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(54) HYSTEROSCOPIC SYSTEM

HYSTEROSKOPISCHES SYSTEM

SYSTÈME HYSTÉROSCOPIQUE

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Description

FIELD OF THE INVENTION

[0001] The present invention relates generally to hysteroscopy systems, and, more particularly, to a hysteroscopy system having a small size for use in an office setting.

BACKGROUND OF THE INVENTION

[0002] Hysteroscopy refers generally to the inspection of a uterine cavity using a hysteroscope with access through the cervix. As such, hysteroscopy allows diagnosis of intrauterine pathology and, furthermore, can be used for surgical intervention. The hysteroscope typically includes a scope and a sheath.

[0003] One problem associated with some current hysteroscopy systems is that they must be used in an operating room setting with the patient being under some type of anesthesia. Anesthesia is required in particular because the size of current hysteroscopes is large and, as such, they can cause discomfort and pain to the patient. For example, a typical hysteroscope may have an outermost diameter of about 9 millimeters. Such hysteroscopes include a scope having a diameter of about 8 millimeters and a sheath having a diameter of about 9 millimeters. In comparison, scientific literature on the subject agrees that hysteroscopy can be performed using a vaginoscopic approach, which can be performed in an office setting, only when the outermost diameter of the hysteroscope is about 6 millimeters or less.

[0004] Another problem associated with current scopes is that they typically include a blunt flange at the scope distal end. The flange extends outwardly from the scope and make it difficult, if not impossible, to use the scope without the sheath and/or without an obturator. Accordingly, the size of some current hysteroscopes is limited to the size of the scope and the sheath, *.e.g.,* a diameter of 9 millimeters.

[0005] WO99/11184 describes a surgical endoscopic cutting device, comprising a cutting means having cutting elements fitted in a protective tube. The cutting elements are motor-driven, the assembly comprising the cutting means being placed in a device which is also provided with a viewing device, in order to permit observation of a treatment. It includes an instrument which passes through a sheath. The instrument may be replaced by a mandrel with a pointed head for use in certain procedures.

[0006] What is needed, therefore, is a hysteroscope system for an office setting that addresses the above-stated and other problems.

SUMMARY OF THE INVENTION

[0007] According to the invention there is provided a hysteroscopy system as recited in the independent claim with preferred features as set forth in the dependent claims.

[0008] Additional aspects of the invention will be apparent to those of ordinary skill in the art in view of the detailed description of various embodiments, which is made with reference to the drawings, a brief description of which is provided below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009]

FIG. 1 is a perspective view of a hysteroscope system.
FIG. 2A is an enlarged perspective view of a distal end of the hysteroscope system.
FIG. 2B is an enlarged side view of the distal end of the hysteroscope system.
FIG. 2C is an enlarged cross-sectional end view of the distal end of the hysteroscope system.
FIG. 2D is an enlarged cross-sectional top view of the distal end of the hysteroscope system.
FIG. 3 shows dimensions associated with the distal end of FIG. 2A.
FIG. 4 is a perspective view of the hysteroscope system having a sheath removed from a scope.
FIG. 5 is an enlarged perspective view of the distal end of the hysteroscope system of FIG. 4.
[0019] FIG. 6 is a perspective view of an alternative embodiment of the hysteroscope system.

[0010] While the invention is susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and will be described in detail herein. It should be understood, however, that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION

[0011] Referring to FIG. 1, a hysteroscope system 100 includes a hysteroscope 102 having, *inter alia,* a sheath 104, an inflow valve 106, an outflow valve 108, a light post 110, and a morcellator 112. The sheath 104 is a generally an elongated tubular member that has a distal end 114 and a proximal end 116. The hysteroscope system 100 also includes an arm 117 that is connected to an imaging device (e.g., a camera) to capture images received via a visualization device (e.g., visualization device 124).

[0012] According to some exemplary embodiments, the hysteroscope system· 100 is intended for morcellation of uterine pathology with a scope and accessories having a sufficiently small diameter that can be inserted into a patient's uterus using the vaginoscopic approach.

In particular, the hysteroscope system 100 provides a way to minimize patient pain because a tenanculum and speculum are not typically used.

[0013] Furthermore, anesthesia is not needed and the medical procedures can be performed in an office setting. This may result, for example, in a quicker surgery with less pain and quicker recovery, and may potentially lower the cost of the surgery. Yet another advantage of the hysteroscope system 100 is that a surgeon has the option to decide if they prefer greater flow instruments (*e.g.,* with a coupled sheath 104) or smaller diameter instruments (*e.g.,* with a removed sheath 104), depending on the patient case.

[0014] Referring to FIG. 2A, the sheath 104 is removably coupled to a scope 118, which is generally an elongated tubular member having (similar to the sheath 104) a distal end 114 and a proximal end 116. More specifically, the sheath 104 is slidably fitted in an overlapping manner over the scope 118. The scope 118 includes an operative member 120, which is in the form of an elongated D-shape tubular member.

[0015] The operative member 120 receives internally a surgical tool 122, which can be selected from a variety of different tools. For example, the surgical tool 122 can be a rotary morcellator, a reciprocating morcellator, or a morcellator having both reciprocal and rotary capabilities. The scope 118 further includes a visualization device 124. The visualization device 124 is adjacent to the operative member 120 and can include various image devices. For example, the visualization device 124 can include fiber-optic technology for illumination and image transmission.

[0016] To maintain continuous outflow, a plurality of outflow holes 126 are formed near the distal end 114 of the sheath 104. The inflow valve 106 (shown in FIG. 1) regulates inflow of a liquid through the operative member 120, as represented by the arrows 107 extending from the operative member 120. The liquid is used, for example, to distend and irrigate the uterus of a patient. Furthermore, the liquid is generally received from an access pump, which delivers the fluid to produce a substantially constant predetermined pressure level within a joint cavity, e.g., a uterus. The outflow valve 108 (shown in FIG. 1) regulates outflow of the liquid through the outflow holes 126 via an outflow channel 128 (shown in FIG. 2C) formed between the sheath 104 and the scope 118. The outflow of the liquid is represented by the arrows 109 extending into the outflow holes 126. The outflow liquid is generally sent to a waste container.

[0017] Referring to FIG. 2B, the sheath 104 has at the distal end 114 a flange 130 extending inwardly towards the scope 118 to form a closed end of the outflow channel 128 (shown in FIG. 2C). The flange 130 has a generally oval shape and includes two pairs of opposite sides 130a-130d.

[0018] According to the illustrated embodiment, the shape of the flange 130 is nonuniform. For example, a second side 130b extends a greater distance internally towards the center of the scope 118 than a first side 130a. Similarly, based on the symmetric features of this embodiment, a fourth side 130d extends a greater distance internally towards the center of the scope 118 than a third side 130c. In alternative embodiments, the flange 130 can have different shapes and sizes.

[0019] Referring to FIGS. 2C-2D, the sheath 104 has an outer surface 104a and an internal surface 104b, and the scope 118 has an outer surface 118a and an internal surface 118b. The internal surface 104b of the sheath 104 defines an internal channel in which the scope 118 and the visualization device 124 are located. The internal surface 118b of the scope 118 defines an internal channel in which the outer member and thus the surgical tool 122 is located.

[0020] The operative member 120 has an outer surface 120a, an internal surface 120b, and a flat outer surface 120c (clearly shown in FIG. 2C). The flat outer surface 120c is spaced away from the internal surface 118b of the scope 118 to form a visualization channel 132 (clearly shown in FIG. 2C) in which the visualization device 124 is located. The visualization channel 132 is only a small part of the larger internal channel of the scope 118.

[0021] The outflow channel 128 is formed between the internal surface 104b of the sheath 104 and the outer surface 118a of the scope 118. An inflow channel 134 is formed in the internal channel of the scope 118. If the surgical tool 122 is removed, the inflow channel 134 is simply the entire internal channel of the scope 118. If the surgical tool 122 is in place, the inflow channel 134 is limited to the area between the surgical tool 122 and the internal surface 120b of the operative member 120.

[0022] Referring to FIG. 3, the hysteroscopy system 100 is designed to have a size that can be used in an office setting. Specifically, the outer most diameter is designed to be about 6 millimeters or less. According to the illustrated embodiment, the outer diameter D1 of the sheath 104 (which is the same as the diameter of the outer surface 104b) is about 5.6 millimeters. For example, in an alternative embodiment the diameter of the sheath 104 is 5.5 millimeters. The outer diameter D2 of the surgical tool 122 (*e.g.,* morcellator) is about 2.9 millimeters.

[0023] The scope 118 has an oval shape with a long diameter D3 of about 5.15 millimeters and a short diameter D4 of about 4.6 millimeters. The operative member 120 has a curvature dimension L1 of about 3.1 millimeters and a flat dimension L2 of about 3.95 millimeters.

[0024] The relatively small dimensions of the hysteroscopy system 100 allows a patient to be treated in an office setting. Generally, medical procedures may be provided to a patient with the use of the current hysteroscopy system 100 such that little or no anesthesia may be necessary. Clearly, one advantage of the hysteroscopy system 100 is that it is sufficiently small in diameter to be suitable for the vaginoscopic approach.

[0025] Referring to FIG. 4, the hysteroscopy system 100 is also usable without the sheath 104 while still pro-

viding continuous flow via a diagnostic cannula 135 (*e.g.,* a cannula having a diameter of about 2.9 millimeters). Specifically, the sheath 104 is removed to allow only the insertion of the scope 118 into a patient, *e.g.,* into an uterus. The removal of the sheath 104 decreases the outermost diameter of the hysteroscopy system 100. For example, in accordance with the dimensions described above in reference to FIG. 3, the outermost diameter decreases to about 5.15 millimeters (the long diameter D3) from about 5.6 millimeters (the outer diameter D1). When the sheath 104 is removed, the outflow can be provided by an operation tool, such as the morcellator 112 described above (shown in FIGS. 1-3), or by the diagnostic cannula 135.

[0026] In contrast to previous scopes, the scope 118 docs not have a flange extending outwards from its distal end. The outward extending flange of the previous scopes unnecessarily increased the outermost diameter of the respective scopes and created an obtrusive distal end that made it difficult, if not impossible, to introduce into a patient without a sheath and obturator.

[0027] Referring to FIG. 5, the hysteroscopy system can be used for diagnostic purposes when the sheath 104 is removed. The sheath 104 is likely to be used in operative cases mostly to clear the visual field before introduction of a morcellator blade. The diagnostic cannula 135, which has a distal end 136, is used to create a smaller overall diameter of the system for diagnostic purposes. According to the dimensions described above, a reduction of approximately 0.5 millimeters can be achieved by removing the sheath 104. Another advantage of the cannula 135 is that it can be made reusable. Yet another advantage of the cannula 135 is that it can be used to distend and irrigate the patient's uterus during the diagnostic procedure.

[0028] The cannula 135 allows for continuous outflow but does not extend beyond the distal end of the scope 118. For example, the cannula 135 provides a replacement for the outflow channel 128, which is removed with the removal of the sheath 104. Specifically, the cannula 135 provides an alternative outflow channel 138 to replace the outflow channel 128 formed by the sheath 104. As such, continuous flow can be maintained even if the sheath 104 is removed.

[0029] Referring to FIG. 6, the hysteroscope system 100 alternatively includes a flow device 140 inserted within the operative member 120. The flow device 140 has an inflow tubular element 142 and an outflow tubular element 144, which can be conjoined elements or separate elements.

[0030] The distal ends of the tubular elements 142, 144 terminate at different points within the operative member 120. Preferably, the distal end of the inflow tubular element 142 terminates at the distal end 114 of the scope 118, and the distal end of the outflow tubular element 144 terminates some distance away from the distal end 114 within the operative member 120. The termination of tubular elements 142, 144 at different points along the operative member 120 eliminates the possibility of fluid short-circuit and provides better circulation and, hence, irrigation within the uterus.

[0031] According to one example, the flow device 140 is made of stainless steel and, as such, can be a reusable device. According to another example, the flow device 140 is made from a much more cost-effective material, such as a polymer. If a polymer is used, the flow device 140 will typically be considered a single-use device.

[0032] In practice, for example, a surgeon will insert the flow device 140 into the operative member 120 of the hysteroscope 102 prior to introduction into the uterus of a patient. After hysteroscope introduction into the uterus, an inflow valve 146 of the flow device 140 will be opened and the uterus will be distended. Then, by opening an outflow valve 148 of the flow device 140, irrigation is achieved. In the case of a diagnostic procedure, the flow device 140 could stay in place for the duration of the surgery. In the case of an operative procedure, the flow device 140 is removed and an operative tool (e.g., the morcellator 112) is inserted into the scope 118.

[0033] While the best modes for carrying out the present invention have been described in detail, those familiar with the art to which this invention relates will recognize various alternative designs and embodiments for practicing the invention within the scope of the appended claims. For example, the sheath 104, the scope 118, and the surgical tool 122 can be circular, oval, or any other smooth shape (*i.e.,* an unobtrusive shape such as a shape that does not have a outward extending flange). In another example, the operative member 120 can have a circular shape or any other similar shape to the illustrated D-shape.

Claims

1. A hysteroscopy system (100), the system comprising:

a scope (118) having an outer surface and an internal channel defined by an inner surface;
a sheath (104) removably coupled to the scope and having a tip (114) at which a distal flange (130) extends internally towards the outer surface of the scope, the sheath further having an inner surface (104b);
an outflow channel (128) formed between the inner surface (104b) of the sheath and the outer surface (118a) of the scope (118);
the distal flange (130) forming a distal end of the outflow channel (128) between the scope (118) and the sheath (104);
an operative channel formed within the internal channel of the scope; and
a visualization channel (132) formed adjacent to the operative channel,
wherein the distal flange has an oval shape,

wherein the oval shape has two opposite sides that extend a greater distance internally towards the center of the scope than two other opposite sides.

2. The hysteroscopy system of claim 1, further comprising a surgical tool (122) inserted within the operative channel, wherein the surgical tool is selected from a group consisting of a rotary morcellator, a reciprocating morcellator, or rotary and reciprocating morcellator.

3. The hysteroscopy system of claims 1 or 2, wherein the visualization channel (132) is configured for receiving a visualization device (124).

4. The hysteroscopy system of any one of claims 1 to 3, wherein the sheath has an outer diameter of about 5.6 millimeters and a long diameter of the scope is about 5.15 millimeters.

5. The hysteroscopy system of any one of claims 1 to 4, wherein the sheath further includes a plurality of outflow holes (126) near the distal flange.

6. The hysteroscopy system of any one of the preceding claims, further comprising an operative member (120) inserted within the scope, the operative member having an outer surface (120a) and an internal channel.

7. The hysteroscopy system of claim 6, wherein the outer surface of the operative member has a generally D-shape.

8. The hysteroscopy system of claim 6 or claim 7, further comprising a tool inserted within the internal channel of the operative member.

9. The hysteroscopy system of claim 8, wherein a fluid can flow through the internal channel of the operative member between the tool and the internal channel of the operative member.

10. The hysteroscopy system of claim 6, further comprising a visualization channel formed between the internal surface of the scope and the outer surface of the operative member.

11. The hysteroscopy system of claim 10, further comprising a visualization device inserted within the visualization channel.

Patentansprüche

1. Hysteroskopiesystem (100), wobei das System Folgendes umfasst:

ein Endoskop (118), das einee äußeren Oberfläche und einen durch eine innere Oberfläche definierten Innenkanal aufweist;
eine Hülle (104), die entfernbar mit dem Endoskop gekoppelt ist und eine Spitze (114) aufweist, an der sich ein distaler Flansch (130) nach innen zu der äußeren Oberfläche des Endoskop erstreckt, wobei die Hülle weiter eine innere Oberfläche (104b) aufweist;
einen Abströmkanal (128), der zwischen der inneren Oberfläche (104b) der Hülle und der äußeren Oberfläche (118a) des Endoskops (118) gebildet ist;
den distalen Flansch (130), der ein distales Ende des Abströmkanals (128) zwischen dem Endoskop (118) und der Hülle (104) bildet;
einen Arbeitskanal, der innerhalb des Innenkanals des Endoskops gebildet ist; und
einen Visualisierungskanal (132), der angrenzend an den Arbeitskanal gebildet ist,
wobei der distale Flansch eine ovale Form aufweist, wobei die ovale Form zwei gegenüberliegende Seiten aufweist, die sich eine größeren Distanz nach innen zur Mitte des Endoskops erstrecken als zwei andere gegenüberliegende Seiten.

2. Hysteroskopiesystem nach Anspruch 1, weiter umfassend ein chirurgisches Instrument (122), dass innerhalb des Arbeitskanals eingefügt ist, wobei das chirurgische Instrument aus einer Gruppe ausgewählt ist, die aus einem rotierenden Morcellator, einem sich hin- und herbewegenden Morcellator oder einem rotierenden und sich hin- und herbewegenden Morcellator besteht.

3. Hysteroskopiesystem nach Anspruch 1 oder 2, wobei der Visualisierungskanal (132) zum Aufnehmen einer Visualisierungsvorrichtung (124) konfiguriert ist.

4. Hysteroskopiesystem nach einem der Ansprüche 1 bis 3, wobei die Hülle einen Außendurchmesser von etwa 5,6 Millimetern aufweist und ein langer Durchmesser des Endoskops etwa 5,15 Millimeter beträgt.

5. Hysteroskopiesystem nach einem der Ansprüche 1 bis 4, wobei die Hülle weiter eine Vielzahl von Abströmlöchern (126) nahe dem distalen Flansch beinhaltet.

6. Hysteroskopiesystem nach einem der vorstehenden Ansprüche, weiter umfassend ein Arbeitselement (120), das innerhalb des Endoskops eingefügt ist, wobei das Arbeitselement eine äußere Oberfläche (120a) und einen Innenkanal aufweist.

7. Hysteroskopiesystem nach Anspruch 6, wobei die

äußere Oberfläche des Arbeitselements eine im Allgemeinen D-Form aufweist.

8. Hysteroskopiesystem nach Anspruch 6 oder Anspruch 7, weiter umfassend ein Instrument, das innerhalb des Innenkanals des Arbeitselements eingefügt ist.

9. Hysteroskopiesystem nach Anspruch 8, wobei ein Fluid durch den Innenkanal des Arbeitselements zwischen dem Instrument und dem Innenkanal des Arbeitselements strömen kann.

10. Hysteroskopiesystem nach Anspruch 6, weiter umfassend einen Visualisierungskanal, der zwischen der inneren Oberfläche des Endoskops und der äußeren Oberfläche des Arbeitselements gebildet ist.

11. Hysteroskopiesystem nach Anspruch 10, weiter umfassend eine Visualisierungsvorrichtung, die innerhalb des Visualisierungskanals eingefügt ist.

Revendications

1. Système hystéroscopique (100), le système comprenant :

un oscilloscope (118) présentant une surface externe et un canal interne défini par une surface interne ;
une gaine (104) couplée de manière amovible à l'oscilloscope et présentant une pointe (114) dans laquelle une bride distale (130) s'étend vers l'intérieur en direction de la surface externe de l'oscilloscope, la gaine présentant en outre une surface interne (104b) ;
un canal de décharge (128) formé entre la surface interne (104b) de la gaine et la surface externe (118a) de l'oscilloscope (118) ;
la bride distale (130) formant une extrémité distale du canal de décharge (128) entre l'oscilloscope (118) et la gaine (104) ;
un canal de service formé dans le canal interne de l'oscilloscope ; et
un canal de visualisation (132) formé à proximité du canal de service,
dans lequel la bride distale présente une forme ovale, dans lequel la forme ovale présente deux côtés opposés qui s'étendent sur une plus grande distance vers l'intérieur en direction du centre de l'oscilloscope que deux autres côtés opposés.

2. Système hystéroscopique selon la revendication 1, comprenant en outre un outil chirurgical (122) inséré dans le canal de service, dans lequel l'outil chirurgical est sélectionné dans un groupe constitué d'un dispositif de morcellement rotatif, d'un dispositif de morcellement à mouvement alternatif ou d'un dispositif de morcellement à mouvement rotatif et alternatif.

3. Système hystéroscopique selon les revendications 1 ou 2, dans lequel le canal de visualisation (132) est configuré pour recevoir un dispositif de visualisation (124).

4. Système hystéroscopique selon l'une quelconque des revendications 1 à 3, dans lequel la gaine présente un diamètre externe d'environ 5,6 millimètres et un diamètre en longueur de l'oscilloscope est d'environ 5,15 millimètres.

5. Système hystéroscopique selon l'une quelconque des revendications 1 à 4, dans lequel la gaine inclut en outre une pluralité de trous de décharge (126) à proximité de la bride distale.

6. Système hystéroscopique selon l'une quelconque des revendications précédentes, comprenant en outre un élément de service (120) inséré dans l'oscilloscope, l'élément de service présentant une surface externe (120a) et un canal interne.

7. Système hystéroscopique selon la revendication 6, dans lequel la surface externe de l'élément de service présente une forme générale en D.

8. Système hystéroscopique selon la revendication 6 ou la revendication 7, comprenant en outre un outil inséré dans le canal interne de l'élément de service.

9. Système hystéroscopique selon la revendication 8, dans lequel un fluide peut s'écouler à travers le canal interne de l'élément de service entre l'outil et le canal interne de l'élément de service.

10. Système hystéroscopique selon la revendication 6, comprenant en outre un canal de visualisation formé entre la surface interne de l'oscilloscope et la surface externe de l'élément de service.

11. Système hystéroscopique selon la revendication 10, comprenant en outre un dispositif de visualisation inséré dans le canal de visualisation.

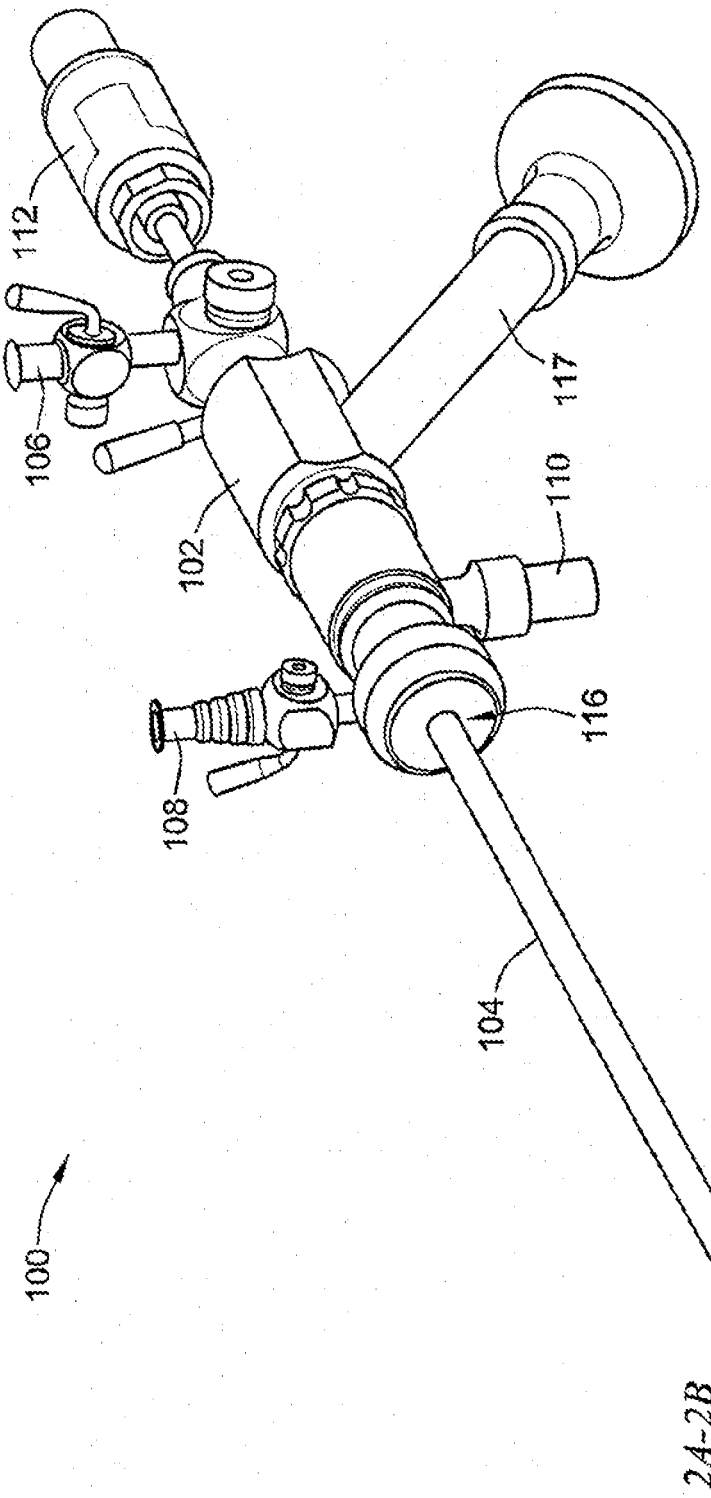

FIG. 1

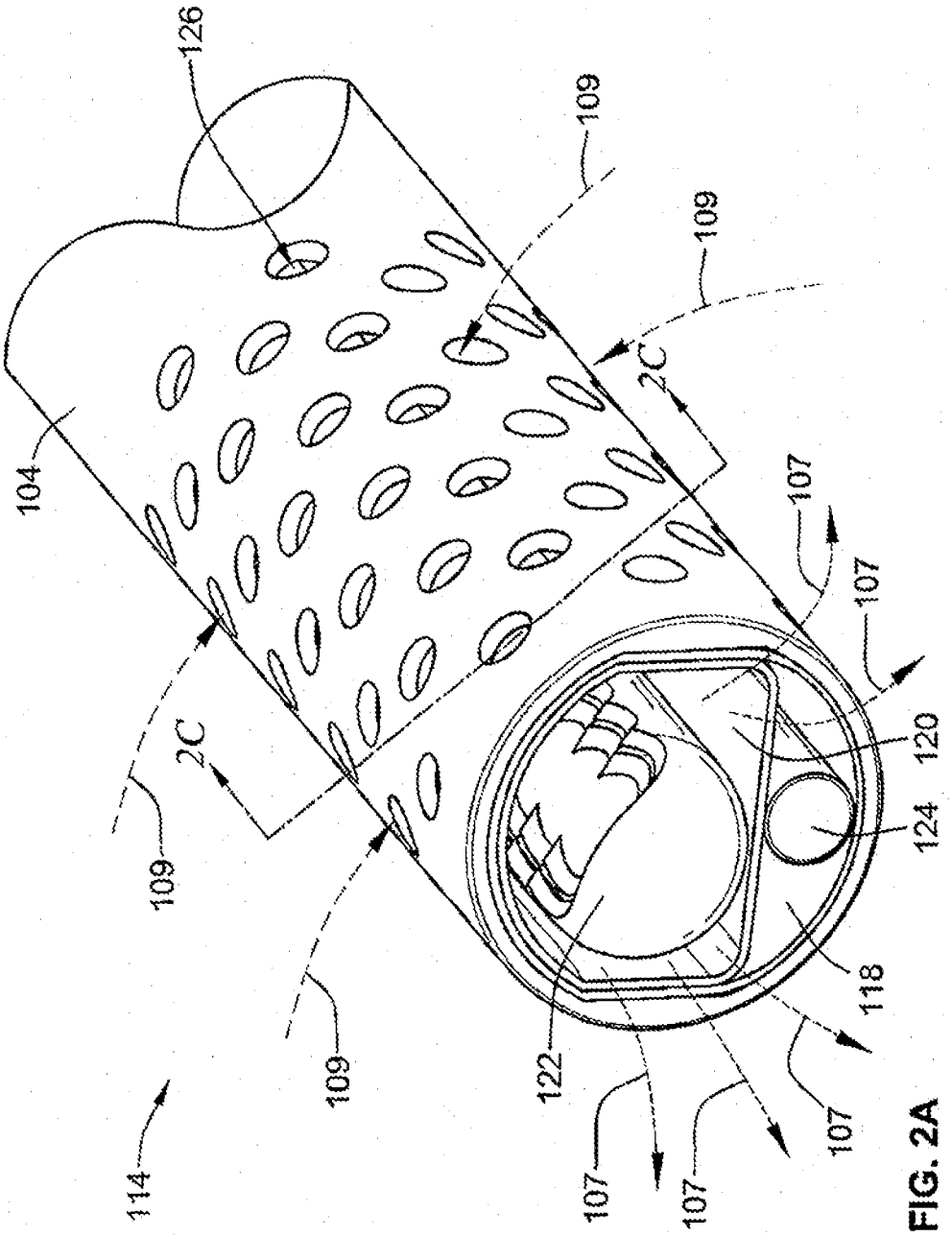
126
109
109
104
2C
107
107
2C
120
109
124
118
109
122
114
107
107
107

FIG. 2A

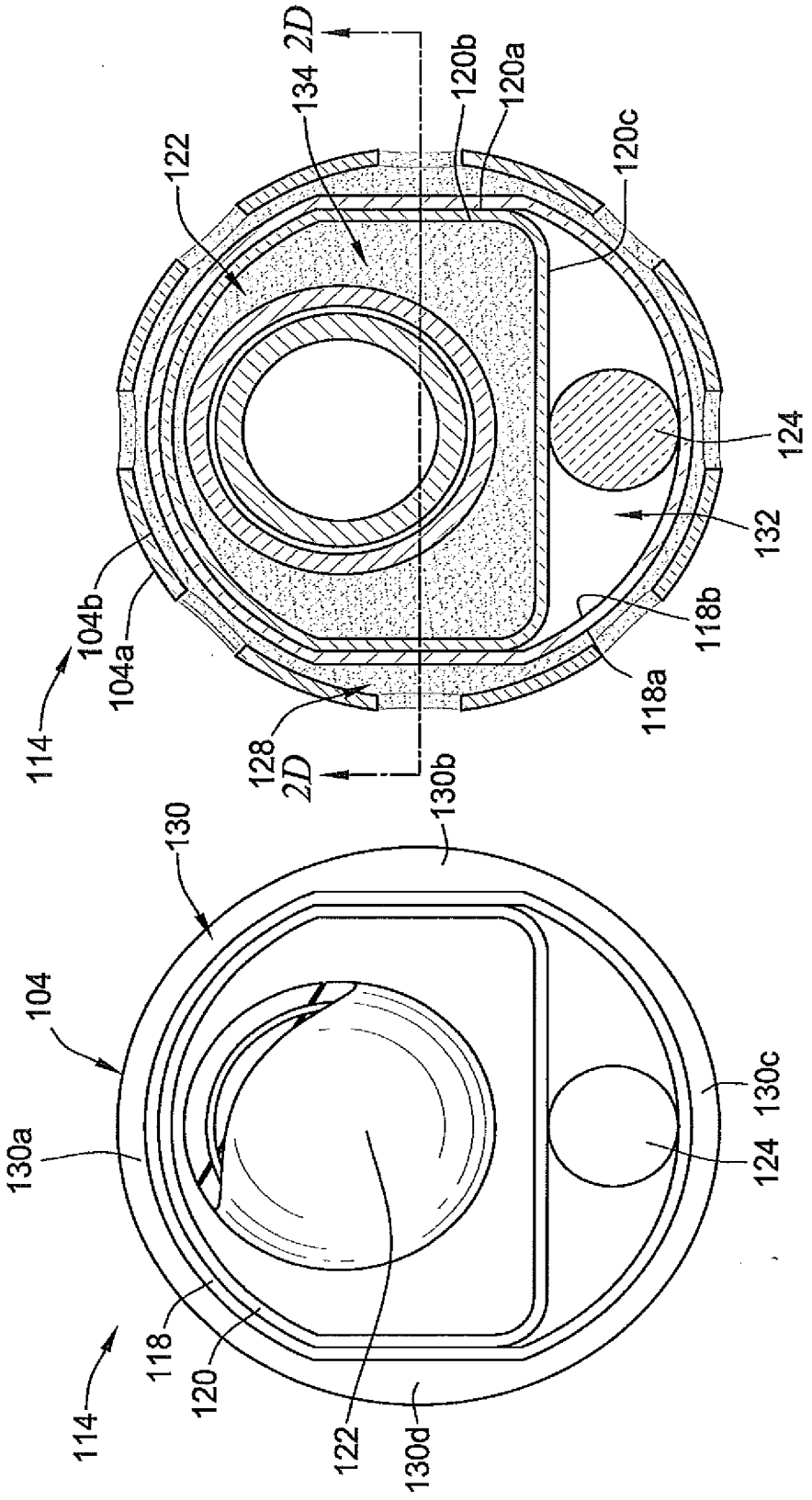
114
104
130a
118
120
122
130d
130
130b
130c
124
104b
104a
128
2D
134
122
120b
120a
120c
132
118b
118a

FIG. 2B

FIG. 2C

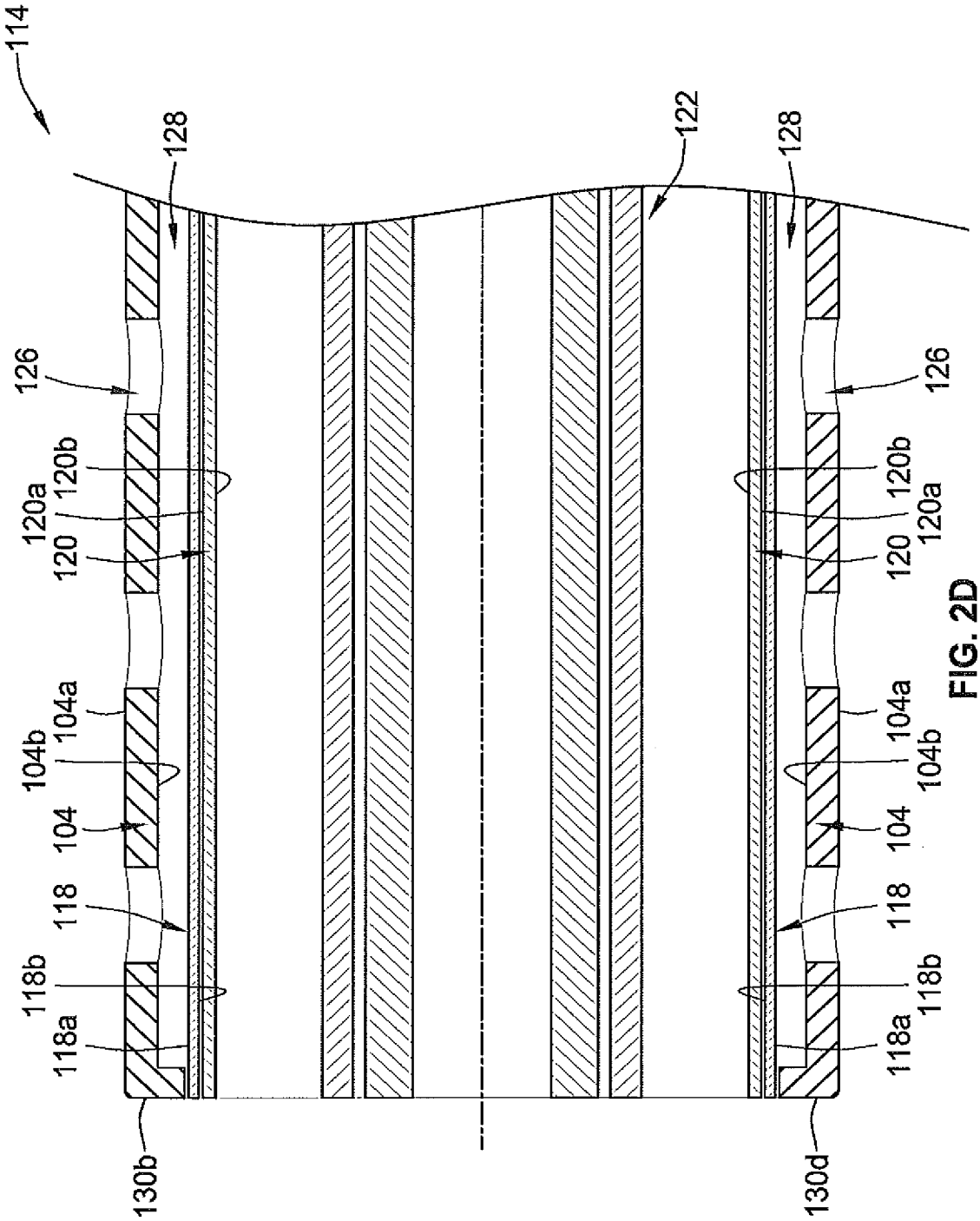
114
128
122
128
126
126
120b
120a
120
120b
120a
120
104a
104b
104
104a
104b
104
118
118
118b
118a
118b
118a
130b
130d

FIG. 2D

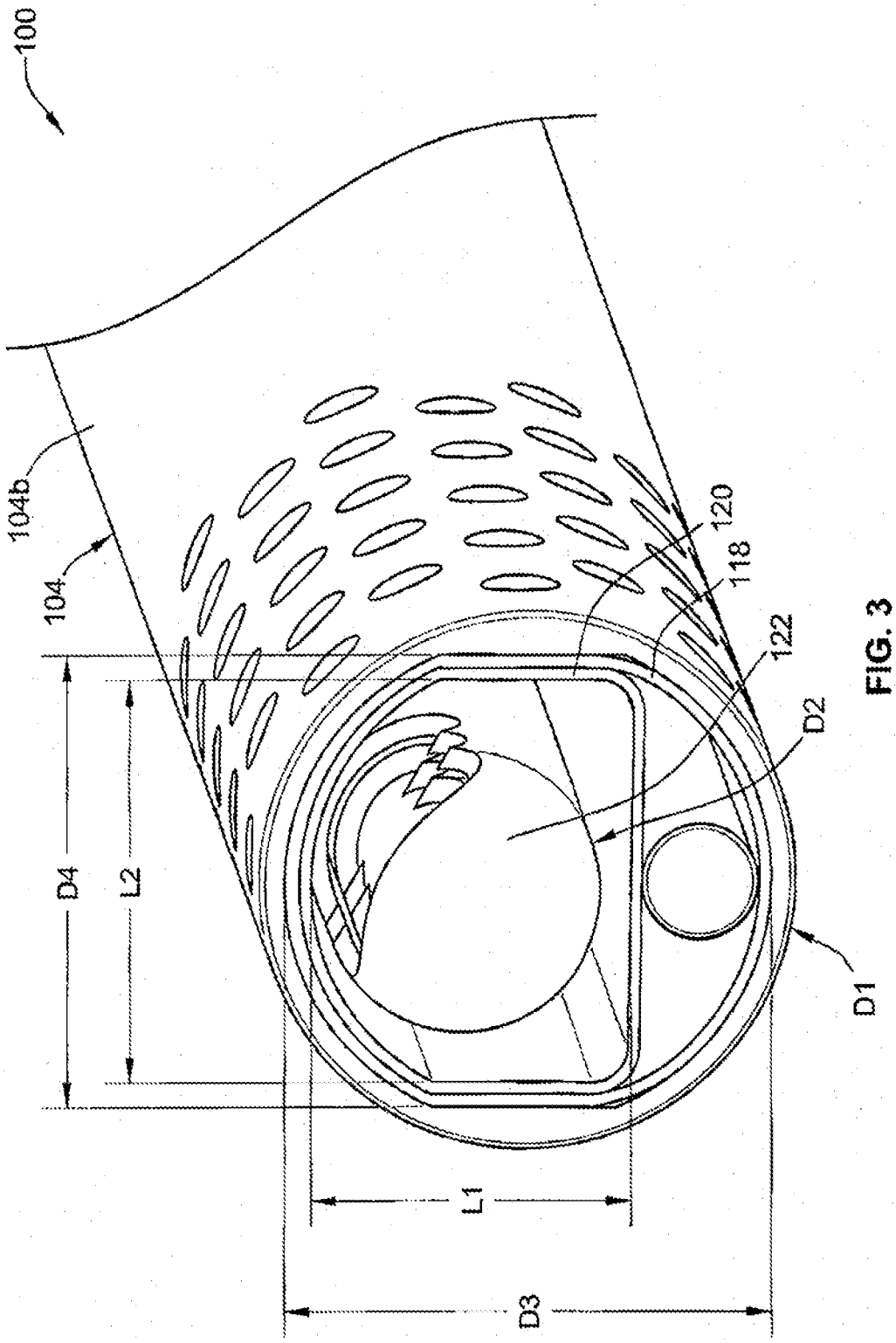

FIG. 3

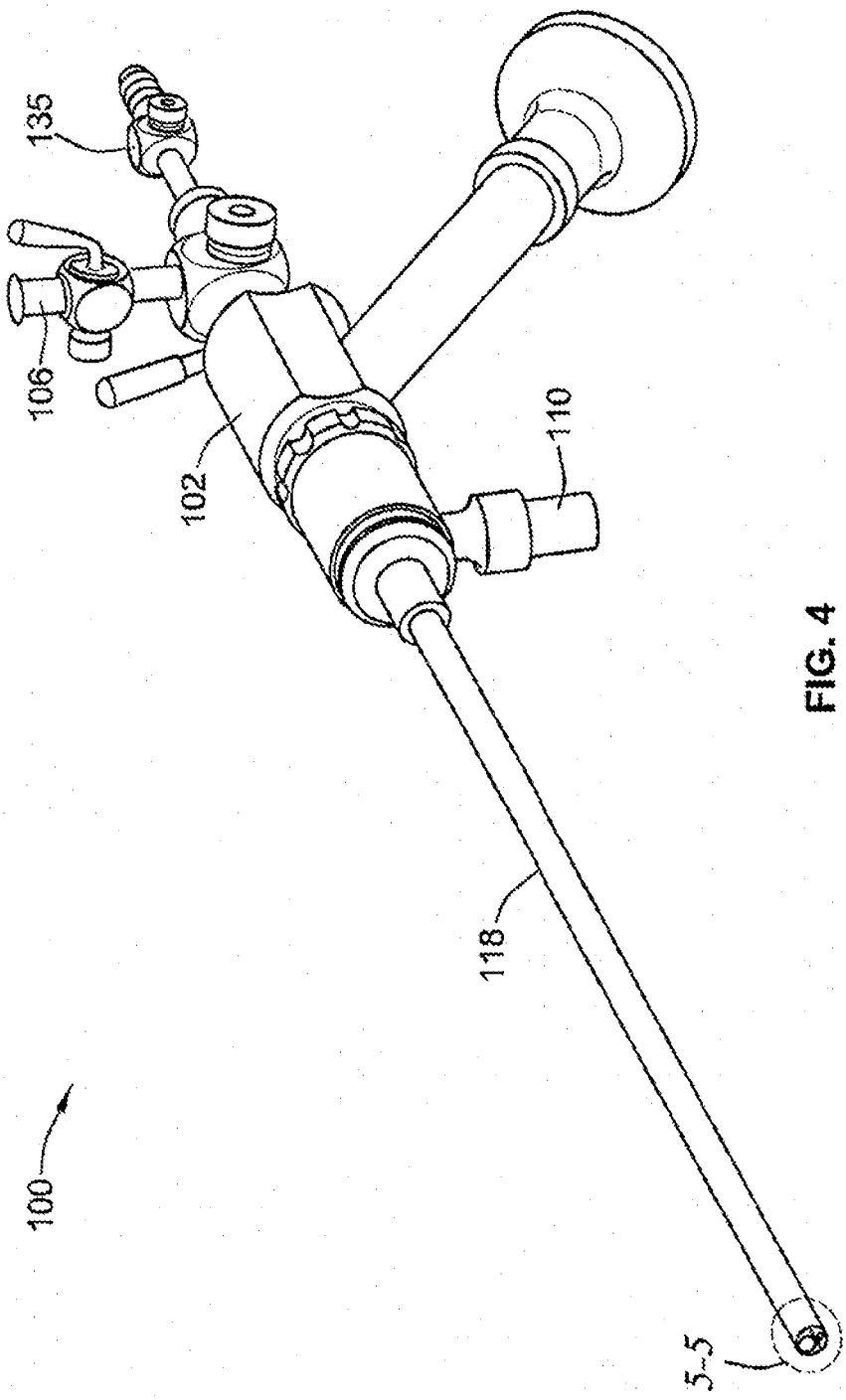

FIG. 4

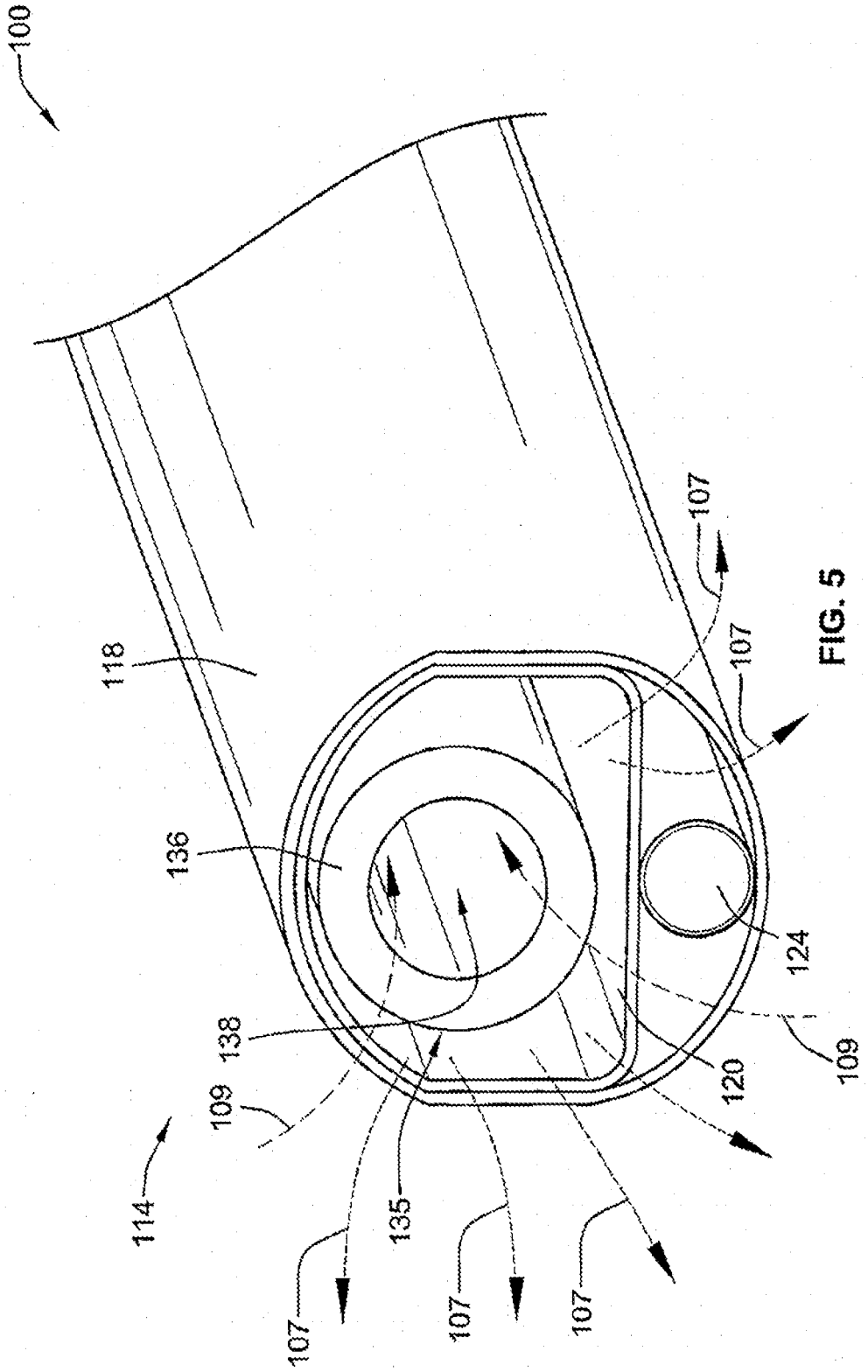

FIG. 5

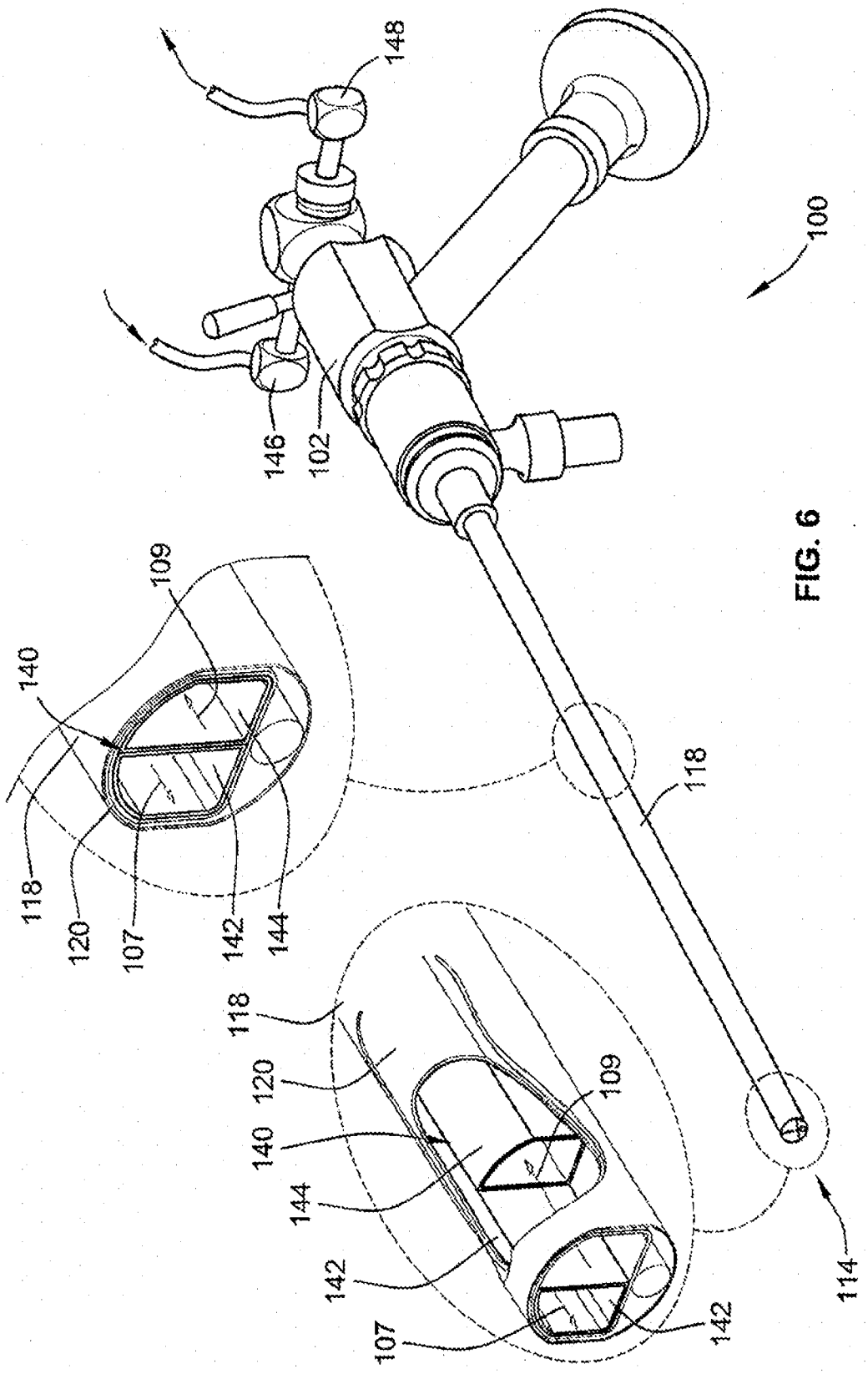
148
146
102
100
109
140
118
120
107
142
144
118
120
140
144
142
107
109
142
118
114

FIG. 6

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO 9911184 A **[0005]**

专利名称(译)	宫腔镜系统		
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摘要(译)

宫腔镜检查系统包括具有内部通道的内窥镜，可移除地联接至内窥镜的护套以及流出通道。 护套具有向内朝向内窥镜的外表面延伸的远侧凸缘。 流出通道形成在护套的内表面和观察镜的外表面之间。 远端凸缘形成流出通道的远端，并且通常位于内窥镜和护套之间。

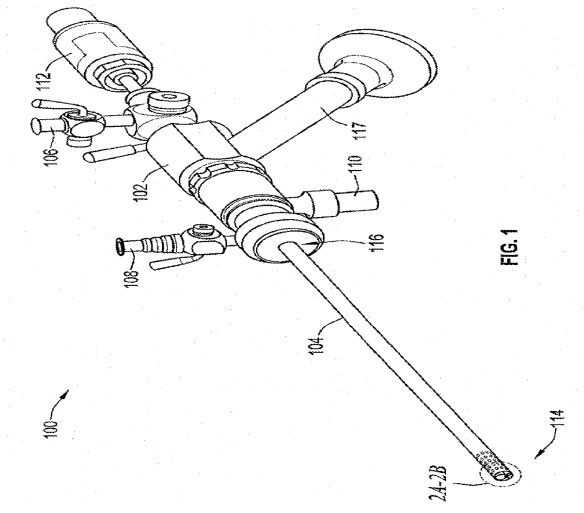

FIG. 1