling ports near the distal end of the outer sleeve do not prevent mucus accumulation within the outer sleeve nor does the sleeve permit the inner catheter to slide out of the sleeve to deposit an embryo or for any purpose whatsoever.

Other background art, still further removed from addressing such problems as mucus accumulation during embryo implanting include Kalayjian U.S. Pat. No. 3,513,830, which discloses an instrument for obtaining body cultures. This instrument employs the use of a cotton swab slidable within a plastic sterilizable outer sleeve. The outer sleeve has a friction-fitted cap, outwardly convex, which can be inserted into a body cavity closed and then opened once inside the desired cavity to allow the cotton-tipped swab to project out of the outer sleeve to take a tissue sample. An object of the Kalayjian invention is apparently to prevent the swab from becoming contaminated either before or after the swab comes in contact with the desired tissue. Kalayjian differs from the present invention in many ways: it is not designed for the purpose of embryo implanting; it is not designed to hold an inner catheter (it holds a wooden swab); it is not designed to be "opened" by a fragile inner catheter (and might well destroy an emerging inner catheter); the cap/tip is designed (internally indented) to match the swab; etc. O'Neil, U.S. Pat. No. 4,652,259, is even further afield. It discloses a urinary catheter assembly and has to do with bacteria protection of the bladder in collecting urine, not mucus and embryo protection for transplanting. The sleeve is built for specific use only in the outer urethra and only the inner catheter is permitted to travel alone through the inner urethra and into the bladder for catheterization. Similarly, Vega, U.S. Pat. No.4,249,536, discloses a urological catheter with a soft pliable cone-shaped tip (containing spiral grooves or hair-like projections) which can open by means of strings attached to the tip. This device also uses magnetic forces to advance the

catheter through the urethra. This device differs in many important ways from the present invention; e.g., the Vega tip opens to a very wide position which could cause significant trauma if used for embryo transfer; the Vega device uses strings to pull open the tip of the catheter, and the tip itself is not a unitary small, light, part of the distal end of the catheter, openable by the pushing of a fragile embryo-transfer type of inner catheter, etc.; and closing such a device is difficult. Whatever end system may be used on a sleeve for embryo transfer, it is obviously vitally important that pieces of the end do not break off and remain in the cervix.

Thus there is a need for a catheter system for implanting embryos which will better protect the embryos from mucus and other damage in an efficient manner.

OBJECTS OF THE INVENTION

A primary object of the present invention is to fulfill the above-mentioned needs by the provision of an improved catheter system for implanting embryos. A further primary object of the present invention is to provide such a catheter system which is efficient, inexpensive, and handy. Other objects of this invention will become apparent with reference to the following invention descriptions.

SUMMARY OF THE INVENTION

According to a preferred embodiment of the present invention, this invention provides a catheter system for assisting implanting embryos in a uterus, comprising: catheter sleeve means, having a sleeve distal end and a sleeve proximal end and having, between such sleeve distal end and such sleeve proximal end, a longitudinal cylindrical hollow having a central longitudinal axis, such catheter sleeve means being structured and arranged for containing an inner catheter in such cylindrical hollow, such catheter sleeve means comprising end cap means, disposed along an intersection of such central axis at such sleeve distal end, for substantially enclosing such cylindrical hollow at such sleeve distal end to protect such cylindrical hollow from accumulating mucuslike material when such catheter sleeve means is pushed through a cervix, such end cap means comprising end opening means, disposed along such intersection of such central axis at such sleeve distal end, for permitting passage of an inner catheter along such central axis from within such cylindrical hollow into a such uterus; such catheter sleeve means being structured and arranged for travel of such sleeve distal end through the cervix for assistance in implanting embryos.

Further, this invention provides such a system wherein such end opening means of such sleeve distal end comprises swivel means constructed and arranged in such manner that such end cap means swivels outward when an inner catheter is pushed through such sleeve distal end; and, further, wherein such end cap means comprises an outwardly convex flexible end on such catheter sleeve means and such end cap opening means comprises a partial transverse cut separating, except for a remaining transverse hinge portion, such outwardly convex flexible end from such catheter sleeve means, whereby such end cap means is constructed and arranged to swivel outward when an inner catheter is pushed through such sleeve distal end. And it provides such a system further comprising: an inner catheter means, having a catheter distal end and a catheter proximal end, for transporting a such embryo through such cylindrical hollow of such outer sleeve means into access to such uterus and for depositing such embryo in such uterus; and, further, wherein such inner catheter means comprises indicia means for indicating longitudinal distance to assist in attaining a desired implanting location.

Also, this invention provides such a system wherein such catheter distal end comprises: catheter distal opening means for depositing such embryo, such catheter distal opening means comprising a side port, adjacent such catheter distal end of such inner catheter means. And it provides such a system wherein such catheter distal end comprises: second end cap means at such catheter distal end for protecting such inner catheter means when such catheter distal end is pushed through such sleeve distal end; and catheter distal opening means for depositing such embryo, such catheter distal opening means comprising a side port adjacent such second end cap means at such catheter distal end of such inner catheter means; and, further, wherein such catheter distal end further comprises strengthening means opposite such catheter distal opening means for strengthening such inner catheter means against breakage. Also, it provides such a system wherein such end opening means at such sleeve distal end of such catheter sleeve means comprises swivel means constructed and arranged in such manner that such end cap means swivels outward when such catheter distal end is pushed through such sleeve distal end.

In addition, it provides such a system wherein such catheter sleeve means further comprises first stop means for limiting insertion to a desired location when such catheter sleeve means is inserted through the cervix; and, further, wherein such inner catheter means

further comprises second stop means settable along such inner catheter means for limiting insertion to a desired implanting location when such inner catheter means is inserted into a such uterus. And it provides such a system wherein such catheter sleeve means further comprises stop means for limiting insertion to a desired location when such catheter sleeve means is inserted into a such uterus.

Even further, in accordance with a preferred embodiment thereof, the present invention provides a catheter system for implanting embryos in a uterus, comprising: a catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve distal end and a sleeve proximal end, for providing safe catheter access to a such uterus by a catheter having a catheter distal end and a catheter proximal end; such sleeve distal end comprising an outwardly convex end cap, for protecting such cylindrical hollow from accumulating mucuslike material when such catheter outer sleeve is pushed through a cervix, and an outwardly-swivelable connection between such end cap and such catheter outer sleeve, for permitting passage of a such catheter distal end from such cylindrical hollow into access to the uterus when such catheter distal end is pushed against such end cap to swivel such end cap outwardly and move such catheter distal end through such sleeve distal end.

Even additionally, this invention provides such a system further comprising: an inner catheter means, having a catheter distal end and a catheter proximal end, for transporting a such embryo through such cylindrical hollow of such outer sleeve into access to such uterus and for depositing such embryo in such uterus. And it provides such a system wherein such catheter distal end comprises: an outwardly convex second end cap for protecting such inner catheter means when such catheter distal end is pushed through such sleeve distal end; and a catheter distal opening for depositing a such embryo, such catheter distal opening comprising a side port adjacent such second end cap. It also provides such a system further comprising: locating means for locating such catheter distal end in a such uterus, such locating means comprising first stop means on such catheter outer sleeve for abutting a cervix entrance to such uterus, and second stop means settable along such inner catheter means for limiting insertion of such catheter distal end of such inner catheter means to a desired implanting location when such inner catheter means is inserted into a such uterus.

Moreover, according to a preferred embodiment of this invention, it provides a catheter system for implanting embryos in a uterus, comprising, in combination, the steps

of: providing a catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve proximal end and a sleeve distal end having an outwardly convex end cap and an outwardly-swivelable connection between such end cap and such catheter outer sleeve; providing a catheter having a catheter proximal end and a catheter distal end having an opening for transmission of a such embryo, such catheter being sized for moving through such longitudinal cylindrical hollow; loading at least one such embryo into such catheter distal end; placing such catheter into such sleeve proximal end of such catheter outer sleeve and moving such catheter forward until such catheter distal end is approaching such sleeve distal end; introducing such sleeve proximal end through a cervix to a desired stop location; further moving such catheter forward into such end cap of such catheter outer sleeve, outwardly swiveling such end cap, and further moving such catheter distal end forward into such uterus to a desired implanting location; and flushing such embryo out of such catheter distal end.

It even further provides such a system wherein such catheter distal end of such catheter comprises: a second end cap for protecting such catheter when such catheter distal end is pushed through such sleeve distal end; and a catheter distal opening for depositing a such embryo, such catheter distal opening comprising a side port adjacent such second end cap; and, further, wherein: such catheter outer sleeve further comprises first stop means located along such catheter outer sleeve for limiting insertion to such desired stop location when such catheter outer sleeve is introduced through the cervix; and such catheter further comprises second stop means settable along such catheter for limiting insertion to such desired implanting location when such inner catheter means is inserted into a such uterus.

Even moreover, in accordance with a preferred embodiment thereof, this invention provides, for use in a catheter system for implanting embryos in a uterus, wherein the steps in such system include providing a catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve proximal end and a sleeve distal end having an outwardly convex end cap and an outwardly-swivelable connection between such end cap and such catheter outer sleeve, providing a catheter having a catheter proximal end and a catheter distal end having an opening for transmission of a such embryo, such catheter being sized for moving through such longitudinal cylindrical hollow, loading at least one such embryo into such catheter distal end, placing such catheter into such sleeve proximal end of such catheter

outer sleeve and moving such catheter forward until such catheter distal end is approaching such sleeve distal end, introducing such sleeve proximal end through a cervix to a desired stop location, further moving such catheter forward into such end cap of such outer sleeve, outwardly swiveling such end cap, and further moving such catheter distal end forward into such uterus to a desired implanting location, and flushing such embryo out of such catheter distal end, a method of making such outwardly-swivelable connection between such end cap and such outer sleeve, comprising the steps of: providing an outwardly convex end portion at such sleeve distal end integral with such catheter outer sleeve; and cutting to partially sever such end portion from such catheter outer sleeve transversely just beneath such end portion around at least about 200 degrees of a circumference around such convex end portion; whereby an unsevered part of such end portion provides a hinge means comprising such outwardly-swivelable connection.

Also, this invention provides, in accordance with a preferred embodiment thereof, a catheter system for assisting implanting embryos in a uterus wherein such end opening means is a slit, normally closed but openable for permitting passage of a such inner catheter pushed along such central axis from within such cylindrical hollow into access to the uterus. It also provides such a system wherein such end opening means of such sleeve distal end is a cross-cut slit, normally closed but openable for permitting passage of a such inner catheter pushed along such central axis from within such cylindrical hollow into access to the uterus.

Even further, according to a preferred embodiment thereof, this invention provides a catheter system for assisting implanting embryos in a uterus, comprising: catheter sleeve means, having a sleeve distal end and a sleeve proximal end and having, between such sleeve distal end and such sleeve proximal end, a longitudinal cylindrical hollow having a central longitudinal axis, such catheter sleeve means being structured and arranged for containing an inner catheter in such cylindrical hollow, such catheter sleeve means comprising end cap means, disposed along an intersection of such central axis at such sleeve distal end, for substantially enclosing such cylindrical hollow at such sleeve distal end to protect such cylindrical hollow from accumulating mucuslike material when such catheter sleeve means is pushed through a cervix, such end cap means comprising end opening means, disposed along such intersection of such central axis at such sleeve distal end, for permitting passage of an inner catheter along such central axis from within such cylindrical

hollow into access to the uterus; said catheter sleeve means being structured and arranged for travel of such sleeve distal end through the cervix for assistance in implanting embryos; and wherein such catheter sleeve means comprises a longitudinal wire-stiffening means for wire-stiffening of such catheter sleeve means. It also provides such a catheter system wherein such wire-stiffening means comprises substantially all of a longitudinal dimension of such catheter sleeve means; and, further, wherein such wire-stiffening means comprises a metal wire; and, further, wherein such metal wire comprises a surface of such longitudinal cylindrical hollow; and, further, wherein such wire-stiffening means is constructed and arranged to permit holding a bent shape and provide shape-maintaining support.

Moreover, according to a preferred embodiment thereof, this invention provides a catheter system for implanting embryos in a uterus, comprising: an inner catheter, having a catheter distal end and a catheter proximal end, structured and arranged to transport the embryos into access to the uterus and to deposit such embryo in the uterus; and a catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve distal end and a sleeve proximal end, structured and arranged to provide safe catheter access to the uterus by such inner catheter; wherein such inner catheter comprises a proximal portion having a larger external diameter than an external diameter of a distal portion of such inner catheter. It also provides such a catheter system wherein such catheter outer sleeve comprises a proximal portion having a larger internal diameter than an internal diameter of a distal portion of such catheter outer sleeve and having a thicker wall than the wall of such distal portion of such catheter outer sleeve.

And it provides such a catheter system wherein a distal end of such distal portion of such catheter outer sleeve comprises more flexible material than a remainder of such distal portion of such catheter outer sleeve, whereby such catheter outer sleeve comprises at least three different stiffnesses along such longitudinal hollow cylinder, in increasing-stiffness order from such distal end to such proximal end of such longitudinal hollow cylinder; and, further, wherein such proximal portion of such inner catheter is at least as long as such proximal portion of such catheter outer sleeve; and, further, wherein such proximal portion of such catheter outer sleeve is at least about 10 centimeters long; and, further, wherein such distal portion of such catheter outer sleeve is at most about 5 centimeters long.

Yet moreover, according to a preferred embodiment thereof, this invention provides

a catheter system for assisting implanting embryos in a uterus, comprising: a catheter outer sleeve having a sleeve distal end and a sleeve proximal end and having, between such sleeve distal end and such sleeve proximal end, a longitudinal cylindrical hollow having a central longitudinal axis, such catheter outer sleeve being structured and arranged to contain an inner catheter in such cylindrical hollow, such catheter outer sleeve comprising a longitudinal wire-stiffener structured and arranged to stiffen such catheter outer sleeve; said catheter outer sleeve being structured and arranged to permit travel of such sleeve distal end through a cervix to assist in implanting embryos; wherein such catheter outer sleeve comprises a proximal portion having a larger internal diameter than an internal diameter of a distal portion of such catheter outer sleeve; and, further, wherein such wire-stiffener comprises substantially all of a longitudinal dimension of such catheter outer sleeve. And it provides such a catheter system further comprising an inner catheter, having a catheter distal end and a catheter proximal end, structured and arranged to transport the embryos into access to the uterus and to deposit the embryos in the uterus; and, further, wherein such inner catheter comprises a proximal portion having a larger external diameter than an external diameter of a distal portion of such inner catheter; and, further, wherein such proximal portion of such inner catheter is at least as long as such proximal portion of such catheter outer sleeve. And it provides such a catheter system wherein such catheter outer sleeve comprises an end cap, disposed along an intersection of such central axis at such sleeve distal end, to substantially enclose such cylindrical hollow at such sleeve distal end to protect such cylindrical hollow from accumulating mucuslike material when such catheter outer sleeve is inserted into the uterus, such end cap comprising an end opener, disposed along such intersection of such central axis at such sleeve distal end, to permit passage of a such inner catheter along such central axis from within such cylindrical hollow into the uterus.

Yet in addition, according to a preferred embodiment thereof, this invention provides a catheter system for implanting embryos in a uterus, comprising: a catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve distal end and a sleeve proximal end, structured and arranged to provide safe catheter access to the uterus by an inner catheter having a catheter distal end and a catheter proximal end; said sleeve distal end comprising an internally substantially-non-concave end cap, structured and arranged to

protect such cylindrical hollow from accumulating mucuslike material when such catheter outer sleeve is pushed through a cervix, and an outwardly-swivelable connection between such end cap and such catheter outer sleeve, such sleeve distal end being structured and arranged to permit non-destructive passage of a such catheter distal end from such cylindrical hollow into access to the uterus when such catheter distal end is pushed against such internally substantially-non-concave end cap, thereby swiveling such end cap outwardly and moving such catheter distal end through such sleeve distal end.

And it provides such a catheter system wherein said outwardly-swivelable connection is a unitary part of such sleeve distal end; and, further, wherein such catheter outer sleeve comprises a long metal tube connected to a short plastic distal end comprising such swivelable end cap; and, further, wherein such outwardly-swivelable connection is a unitary part of such sleeve distal end, and such end cap is a unitary part of such sleeve distal end. It further provides such a catheter system wherein an internal surface of such internally substantially-non-concave end cap lies substantially within a single flat plane; and, further, wherein said internally substantially-non-concave end cap is outwardly convex. Also, this invention provides such a catheter system wherein such sleeve distal end further comprises mucus-trapping means for trapping nearby mucus during a such passage of a such catheter distal end from such cylindrical hollow into access to the uterus; and, further, wherein such mucus-trapping means comprises roughened surface portions to assist in such trapping of mucus. And it provides such a catheter system wherein such roughened surface portions comprise both external and internal surfaces of such sleeve distal end; and, further, wherein such end cap comprises an outwardly convex flexible end on such catheter outer sleeve and such outwardly-swivelable connection comprises a partial planar cut separating, except for a remaining transverse hinge portion, such outwardly convex flexible end from such catheter outer sleeve, whereby such end cap comprises a planar internal surface; and, further, wherein said partial planar cut comprises an angle between such planar internal surface and a transverse plane perpendicular to a longitudinal axis of such longitudinal hollow of from about 0 degrees to about 45 degrees; and, further, wherein said angle is from about fifteen degrees to about twenty degrees.

Even in addition, according to a preferred embodiment thereof, this invention provides a catheter system for single-person implanting of an embryo in a uterus,

comprising, in combination, the steps of: providing a wire-stiffened catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve proximal end and a sleeve distal end, wherein a proximal portion of such cylindrical hollow has a larger internal diameter than an internal diameter of a distal portion of such cylindrical hollow; providing an inner catheter having a catheter proximal end and a catheter distal end having an opening for transmission of a such embryo, such catheter being sized for moving through such longitudinal cylindrical hollow, wherein a proximal portion of such inner catheter has a greater catheter wall thickness than a distal portion of such inner catheter, and wherein such proximal portion of such inner catheter has a larger external diameter than an external diameter of such distal portion of such inner catheter, and said inner catheter being structured and arranged to supportingly fit within such outer sleeve, thereby providing substantially greater catheter system stiffness; affixing a syringe at such proximal end of such inner catheter;

loading such embryo into such inner catheter distal end; placing such inner catheter into such proximal end of such outer sleeve and moving such inner catheter forward until such inner catheter distal end is approaching such sleeve distal end; introducing such sleeve proximal end into a cervix to a desired stop location; further moving such inner catheter forward into such end cap of such outer sleeve, outwardly swiveling such end cap, and further moving such catheter distal end forward into access to the uterus to a desired implanting location; and flushing such embryo out of such catheter distal end.

It also provides such a catheter system wherein, during such step of further moving such inner catheter forward, forward travel of such inner catheter is limited by a distal end of such proximal portion of such inner catheter being blocked when reaching a distal end of such proximal portion of such outer sleeve, thereby assisting in avoiding injury to the uterus from too much forward travel of such inner catheter; and, further, wherein such step of moving such inner catheter forward may be accomplished by one hand of a catheter system user because of such substantially greater catheter system stiffness.

And it also provides a described catheter system wherein such inner catheter means further comprises, located adjacent such proximal end of such inner catheter means, indicator means for indicating a direction of opening of such side port. It also provides a described catheter system wherein such catheter outer sleeve further comprises a bend in

such distal portion of such catheter outer sleeve to better assist in pushing through the cervix; and, further, wherein such catheter outer sleeve further comprises, located adjacent such proximal end of such catheter outer sleeve, indicator means for indicating a direction of such bend of such distal portion of such catheter outer sleeve. And it also provides a described catheter system wherein such swivel means is constructed and arranged in such manner that such end cap means swivels back to a closed position when such catheter sleeve means is pulled from the cervix.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partial sectional elevation view illustrating a preferred embodiment of a catheter system for implanting embryos, according to the present invention, shown inserted into a woman's uterus.

FIG. 2 is an exploded elevation view of the catheter system.

FIG. 3 is an enlarged, fragmented elevation view, in cross section, of a preferred embodiment of the outer sleeve of the catheter system.

FIG. 4 is a enlarged elevation view of the introducing-implanting end of the outer sleeve.

FIG. 5 is a cross-section plan view of the outer sleeve through section 5-5 of Fig.4.

FIG. 6 is an enlarged perspective view of the outer sleeve end, shown in its open position.

FIG. 7 is an enlarged cross-sectional elevation view of the implanting end of the inner catheter.

FIG. 8 is an enlarged elevation view of the implanting end of the inner catheter.

FIG. 9 is a cross-section plan view of the inner catheter through section 9-9 of Fig. 8.

FIG. 10 is an enlarged cross-section partial elevation view showing the inner catheter within the outer sleeve at its implanting end.

FIG. 11 is a perspective view showing a second embodiment of the implanting end of the inner catheter.

FIG. 12 is a perspective view showing a third embodiment of the implanting end of the inner catheter.

FIGS. 13 through 19 illustrate a preferred embodiment of the method of use of the

catheter system of the present invention.

FIG. 20 is a enlarged elevation view of the introducing-implanting end of the outer sleeve illustrating alternate, but less preferred, embodiments of the end opening means.

FIG. 21 is a top view of the embodiments of FIG. 20 illustrating a first alternate embodiment of the end opening means.

FIG. 22 is a top view of the embodiments of FIG. 20 illustrating a second alternate embodiment of the end opening means.

FIG. 23 is a top view illustrating an additional preferred embodiment of the catheter system of the present invention.

FIG. 24 is a cross-sectional view of the additional preferred embodiment, taken through the center lines looking downward, illustrating in detail the preferred construction and the outer sleeve as it relates to the inner catheter.

FIG. 25 is a perspective view of the winged locking mechanism for connecting a syringe to the catheter system.

FIG. 26 is an enlarged view, partially in section, of a preferred embodiment of the end cap of the outer sleeve and the implanting end of the inner catheter.

FIG. 27 is an enlarged cross-sectional view of the outer sleeve containing the inner catheter taken through section 27-27 of FIG. 23.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT AND THE BEST MODE OF PRACTICE

Shown in FIG.1 is a preferred embodiment of the catheter system **20** of the present invention, shown inserted into the uterus **21** of a woman for the purpose of depositing embryos **22**. The catheter system **20** is comprised of catheter sleeve means embodied by catheter outer sleeve **24** and inner catheter means embodied by an inner catheter **25**. The outer sleeve **24** contains and protects the inner catheter **25** (the two being concentrically disposed), and the embryos **22** within, while the catheter system **20** is inserted into the vagina, through the cervix **26**, and into the uterus **21**. Then there is performed embryo depositing and placement at a predetermined depth (from the exterior of the cervix) **D1** within the uterus **21**. Once deposited within the uterus **21**, the embryos **22** will normally eventually attach to the uterus wall **27**.

The outer sleeve **24** is substantially tubular, as shown, and has a longitudinal round-cylindrical hollow **28** (having interior surface **30**) appropriately sized for loosely containing the inner catheter **25** and extending the full length of the outer sleeve **24** (i.e., from its distal or depositing end **31** to its proximal or manipulating end **40**). Integral with the outer sleeve **24**, and at its depositing end **31**, is end cap means preferably embodied by a swivelable cap **32** which remains in a closed position **33** (see FIGS. 3, 4, and 10), closing, streamlining, and protecting the depositing end **31**, and blocking the cylindrical hollow **28**, until being pushed forwardly to an open position **34** by the extending movement of the inner catheter **25**. The swivelable cap **32**, while remaining in a closed position **33**, protects the interior of the outer sleeve **24** at the depositing end **31** from accumulating deposits of mucus **35** when the outer sleeve **24** is inserted through the cervix **26**.

The outer sleeve **24** incorporates a stop means embodied by a flange **36** extending outwardly perpendicular from the outer sleeve **24** and of a diameter suitable for providing a limiting stop **37** at the entrance **38** of the cervix **26**, and thus controlling the depth **D2** that the outer sleeve **24** can be inserted into the cervix **26**. This depth **D2** is greater than the distance required to pass through the cervix **26**, but less than the depth desired for depositing the embryos **22**. This portion of the outer sleeve **24** (which is inserted through the cervix **26** to depth **D2**), extending from flange **36** to the swivelable cap **32**, is the insertable portion **29** which is relatively small in outside diameter and flexible enough for conforming to the shape of the cervical passage.

Extending from flange **36** toward the manipulating (proximal) end **40**, the outer sleeve **24** incorporates an increased outer diameter **41** for added rigidity in controlling the insertion of the catheter system **20** of the preferred embodiment of the present invention into the cervix **26**. Also incorporated as a feature of the increased outer diameter **41** portion, located near the manipulating end **40**, is handle means **42** for convenience of grasping the outer sleeve **24**. Located at the manipulating end **40** of the outer sleeve **24** is a second flange **43** useful (as will be described) for controlling the movement of the inner catheter **25** in providing the desired implanting depth **D1**.

Alternately, it is noted that, as another preferred embodiment in which the sleeve may be bendable to conform to the shape of the cervix rather than flexible as stated above,

outer sleeve **24** may be made of, for example, a thin-walled stainless steel tube (preferably about 2 mm in outside diameter with a wall thickness of about 0.2 mm). Then insertable portion **29** may be bent to a specific cervical shape. In this embodiment, the distal end (about the last 1 cm thereof) of sleeve **24** is still made of a soft plastic to permit making an end cap as shown in this specification (preferably with about a 3 mm nominal outer diameter and with an internal diameter fitting tightly over the distal end of the stainless steel tube to provide integrity. This alternative embodiment (embodying herein such catheter system wherein such catheter outer sleeve comprises a long metal tube connected to a short plastic distal end comprising such swivelable end cap), while possibly not economically optimal, also provides additional stiffness and support to the catheter system, which is important; and such support will be discussed further with respect to the embodiment of FIGS. 23 et seq.

With respect to the drawings, again, he inner catheter **25** is a hollow, flexible, very-small-diameter longitudinal tube, sized to fit, and be free to slide concentrically within, the longitudinal cylindrical hollow **28** of the outer sleeve **24** along its axis or centerline **CL** (see FIG. 3). At the depositing (distal) end **39**, the inner catheter **25** preferably incorporates an integral domed end cap **44** with a side port **45** interconnecting to the round-cylindrical interior passage **57** of the inner catheter **25**. At the manipulating (proximal) end **46** of the inner catheter **25** is a receiver **47** into which a syringe **48** may be inserted. In use, the distal or depositing end **39** of the inner catheter **25** is loaded with buffer solution and embryos, then inserted into the manipulating end **40** of the outer sleeve **24** far enough so that the depositing end **39** approaches but does not contact the swivelable cap **32** (in its normal closed position); thus the depositing end **39** of the inner catheter **25** is not yet protruding from the depositing end **31** of the outer sleeve **24**. Based upon prior soundings of the depth of the uterus, the desired depth **D1** at which the embryos are to be deposited is determined. The amount this depth **D1** is greater than the distance **D2** (that the insertable portion **29** of the outer sleeve **24** inserts into the cervix **26**) determines the distance **D3** that the inner catheter **25** will be required to extend beyond the end of the outer sleeve **24** for implanting. When this distance **D3** is established and added to distance that the inner catheter **25** is short of exiting from the outer sleeve **24**, a snug-fitting second stop means embodied by movable

stop **50** is positioned on the inner catheter **25** a corresponding distance away from the second flange **43** of the outer sleeve **24**.

The catheter system **20** is then inserted into the uterus **21** through the cervix **26**. Any mucus **35** that the insertable portion **29** of the outer sleeve **24** encounters and picks up remains on its exterior. After the described preferred insertion of the insertable portion **29** of the outer sleeve **24** into the uterus, the inner catheter **25**, held concentrically by the outer sleeve **24**, is pushed forward along the axis or longitudinal centerline **CL** of the outer sleeve **24** the distance available until the movable stop **50** contacts the outer sleeve's second flange **43**. This forward concentric movement of the inner catheter **25** pushes its domed end cap **44** against the outer sleeve's swivelable cap **32** (situate also along the centerline **CL** of the outer sleeve **24**), opening it, and allowing the inner catheter **25** to extend beyond the outer sleeve **24** to the depth **D1**. Any mucus **35** encountered and picked up by the outer sleeve **24** (especially at its swivelable cap **32**) is pushed aside by the opening movement of the swivelable cap **32**. Thus the inner catheter **25** in exiting from the interior of the outer sleeve **24** remains free of mucus **35**. With the embryos **22**, which are to be implanted, contained inside near the side port **45** at the depositing end **39** of the inner catheter **25**, and the inner catheter **25** shielded from passing through an accumulation of mucus **35**, the depositing of embryos **22** is not hindered by mucus **35**. This arrangement embodies in this invention an end cap means, disposed along an intersection of such central axis at such sleeve distal end, for substantially enclosing such cylindrical hollow at such sleeve distal end to protect such cylindrical hollow from accumulating mucuslike material when such catheter sleeve means is inserted into a such uterus, such end cap means comprising end opening means, disposed along such intersection of such central axis at such sleeve distal end, for permitting passage of an inner catheter along such central axis from within such cylindrical hollow into a such uterus. Once the inner catheter **25** is positioned at depth **D1**, the embryos **22**, in their buffer solution, are hydraulically flushed from the side port **45** by means of the syringe **48** (and the flow of liquid through the interior passage **57** in well-known ways). After the embryos **22** are deposited within the uterus **21**, the catheter system **20** is withdrawn from the cervix **26**, uterus **21** and the vagina.

FIG. 2 illustrates the relative proportions of the components of the catheter system

20, shown un-assembled, and composed of the outer sleeve **24**, inner catheter **25** and the movable stop **50**. Additionally illustrated in enlarged shortened cross section in FIG. 3 is the outer sleeve **24**. Its features include the insertable portion **29** extending from the depositing end **31**, with the swivelable cap **32** located centrally at the axis or centerline **CL**, to the flange **36** whose upper surface is the limiting stop **37** to restrict further insertion into the cervix **26**. Extending from the flange **36** to the manipulating end **40**, the outer sleeve **24** is of increased outer diameter **41**. At the manipulating end **40** is a second flange **43** for providing a gauging surface with which the movable stop **50** may make contact. The longitudinal round-cylindrical hollow **28** extends from depositing end **31** to manipulating end **40** along axis or centerline **CL**. Additionally located near the manipulating end **40** is a handle means **42** which is sized and shaped for convenient handling of the outer sleeve **24**. The movable stop **50** is made of silicone and has an inside diameter that is sized for a snug fit over the outside diameter of the concentrically-located inner catheter **25**. The fit allows the movable stop **50** to be positioned as required on the inner catheter **25**, yet remain in that position during use. The inner catheter **25** has a depositing end **39** and at the opposite (proximal) end, a receiver **47** with an appropriately-sized internal socket for the snug-fitting attachment of a syringe. The proportional lengths of the outer sleeve **24** and the inner catheter **25** are such that a first person can insert and position the outer sleeve **24** within the patient and advance the inner catheter **25** while a second person can, from a convenient distance, handle the syringe **48** and perform the flushing of the embryos into the uterus.

In further description of the outer sleeve **24**, in addition to FIG.3, the depositing end **31** is shown in elevation view in FIG. 4, in cross-section in FIG. 5 and in perspective in FIG. 6. The material from which the entire outer sleeve **24** is constructed could preferably be siliconized polyvinylchloride, plastisol polyvinyl, or polyethylene. Alternately, either the entire insertable portion **29**, or the end 0.5-1.0 centimeter of the depositing end **31** of the insertable portion **29** could be made of such just-mentioned material whereas the remainder of the outer sleeve **24** could be constructed of borosilicate or, as mentioned earlier, of a metal tubing like stainless steel. The insertable portion **29** preferably is about 1.8-2.0 millimeters in outside diameter with a length of about 3.5 centimeters. The increased outer diameter **41** portion is preferably about 4.0 millimeters in outside diameter. Extending

concentrically the length of the outer sleeve **24**, excepting the swivelable cap **32** at the depositing end **31**, the interior diameter **30** of the cylindrical hollow **28** is preferably about 1.5 millimeters. In manufacture, the depositing end **31** could be initially completely blocked with an integral outwardly convex end (preferably hemispherical), then a very thin transverse cut **55** (see FIG. 4), preferably by blade, but which may also be made by laser, would be made, nearly severing the hemisphere (preferably about 300 degrees of the circumference around the convex end, depending upon the material and geometry of the sleeve end, and preferably at least about 200 degrees of the circumference so that the hinge-action may operate properly), with the remaining un-severed portion forming the hinge **56**. The cut **55**, by blade, would extend roughly perpendicular to (no more slanted than about 45 degrees in the direction of swivel) and fully through the longitudinal cylindrical hollow **28** with the uncut amount being the hinge **56** as shown in cross-section in FIG. 5. Then the hemisphere, i.e. the swivelable cap **32**, remaining intact and partially attached to the depositing end **31** of the insertable portion **29**, in the closed position **33**, blocks the interior of cylindrical hollow **28** until being forcibly moved to an open position **34** as shown in FIG. 6 (by the movement along the axis or centerline **CL** of the inner catheter **25**).

Although the preferred configuration of the depositing end **31** of the outer sleeve **24** has been fully described, alternate (but less preferred) configurations can be used herein. For example, illustrated in FIG. 20 (in a view similar to that of FIG. 4 but without the transverse cut **55**) is the outer sleeve **24** comprising an insertable portion **29** having an approximately hemispherical depositing end **31**. Specifically illustrated in FIG. 20 is the first alternate embodiment of the end opening means embodied by a single cut or slit **53** (**53A** in FIG. 21) on the hemispherical depositing end **31** of outer sleeve **24**. FIG. 21 is a top view illustrating the cut or slit **53A**. This embodies herein a system wherein such end opening means is a slit, normally closed but openable for permitting passage of a such inner catheter pushed along such central axis from within such cylindrical hollow into a such uterus. FIG. 22 is an alternate top view of FIG. 20 illustrating a second alternate embodiment of the end opening means which is embodied by a cross-cut slit **53B** on the hemispherical depositing end **31** of outer sleeve **24**. The single slit **53A** and the cross-cut slit **53B** in, respectively, the first and second alternate embodiments of the end opening

means are normally closed to maintain a closed depositing end **31** along the axis or centerline **CL** but are openable when and if catheter distal end **39** is pushed through said sleeve distal end **31** (occurring also along axis or centerline **CL**). The second alternate embodiment embodies herein such a system wherein such end opening means of such sleeve distal end is a cross-cut slit, normally closed but openable for permitting passage of a such inner catheter pushed along such central axis from within such cylindrical hollow into a such uterus.

The inner catheter **25**, is a lengthy (preferably about 70 centimeters in overall length) flexible tube preferably constructed in one piece of Teflon or polyethylene with about a 0.5 millimeter inside diameter and about a 1.2 millimeter outside diameter (with the exception, of course, of the described special features at both ends). At the manipulating end **46** is the receiver **47** for accepting a syringe **48** (see FIG. 1). At the depositing end **39** is a second end cap means embodied by a domed end cap **44** (roughly hemispherical for fending off mucus and pushing smoothly on swivelable cap **32**) and also catheter distal opening means embodied by side opening or port **45** for discharging the embryos to be deposited. With the depositing end **39** of the inner catheter **25** shown in longitudinal cross-section in FIG.7, the round domed end cap **44** is shown blocking the straight through flow path of the interior passage **57**. Located through the side wall, directly under the domed end cap **44**, is the side port **45**, which is preferably a round opening which intersects with, and completes the interior passage **57** allowing a side discharge path. At the location on the inner catheter **25** opposite to where the side port **45** intersects the interior, structural strength is compromised, and as a preventative against breakage, strengthening means embodied by the strengthened intersection **58**, radiused with additional material, is provided. In addition to adding strength, the intersection **58**, being radiused, also provides for a smoother, more streamlined flow path. This helps in cleaning, loading and flushing the inner catheter **25**.

In FIG. 8, the inner catheter **25** is shown rotated approximately **45** degrees with the side port **45** shown completing the flow path of the interior passage **57**. Also shown are indicia means embodied by indicia or markings **60**, which are evenly spaced and continue the full length on the exterior of the inner catheter **25**. These markings **60** may be graduated divisions referring to the volume of the interior passage **57** beginning at the side port **45**.

Their use is described, for example, in FIGS. 14A-14C. Indicia means for indicating longitudinal distance to assist in attaining a desired implanting location, embodied by similar additional graduated markings **60** (see FIG. 13) referring to length may be included to establish the location at which the movable stop **50** is positioned to provide a given extension dimension of the inner catheter **25** from the end of the outer sleeve **24**. A cross-section through the inner catheter **25** at the side port **45** location is shown in FIG. 9. The additional wall thickness derived from the radiused intersection **58** is shown in location opposite the side port **45**.

FIG. 10 illustrates in cross-section the depositing ends **31** of the outer sleeve **24**, and within its cylindrical hollow **28**, the inner catheter **25**, both positioned approximately as they would be while being inserted into the desired uterus position. With the swivelable cap **32** in its normally closed position **33**, the inner catheter **25** is protected from any accumulation of mucus. When the inner catheter **25** is extended from the outer sleeve **24**, the domed end cap **44** contacts the underside of the swivelable cap **32** of the outer sleeve **24**, pushing it to the open position **34** (shown by dotted lines) as the hinge **56** flexes. As the inner catheter **25** extends out of the outer sleeve **24**, any remaining mucus which may be encountered is pushed aside or collected on the domed end cap **44** and not forced into the side port **45**.

Although the preferred shape of the depositing end **39** of the inner catheter **25** has been fully described, alternate methods of construction are illustrated in FIGS. 11 & 12 with the interior passage **57** continuing straight and unobstructed, without the domed end cap, and exiting the end of the inner catheter **25**. FIG. 11 incorporates side wall relief or opening means embodied by two reliefs **61**, spaced at 180 degrees apart, at the end of the inner catheter **25**. Thus, for example, even in the event of the depositing end **39** of the inner catheter **25** butting firmly against a wall of the uterus, the embryos may be discharged from the inner catheter **25** through the reliefs **61**. In the most simplified form, the inner catheter **25** of FIG. 12 incorporates a blunt end opening **62**. Although the benefits from the features of the previously described inner catheters are not available with a blunt opening **62**, the combined use with the outer sleeve **24**, as herein taught, offers protection from mucus while within the outer sleeve **24**.

FIGS. 13 through 19 describe pictorially the steps involved in the use of the catheter

system **20**. With reference to FIG. 13, prior to the use of the catheter system **20**, a sounding is performed to determine the depth of the uterus **21** and the distance **D1** from the entrance **38** of the cervix **26** to the location within the uterus **21** where the embryos **22** are to be deposited for implanting. The depositing end **39** of the inner catheter **25** is inserted into the interior of the outer sleeve **24** at the manipulating end **40** and the movable stop **50** is adjusted to the proper position as shown in FIG. 13. "S" represents the depth of the uterus **21** as determined by the sounding. The desired depth at which the embryos are to be deposited is shown as **D1**. **D2** is the distance that the insertable portion **29** of the outer sleeve **24** will insert into the cervix **26**. **D3** is the distance that the inner catheter **25** will be required to extend beyond the end of the outer sleeve **24** for implanting at the desired depth **D1**. **D4** is the distance that the inner catheter **25** will be short of exiting from within the outer sleeve **24** when the implanting process is begun. The sum of distances **D3** and **D4** is **E1**, the extending distance, the amount the inner catheter **25** will extend for implanting. The extending distance **E1** is equal to **E2**, the measurement at which the snug fitting movable stop **50** is to be positioned, the distance short of contacting the second flange **43** at the manipulating end **40** of the outer sleeve **24**. As discussed with FIG. 8, markings **60** may be incorporated on inner sleeve **25** to provide dimensional aid in locating movable stop **50** at distance **E2** from second flange **43**.

After adjustment is completed, the inner catheter **25** (with the movable stop **50** being unmoved and remaining in place) is withdrawn from the outer sleeve **24**. The interior of the inner catheter **25** is rinsed with a buffer solution by a tuberculin syringe (in a well known manner) and then loaded as illustrated in FIGS. 14A, 14B, and 14C and according to the following instructions. As shown in FIG. 14A, with a syringe **48** inserted into the receiver **47** at the manipulating end **46** of the inner catheter **25**, draw buffer solution **63** into the side port **45** at the depositing end **39** to the marking **60** corresponding to about 0.2 milliliters. Draw in a small amount of air, then load embryos **22** into side port **45** as in FIG. 14B. Draw in another small amount of air, then draw up about 0.005 milliliters of buffer solution **63**. FIG. 14C shows inner catheter **25** appropriately loaded with buffer solution **63**, two air spaces **64** and embryos **22**, with markings **60** used to determine quantities.

Then, as shown in FIG. 15A, insert the inner catheter **25** into cylindrical hollow **28** at

the manipulating end **40** of the outer sleeve **24** until the depositing end **39** of the inner catheter **25** is just short of contacting the swivelable cap **32** (or the less preferred alternate slits **53**) of the outer sleeve **24** (as shown in FIG. 15B). In this position, the swivelable cap **32** remains in the closed position **33**. Then, with the catheter system **20** now prepared for usage, insert the depositing end **31** of the insertable portion **29** of the outer sleeve **24** into the cervix **26** of the patient, as shown in FIG. 16A. Then (see FIG. 16B) insert the outer sleeve **24** through the cervix **26**, until its limiting stop **37** of flange **36** contacts the cervix entrance **38**.

Then, after the outer sleeve **24** is in position, advance the inner catheter **25** until the movable stop **50** contacts the second flange **43** of the outer sleeve **24**. During this process, as shown in FIG. 17, the inner catheter **25** pushes aside the swivelable cap **32** (or through the less preferred slits **53**) of the outer sleeve **24** to the open position **34**. When advancement is completed, the depositing end **39** of the inner catheter **25** is properly positioned in the uterus **21** for implanting. Next, as shown in FIG. 18, using syringe **48** inserted into the receiver **47** of the inner catheter **25**, slowly inject about 0.02 to 0.03 milliliters of the contents of the inner catheter **25** into the uterus **21**. This injection transfers a small amount of buffer solution **63** along with the embryos **22** from the side port **45** into a desired location within the uterus **21** where the embryos **22** may attach the uterus wall **27**. Then, after such implanting, the catheter system **20** is to remain unmoved for about one minute. Then, carefully withdraw the outer sleeve **24** and inner catheter **25** from the patient, and, as shown in FIG. 19, with a microscope **66**, insure that embryos do not remain in the inner catheter **25**.

FIG. 23 illustrates another preferred embodiment **70** of the present invention. This preferred embodiment **70** of the present invention operates in essentially the same manner and for the same purpose as has been described above, but with the differences as below described. Preferred embodiment **70** of the catheter system of the present invention includes an outer sleeve **68** and an inner catheter **69**. In FIG. 23, the distal end **71** of the inner catheter **69** protrudes from the distal end **72** of the outer sleeve **68** through the open end cap **73** of the outer sleeve **68**.

The outer sleeve **68** is a long cylindrical tube with a preferred length of

approximately 15 centimeters (cm), which sleeve **68** contains the inner catheter **69**, the two being concentrically arranged. Outer sleeve **68** includes distal end **72**, end cap **73**, distal portion **75**, proximal portion **76**, and winged flange **77**. The smaller-outer-diameter distal portion **75** of the outer sleeve **68** is connected to the larger-outer-diameter proximal portion **76** of the outer sleeve by a diameter-step **90** characterized by a preferred gradual change at preferably about 45 degrees (as shown, see FIG. 24). This gradual diameter-step **90** allows the distal portion **75** with a smaller outer diameter **OD6** to gradually change into the proximal portion **76** with a larger outer diameter **OD7**. This gradual diameter-step **90** eliminates a sudden change in outer diameter which might otherwise be the site of a weak point which could bend or break easily.

The distal end **72** of the outer sleeve **68** (when end cap **73** is closed) is outwardly rounded and functions as a probe to find the pathway through the cervical canal before the end cap **73** of the outer sleeve **68** is opened. The distal end **72** of the outer sleeve **68**, preferably about 5 the last millimeters (mm), may be made about a millimeter larger in diameter (preferably gradually rounded on both ends of the 5-millimeter-long bulge) than the rest of distal portion **75** to allow the physician to feel when the distal end **72** has passed through the cervix.

The end cap **73** of the outer sleeve **68** is shown in an expanded sectional view in FIG. 26. The end cap **73** of the outer sleeve **68** is preferably formed by making a cut **74** in the most distal 1.0 to 1.5 millimeters of the distal end **72** of the outer sleeve **68**. This cut **74** is preferably made through the point of the distal end **72** of the outer sleeve where the sleeve solid changes from solid to hollow, as shown. By making the cut **74** here, the inner surface **81** of the end cap **73** of the outer sleeve **68** is made flat and planar, without a chamber or hollow. This solid surface makes the end cap **73** of the outer sleeve **68** easier to open when pushed against by the distal end **71** of the inner catheter **69**. That is, the distal end **71** of the inner catheter **69** does not catch or snag in a depression on the inner surface **81** of the end cap **73** of the outer sleeve **68** when it is pushed against the inner surface **81** of the end cap **73**. It is thus highly preferred that the inside of the end cap **73** of the present invention (including the embodiment of FIG. 3) be substantially non-concave (embodying herein that an internal surface of such internally substantially-non-concave end cap lies substantially

within a single flat plane). This end cap embodies herein end cap means, disposed along an intersection of such central axis at such sleeve distal end, for substantially enclosing such cylindrical hollow at such sleeve distal end to protect such cylindrical hollow from accumulating mucuslike material when such catheter sleeve means is pushed through a cervix, such end cap means comprising end opening means, disposed along such intersection of such central axis at such sleeve distal end, for permitting passage of an inner catheter along such central axis from within such cylindrical hollow into access to the uterus.

The cut angle **82** of the end cap **73** is preferred to be between 0 and 45 degrees and is highly preferred to be between 15 and 20 degrees. This preferred range of cut angle **82** of the end cap **73** is important in this preferred embodiment for several reasons. A small angle assists in the ease of swivelability when the inner catheter **69** pushes on end cap **73**. Also, if the outer sleeve **68** encounters resistance from the top, as it passes through the cervix **26** (see, e.g., FIG. 1), the end cap **73** of the outer sleeve **68** will be pushed tighter in the closed position instead of possibly sliding and breaking. In addition, with the preferred low cut angle **82** of the end cap **73**, when the inner catheter **69** is withdrawn from the outer sleeve **68**, the end cap **73** will close more readily (embodying herein wherein such swivel means is constructed and arranged in such manner that such end cap means swivels back to a closed position when such catheter sleeve means is pulled from the cervix). In addition, with a low cut angle **82** of the end cap **73**, the end cap **73** will not be easily twisted when the further preferred embodiment **70** passes through the cervix **26**. With a higher cut angle **82** of the end cap **73**, the end cap **73** may become twisted when it encounters resistance through the cervix **26**, which might injure the cervical mucosa. Also, if the end cap **73** becomes twisted or displaced because of a very tight cervical canal, this low cut angle **82** of the end cap **73** will lower the risk of injuring the cervix **26**. (see FIG. 1 for relationship of this further preferred embodiment **70** within the cervix **26** and uterus **21**). It is again noted that if the end cap is torn off and lodges in the cervix, that would be an intolerable medical result, so the cut angle problems mentioned are significant. End cap **73** and its hinge embody herein an outwardly-swivelable connection between such end cap and such catheter outer sleeve, such sleeve distal end being structured and arranged to permit non-destructive passage of a

such catheter distal end from such cylindrical hollow into access to the uterus when such catheter distal end is pushed against such internally substantially-non-concave end cap, thereby swiveling such end cap outwardly and moving such catheter distal end through such sleeve distal end.

In this preferred embodiment **70**, the distal portion **75** of the outer sleeve **68** is preferably approximately 4 centimeters in length, and preferably no more than 5 cm in length. The length of the distal portion **75** of the outer sleeve **68** provides a marker for the depth of insertion into the cervix **26**, as 3.5 to 4.0 centimeters is an average measurement for the depth of the cervix **26** (see FIG. 1, **D2**). In this preferred embodiment **70**, the inner diameter of the distal portion **75** of the outer sleeve **68** is preferably approximately 1.6 mm in diameter and the outer diameter **OD6** of the distal portion **75** of the outer sleeve **68** is preferably approximately 2.5 mm in diameter.

In this preferred embodiment **70**, the proximal portion **76** of the outer sleeve **68** is preferably approximately 11 to 12 cm in length and such proximal portion of such catheter outer sleeve is preferably at least about 10 centimeters long. The outer diameter **OD7** of the proximal portion **76** of the outer sleeve **68** is preferably approximately 3.5 to 3.8 mm in diameter. The inner diameter **ID7** of the proximal portion **76** of the outer sleeve **68** is preferably approximately 2.8 to 3.0 mm in diameter. Because of its larger outer diameter **OD7** and inner diameter **ID7** and thicker wall, the proximal portion **76** of the outer sleeve **68** is thicker and stiffer than the distal portion **75** of the outer sleeve **68** (this arrangement embodying herein outer sleeve comprising a proximal portion having a larger internal diameter than an internal diameter of a distal portion of such catheter outer sleeve and having a thicker wall than the wall of such distal portion of such catheter outer sleeve). Added stiffness helps make it easier for a physician to insert the outer sleeve **68** through the cervix **26** (See FIG. 1).

FIG. 27 illustrates a cross-sectional view, at section **27-27** of FIG. 23. Among other things, FIG. 27 illustrates longitudinal wire **93** embedded in the inner surface **94** of the outer sleeve **68** and extending slightly, as shown, into the hollow cylindrical tube of the outer sleeve **68**. The preferably continuous longitudinal wire **93** is preferably embedded in the inner surface **94** of the outer sleeve **68** in the manner shown (embodying herein wherein

such metal wire comprises a surface of such longitudinal cylindrical hollow) from the winged flange **77** at proximal end **78** of through the gradual diameter-step **90** to approximately a location **79** preferably about 5 mm from the distal end **72** of the outer sleeve **68** (embodying herein wire-stiffening means comprising substantially all of a longitudinal dimension of such catheter sleeve means). This wire **95** increases the stiffness of the proximal portion **76** of the outer sleeve **68**, strengthens the gradual change **90**, increases the stiffness of the distal portion **75** of the outer sleeve **68** and allows the distal portion **75** of the outer sleeve **68** to bend and hold a shape to "remember" a specific shape to fit an individual cervical anatomy. Preferably, the metal wire **93** is about 0.2 mm in diameter and made of 304 SS wire. This outer sleeve arrangement embodies herein such catheter sleeve means being structured and arranged for travel of such sleeve distal end through the cervix for assistance in implanting embryos, and wherein such catheter sleeve means comprises a longitudinal wire-stiffening means for wire-stiffening of such catheter sleeve means.

With special reference to FIG. 24, in this preferred embodiment **70**, the outer sleeve **68** is preferably an integral, unitary piece made from the same plastics family but with three different softnesses/stiffnesses as below described. The proximal portion **76** is preferably the stiffest, least soft, portion because of its increased inner diameter **ID7** and outer diameter **OD7** and wall thickness and because of the wire **93** embedded in its inner surface **94** (preferably made of a 65D durometer resin, preferably DOW [TM] polyurethane 2363/65D). It is noted that the outer diameter of this proximal portion may be further increased and stiffened by mounting thereon an additional tube/sleeve of selected stiff material. The distal portion **75** of the outer sleeve **68** is preferably softer and less stiff because of its smaller inner diameter and outer diameter (and thinner wall) but is also reinforced by the wire **93** embedded in its inner surface **94** which wire **93** also allows the distal portion **75** of the outer sleeve to "remember" a specific shape (also preferably made of a 65D durometer resin, preferably DOW [TM] polyurethane 2363/65D). The distal end **72** of the outer sleeve is preferably softest and least stiff because the wire does not extend all the way to the distal end **72**. Also, the preferred material is softer and more flexible and permits the hinge **84** to work properly when end cap **73** is cut as described (no more than about a cm at the distal

end **72** is preferably made of DOW [TM] polyurethane 2363 [medical grade] 80A). This arrangement embodies herein wherein a distal end of such distal portion of such catheter outer sleeve comprises more flexible material than a remainder of such distal portion of such catheter outer sleeve, whereby such catheter outer sleeve comprises at least three different stiffnesses along such longitudinal hollow cylinder, in increasing-stiffness order from such distal end to such proximal end of such longitudinal hollow cylinder.

The proximal end **78** of the outer sleeve **68** is preferably attached to winged flange **77** as illustrated in FIG. 25. The winged flange **77** helps the physician hold the preferred embodiment **70**. The winged flange **77** is also preferably marked with an indicator **100** (embodying herein an "indicator means") to help the physician mark the direction of the above-mentioned bend (as, for example, illustrated in FIG. 23) in the outer sleeve **68**.

FIG. 26 illustrates preferable "roughened" areas **83** (for the purpose of mucus-trapping) located on the exterior surface **99** of the distal portion **75** of the outer sleeve **68.** These roughened areas **83** may preferably contain hair-like protrusions, as shown, or may consist of other surface-roughening in the material of distal portion **75** of the outer sleeve **68**. These roughened areas **83** act to keep mucus from attaching to the distal end **71** of the inner catheter **69** when the end cap **73** is opened by capturing the end-cap-area mucus, thus helping keep mucus away from the emerging inner catheter (embodying herein mucus-trapping means for trapping nearby mucus during a such passage of a such catheter distal end from such cylindrical hollow into access to the uterus). FIG. 26 also illustrates preferable roughened areas **89** located on the interior surface **85** of the distal end **72** of the outer sleeve **68**. These roughened areas **89** also, similarly, help to keep and hold trapped any mucus entering (e.g., by capillary action when the end cap opens) into the interior of the distal end **72** of the outer sleeve **68** (when the end cap **73** is opened) rather than clinging to the inner catheter **69**.

The inner catheter **69** is preferably made of an inner tube catheter **103** and a proximal supporting tube **104**. The inner tube catheter **103** is preferably approximately 20 centimeters in length. The inner tube catheter **103** is preferably made of polyethylene. The proximal supporting tube **104** is preferably approximately 10-12 centimeters in length and can be made of a stiffer plastic than the inner tube catheter **103**, of the same family but

stiffer. The proximal supporting tube **104** is preferably manufactured by adhering an additional sheath of tubing around the most proximal 10-12 centimeters of the inner tube catheter **103**. So, the inner catheter **103** is preferably continuous throughout the length of the inner catheter **69**, and the proximal supporting tube **104** is preferably a separate length of tube which is attached (as by adhering in well-known ways, preferably near the proximal end **88**) in place preferably around the most proximal 10 to 12 centimeters of the inner tube catheter **103**. The inner tube catheter **103** and the proximal supporting tube **104** together comprise the inner catheter **69**.

The inner diameter of the inner catheter **69** is preferably continuous throughout the length of the inner catheter **69** and is preferably approximately 1 mm in diameter. The outer diameter of the inner tube catheter **103** is preferably approximately 1.5 mm in diameter. The outer diameter of the proximal supporting tube **104** is preferably approximately 2.5 mm (these dimensions/arrangement embodying herein wherein such inner catheter comprises a proximal portion having a larger external diameter than an external diameter of a distal portion of such inner catheter). The inner catheter **103**, as noted, is preferably thin and very soft to prevent trauma to the surrounding uterus or to the embryos being transferred. However, it can be difficult for a long soft catheter to push through the end cap **73** of the outer sleeve **68** as described above. The addition of the proximal supporting tube **104** allows the length of inner catheter **103** to be significantly shortened and gives it the strength it needs to push through the outer sleeve **68** and for easier handling by the physician. As described in relation to previous embodiments, the distal end **71** of the inner catheter **69** preferably contains a side opening **105** for the deposit of embryos. As shown if FIG. 23, it is preferred that such proximal portion of such inner catheter is at least as long as such proximal portion of such catheter outer sleeve.

FIG. 27 illustrates a cross-section at section **27-27** of FIG. 23 showing the proximal portion **76** of the outer sleeve **68** containing the proximal supporting tube **104** wrapped around the inner tube catheter **103**. The proximal supporting tube **104** preferably slides through the outer sleeve **68** as illustrated in FIG. 27. The proximal supporting tube **104** cannot extend into the distal portion **75** of the outer sleeve **68** because the inner diameter of the distal portion **75** of the outer sleeve **68** is not sufficiently large to accommodate the outer

diameter **OD7** of the proximal supporting tube **104**. This gives the physician a safe stop or block to avoid injury by extending the inner catheter **69** too far into the uterus and also a method for measuring the distance that the inner catheter **69** has traveled through the cervix **26** before depositing the embryos **22** into the uterus **21**. The inner catheter **69** is preferably attached at its most proximal end **106** to a Luer lock **107**. The Luer lock **107** is preferably attachable to a syringe **108**. The Luer lock **107** preferably has a marker **109** which helps indicate to the physician the location of the side-eye opening **105** in the distal end **71** of the inner catheter **69**.

The proximal supporting tube **104** serves many purposes in addition to lending strength to the inner catheter **69**. In apparatus without the proximal supporting tube **104**, the inner catheter **69** attached to a relatively heavy syringe **108** is a very flimsy combination. So, while the physician introduced the outer sleeve **68** through the cervix **26** s/he was required to bend the inner catheter **69** to be able to hold the syringe and the inner catheter **69** in the same hand. Generally, the embryos are loaded into the very tip of the inner catheter **69**. Bending the catheter and the heat from the physician's hand required by the direct contact between the hand and the catheter when holding it, may cause a volume change inside the catheter, which may accidentally and prematurely push the embryos out of the tip of the inner catheter **69**. Alternatively, the physician may require the assistance of a third hand, which can be awkward. Without supporting tube **104**, the physician was required to insert the outer sleeve **68** through the cervix **22**. Then, when the outer sleeve **68** was in place, the physician would introduce the inner catheter **69** into the outer sleeve **68**. However, pushing a long, thin, soft catheter through the outer sleeve **68** can be very difficult. Throughout this procedure, the physician risks dropping the inner catheter **69** attached to the syringe **108** and damaging the embryos. Also, the weight of the syringe **108** on the end of a long thin catheter may pull the syringe **108** attached to the inner catheter **69** out of the outer sleeve **68** resulting in embryo damage or loss. This preferred embodiment **70**, with the proximal supporting tube **104**, eases some of these technical difficulties and makes the transfer process easier. Because of the increased rigidity of the supporting tube, the physician can more readily introduce the entire preferred embodiment **70** as one unit, with the inner catheter **69** already placed inside the outer sleeve **68**, through the cervix **22**.

The inner catheter **69** can be placed inside the outer sleeve **68** with the end cap **73** closed so that the inner catheter **69** is protected from mucus or bending by the outer sleeve **68**. The portion of the inner catheter **69** which extends beyond the manipulative end **97** of the outer sleeve **68** is stiffened and reinforced by the proximal supporting tube **104** and is strong enough to feel solid and support the weight of the syringe **108**. The physician does not need to hold the inner catheter **69** attached to the syringe separately and no third hand is necessary. The risk of dropping the syringe is much lower because the catheter with a syringe is firmly inserted in the outer sleeve **68** and the position is horizontal. The risk of accidentally pushing the embryos out of the catheter are significantly reduced because the inner catheter **69** is kept straight by the outer sleeve **68** and the physician's hand only touches the syringe **108** or the proximal supporting tube **104** and does not come into direct contact with the inner catheter **69**. Increasing embryo protection from mucus and increasing the ease with which the physician can perform the procedure will increase the probability of a positive outcome for the patient. Clinical studies using the within inventions (including the described swivelable end cap) for protecting embryos have indicated a better implantation rate and a better pregnancy rate.

The above description taken with the descriptions of FIGS. 13 et seq. hereof embody a catheter system for single-person implanting of an embryo in a uterus, comprising, in combination, the steps of: providing a wire-stiffened catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve proximal end and a sleeve distal end, wherein a proximal portion of such cylindrical hollow has a larger internal diameter than an internal diameter of a distal portion of such cylindrical hollow;

providing an inner catheter having a catheter proximal end and a catheter distal end having an opening for transmission of a such embryo, such catheter being sized for moving through such longitudinal cylindrical hollow, wherein a proximal portion of such inner catheter has a greater catheter wall thickness than a distal portion of such inner catheter, and wherein such proximal portion of such inner catheter has a larger external diameter than an external diameter of such distal portion of such inner catheter, and such inner catheter being structured and arranged to supportingly fit within such outer sleeve, thereby providing substantially greater catheter system stiffness; affixing a syringe at such proximal end of

such inner catheter; loading such embryo into such inner catheter distal end; placing such inner catheter into such proximal end of such outer sleeve and moving such inner catheter forward until such inner catheter distal end is approaching such sleeve distal end; introducing such sleeve proximal end into a cervix to a desired stop location; further moving such inner catheter forward into such end cap of such outer sleeve, outwardly swiveling such end cap, and further moving such catheter distal end forward into access to the uterus to a desired implanting location; and flushing such embryo out of such catheter distal end; and, further, wherein, during such step of further moving such inner catheter forward, forward travel of such inner catheter is limited by a distal end of such proximal portion of such inner catheter being blocked when reaching a distal end of such proximal portion of such outer sleeve, thereby assisting in avoiding injury to the uterus from too much forward travel of such inner catheter; and, further, wherein such step of moving such inner catheter forward may be accomplished by one hand of a catheter system user because of such substantially greater catheter system stiffness.

Although applicant has described applicant's preferred embodiments of this invention, it will be understood that the broadest scope of this invention includes such modifications as diverse shapes and sizes and materials. Such scope is limited only by the below claims as read in connection with the above specification. Further, many other advantages of applicant's invention will be apparent to those skilled in the art from the above descriptions and the below claims.

What is claimed is:

1) A catheter system for assisting implanting embryos in a uterus, comprising:

a) catheter sleeve means, having a sleeve distal end and a sleeve proximal end and having, between said sleeve distal end and said sleeve proximal end, a longitudinal cylindrical hollow having a central longitudinal axis, said catheter sleeve means being structured and arranged for containing an inner catheter in said cylindrical hollow, said catheter sleeve means comprising

i) end cap means, disposed along an intersection of said central axis at said sleeve distal end, for substantially enclosing said cylindrical hollow at said sleeve distal end to protect said cylindrical hollow from accumulating mucuslike material when said catheter sleeve means is pushed through a cervix, said end cap means comprising

(1) end opening means, disposed along said intersection of said central axis at said sleeve distal end, for permitting passage of an inner catheter along said central axis from within said cylindrical hollow into access to the uterus;

b) said catheter sleeve means being structured and arranged for travel of said sleeve distal end through the cervix for assistance in implanting embryos; and

c) wherein said catheter sleeve means comprises a longitudinal wire-stiffening means for wire-stiffening of said catheter sleeve means.

2) The catheter system according to Claim 1 wherein said wire-stiffening means comprises substantially all of a longitudinal dimension of said catheter sleeve means.

3) The catheter system according to Claim 1 wherein said wire-stiffening means comprises a metal wire.

4) The catheter system according to Claim 3 wherein said metal wire comprises a surface of said longitudinal cylindrical hollow.

5) The catheter system according to Claim 1 wherein said wire-stiffening means is constructed and arranged to:

a) permit holding a bent shape; and

b) provide shape-maintaining support.

6) A catheter system for implanting embryos in a uterus, comprising:

a) an inner catheter, having a catheter distal end and a catheter proximal end, structured and arranged to transport the embryos into access to the uterus and to deposit said embryo in the uterus; and

b) a catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve distal end and a sleeve proximal end, structured and arranged to provide safe catheter access to the uterus by said inner catheter;

c) wherein said inner catheter comprises a proximal portion having a larger external diameter than an external diameter of a distal portion of said inner catheter.

7) The catheter system according to Claim 6 wherein said catheter outer sleeve comprises a proximal portion

a) having a larger internal diameter than an internal diameter of a distal portion of said catheter outer sleeve and

b) having a thicker wall than the wall of said distal portion of said catheter outer sleeve.

8) The catheter system according to Claim 7 wherein a distal end of said distal portion of said catheter outer sleeve comprises more flexible material than a remainder of said distal portion of said catheter outer sleeve, whereby said catheter outer sleeve comprises at least three different stiffnesses along said longitudinal hollow cylinder, in increasing-stiffness order from said distal end to said proximal end of said longitudinal hollow cylinder.

9) The catheter system according to Claim 7 wherein said proximal portion of said inner catheter is at least as long as said proximal portion of said catheter outer sleeve.

10) The catheter system according to Claim 9 wherein said proximal portion of said catheter outer sleeve is at least about 10 centimeters long.

11) The catheter system according to Claim 9 wherein said distal portion of said catheter outer sleeve is at most about 5 centimeters long.

12) A catheter system for assisting implanting embryos in a uterus, comprising:

a) a catheter outer sleeve having a sleeve distal end and a sleeve proximal end and having, between said sleeve distal end and said sleeve proximal end, a longitudinal cylindrical hollow having a central longitudinal axis, said catheter outer sleeve being structured and arranged to contain an inner catheter in said cylindrical hollow, said catheter outer sleeve comprising a longitudinal wire-stiffener structured and arranged to stiffen said catheter outer sleeve;

b) said catheter outer sleeve being structured and arranged to permit travel of said sleeve distal end through a cervix to assist in implanting embryos;

c) wherein said catheter outer sleeve comprises a proximal portion having a larger internal diameter than an internal diameter of a distal portion of said catheter outer sleeve.

13) The catheter system according to Claim 12 wherein said wire-stiffener comprises substantially all of a longitudinal dimension of said catheter outer sleeve.

14) The catheter system according to Claim 12 wherein said wire-stiffener comprises a metal wire.

15) The catheter system according to Claim 14 wherein said metal wire comprises a surface of said longitudinal cylindrical hollow.

16) The catheter system according to Claim 12 wherein said wire-stiffener is constructed and arranged to:

a) permit holding a bent shape; and

b) provide shape-maintaining support.

17) The catheter system according to Claim 12 wherein said proximal portion of said catheter outer sleeve is at least about 10 centimeters long.

18) The catheter system according to Claim 17 wherein said distal portion of said catheter outer sleeve is at most about 5 centimeters long.

19) The catheter system according to Claim 12 further comprising:

a) an inner catheter, having a catheter distal end and a catheter proximal end, structured and arranged to transport the embryos into access to the uterus and to deposit the embryos in the uterus.

20) The catheter system according to Claim 19 wherein said inner catheter comprises a proximal portion having a larger external diameter than an external diameter of a distal portion of said inner catheter.

21) The catheter system according to Claim 20 wherein said proximal portion of said inner catheter is at least as long as said proximal portion of said catheter outer sleeve.

22) The catheter system according to Claim 21 wherein said catheter outer sleeve comprises

a) an end cap, disposed along an intersection of said central axis at said sleeve distal end, to substantially enclose said cylindrical hollow at said sleeve distal end to protect said cylindrical hollow from accumulating mucuslike material when said catheter outer sleeve is pushed through the cervix, said end cap comprising

i) an end opener, disposed along said intersection of said central axis at said sleeve distal end, to permit passage of a said inner catheter along said central axis from within said cylindrical hollow into access to the uterus.

23) The catheter system according to Claim 12 wherein said catheter outer sleeve comprises

a) an end cap, disposed along an intersection of said central axis at said sleeve distal end, to substantially enclose said cylindrical hollow at said sleeve distal end to protect said cylindrical hollow from accumulating mucuslike material when said catheter outer sleeve is pushed through the cervix, said end cap comprising

i) an end opener, disposed along said intersection of said central axis at said sleeve distal end, to permit passage of a said inner catheter along said central axis from within said cylindrical hollow into access to the uterus.

24) A catheter system for implanting embryos in a uterus, comprising:

a) a catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve distal end and a sleeve proximal end, structured and arranged to provide safe catheter access to the uterus by an inner catheter having a catheter distal end and a catheter proximal end;

b) said sleeve distal end comprising

i) an internally substantially-non-concave end cap, structured and arranged to protect said cylindrical hollow from accumulating mucuslike material when said catheter outer sleeve is pushed through a cervix, and

ii) an outwardly-swivelable connection between said end cap and said catheter outer sleeve, said sleeve distal end being structured and arranged to permit non-destructive passage of a said catheter distal end from said cylindrical hollow into access to the uterus when said catheter distal end is pushed against said internally substantially-non-concave end cap, thereby swiveling said end cap outwardly and moving said catheter distal end through said sleeve distal end.

25) The catheter system according to Claim 24 wherein:

a) said outwardly-swivelable connection is a unitary part of said sleeve distal end.

26) The catheter system according to Claim 25 wherein:

a) said end cap is a unitary part of said sleeve distal end.

27) The catheter system according to Claim 25 wherein:

a) said outwardly-swivelable connection is a unitary part of said sleeve distal end; and

b) said end cap is a unitary part of said sleeve distal end.

28) The catheter system according to Claim 24 wherein:

a) an internal surface of said internally substantially-non-concave end cap lies substantially within a single flat plane.

29) The catheter system according to Claim 24 wherein:

a) said internally substantially-non-concave end cap is outwardly convex.

30) The catheter system according to Claim 24 wherein said sleeve distal end further comprises:

a) mucus-trapping means for trapping nearby mucus during a said passage of a said catheter distal end from said cylindrical hollow into access to the uterus.

31) The catheter system according to Claim 30 wherein:

a) said mucus-trapping means comprises roughened surface portions to assist in said trapping of mucus.

32) The catheter system according to Claim 31 wherein:

a) said roughened surface portions comprise both external and internal surfaces of said sleeve distal end.

33) The catheter system according to Claim 24 wherein:

a) said end cap comprises an outwardly convex flexible end on said catheter outer sleeve and said outwardly-swivelable connection comprises a partial planar cut separating, except for a remaining transverse hinge portion, said outwardly convex flexible end from said catheter outer sleeve, whereby said end cap comprises a planar internal surface.

34) The catheter system according to Claim 33 wherein:

a) said partial planar cut comprises an angle between said planar internal surface and a transverse plane perpendicular to a longitudinal axis of said longitudinal hollow of from about 0 degrees to about 45 degrees.

35) The catheter system according to Claim 34 wherein:

a) said angle is from about fifteen degrees to about twenty degrees.

36) A catheter system for single-person implanting of an embryo in a uterus, comprising, in combination, the steps of:

a) providing a wire-stiffened catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve proximal end and a sleeve distal end,

i) wherein a proximal portion of said cylindrical hollow has a larger internal diameter than an internal diameter of a distal portion of said cylindrical hollow;

b) providing an inner catheter having a catheter proximal end and a catheter distal end having an opening for transmission of a said embryo, said catheter being sized for moving through said longitudinal cylindrical hollow,

i) wherein a proximal portion of said inner catheter has a greater catheter wall thickness than a distal portion of said inner catheter, and

ii) wherein said proximal portion of said inner catheter has a larger external diameter than an external diameter of said distal portion of said inner catheter, and

iii) said inner catheter being structured and arranged to supportingly fit within said outer sleeve, thereby providing substantially greater catheter system stiffness;

c) affixing a syringe at said proximal end of said inner catheter;

d) loading said embryo into said inner catheter distal end;

e) placing said inner catheter into said proximal end of said outer sleeve and moving said inner catheter forward until said inner catheter distal end is approaching said sleeve distal end;

f) introducing said sleeve proximal end into a cervix to a desired stop location;

g) further moving said inner catheter forward into said end cap of said outer sleeve, outwardly swiveling said end cap, and further moving said catheter distal end forward into access to the uterus to a desired implanting location; and

h) flushing said embryo out of said catheter distal end.

37) The catheter system according to Claim 36 wherein, during said step of further moving said inner catheter forward, forward travel of said inner catheter is limited by a distal end of said proximal portion of said inner catheter being blocked when reaching a distal end of said proximal portion of said outer sleeve, thereby assisting in avoiding injury to the uterus from too much forward travel of said inner catheter.

38) The catheter system according to Claim 36 wherein said step of moving said inner catheter forward may be accomplished by one hand of a catheter system user because of said substantially greater catheter system stiffness.

39) A catheter system for assisting implanting embryos in a uterus, comprising:

a) catheter sleeve means, having a sleeve distal end and a sleeve proximal end and having, between said sleeve distal end and said sleeve proximal end, a longitudinal cylindrical hollow having a central longitudinal axis, said catheter sleeve means being structured and arranged for containing an inner catheter in said cylindrical hollow, said catheter sleeve means comprising

i) outwardly convex end cap means, disposed along an intersection of said central axis at said sleeve distal end, for substantially enclosing said cylindrical hollow at said sleeve distal end to protect said cylindrical hollow from accumulating mucuslike material when said catheter sleeve means is pushed through a cervix, said end cap means comprising

(1) end opening means, disposed along said intersection of said central axis at said sleeve distal end, for permitting passage of an inner catheter along said central axis from within said cylindrical hollow into the uterus;

(2) said catheter sleeve means being structured and arranged for travel of said sleeve distal end through the cervix for assistance in implanting embryos.

40) A catheter system according to Claim 39 wherein said end opening means of said sleeve distal end comprises swivel means constructed and arranged in such manner that said end cap means swivels outward when an inner catheter is pushed through said sleeve distal end.

41) A catheter system according to Claim 40 wherein said end cap means comprises an outwardly convex flexible end on said catheter sleeve means and said end cap opening means comprises a partial transverse cut separating, except for a remaining transverse hinge portion, said outwardly convex flexible end from said catheter sleeve means, whereby said end cap means is constructed and arranged to swivel outward when an inner catheter is pushed through said sleeve distal end.

42) A catheter system according to Claim 39, further comprising:

a) an inner catheter means, having a catheter distal end and a catheter proximal end, for transporting a said embryo through said cylindrical hollow of said outer sleeve means into access to the uterus and for depositing said embryo in the uterus.

43) A catheter system according to Claim 42 wherein said inner catheter means comprises a plurality of indicia means for indicating longitudinal distance to assist in attaining a desired implanting location.

44) A catheter system according to Claim 42 wherein said catheter distal end comprises:

a) catheter distal opening means for depositing said embryo, said catheter distal opening means comprising a side port, adjacent said catheter distal end of said inner catheter means.

45) A catheter system according to Claim 42 wherein said catheter distal end comprises:

a) second end cap means at said catheter distal end for protecting said inner catheter means when said catheter distal end is pushed through said sleeve distal end; and

b) catheter distal opening means for depositing said embryo, said catheter distal opening means comprising a side port adjacent said second end cap means at said catheter distal end of said inner catheter means.

46) A catheter system according to Claim 45 wherein said catheter distal end further comprises:

a) strengthening means opposite said catheter distal opening means for strengthening said inner catheter means against breakage.

47) A catheter system according to Claim 45 wherein said end opening means at said sleeve distal end of said catheter sleeve means comprises swivel means constructed and arranged in such manner that said end cap means swivels outward when said catheter distal end is pushed through said sleeve distal end.

48) A catheter system according to Claim 47 wherein said catheter sleeve means further comprises first stop means for limiting insertion to a desired location when said catheter sleeve means is inserted into the uterus.

49) A catheter system according to Claim 48 wherein said inner catheter means further comprises second stop means settable along said inner catheter means for limiting insertion to a desired implanting location when said inner catheter means is inserted through the cervix.

50) A catheter system according to Claim 39 wherein said catheter sleeve means further comprises an integral stop means for limiting insertion to a desired location when said catheter sleeve means is inserted into the uterus.

51) A catheter system for implanting embryos in a uterus, comprising:

a) a catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve distal end and a sleeve proximal end, for providing safe catheter access to the uterus by a catheter having a catheter distal end and a catheter proximal end;

b) said sleeve distal end comprising

I. an outwardly convex end cap, for protecting said cylindrical hollow from accumulating mucuslike material when said catheter outer sleeve is pushed through a cervix, and

ii. an outwardly-swivelable connection between said end cap and said catheter outer sleeve, for permitting passage of a said catheter distal end from said cylindrical hollow into access to the uterus when said catheter distal end is pushed against said end cap to swivel said end cap outwardly and move said catheter distal end through said sleeve distal end.

52) A catheter system according to Claim 51 further comprising:

a) an inner catheter means, having a catheter distal end and a catheter proximal end, for transporting a said embryo through said cylindrical hollow of said outer sleeve into access to the uterus and for depositing said embryo in the uterus.

53) A catheter system according to Claim 52 wherein said catheter distal end comprises:

a) an outwardly convex second end cap for protecting said inner catheter means when said catheter distal end is pushed through said sleeve distal end; and

b) a catheter distal opening for depositing a said embryo, said catheter distal opening comprising a side port adjacent said second end cap.

54) A catheter system according to Claim 53 further comprising:

a) locating means for locating said catheter distal end in the uterus, said locating means comprising

i) first stop means on said catheter outer sleeve for abutting a cervix entrance to the uterus, and

ii) second stop means settable along said inner catheter means for limiting insertion of said catheter distal end of said inner catheter means to a desired implanting location when said inner catheter means is inserted into the uterus.

55) A catheter system for implanting embryos in a uterus, comprising, in combination, the steps of:

a) providing a catheter outer sleeve having a longitudinal cylindrical hollow between a sleeve proximal end and a sleeve distal end having an outwardly convex end cap and an outwardly-swivelable connection between said end cap and said catheter outer sleeve;

b) providing a catheter having a catheter proximal end and a catheter distal end having an opening for transmission of a said embryo, said catheter being sized for moving through said longitudinal cylindrical hollow;

c) loading at least one said embryo into said catheter distal end;

d) placing said catheter into said sleeve proximal end of said catheter outer sleeve and moving said catheter forward until said catheter distal end is approaching said sleeve distal end;

e) introducing said sleeve proximal end through a cervix to a desired stop location;

f) further moving said catheter forward into said end cap of said catheter outer sleeve, outwardly swiveling said end cap, and further moving said catheter distal end forward into the uterus to a desired implanting location; and

g) flushing said embryo out of said catheter distal end.

56) A catheter system according to Claim 55 wherein said catheter distal end of said catheter comprises:

a) a second end cap for protecting said catheter when said catheter distal end is pushed through said sleeve distal end; and

b) a catheter distal opening for depositing a said embryo, said catheter distal opening comprising a side port adjacent said second end cap.

57) A catheter system according to Claim 56 wherein:

a) said catheter outer sleeve further comprises first stop means located along said catheter outer sleeve for limiting insertion to said desired stop location when said catheter outer sleeve is introduced through the cervix; and

b) said catheter further comprises second stop means settable along said catheter for limiting insertion to said desired implanting location when said inner catheter means is inserted into the uterus.

58) A catheter system according to Claim 55 wherein said outwardly-swivelable connection between said end cap and said outer sleeve is made by a method comprising the steps of:

a) providing an outwardly convex end portion at said sleeve distal end integral with said catheter outer sleeve; and

b) cutting to partially sever said end portion from said catheter outer sleeve transversely just beneath said end portion around at least about 200 degrees of a circumference around said convex end portion;

c) whereby an unsevered part of said end portion provides a hinge means comprising said outwardly-swivelable connection.

59) A catheter system for assisting implanting embryos in a uterus, comprising:

a) catheter sleeve means, having a sleeve distal end and a sleeve proximal end and having a longitudinal cylindrical hollow between said sleeve distal end and said sleeve proximal end, for containing an inner catheter in said cylindrical hollow, said catheter sleeve means comprising

i) end cap means at said sleeve distal end for substantially enclosing said cylindrical hollow at said sleeve distal end to protect said cylindrical hollow from accumulating mucuslike material when said catheter sleeve means is pushed through a cervix, and

ii) end opening means at said sleeve distal end for permitting passage of an inner catheter from within said cylindrical hollow into access to the uterus;

b) wherein said end opening means of said sleeve distal end comprises swivel means constructed and arranged in such manner that said end cap means swivels outward when an inner catheter is pushed through said sleeve distal end.

60) A catheter system according to Claim 59 wherein said end cap means comprises an outwardly convex flexible end on said catheter sleeve means and said end cap opening means comprises a partial transverse cut separating, except for a remaining transverse hinge portion, said outwardly convex flexible end from said catheter sleeve means, whereby said end cap means is constructed and arranged to swivel outward when an inner catheter is pushed through said sleeve distal end.

61) A catheter system for assisting implanting embryos in a uterus, comprising:

a) catheter sleeve means, having a sleeve distal end and a sleeve proximal end and having a longitudinal cylindrical hollow between said sleeve distal end and said sleeve proximal end, for containing an inner catheter in said cylindrical hollow, said catheter sleeve means comprising

i) end cap means at said sleeve distal end for substantially enclosing said cylindrical hollow at said sleeve distal end to protect said cylindrical hollow from accumulating mucuslike material when said catheter sleeve means is pushed through a cervix, and

ii) end opening means at said sleeve distal end for permitting passage of an inner catheter from within said cylindrical hollow into access to the uterus;

b) an inner catheter means, having a catheter distal end and a catheter proximal end, for transporting a said embryo through said cylindrical hollow of said outer sleeve means into access to the uterus and for depositing said embryo in the uterus;

c) wherein said catheter distal end comprises:

i) second end cap means at said catheter distal end for protecting said inner catheter means when said catheter distal end is pushed through said sleeve distal end; and

ii) catheter distal opening means for depositing said embryo, said catheter distal opening means comprising a side port adjacent said second cap means at said catheter distal end of said inner catheter means; and

d) wherein said end opening means at said sleeve distal end of said catheter sleeve means comprises swivel means constructed and arranged in such manner that said end cap means swivels outward when said catheter distal end is pushed through said sleeve distal end.

62) A catheter system according to Claim 61 wherein said catheter sleeve means further comprises first stop means for limiting insertion to a desired location when said catheter sleeve means is inserted through the cervix.

63) A catheter system according to Claim 62 wherein said inner catheter means further comprises second stop means settable along said inner catheter means for limiting insertion to a desired implanting location when said inner catheter means is inserted into the uterus.

64) A catheter system according to Claim 39 wherein said end opening means is a slit, normally closed but openable for permitting passage of a said inner catheter pushed along said central axis from within said cylindrical hollow into access to the uterus.

65) A catheter system according to Claim 39 wherein said end opening means of said sleeve distal end is a cross-cut slit, normally closed but openable for permitting passage of a said inner catheter pushed along said central axis from within said cylindrical hollow into access to the uterus.

66) The catheter system according to Claim 44 wherein said inner catheter means further comprises:

a) located adjacent said proximal end of said inner catheter means, indicator means for indicating a direction of opening of said side port.

67) The catheter system according to Claim 16 wherein said catheter outer sleeve further comprises a bend in said distal portion of said catheter outer sleeve to better assist in pushing through the cervix.

68) The catheter system according to Claim 67 wherein said catheter outer sleeve further comprises:

a) located adjacent said proximal end of said catheter outer sleeve, indicator means for indicating a direction of said bend of said distal portion of said catheter outer sleeve.

69) A catheter system according to Claim 40 wherein said swivel means is constructed and arranged in such manner that said end cap means swivels back to a closed position when said catheter sleeve means is pulled from the cervix.

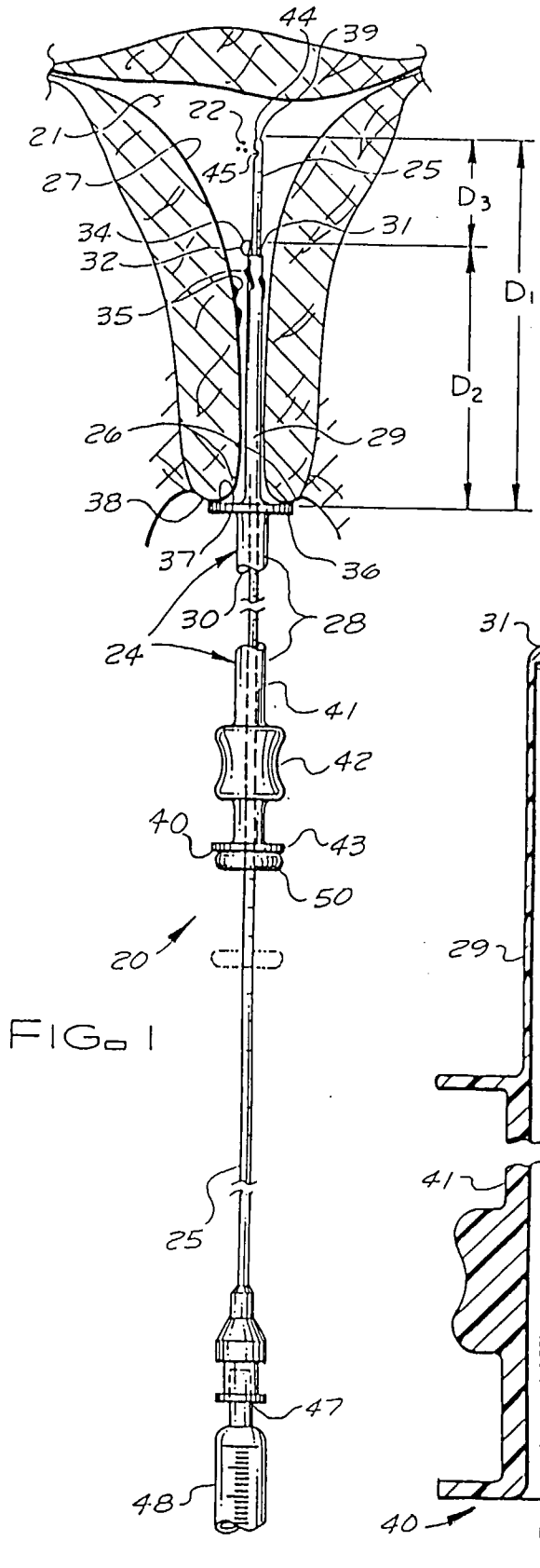


FIG. 1

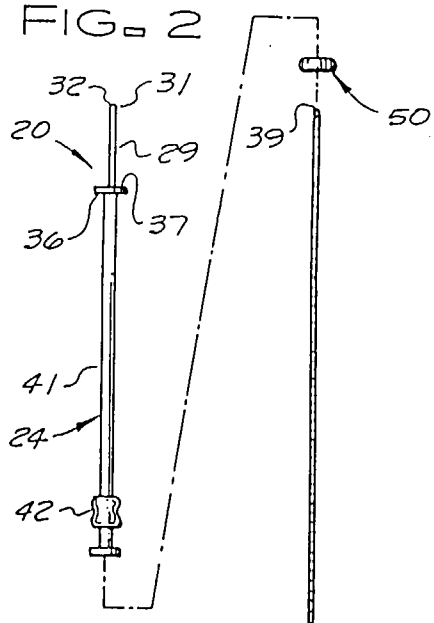


FIG. 2

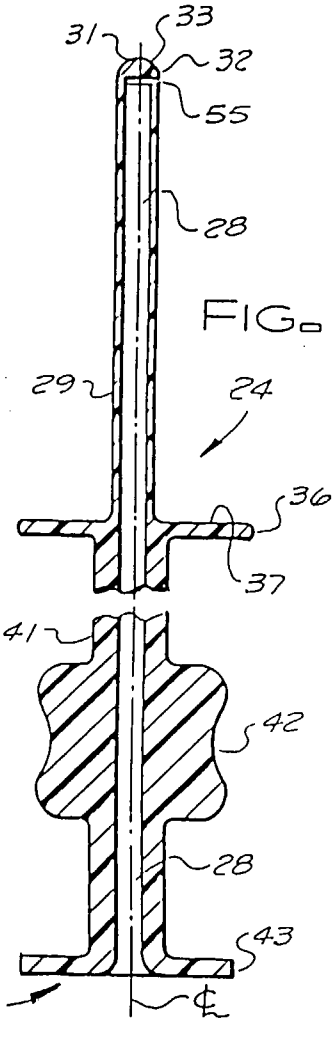
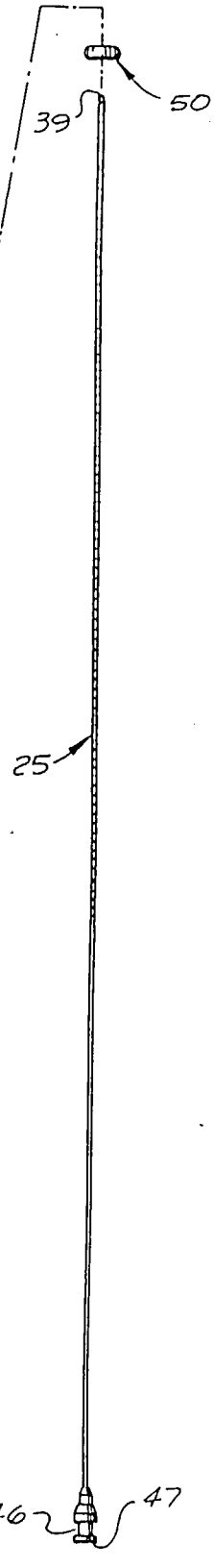


FIG. 3



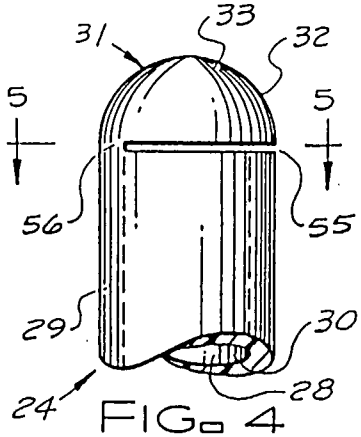


FIG. 4

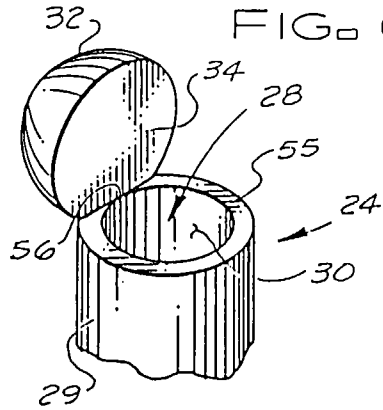
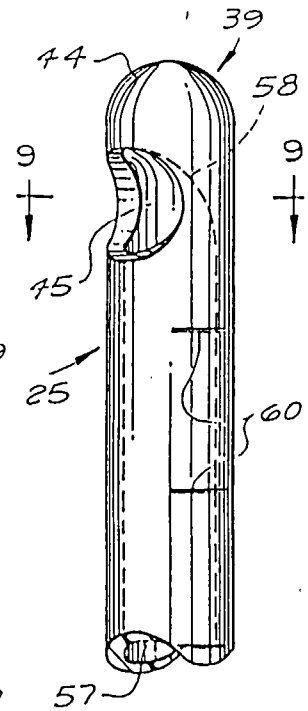


FIG. 6



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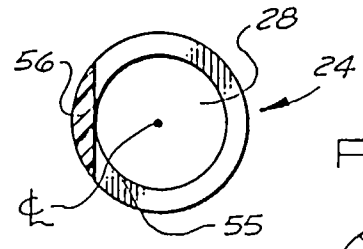


FIG. 5

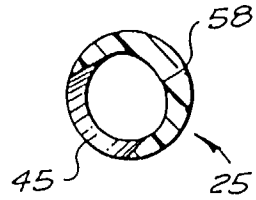


FIG. 9

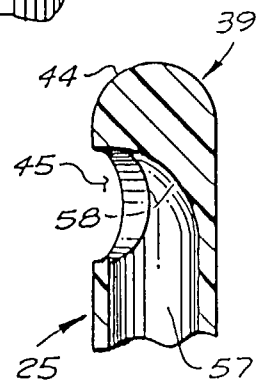


FIG. 7

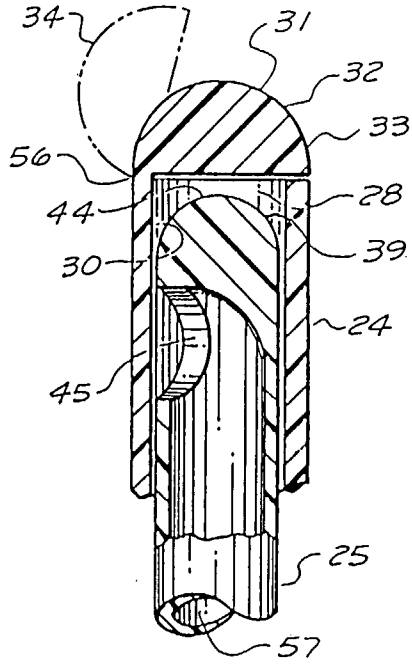


FIG. 10

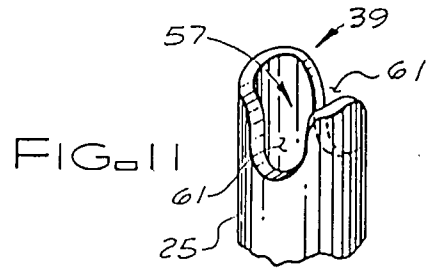


FIG. 11

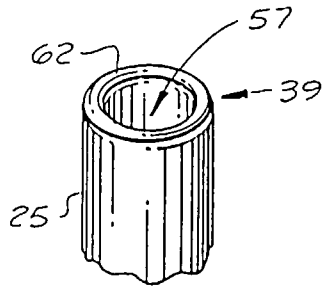
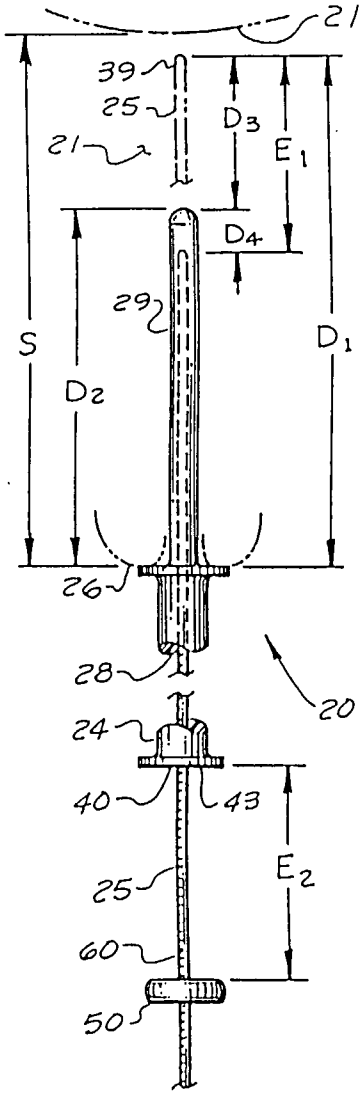


FIG. 12

FIG. 13



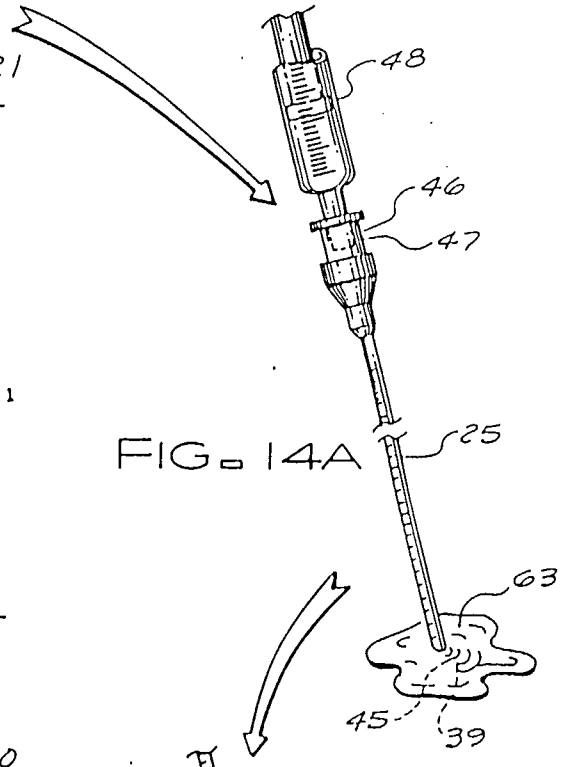


FIG. 14A

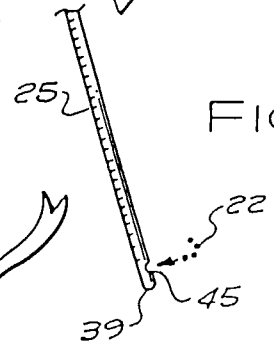


FIG. 14B

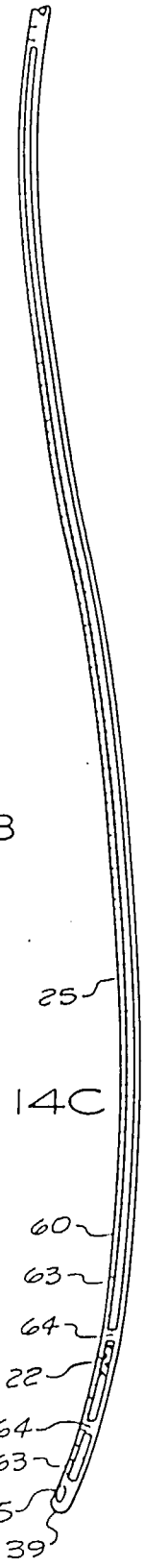


FIG. 14C

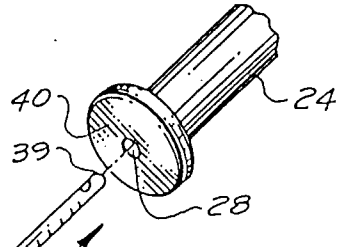


FIG. 15A

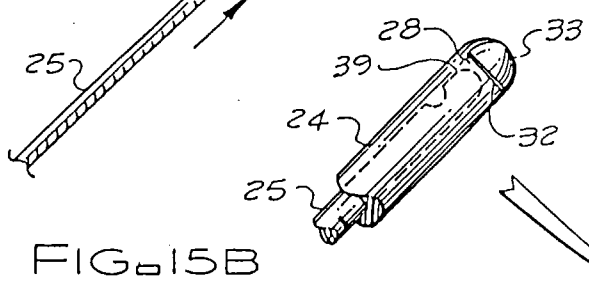


FIG. 15B

FIG. 16A

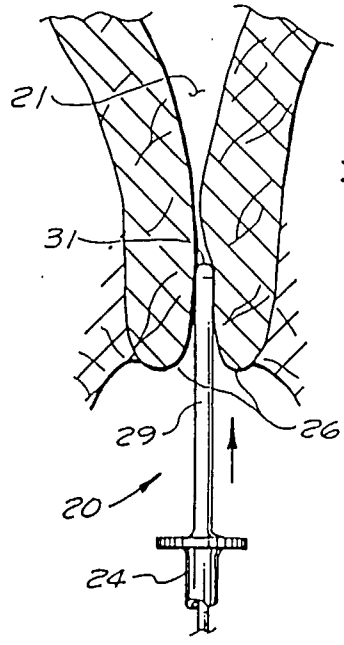


FIG. 16B

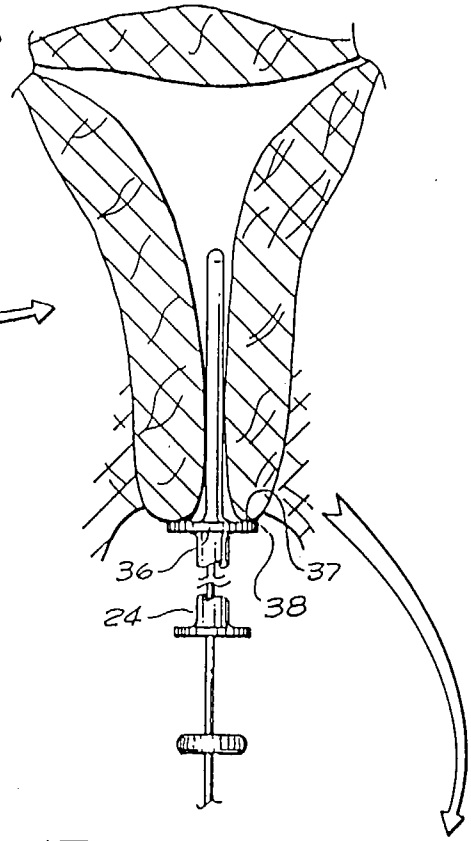


FIG. 17

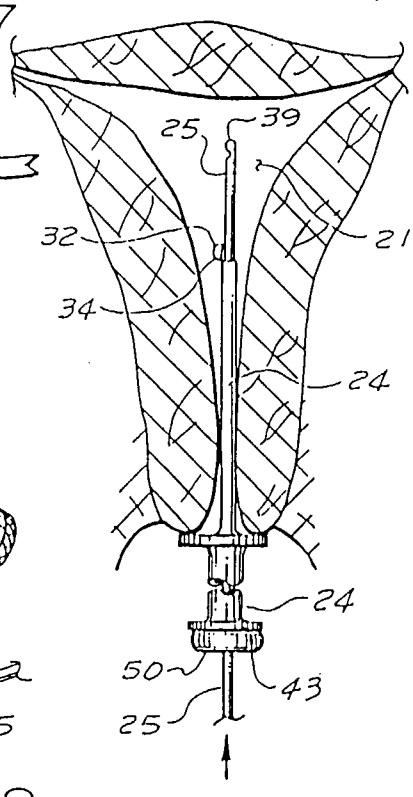
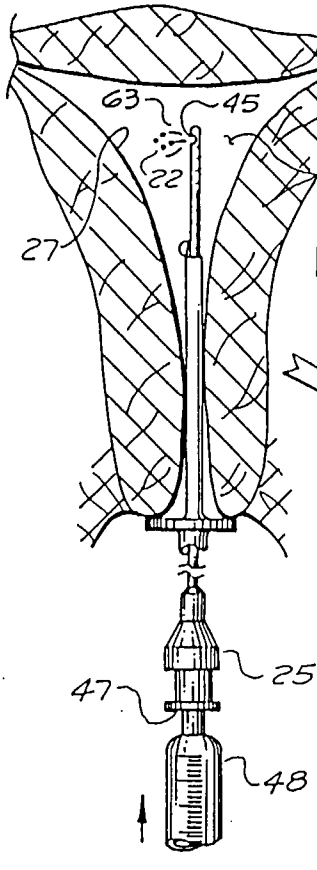


FIG. 18



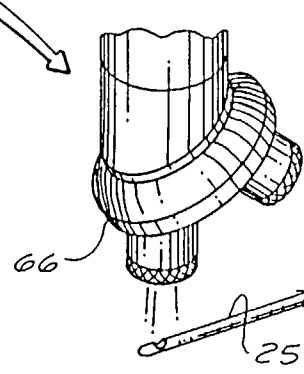


FIG. 19

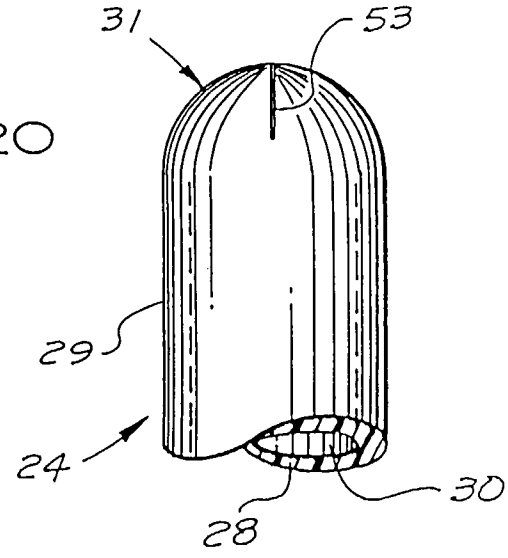


FIG. 20

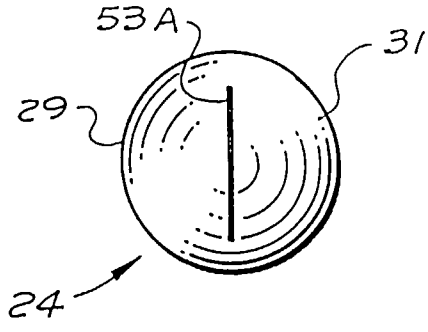


FIG. 21

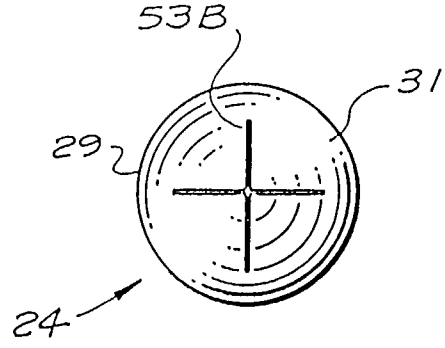


FIG. 22

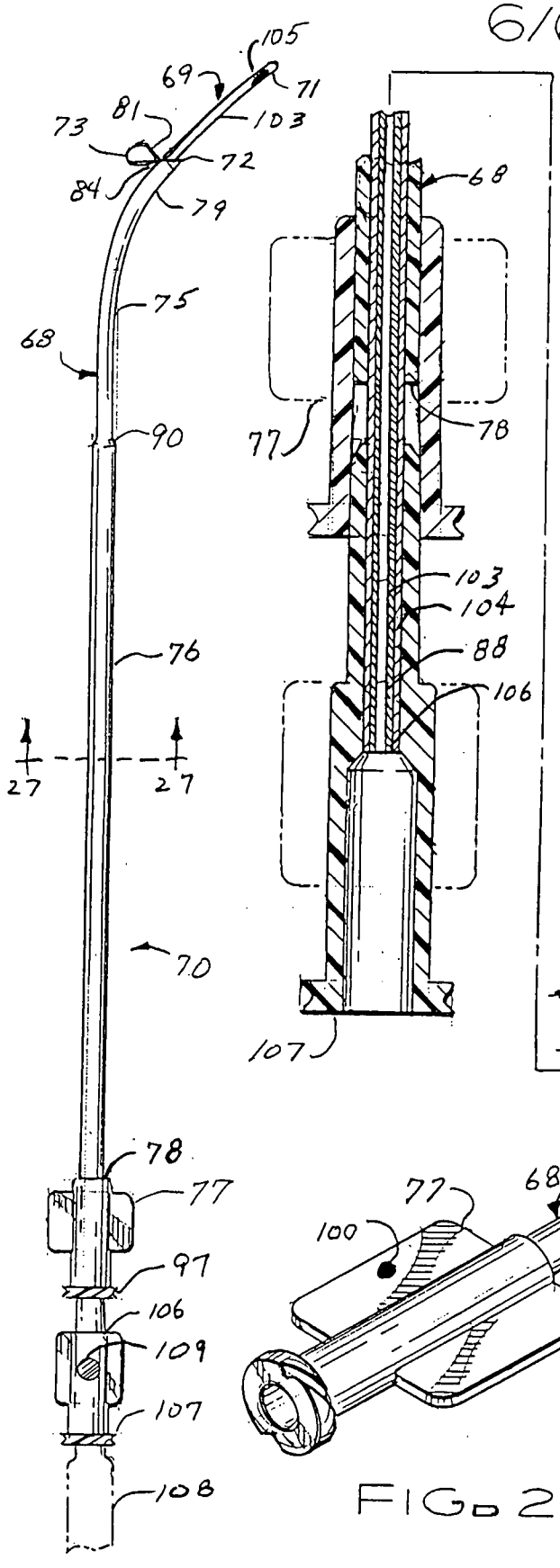


FIG. 23

FIG. 25

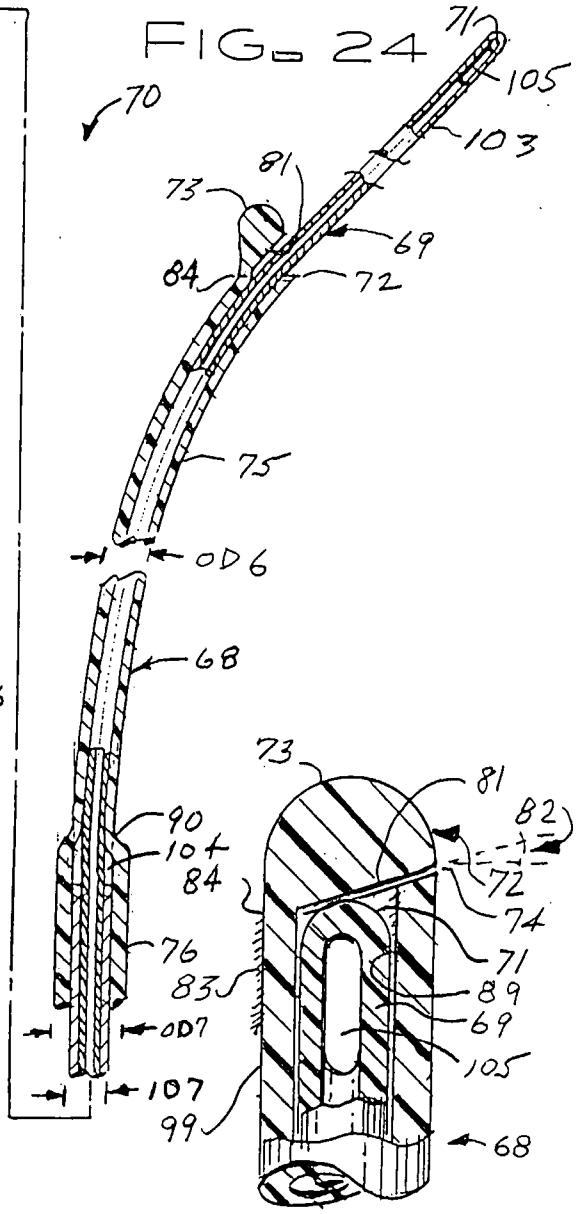


FIG. 24

FIG. 26

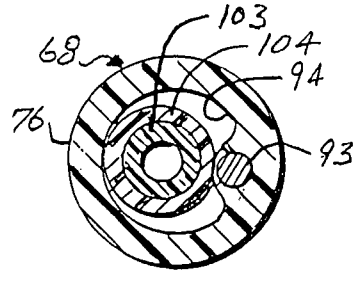


FIG. 27

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09/542,060 3 April 2000 (03.04.2000) US

(71) Applicant and
(72) Inventor: TAO, Jun [CN/US]; 5333 W. Mercury Place, Chandler, AZ 85226 (US).

(74) Agent: STONEMAN, Martin, L.; Stoneman Law Offices, Ltd., 3113 North 3rd Street, Phoenix, AZ 85012 (US).

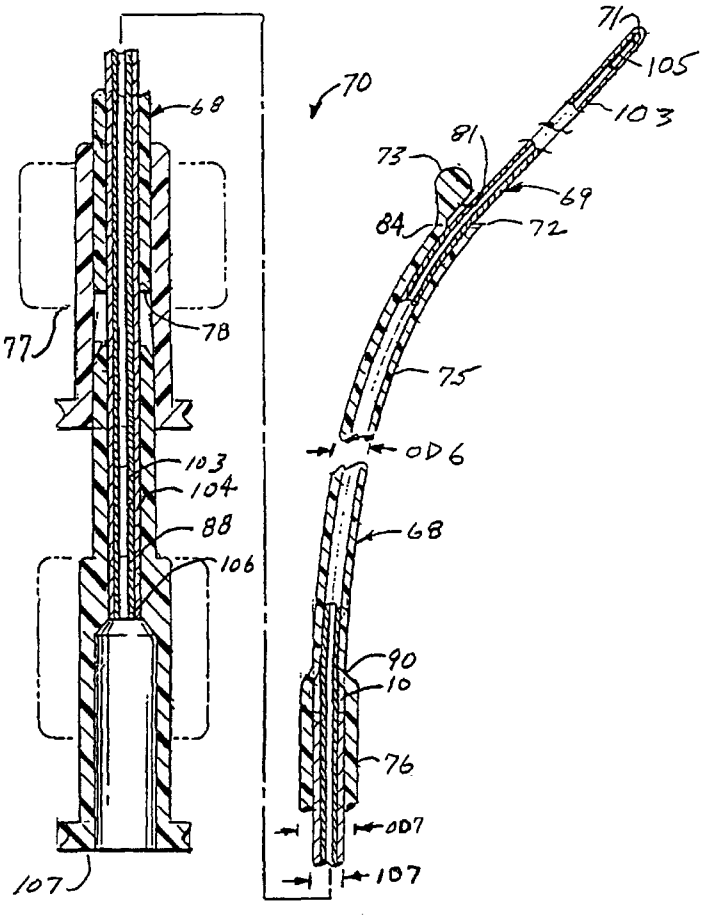
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: CATHETER SYSTEM FOR IMPLANTING EMBRYOS



(57) Abstract: Described is a catheter system (20) for implanting embryos into a woman's uterus. The catheter system utilizes a protective catheter sleeve (24) for introducing a catheter into the uterus without mucus contamination of an inner catheter (25). Once the sleeve containing the inner catheter is introduced into the uterus, the protected inner catheter, carrying the embryos, is pushed through a swivelable distal end cap (32) on the sleeve to a desired implanting location. The distal end of the inner catheter has a protective cap and a side opening for embryo release. Also, stiffness and indicia features of the outer sleeve and inner catheter assist in the physician's handling of the catheter system and in ensuring a desired uterus location for implanting.

WO 01/74417 A3

(88) Date of publication of the international search report:
21 March 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/10220

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/48
US CL :600/034

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/033, 034, 035, 114; 604/48, 54, 55, 514, 518

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,010,448 A (THOMPSON) 04 January 2000, see entire document.	1-69
Y	US 4,865,589 A (SIMMET et al.) 12 September 1989, see entire document.	1-69

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search 04 JUNE 2001	Date of mailing of the international search report 15 NOV 2001
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