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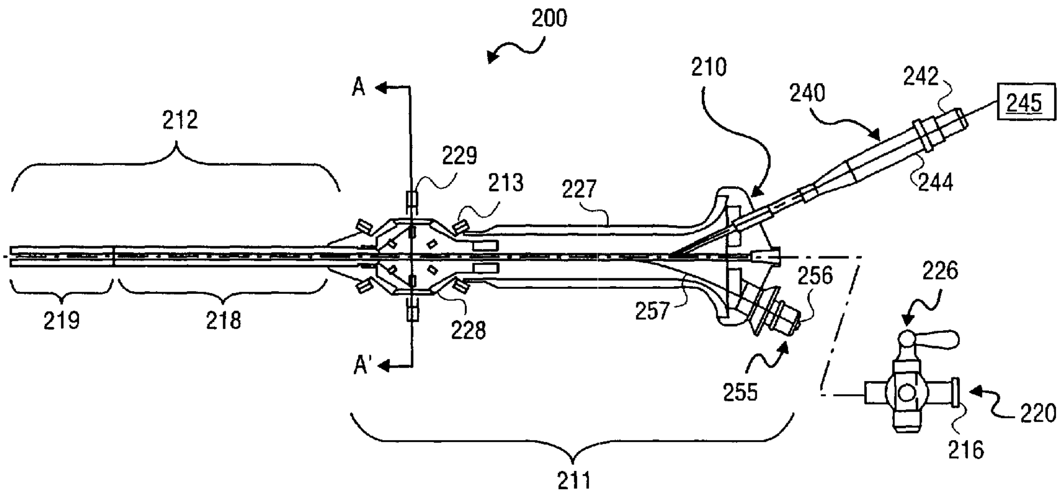
(54) Title: UTERINE DEVICES AND METHOD OF USE



(57) Abstract: A microcatheter for use with endoscopic embryo implantations including a flexible hollow shaft with a back end and an open front end; an angled tip extending from the open front end; and a cutting edge formed around at least a portion of the periphery of the angled tip. An apparatus including a handle; a first tubular body coupled to the handle and a second tubular body comprising a polymer material coupled to a distal end of the first tubular body and the distal end defining a guide face, wherein the first tubular body and the second tubular body are co-linearly aligned and collectively define a first lumen therethrough extending from an entry port to the guide face; wherein the second tubular body has a dimension adequate for insertion into a uterus of a human subject, and wherein the guide face comprises an outside diameter less than an outside diameter of the second tubular body. Also, a method of using a hysteroscope having a single operating channel.

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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.

UTERINE DEVICES AND METHOD OF USE

BACKGROUND

Field of the Invention

The invention relates to generally to intra-uterine devices, including hysteroscopes and related devices for microsurgical use such as use in the field of embryo implantation.

Description of Related Art

Improving the success of in vitro fertilization (IVF) depends on many factors, one of which is the delivery or transfer of the embryo to the endometrial lining of the uterus and the successful implantation of the embryo therein. It is well known in the art that assisting an embryo to adhere to, or implant within, a predetermined area of the endometrial lining of the uterine wall, as opposed to simply releasing the embryo into the uterus, will enhance the success of IVF.

One method of assisted embryo transfer is found in U.S. Patent No. 6,010,448 to Thompson in which an embryo is transferred with the aid of an endoscopic device, via a flexible catheter, to the endometrial lining and affixed thereto with an adhesive.

Another method of embryo transfer is taught in U.S. Patent No. 5,360,389 to Chenette in which, after using pressurized CO_2 gas to distend the uterine walls, an endoscope is used to select an implantation site. A catheter is then used to forcibly inject the embryos into the endometrial lining.

While the embryo transfer methods of these prior art types may be generally satisfactory for their intended purposes, implantation problems can arise in which the trauma to the delicate embryos by either an injection or "adhesion" may yield less than optimal solutions and fail to achieve high IVF success rates. Accordingly, improved devices that may be useful, in one aspect, in intrauterine procedures such as IVF are desired. An improved embryo transfer method is also desired.

SUMMARY

A catheter, an endoscope (hysteroscope), and a method of introducing at least one embryo into a uterus of a subject is described. One object of the device(s) and/or method is to provide a simple gentle method for intrauterine procedures such as embryo transfer and implantation. To accomplish this gentle transfer, an improved microcatheter with an angled tip is described. The microcatheter is able to work as both a microsurgical instrument, used in a method described herein to form an embryo-receiving pocket within the endometrial lining of a subject's uterus, and as the vehicle for transferring an embryo into the pocket. It has been observed that by gently securing an embryo within a pocket of endometrial lining, many of the risks of IVF, such as a tubal pregnancy, misplacement of the embryo, and loss of the embryo can be minimized. Tubal pregnancies, for example, are virtually eliminated according to this method.

Another benefit of actively implanting the embryo within the endometrial lining (the "within method") is derived from the fact that older embryos (e.g., 2 to 7 days after fertilization) may be used, thus providing for a longer period of observation which allows the most viable embryos to be selected. Higher accuracy in selecting the most viable older embryos yield the additional benefit that fewer embryos need to be implanted to assure a viable pregnancy, thereby minimizing the risk of high-order multiple births associated with those common IVF methods which place larger quantities of less mature embryos within the uterus. See, article by Doug Brunk in Ob. Gyn. News (Volume 35, number 23 at page 1-3) entitled "Blastocyst Transfer Cuts Multiples Risk".

The within method preferably uses direct visualization of the implantation area or site through an endoscopic device. To enhance the field of vision of the endoscope and to increase the maneuverability of the endoscope

within the uterus, the uterine walls may be distended by pressurizing the uterus with an inert, harmless insufflation gas such as N_2 gas. Other gases may also work, however, the use of pure CO_2 gas is contraindicated because of toxicity. Gynecologic & Obstetric Investigation, Volume 43(2) at pages 73-5, 1997, entitled "Assisted implantation: direct intraendometrial embryo transfer." This article explains that the introduction of CO_2 gas into the uterus to distend the uterine wall and improve endoscopic viewing, (such as that claimed in U.S. Patent No. 5,360,389), also raises the risk of acidifying the endometrial lining and therefore reduces the viability of the implanted embryo. Moreover, mixtures of CO_2 and atmospheric air are generally not safe because of concern over fatal air embolism.

To enhance the positioning of the microcatheter at the implantation site, a hysteroscope, which is an endoscopic device for intrauterine use, is used. The hysteroscope both provides direct visualization within the uterus and acts as a guide and support for the microcatheter.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of an embodiment of a microcatheter.

Figure 2 is a perspective front view of the tip of the microcatheter of **Figure 1**.

Figure 3 is a partial cut-away side view of the tip of the microcatheter of **Figure 1**.

Figure 4 is a schematic, cross-sectional side view of one embodiment of a hysteroscope.

Figure 5 is a cross-sectional side view of a portion of the hybrid insertion arm portion of the hysteroscope of **Figure 4**.

Figure 6 is a cross-sectional view of the hysteroscope of **Figure 4** through line A-A′ of **Figure 5**.

Figure 7 is a schematic, cross-sectional side view of another embodiment of a hysteroscope.

Figure 8 is a partial cross-sectional view of the hysteroscope of **Figure 7** through line A-A'.

Figure 9 is a cross-sectional side view of a portion of the hybrid insertion arm portion of the hysteroscope of **Figure 7**.

Figure 10 is a cross-sectional view of the hysteroscope of **Figure 7** through line B-B' of **Figure 9**.

Figure 11 is a cut-away side view of the end of the microcatheter of **Figure 1** containing an embryo for implantation.

Figure 12 is a first sequential view of an embodiment of a method of assisted embryo implantation, which shows the survey of the endometrial lining for an implantation site.

Figure 13 is a second sequential view of the method of assisted embryo implantation, which shows the formation of an embryo-receiving pocket at the selected implantation site.

Figure 14 is a third sequential view of the method of assisted embryo implantation, which shows the implantation of the embryo within the pocket of **Figure 13**.

Figure 15 is a fourth sequential view of the method of assisted embryo implantation, which shows the closure of the embryo-receiving pocket over the embryo.

DETAILED DESCRIPTION

Referring now to the drawings, illustrated in **Figures 1-3** is one embodiment of a microcatheter. Microcatheter 10 includes, in this embodiment, operational syringe 20, with plunger 21, connected to proximal end 22 of flexible hollow shaft 25 which terminates at a distal end to form shaped end 30. Proximal end 22 may be coupled, in one embodiment, to a leur-lock fitting.

Shaft 25 defines a lumen therethrough for, representatively, introducing one or more embryos into a uterus of a subject. In one embodiment, shaft 25 is an extruded one piece polymer material. Suitable polymers for shaft 25 are preferably polycarbonate (e.g., transparent polycarbonates). Tetrafluoroethylene (e.g., TEFLON™) materials may also be suitable. A suitable outside diameter for a proximal portion of shaft 25 is on the order of one millimeter (mm) or less. Shaft 25 includes a distal portion including shaped end 30.

Shaped end 30 of microcatheter 10 includes base region 31 of a similar diameter as the flexible hollow shaft 25 (e.g., 1 mm or less) and then tapers 32 over 1 to 3 mm into narrow distal end 33 which is ideally between 10 and 15 mm in length, with a representative outside diameter of 0.8 mm or less. In one embodiment, distal end 33 has an interior diameter of about 400 to 500 micrometers (μm). Distal end 33 includes bend portion 39 deflected at an angle (α) between 5 and 45 degrees, preferably 10 and 15 degrees from an axis defined by the proximal portion of shaft 25 (in this case deflected upward as viewed). Microcatheter also includes angled tip (angled opening) 34 angled 10 to 45° (angle γ), in this case opposite the above-referenced deflection angle α. Angled tip 34 is the vehicle through which an embryo is delivered into the implantation site and may also be the microsurgical instrument used to form an implantation pocket within the endometrial lining as described with reference to **Figures 12-15** and the accompanying text. Beveled or tapered edge 35 may be added to angled tip 34 to yield a more refined cutting tool.

Referring now to the drawings, illustrated in **Figures 4-6** is one embodiment of a hysteroscope. Hysteroscope 100 is a two-part device, with operational section 111 at one end and hybrid insertion arm 112 at the other end. Operational section 111 is held by the operator during an intrauterine procedure, and a portion of hybrid insertion arm 112 is inserted into a subject's uterus. Supported on operational section 111 is eyepiece 113, used to visualize inside a uterus; control knob 114 used to maneuver a control structure (e.g., one or more braided wires extending to hybrid insertion arm 112 to actuate hybrid insertion arm 112 (the actuation shown in ghost lines)); and a series of access ports 115-117 extending from operational section 111 through one or more lumens inside both proximal portion 118 and distal portion 119 which form hybrid insertion arm 112. Hybrid insertion arm 112 is, in this embodiment, generally tubular and includes proximal portion 118 of a generally rigid material and distal portion 119 of a relatively flexible material (e.g., a polymer material).

The one or more lumens defined by access ports 115-117 extend through proximal portion 118 and distal portion 119 and exit or terminate at distal end 130 of distal portion 119 through guide face 131. Included among the one or more lumens is operative channel or lumen 120. Operative channel 120 extends between distal end 130 and, representatively access port 116. Operative channel 120 has a diameter suitable for insertion of a microcatheter therethrough for the purpose of performing a microsurgical procedure.

In one embodiment, distal end 130 of hybrid insertion arm 112 has edge radius 132 (e.g., a rounded edge) to facilitate gradual and gentle insertion through a subject's cervix. Edge radius provides less trauma than a blunt ended instrument and is generally able to gain entry into a smaller opening than a blunt instrument. To further aid the operator during insertion, series of locator marks 133 may be added to an exterior of hybrid insertion arm 112 to help the operator gauge the position of hybrid insertion arm 112 within a subject's uterus.

Prior art hysteroscopes with wholly flexible insertion sections are often difficult to control precisely during an intrauterine procedure. In the case of an intrauterine microsurgical procedure, hybrid insertion arm 112, having, in one embodiment, a rigid tubular proximal portion 118, preferably constructed of a smooth material such as stainless steel, seamlessly grafted/bonded to flexible tubular polymer (plastic-like) distal portion 119, is more easily maneuvered within a uterus and provides a more stable platform from which to perform the microsurgery and/or embryo implantation than from a wholly flexible hysteroscopic insertion arm.

Hybrid insertion arm 112 with both rigid proximal portion 118 and flexible distal portion 119 may be attached to a variety of hysteroscopic devices and should not be limited to being attached to, or supported by, operational section 111 detailed herein.

Often during an intrauterine procedure, uterine insufflation is desirable. Referring to **Figure 4**, illustrated in hysteroscope 100 is gas port 115 which feeds into operational port 116 to operational channel 120. By sharing operational channel 120 between instruments and insufflation gas, a diameter of insertion arm 112 may be minimized yet provide the desired functions required of a hysteroscope.

Illumination within a subject's uterus may be added via illumination train extending through lumen 135 of hysteroscope 100. Lumen 135 extends, in one embodiment shown in **Figures 4-6**, between operational section 111 and hybrid insertion arm 112. Access to lumen 135 is provided by light port 117 where a light source may be coupled, preferably remotely so as not to hinder an operator's maneuvering of the device. Representatively, one or more illumination fibers 121 may extend a sufficient distance in a proximal direction from access port 117 and be coupled to light source 145 at its proximal end, so that light source 145 may remain stationary (e.g., on a table top), while hysteroscope 100 is maneuvered. In one embodiment, one or more illumination fibers 121 is inserted through lumen 135 and terminate at distal end 130. In one embodiment, one or more illumination fibers 121 include a distal end of ground glass with a blunt or, as viewed, vertical cross-section. Preferably, the distal end of one or more illumination fibers 121 aligns (is co-extensive with) distal end 130. Accordingly, in the embodiment where distal end 130 has a rounded edge, such rounded edge, in one embodiment, does not include the entire cross-section of distal end 130. Referring to **Figure 5** and **Figure 6**, guide face 131 has a blunt or, as viewed, a vertical profile (β of 90°).

In this embodiment, operational channel 120 and lumen 135 are disposed within a cross-section of guide face 131.

In addition to an illumination train, hysteroscope 100 includes an image train. The image train includes lumen 136 extending between operational section 111 and hybrid insertion arm 112. At the operational section end, eyepiece 113 is disposed within or coupled about lumen 316. A video camera may alternatively be coupled about lumen 136 to provide video images of the uterus. At the hybrid insertion arm end, one or more lenses 37 is/are disposed within or coupled about lumen 136. In the embodiment shown in **Figures 4-6**, lumen 136 including one or more lenses 137 is disposed within a cross-section of guide face 131. An optical fiber may be disposed within lumen 136 in between the viewing device (e.g., eyepiece 113) and one or more lenses 137.

Figure 7 shows a schematic, cross-sectional view of another embodiment of a hysteroscope. In this embodiment, hysteroscope 200 includes operational section 211 at one end (a proximal end) and hybrid insertion arm 212 at a second end (a distal end). Hybrid insertion arm 212 is generally tubular (defining one or more lumens therethrough) and includes proximal portion 218 of a generally rigid material, such as stainless steel, and distal portion 219 of a relatively flexible material (e.g., a polymer material such as polycarbonate). Representatively, proximal portion 218 has a length on the order of about 8 to 19 centimeters (cm) with about an outside diameter (OD) on the order of 3 to 4 mm. Distal portion 219 has a representative length of 3 to 10 cm and a representative OD of 2.5 to 4 mm, preferably 3.0 to 3.5 mm, and preferably a representative diameter slightly smaller (at least toward distal end 230) than proximal portion 218.

Referring to **Figure 7**, operational section 211 includes handle portion 227 that is preferably knurled for better holding and feel. Coupled to a distal end of handle portion 227 is lever holder 228. Disposed within lever holder 228 is articulating lever 229 that is coupled through, for example, wire members (e.g., braided wire members) to distal portion 229. Representatively, deflection of articulating lever 229 about lever holder 228 deflects distal portion 219 of hybrid insertion arm 212 to the same degree. In one embodiment, articulating lever 229 rotates about a single axis 60° in two directions (e.g., clockwise and counterclockwise) for a total range of deflection of 120°. Protruding stops 213 on lever holder 228 may be included to limit articulation of articulating lever 229.

Figure 8 shows a cross-section of lever holder 228 through line A-A' of **Figure 7**. Lever holder 228 includes, in this embodiment, articulating lever 229 coupled to C-shaped wire mount 263 within primary lumen 225. As viewed, two wire members 262, such as braided wire members, are coupled to wire mount 263 at opposite sides thereof (e.g., 12 o'clock and 6 o'clock as viewed, respectively). Wire mount 263 is coupled to articulating lever 229 through lever holder 266.

Referring again to **Figure 7**, at a proximal end of handle portion 227 of hysteroscope 200 is access port 216. Access port 216 provides access to operational channel or lumen 220. Operational channel 220 extends through the device from operational section 211 to hybrid insertion arm 212 terminating at distal tip 230. In this embodiment, access port 216 is axially aligned with operational channel 220. In one regard, the axial alignment aids the insertion of instruments such as a microcatheter into operational channel 220.

Also at a proximal end of handle portion 227 of hysteroscope 200 is a portion of illumination train 240 including illumination holder 244. A plurality of illumination fibers (e.g., glass fibers) are disposed within illumination holder 244 and join operational channel 220 within handle 227. As illustrated more clearly in **Figure 10** described below, in one embodiment, operational channel 220 and the plurality of illumination fibers are axially aligned and disposed within a primary lumen extending from operational section 211 to hybrid insertion arm 212. Light post 242 is disposed at a distal end of illumination holder 244 and may itself be a light source to the illumination fibers or be coupled to a light source. For example, light source 245 may be located remotely so as not to inhibit an operator's use of the device. At a proximal end of illumination holder 244, the illumination fibers are surrounded by tubing or sheathing and the tubing or sheathing is coupled to handle portion 227.

Still referring to **Figure 7**, at a proximal end of handle 227 is a portion of image train 255 including eyepiece 256. Eyepiece 256 is coupled to lumen 236 (see **Figures 9** and **10**) which joins operational channel 220 within handle 227 and is axially aligned within a primary lumen extending from operational section 211 to hybrid insertion arm 212.

Coupled at a proximal end of operational channel 220 is valve or stopcock 226 to, in one position, seal or block operational channel 220 and, in another position, to allow insufflation gas or an instrument such as a microcatheter to be passed through operational channel 220. In another embodiment, stopcock 226 may have three positions to, for example, provide individual access ports for an instrument and for insufflation gas. In one embodiment, stopcock 226 is sterilizable, removable and replaceable. A microcatheter and/or insufflation gas, in one embodiment, may alternatively be introduced to operational channel 220 at entry port 216. As illustrated in **Figure 4**, a proximal end of handle 127 has, in this embodiment, a concave shape with entry port 216 at about the center axis of the end of handle 127 and illumination train 240 and image train disposed radially in alternative directions from the axis.

Figure 9 shows a schematic, cross-sectional side view of a distal end of hybrid insertion arm 212. **Figure 10** shows a cross-section through line B-B′ of **Figure 9**. Each figure shows primary channel 225 extending through hybrid insertion arm 212 to distal end 230. In one embodiment, primary channel 225 is a polymeric material of having a diameter on the order of 1.3 mm. Disposed within primary channel 225, in this embodiment, is operational channel 220 and illumination lumen 236. In a preferred embodiment, operational channel 220 has an inside diameter (ID) of about 1.5 mm or less, preferably 1.3 mm. Also disposed within primary channel 225 are a plurality of illumination fibers 280 (each having a representative diameter on the order of 0.12 mm) forming part of illumination train 240 extending back to illumination holder 244 and light post 242 and operational section 211. In this embodiment, illumination fibers 288 surround operational channel and image lumen 236. Still further disposed in operational channel 220 is image lumen 236 which forms part of image train 255 and is coupled, in one embodiment, to eyepiece 256 in operational section 211. Image fiber 257, such as a 10K image fiber commercially available from Fujikura America, Inc. of Marietta, Georgia may be disposed in image lumen 236 and coupled to eyepiece 256. At a distal end of image lumen 236 is one or more lenses 237, such as a GRIN, ILH-.5-WD15 lens commercially available from NSG America, Inc. of Somerset, New Jersey.

Disposed outside of primary channel 225, preferably within a separate lumen or lumens or sheaths is co-axially disposed dumb bell 275 coupled (e.g., via adhesive) to distal end 230 of hybrid insertion arm 212. Wire members 262 are coupled to dumb bell 275 to provide for articulation of distal portion 219 of hybrid insertion arm 212 by articulating lever 229.

Referring to **Figure 9**, distal end 230 of hybrid insertion arm 212 has a rounded edge 232 and a blunt (e.g., vertical) guide face 231. Accordingly, guide face 231 has a smaller diameter than the outside diameter of distal portion 219 of hybrid insertion arm 212. It is appreciated that edge 232 need not be rounded but could be linearly-sloped. Primary channel 225 is disposed within blunt guide face 231 so that illumination fibers 280 (see **Figure 7**) may terminate with a blunt edge at guide face 231. Rounded edge 232 facilitates insertion into a subject.

Figures 11-15 show the sequential performance of an embryo implantation procedure representatively using microcatheter 10 and hysteroscope 200. The biology, timing and biochemistry involved in embryo selection and in optimizing the subject for implantation is not the topic of this invention. It is well known by those skilled in the art of how best to harvest and fertilize eggs and how best to select viable embryos. Volumes of scientific literature also exists on the hormonal, pharmaceutical and other chemical factors which should be orchestrated, monitored and taken into account when selecting the timing for embryo implantation. Accordingly, such information is omitted.

Prior to any intrauterine activity, an embryo must be placed in microcatheter 10. Microcatheter 10 will be used to both prepare the site for implantation and to transfer the embryo "E" into the site. Shown in **Figure 11** is an embryo "E" immersed in a culture medium "CM" placed near distal end 33 of microcatheter 10. The culture medium "CM" serves the important role of maintaining the health and viability of the embryo "E" during the procedure. In this embodiment, the culture medium "CM" used is a "modified Human Tubal Fluid'" manufactured by Irvine Scientific of Irvine, California. Considering the rapid pace of advancements in IVF, new and varied culture media will undoubtedly be developed or become available. Accordingly, the method described should not be limited to that culture media described herein, but rather to any suitable culture media which serves the function of maintaining embryo viability during the implantation procedure.

Prior to placing the embryo "E" into microcatheter 10, a first quantity of culture medium "CM" is drawn into microcatheter 10 and followed by a back measure of atmospheric air "A2". Next, the embryo "E", bathed in more culture medium "CM", is drawn into distal end 33 of microcatheter 10 followed by a front measure of atmosphere air "A", thereby sandwiching the embryo "E" between a first and second measure of atmospheric air "A " and "A2". Once loaded with the embryo "E", microcatheter 10 is ready for use in the implantation procedure. Each measure of atmospheric air is, for example, about three to twenty microliters in volume.

To begin the preferred implantation procedure, distal portion 212 of representatively hysteroscope 200 is guided into the uterus "U" (**Figure 12**). During the insertion of the hysteroscope 200, N_2 gas 101 is fed into the uterus "U" pressurizing or insufflating the uterus "U" and thereby distending the uterine walls "W". Depending on the needs of the operator, and the uterus of the subject, the gas 101 may be automatically maintained at a constant pressure or the operator may vary the pressure. The distension of the uterine walls "W" enhances the visualization through hysteroscope 200 within the uterus "U".

Once an embryo implantation site "I" is selected, distal end 30 of microcatheter 10 is inserted into the endometrial lining "L" (**Figure 13**) and the angled tip 34 is moved generally along the path of arrow 300 making a small incision 2 to millimeters (mm) deep in the endometrial lining "L" to form a small flap "F". The front measure of atmospheric air "A " is then released from microcatheter 30 and acts to lift up the small flap "F" of the endometrial lining "L".

Shown in **Figure 14** is the embryo-receiving pocket "P" formed beneath the small flap "F". The actual implantation of the embryo "E" into the embryo-receiving pocket "P" is performed with the same microcatheter 30 used to form the embryo-receiving pocket "P" and is accomplished by depressing plunger 21 of syringe 20 (see **Figure 1**) to gently urge the embryo "E" and the back measure of atmospheric air "A2" out of microcatheter 30 and into embryo-receiving pocket "P".

The back measure atmospheric air "A2" forms a cushion around the embryo "E" which helps to protect it when the microcatheter is removed (**Figure 15**) and the small flap "F" drops back into place over the embryo "E" along the line of arrow 201. To complete the procedure, hysteroscope 200 is then gently removed from the subject and post-IVF precautions and protocols should be used. Another possible advantage of a successful implantation of the embryo "E" within the endometrial lining "L" is that the length of the post-IVF precautions may be reduced.

Dependent on the subject, the number of viable embryos available and the aperture, up to two embryos may be implanted into a single pocket "P". In the case of embryo implantations into multiple pockets, additional embryos, each bathed in culture medium, are sandwiched between a measure of atmospheric air within the microcatheters and implanted into separately formed pockets "P".

Certain presently preferred embodiments of apparatus and methods for practicing the invention have been described herein in some detail and some potential modifications and additions have been suggested. Other modifications, improvements and additions not described in this document may also be made without departing from the principles of the invention. For example, the microcatheter (e.g., microcatheter 10) and hysteroscope (e.g., hysteroscope 200) have been described with reference to an IVF procedure. It is appreciated that such devices need not be specified together and either may have other uses beyond IVF procedures. Representatively, the hysteroscope may be used in connection with other devices such as biopsy forceps or other procedures such as irrigation/aspiration.

CLAIMS

What is claimed is:

1. A microcatheter for use with endoscopic embryo implantations comprising:

a flexible hollow shaft with a back end and an open front end;

an angled tip extending from the open front end; and

a cutting edge formed around at least a portion of the periphery of the angled tip.

2. The microcatheter of claim 1, wherein the angled tip is formed at an angle of 5 to 45 degrees relative to the open front end.

3. The microcatheter of claim 2, wherein the angled tip is formed at an angle of 10-15 degrees relative to the open front end.

4. The microcatheter of claim 1, further comprising a tapered region approximately 1.5 centimeters from the angled tip where by the diameter of the flexible hollow shaft is reduced by approximately 20 percent.

5. The microcatheter of claim 1, further comprising a tapered region approximately 1.5 centimeters from the angled tip whereby the diameter of the flexible hollow shaft is reduced from an external diameter from approximately 1.0 millimeters to an angled tip diameter of about 0.80 millimeters.

6. The microcatheter of claim 1, wherein the cutting edge comprises a tapered region.

7. The microcatheter of claim 1, wherein the cutting edge comprises a beveled region.

8. An apparatus comprising:

a handle;

a first tubular body having a proximal end coupled to the handle and a distal end, the proximal end defining an entry port;

a second tubular body, comprising a polymer material and having a proximal end and a distal end, the proximal end of the second tubular body coupled to the distal end of the first tubular body and the distal end defining a guide face,

wherein the first tubular body and the second tubular body are co-linearly aligned and collectively define a first lumen therethrough extending from the entry port to the guide face, the first lumen having a dimension adequate to accommodate in a co-linear alignment with the first tubular body:

a second lumen having a dimension adequate to accommodate an instrument therethrough;

at least one illumination fiber; and

a third lumen comprising at least one lens disposed at a distal end of the second tubular body;

wherein the second tubular body has a dimension adequate for insertion into a uterus of a human subject, and

wherein the guide face comprises an outside diameter less than an outside diameter of the second tubular body.

9. The apparatus of claim 8, wherein the handle has a proximal end and a distal end and the first tubular body extends through the handle, such that the entry port is disposed at the proximal end of the handle.

10. The apparatus of claim 8, further comprising:

an articulating body coupled to the first tubular body and adapted to be articulated by an operator of the apparatus; and

at least one wire coupled to the articulating body and to the distal end of the second body within the first lumen and outside the second lumen.

11. The apparatus of claim 10, wherein the articulating body is adapted to articulate the distal end of the second body up to 60° in at least two directions.

12. The apparatus of claim 10, wherein the articulating body is adapted to be articulated coaxially about the first tubular body.

13. The apparatus of claim 10, further comprising a light source coupled to the illumination fiber and disposed at a distance from handle such that the handle may be maneuvered without a concomitant maneuvering of the light source.

14. The apparatus of claim 8, wherein the first tubular body comprises a metal material.

15. The apparatus of claim 8, further comprising a valve coupled to the entry port, the valve having at least one position providing access to the entry port.

16. The apparatus of claim 15, wherein the valve comprises a removable stopcock.

17. A method comprising:

inserting a hysteroscope comprising a proximal end and a distal end into a uterus of a subject, the hysteroscope having a single operational channel defined between the proximal end and the distal end;

introducing an insufflation gas through the operational channel; and

introducing an instrument through the operational channel.

18. The method of claim 17, wherein the instrument is a catheter.

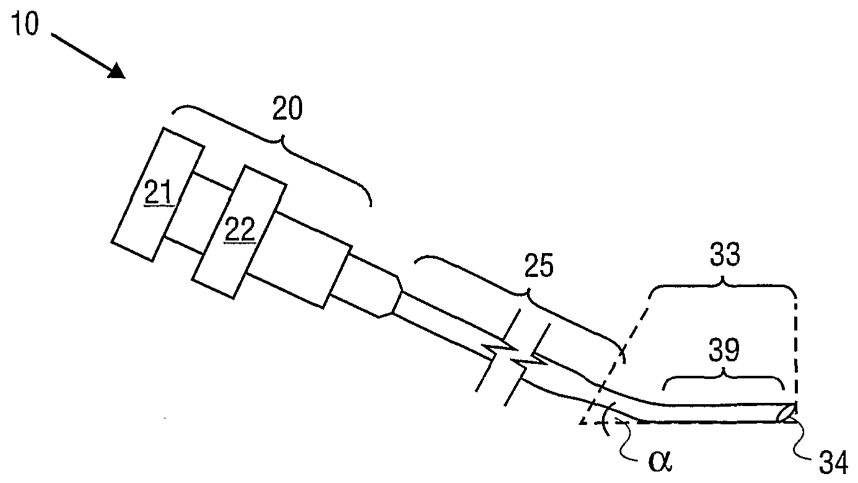

FIG. 1

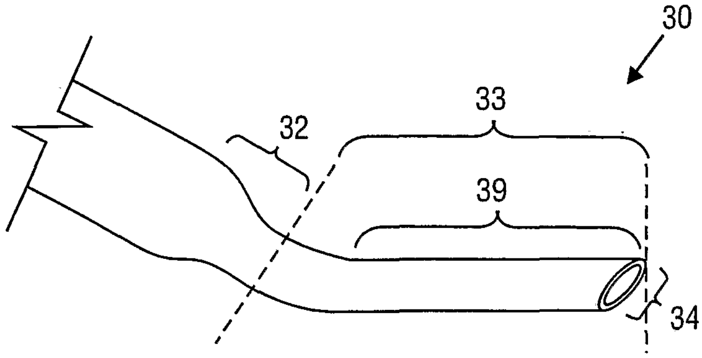

FIG. 2

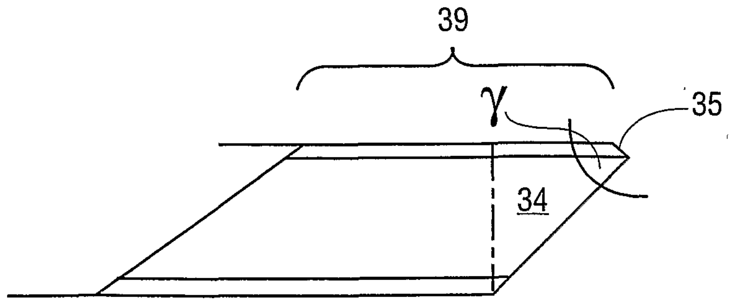

FIG. 3

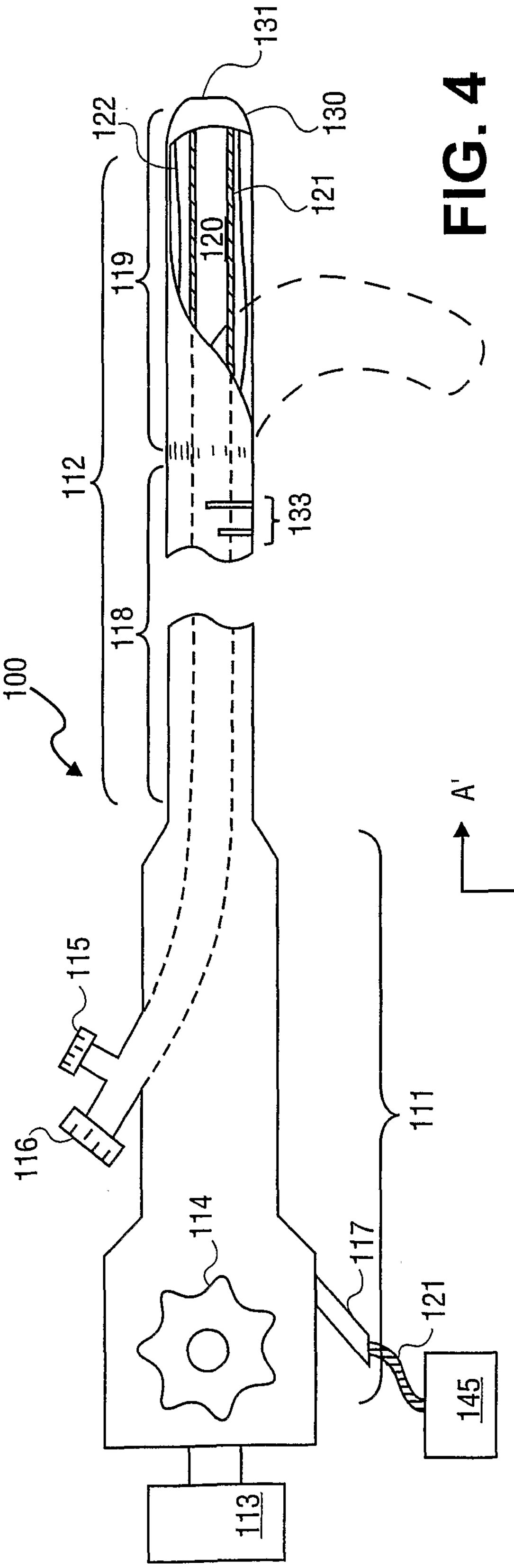

FIG. 4

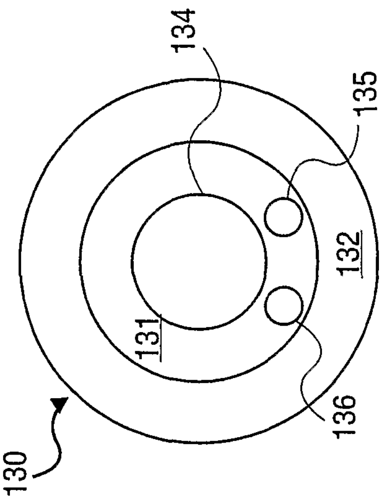

FIG. 6

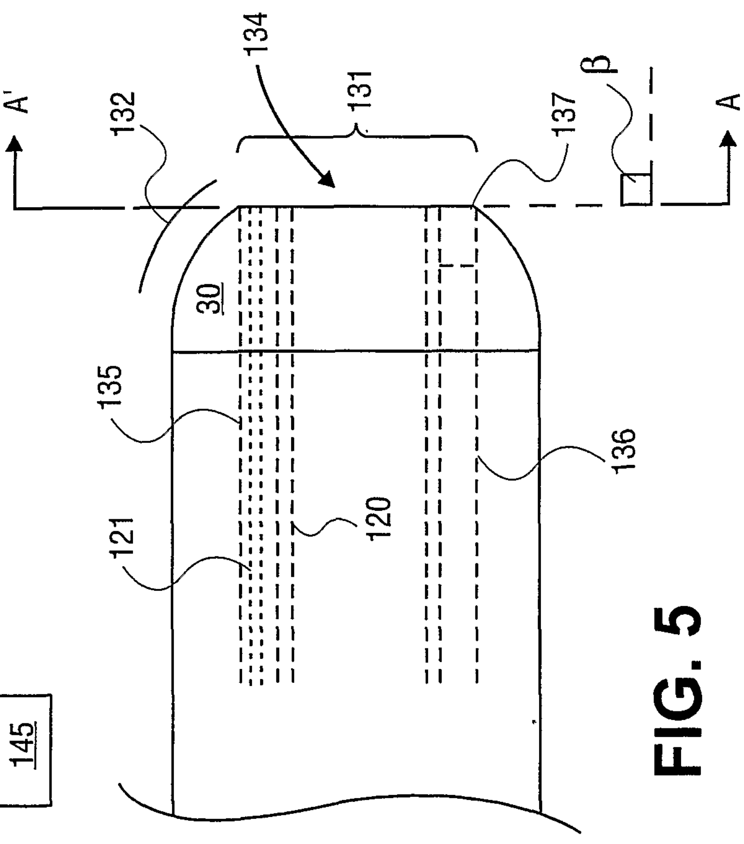

FIG. 5

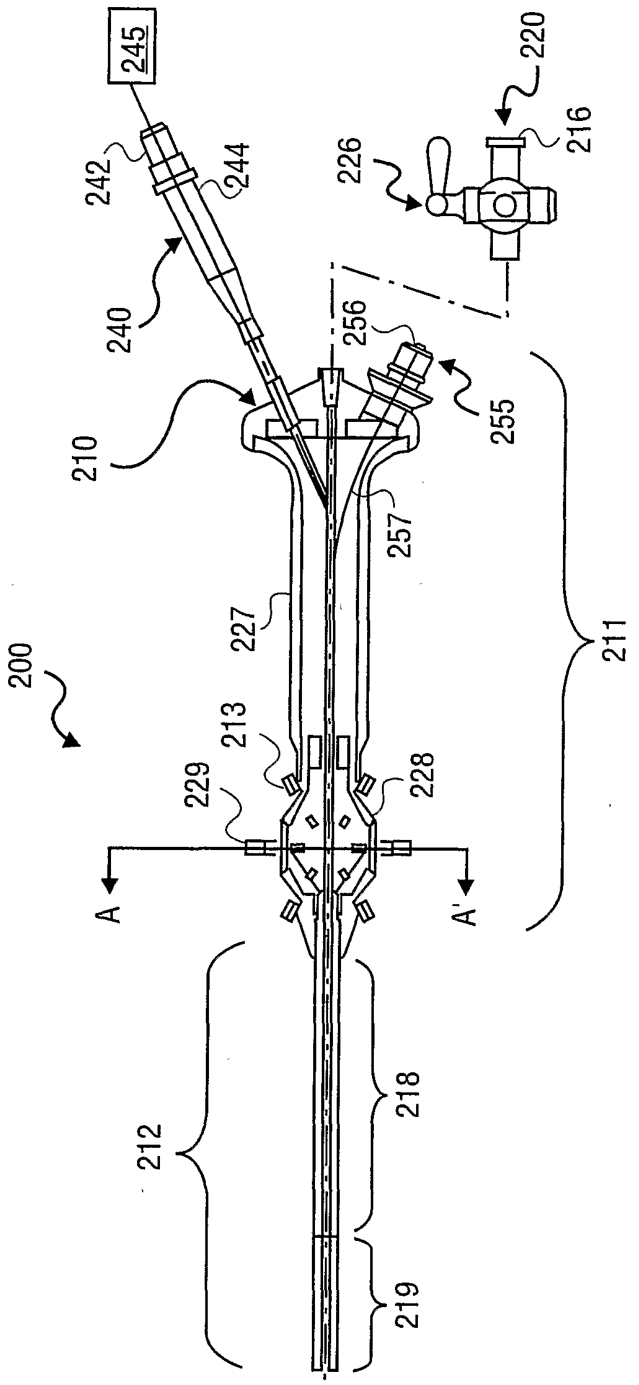
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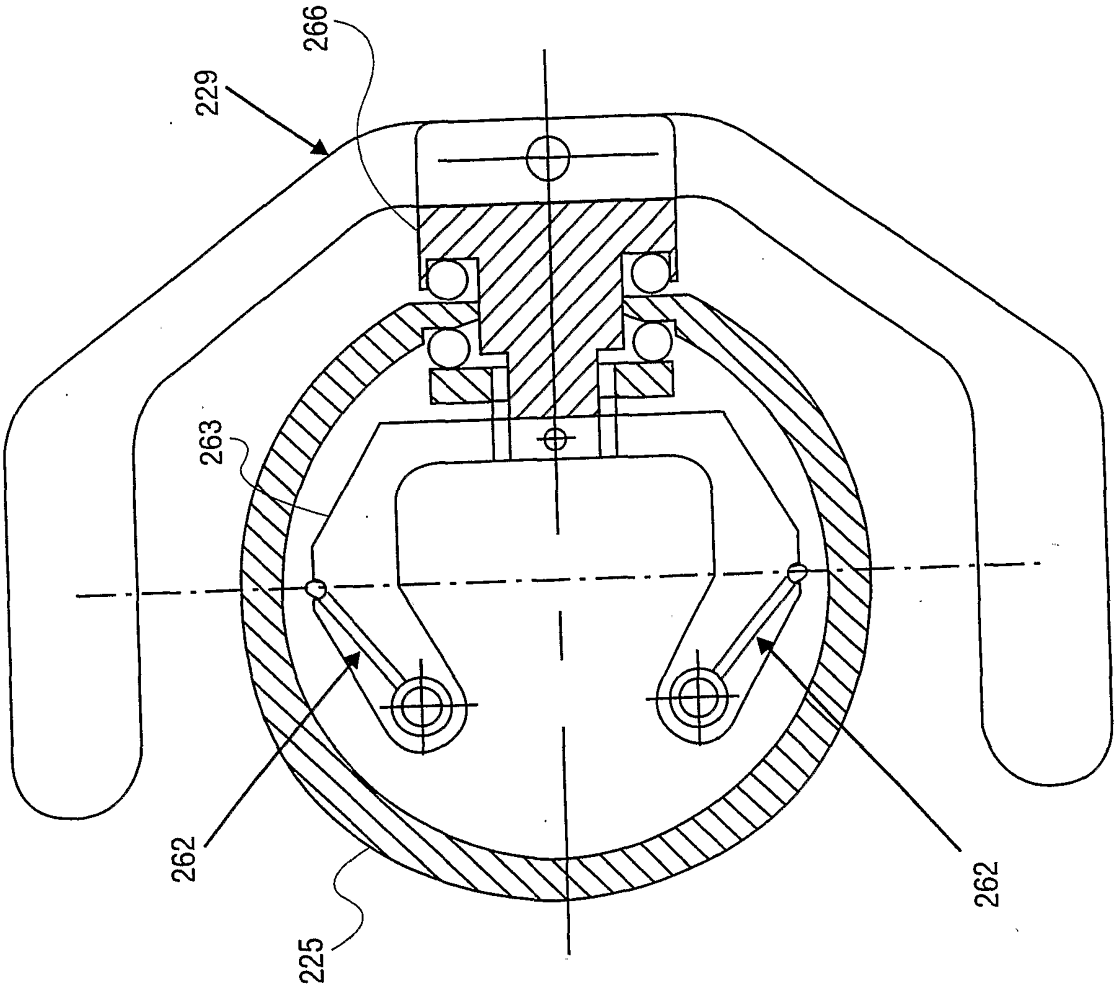
FIG. 7

FIG. 8



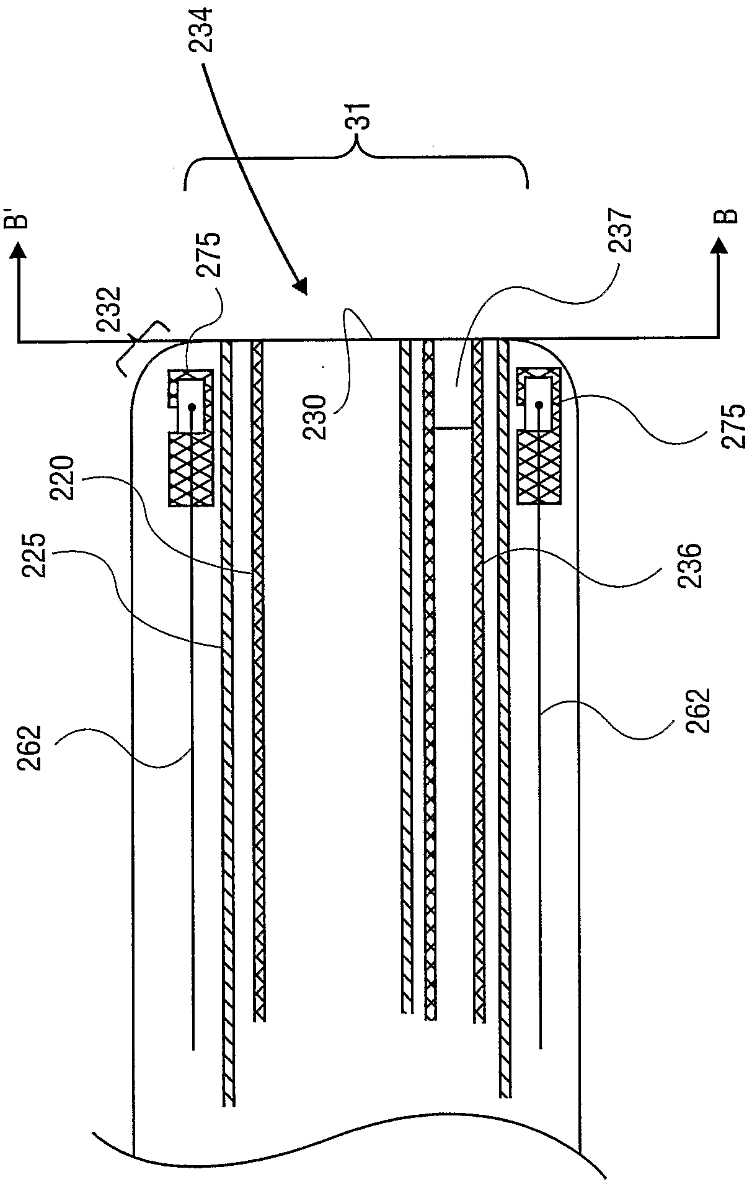
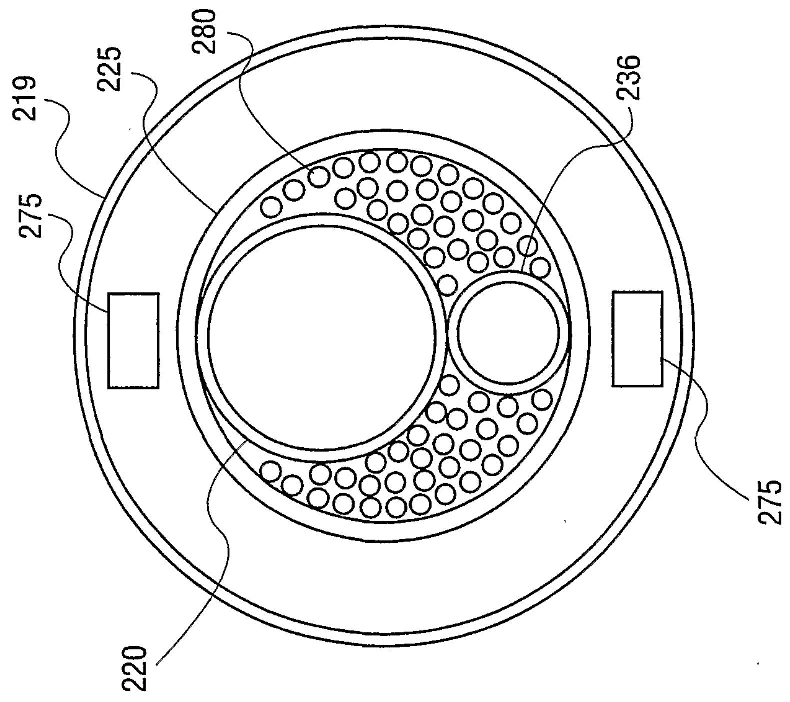


FIG. 9

FIG. 10



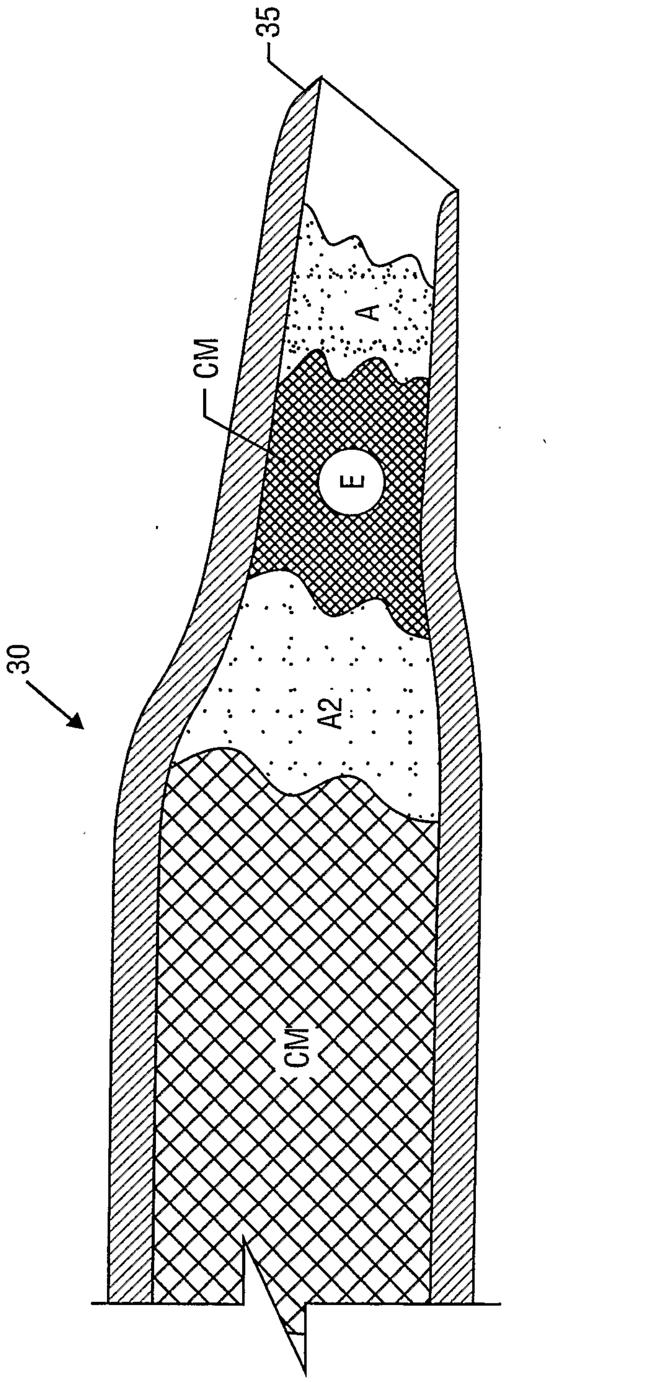


FIG. 11

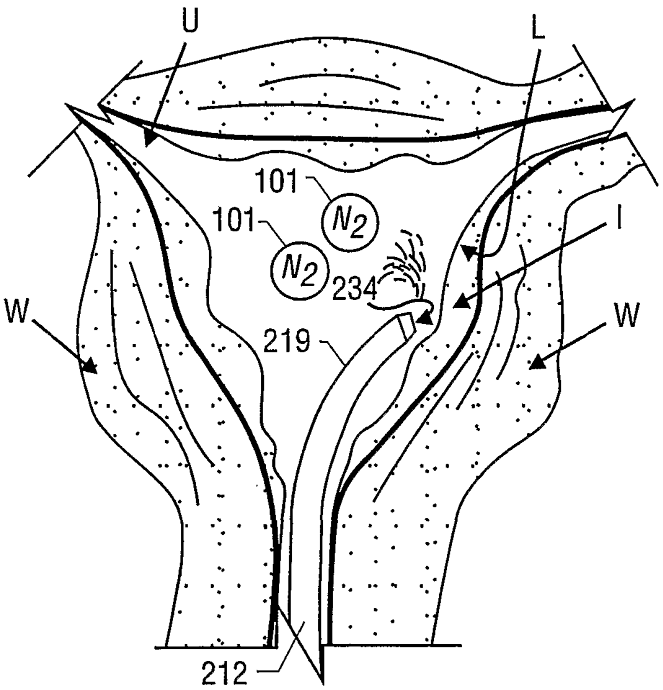


FIG. 12

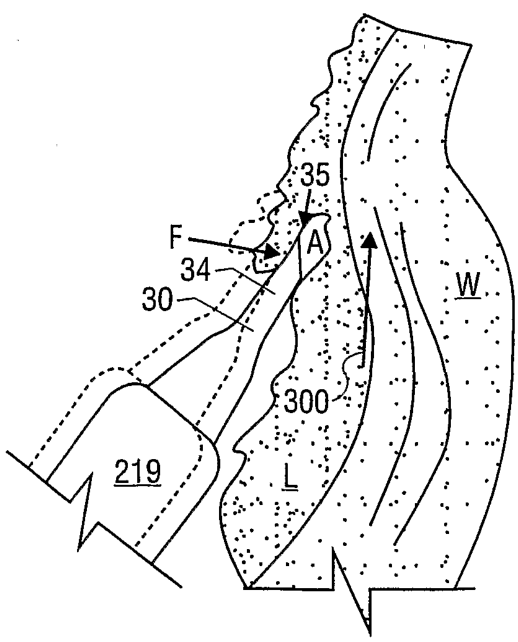


FIG. 13

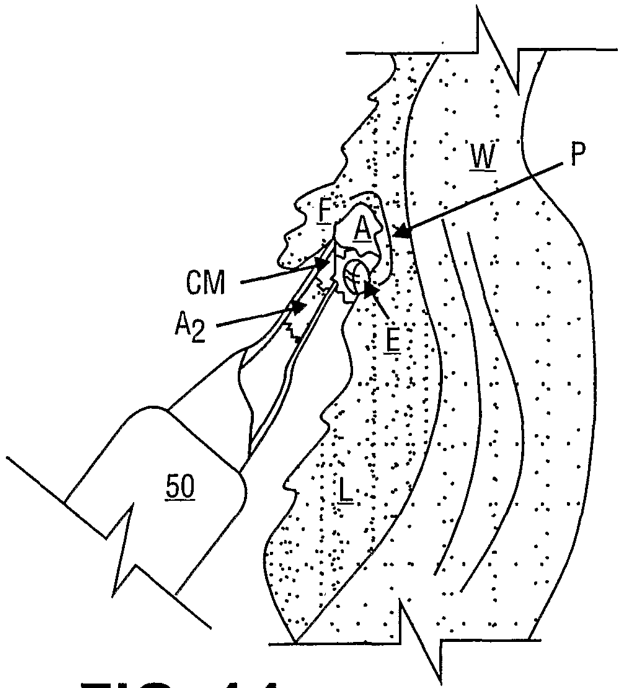


FIG. 14

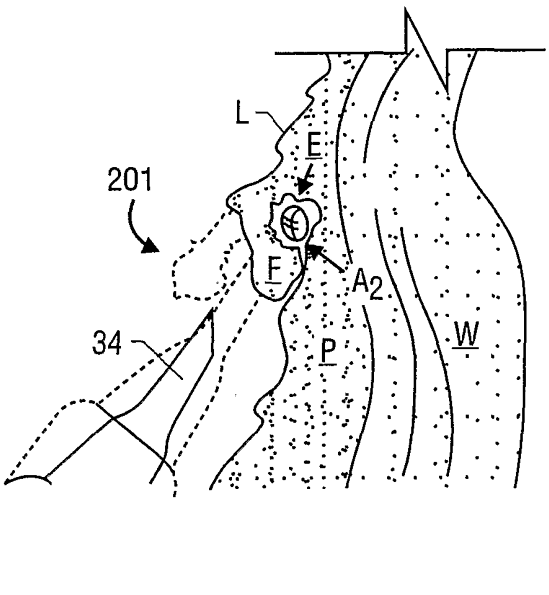


FIG. 15