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(54) **SCOPE FOR MANAGING DIFFICULT PATHWAYS AND METHOD TO IMPROVE VISIBILITY OF THE SAME**

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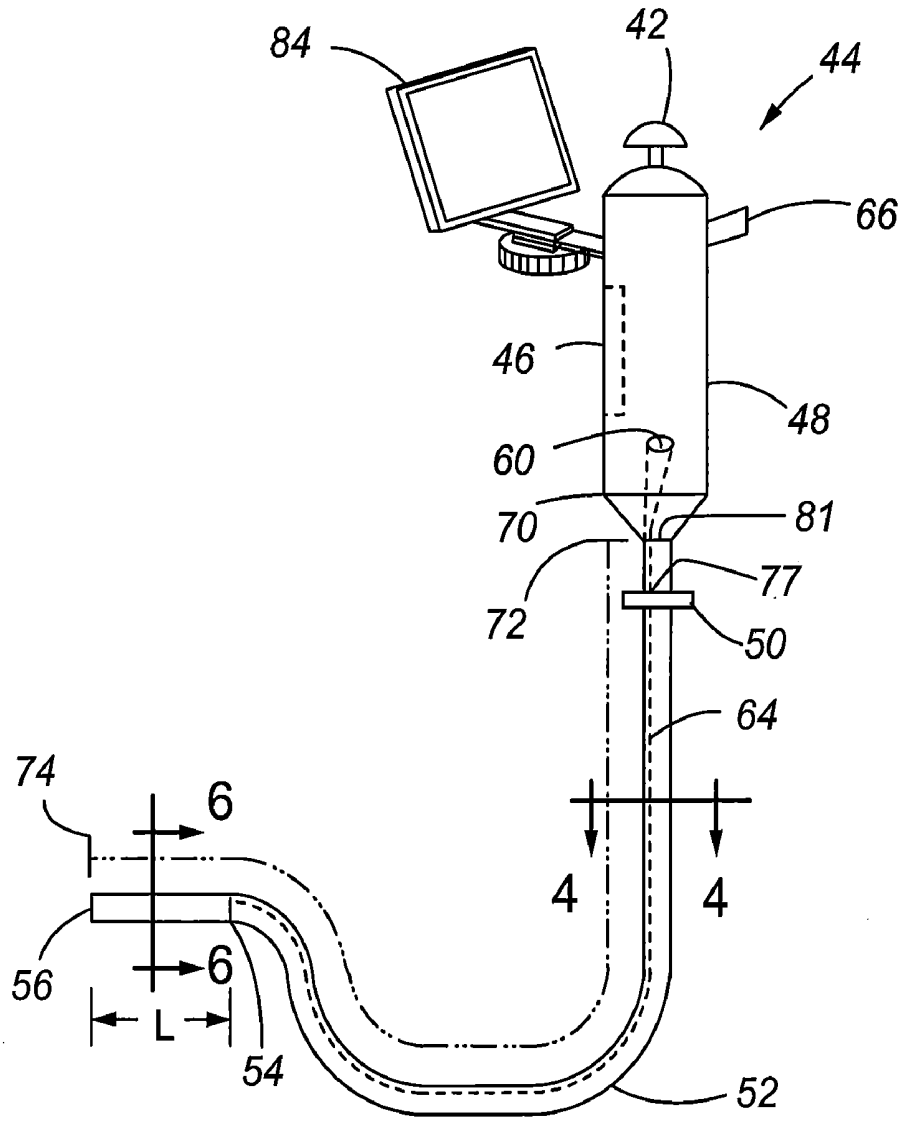
(57) **ABSTRACT**

A scope adapted for insertion, manipulation and improved visibility in a difficult pathway is disclosed. The scope comprises at least one module for manipulating the scope. The scope may further comprise an illumination source, an image sensor, a power source, and a viewing member for viewing images of a cavity or other anatomical member of a patient. The scope may further comprise alternative pathways for air or fluid flow to exit the distal tip for the purpose of minimizing trauma and improving visibility. In one embodiment the scope is intended to facilitate insertion of an intubating device, which comprises an elongated semi-rigid stylet including first and second ends and at least one inner lumen connected to a module. Additionally, a flexible tip is provided for manipulating one end of the scope and allowing greater flexibility when maneuvering a difficult pathway. A method for navigating a difficult pathway is also disclosed.



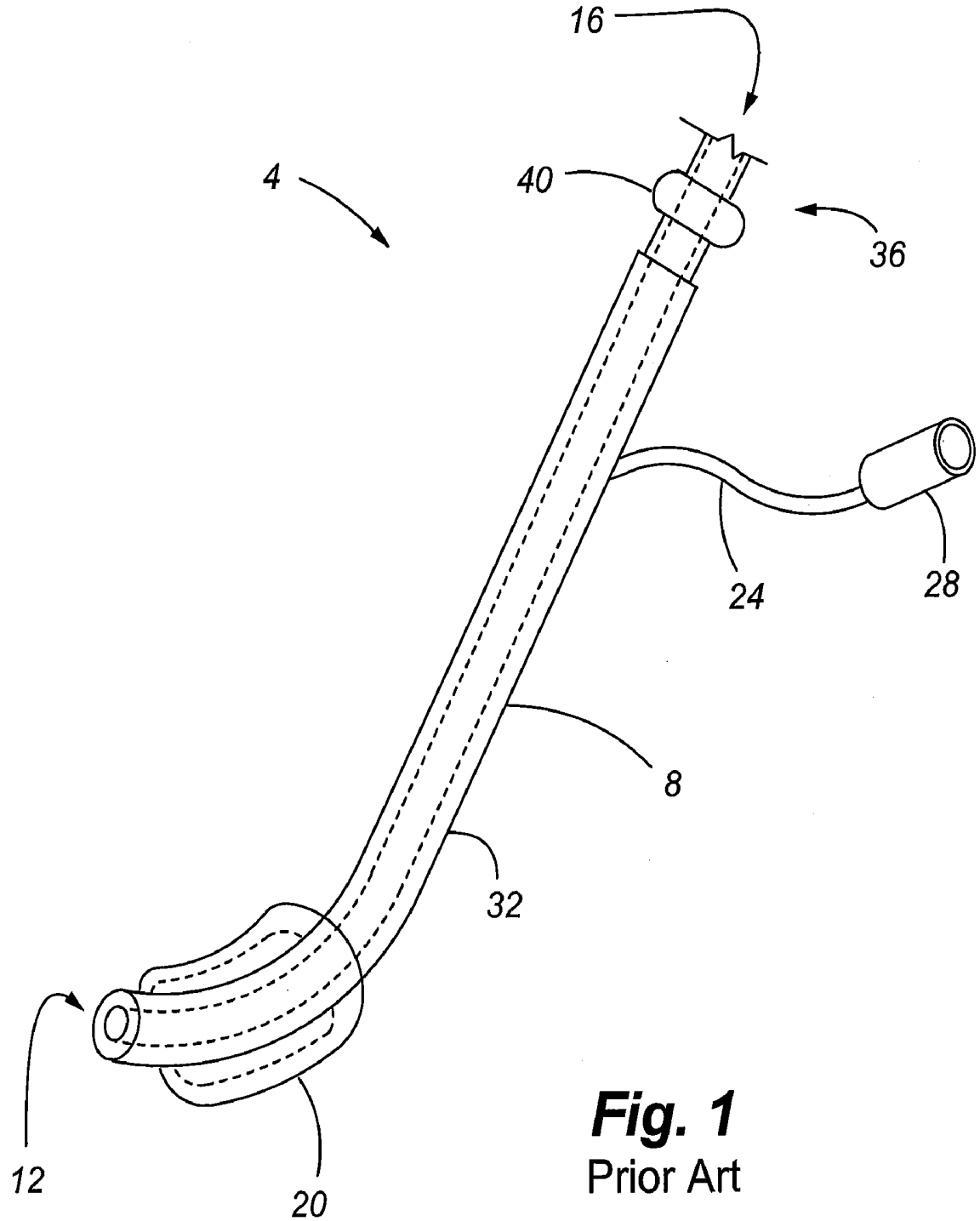


Fig. 1
Prior Art

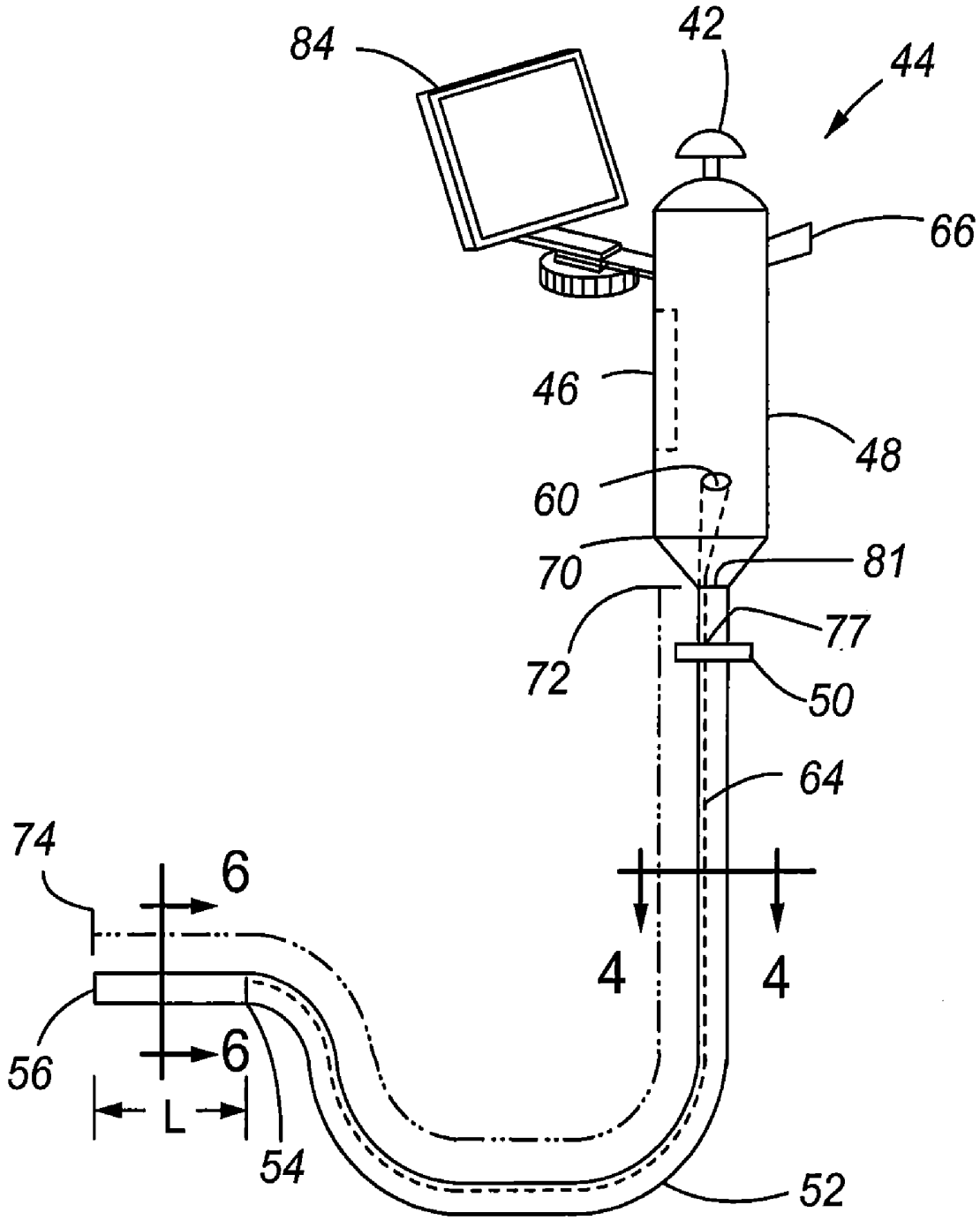


Fig. 2

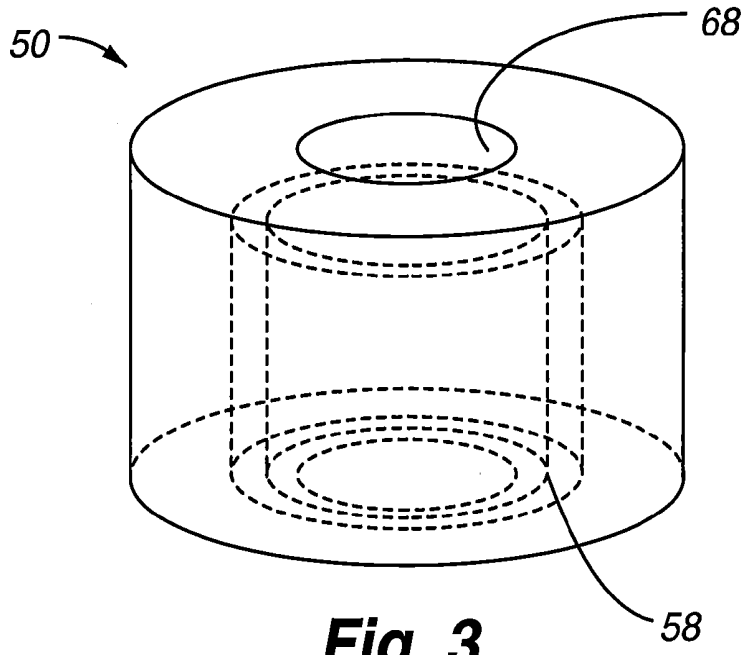


Fig. 3

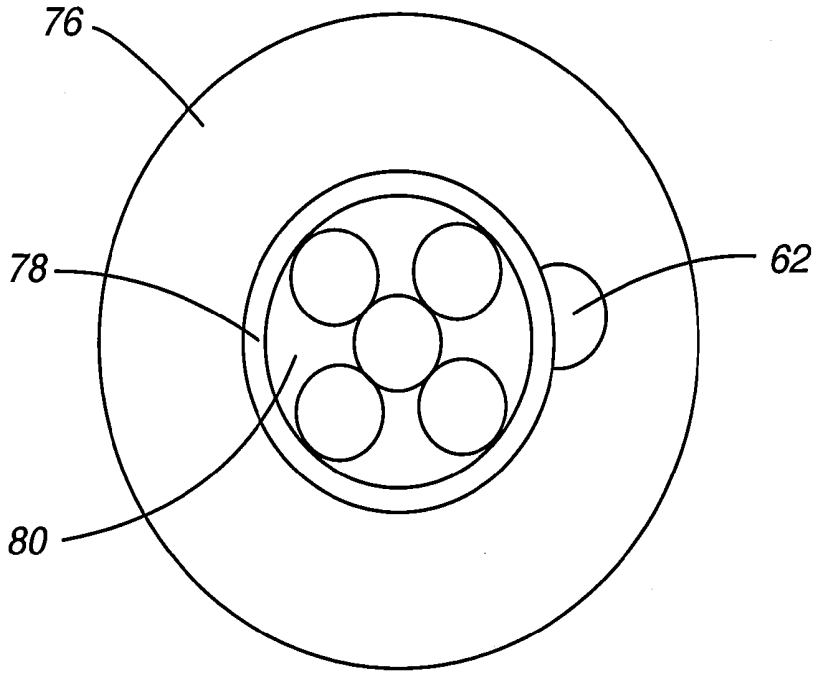


Fig. 4

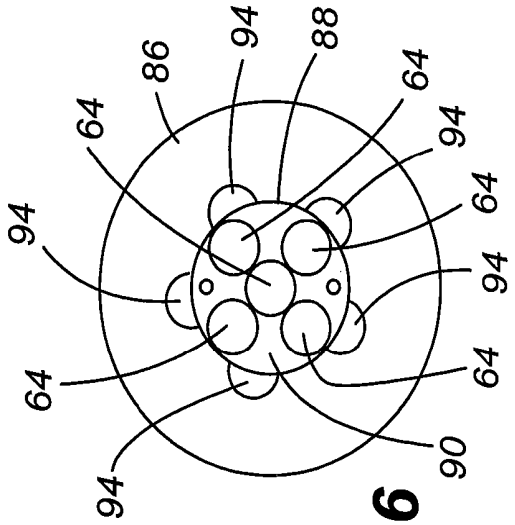

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Fig. 6

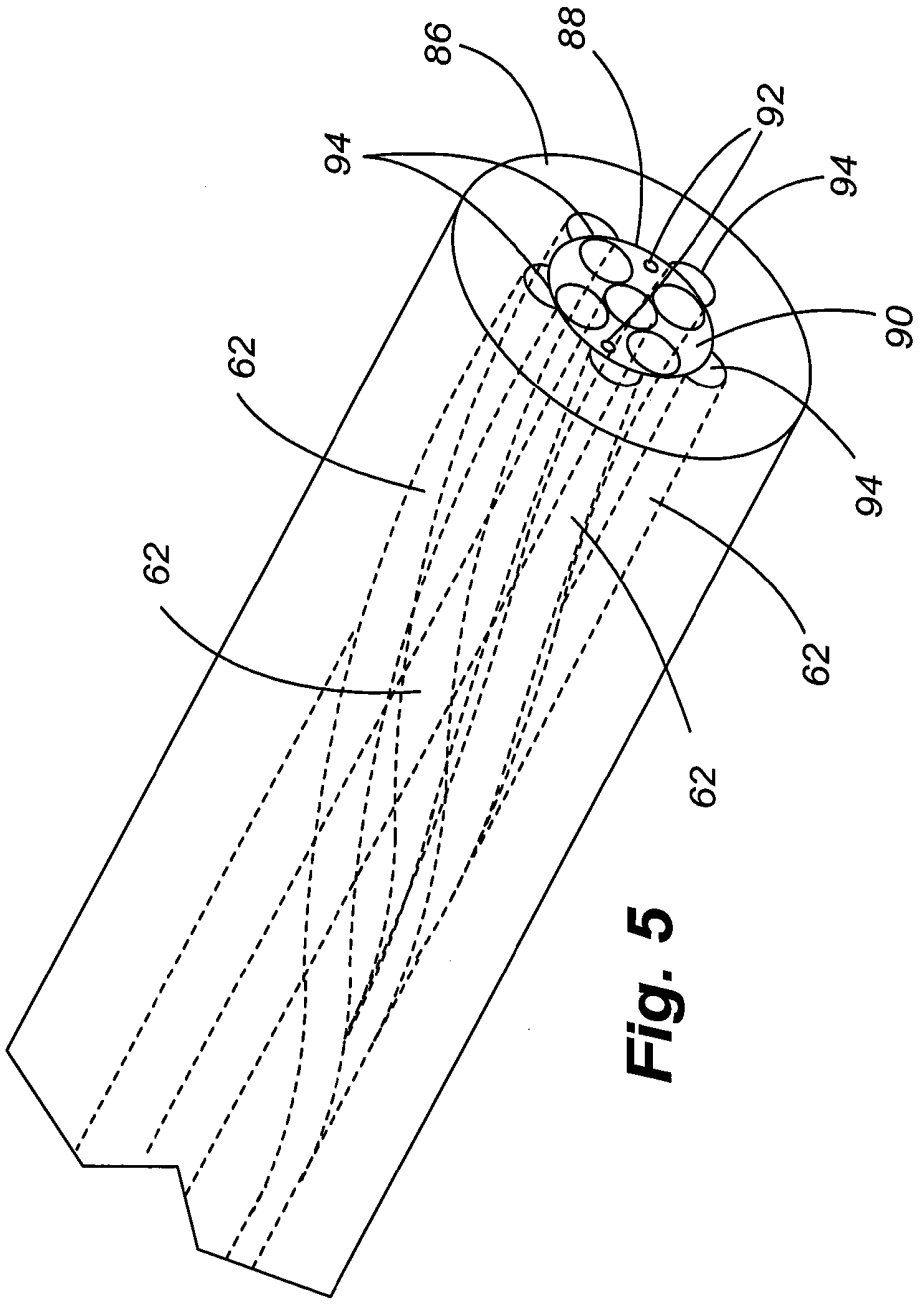
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Fig. 5

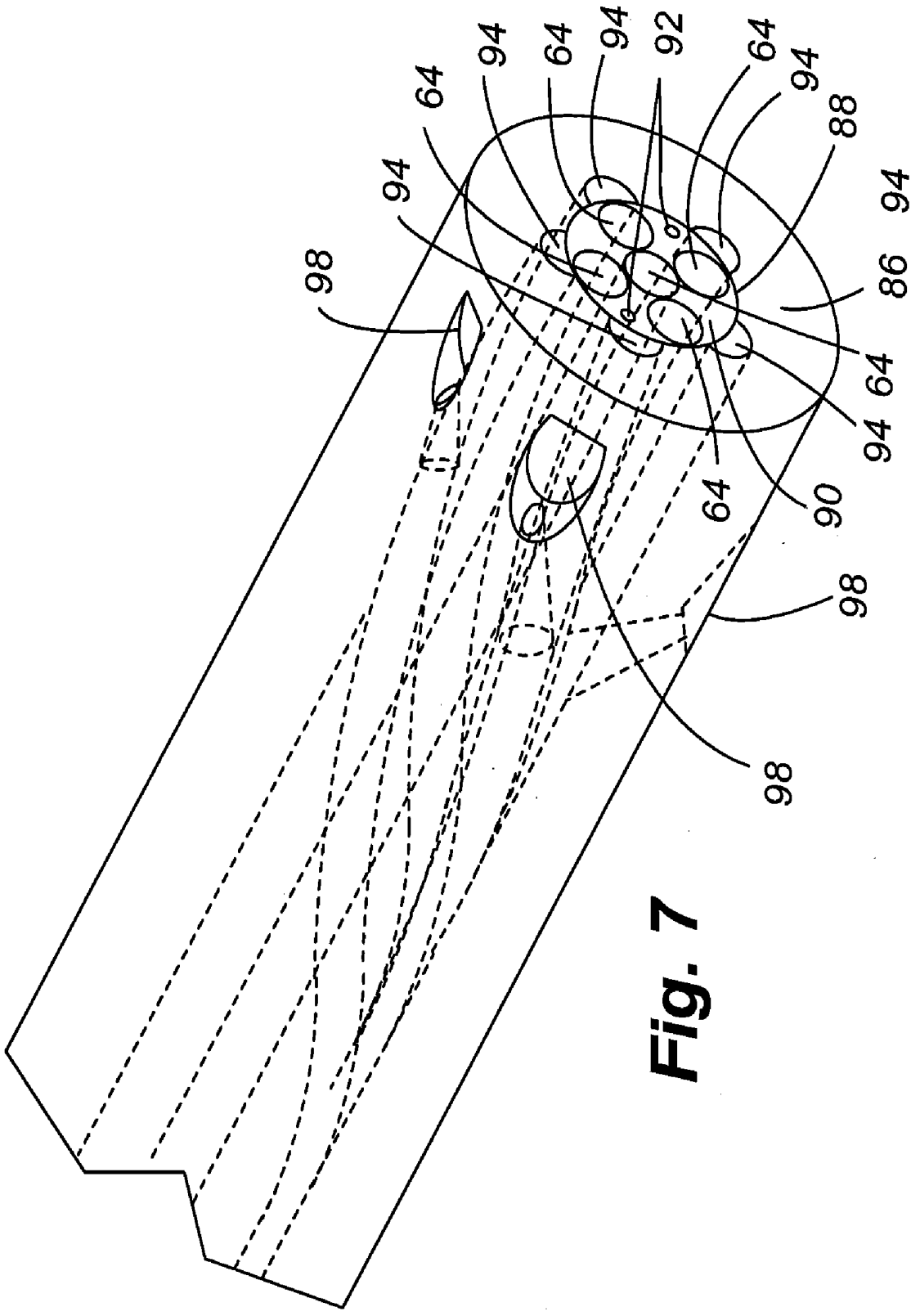

Fig. 7

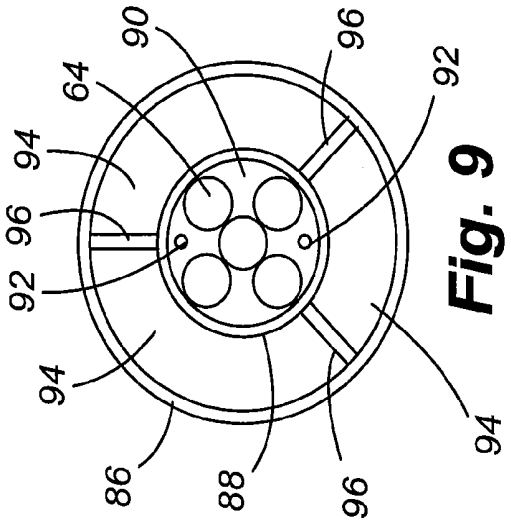

Fig. 9

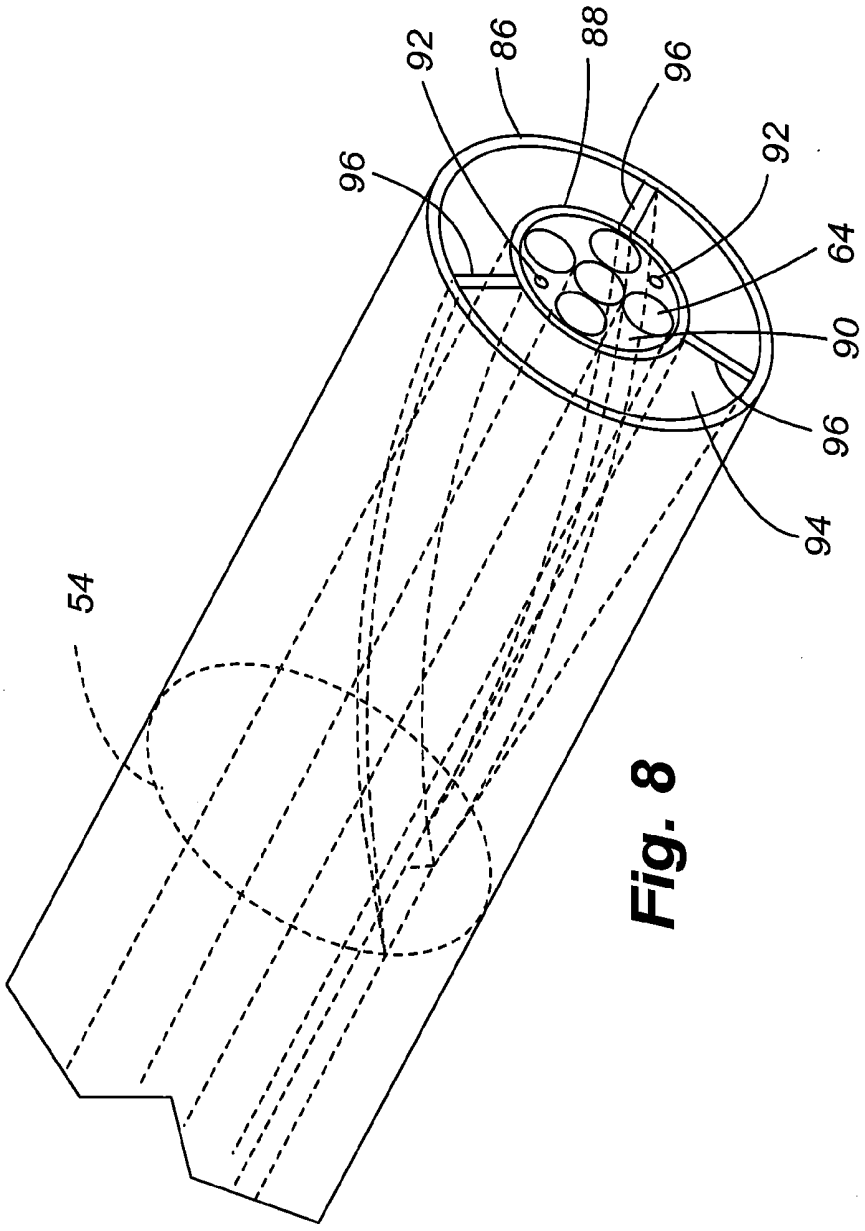

Fig. 8

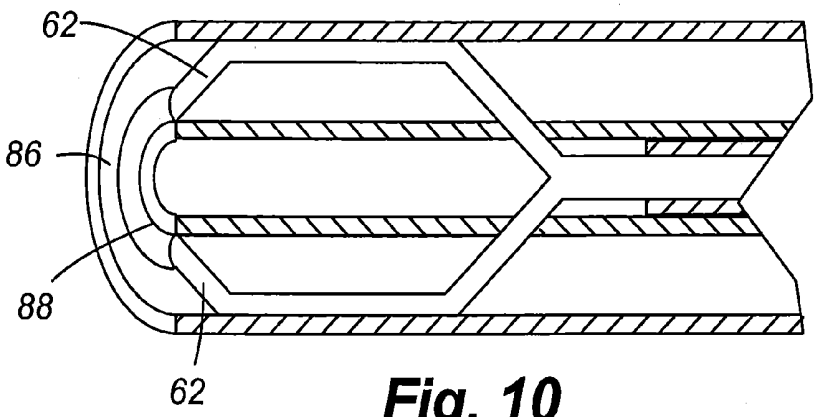

Fig. 10

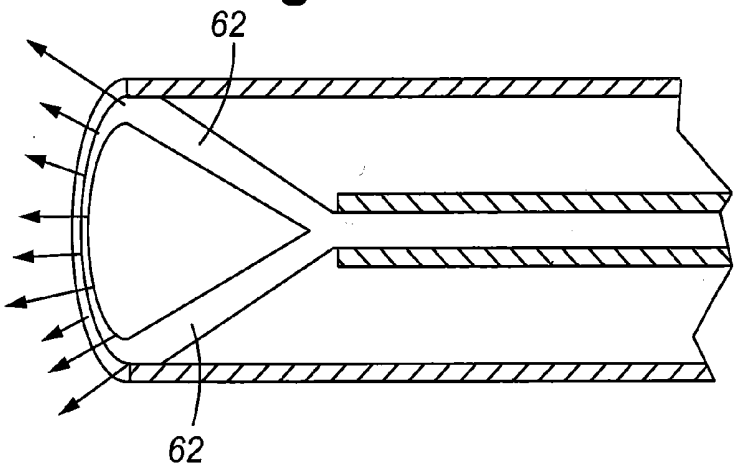

Fig. 11

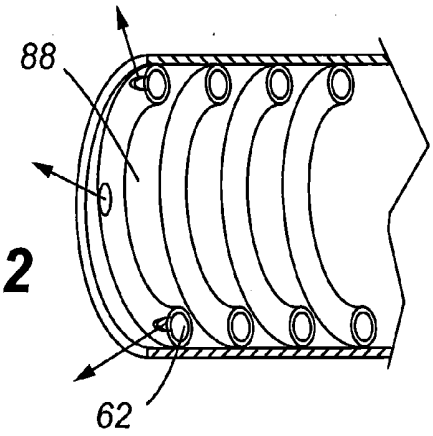

Fig. 12

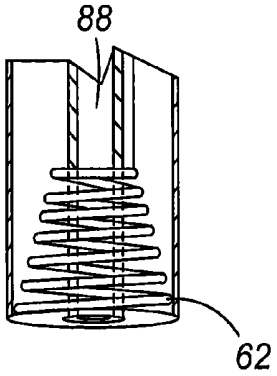

Fig. 13

SCOPE FOR MANAGING DIFFICULT PATHWAYS AND METHOD TO IMPROVE VISIBILITY OF THE SAME

FIELD OF THE INVENTION

[0001] The present invention relates generally to medical devices for examining a cavity or orifice of a patient. More specifically, it relates to one of a variety of scopes, such as a scope for orotracheal intubation, which provides a method to obtain an enhanced view of the patient's cavity or orifice, and further provides flexibility to allow direction of a distal tip located on the scope to facilitate insertion and manipulation of the scope.

BACKGROUND

[0002] Many medical procedures require insertion and manipulation of a scope; some scopes used in the medical field include: borescopes, fiberscopes, videoscopes, neurosurgical scopes and intubating scopes. Taking the example of an intubating scope, the procedure often requires insertion of the scope into an endotracheal tube (ETT), which is further inserted into the trachea of a patient. The ETT ensures proper ventilation in the patient, and also allows for the delivery of various gases to the patient, such as an anesthetic or oxygen.

[0003] In a typical intubation procedure, the ETT is introduced through the mouth of the patient. Simultaneously, a metal laryngoscope blade (i.e. Miller or MAC Blade) can be used to move the patient's tongue so that the patient's epiglottis and vocal cords can be viewed by the operator. The ETT is then advanced until it is positioned at the proper location in the patient's trachea. Once the ETT is properly positioned, a cuff affixed to the ETT can be inflated to seal the patient's airway passage and allow for the flow of ambient gases. A proper procedure firmly fixes the endotracheal tube in place in the patient's trachea. At this time, the laryngoscope can be withdrawn leaving the ETT in the body.

[0004] In some situations, the patient's epiglottis or anatomical features, blood or other secretions, and sometime even debris, may present what is known as a "difficult airway". In a difficult airway situation, the currently available metal laryngoscope blades can cause trauma to soft tissue, teeth and other areas of the patient due to, in part, the size, rigidity and low versatility of the blade. As a result, some practitioners have begun using flexible scopes which are inserted into the ETT, some of which allow the practitioner to view the airway during insertion of the ETT into the trachea via fiber-optics, to avoid inducing trauma to sensitive features of the airway. The tip of the scope contains an imaging element which communicates images from the distal end of the scope (typically located near the distal end of the ETT) to the proximal end of the scope, and then to a portable monitor or eyepiece. The images displayed on the monitor or eyepiece can be viewed by the operator during insertion of the ETT.

[0005] However, prior art devices currently available are ineffective for manipulating soft tissue in the airway and dealing with secretions and other debris to obtain a clear view of the tracheal inlet. If the tip of the scope is covered or obsecured by soft tissue, secretions or other debris, the practitioner will obtain an inaccurate or incomplete image of the trachea, and an effective intubation will likely be delayed. Patients in emergency situations require effective intubations on the practitioner's first intubation attempt.

[0006] For example, U.S. Pat. No. 5,817,015 to Adair discloses an endoscope having at least one longitudinal channel formed around its periphery for transmitting fluids or for receiving an operative instrument or carrying light transmitting fibers. However, Adair does not disclose an apparatus capable of injecting gas or fluid other than in a longitudinal direction, and thereby providing freedom to navigate a scope in a tight or difficult passageway.

[0007] U.S. Patent Application Publication No. US 2006/0047184 to Banik, et al. discloses an endoscopic imaging system for examining a patient's body cavity including an endoscope having a distal end, a proximal end and a number of lumens therein. One or more distal gas ports are disposed at or adjacent the distal end of the endoscope. Banik et al. also fails to disclose injecting gas or fluid in a non-longitudinal direction, and furthermore does not provide for the symmetrical arrangement of ports as does the current invention.

[0008] U.S. Pat. No. 5,685,823 to Ito, et al. discloses an endoscope including a front end having fluid discharge openings, and further having a fluid injection nozzle connected to the fluid discharge opening. The '823 Patent only discloses the injection of fluid through discharge openings located at the front end, which are limited in the direction of flow of fluid or other substance transmitted through the injection nozzles.

[0009] U.S. Pat. No. 5,464,008 to Kim discloses a defogger for the objective lens of a laparoscope providing a channel in a longitudinal direction of the laparoscope. Gas from an insufflator is supplied to the channel exteriorly of a body being operated upon. While the channel directs gas across the surface of the objective lens, it does not direct gos or fluid outwardly for clearing an area in front of the lens.

[0010] Thus, a need exists for providing an intubating scope that can be used in conjunction with an ETT in difficult airway situations that is effective in dealing with obstructive soft tissue, secretions and other debris, and is easy to use. Furthermore, there is a need for an intubating scope that is flexible and allows for redirection of the distal tip within the difficult airway.

SUMMARY OF THE INVENTION

[0011] These and other needs are addressed by the various embodiments and configurations of the present invention:

[0012] It is an object of the present invention to provide a scope for insertion into a cavity or orifice of a patient, such as an intubating scope, which comprises a flexible, controllable tip to allow a practitioner to navigate a difficult pathway while avoiding or minimizing patient trauma.

[0013] It is another object of the present invention to provide a scope that provides a clear image of a patient's trachea or other cavity during insertion so as to avoid or minimize trauma to the patent and to facilitate navigation and locate a path for insertion of the scope. The scope includes alternative pathways for air or fluid flow to exit the distal tip for the purpose of minimizing trauma and improving visibility.

[0014] According to one embodiment of the present invention, the scope is adapted to be used with an endotracheal tube during orotracheal intubation is provided that includes a module for manipulating the intubating scope. The module includes an illumination source, an image sensor, a power source, and a viewing member. Further, an elongated semi-malleable stylet including first and second ends and at least one inner lumen therein is connected to the module at the first end thereof. Additionally, a first end of a flexible tip is connected to a second end of the stylet. The flexible tip includes

first and second ends, at least one inner lumen extending from the first end to the second end, and at least one pathway extending from the first end to the second end and spaced apart from the inner lumen.

[0015] When connected, the inner lumen of the stylet is coaxial with the inner lumen of the flexible tip. Furthermore, the intubating scope includes at least one fiber-optic bundle having first and second ends. The first end of the bundle is mounted within the module and the second end of the bundle is mounted within the flexible tip, wherein the bundle includes illumination fibers and/or imaging fibers for allowing viewing of a cavity of a patient via the flexible tip.

[0016] According to another embodiment of the present invention, a modified flexible tip is adapted to be used with a scope during insertion and manipulation of the scope is provided. The flexible tip comprises a first end and a second end, and an outer layer connected to an inner layer. The flexible tip further includes a lumen located within the inner layer that extends from the first end to the second end. Moreover, the flexible tip includes at least one tunnel or pathway located within the outer layer and extending from the receiving area to an outlet port at a first location near the second end.

[0017] In another embodiment, the flexible tip includes at least one other pathway located within the outer layer. The at least one other pathway extends from the first end of the flexible tip to an outlet port at a second location spaced apart from the first location near the second end.

[0018] According to another embodiment of the present invention, the distal tip includes alternative pathways for air or fluid flow to exit the scope for the purpose of minimizing trauma and improving visibility. These pathways manipulate the direction of flow of air and fluid, creating a clean zone in front of the lens by clearing debris, secretions and soft tissue away from the distal tip.

[0019] Thus according to one embodiment of the present invention, a flexible tip for use with a scope is disclosed which comprises:

[0020] a first end and a second end;

[0021] an outer layer and an inner layer extending longitudinally from the first end to the second end;

[0022] a lumen located within the inner layer and extending longitudinally from the first end to the second end;

[0023] the flexible tip further comprising at least four pathways exterior to the lumen located within the inner layer, each of the at least four pathways positioned in a first concentric arrangement about and proximate to an outer circumference of the lumen and terminating proximate to at least one exterior surface of the outer layer for distributing fluid or gas from the first end of the flexible tip to the at least one outlet.

[0024] According to another embodiment of the present invention, a scope is disclosed which comprises:

[0025] a module having a least an illumination source, an image sensor, and a power source;

[0026] an elongated stylet having a first length with first and second ends and at least one centrally positioned inner lumen therein, the first end of the first length of the stylet proximate to the module, the first length of the elongated stylet having at least one pathway exterior to the at least one centrally positioned inner lumen;

[0027] the at least one centrally positioned inner lumen further comprising a first concentric arrangement, within the at least one inner lumen of the first length comprising at least one first fiber for illumination and at least one second fiber for receiving images;

[0028] the elongated stylet having a second length with first and second ends, the first end of the second length of the elongated stylet connected to the second end of the first length of the elongated stylet, the second end of the second length comprising a lens coupled to the at least one second fiber for receiving images, the second length of the elongated stylet having at least one centrally positioned inner lumen in communication with the at least one centrally positioned inner lumen of the first length of the elongated stylet;

[0029] the second length of the elongated stylet further comprising at least four pathways exterior to the at least one centrally positioned inner lumen of the second length of the elongated stylet, each of said at least four pathways positioned in a second concentric arrangement about and proximate to an outer circumference of the at least one centrally positioned inner lumen of the second length and terminating proximate to at least one exterior surface of the second length of the elongated stylet for distributing a gas, liquid, fluid or other substance supplied from the module through the at least one pathway of the first length and the at least four pathways of the second length.

[0030] According to yet another embodiment of the present invention, a scope is disclosed which comprises:

a module having a least an illumination source, an image sensor, and a power source:

[0031] an elongated stylet having a first length with first and second ends and at least one centrally positioned inner lumen therein, the first end of the first length of the stylet proximate to the module, the first length of the elongated stylet having at least one pathway exterior to the at least one centrally positioned inner lumen;

[0032] the at least one centrally positioned inner lumen further comprising a first concentric arrangement, within the at least one inner lumen of the first length comprising at least one first fiber for illumination and at least one second fiber for receiving images;

[0033] the elongated stylet having a second length with first and second ends, the first end of the second length of the elongated stylet connected to the second end of the first length of the elongated stylet, the second end of the second length comprising a lens coupled to the at least one second fiber for receiving images, the second length of the elongated stylet having at least one centrally positioned inner lumen in communication with the at least one centrally positioned inner lumen of the first length of the elongated stylet;

[0034] the second length of the elongated stylet further comprising at least four pathways exterior to the at least one centrally positioned inner lumen of the second length of the elongated stylet, each of said at least four pathways positioned in a second concentric arrangement about and proximate to an outer circumference of the at least one centrally positioned inner lumen of the second length and terminating proximate to at least one exterior surface of the second length of the elongated stylet for distributing a gas, liquid, fluid or other substance supplied from the module through the at least one pathway of the first length and the at least four pathways of the second length;

[0035] a display coupled to the module and in communication with the lens via the imaging fibers for viewing images proximate to the second end of the second length of the elongated stylet;

[0036] articulation wires extending longitudinally through the first and second lengths of the elongated stylet, the articulation wires coupled to a lever for manipulating the direction and/or orientation of the second end of the second length of the elongated stylet;

[0037] wherein the at least four pathways terminate about an outer circumference of the second length of the elongated stylet for ejecting a gas, liquid, fluid or other substance at a direction tangential to the longitudinal axis of the second length of the elongated stylet.

BRIEF DESCRIPTION OF THE DRAWINGS

[0038] FIG. **1** is a perspective view of an endotracheal tube in accordance with the prior art;

[0039] FIG. **2** is a perspective view of an intubating scope in accordance with one embodiment of the present invention;

[0040] FIG. **3** is a perspective view of a connector used to fasten the intubating scope to the endotracheal tube;

[0041] FIG. **4** is a cross-sectional view of the stylet about axis A-A in FIG. **2**;

[0042] FIG. **5** is a detailed perspective view of the flexible tip of the intubating scope of FIG. **2** according to one embodiment of the present invention;

[0043] FIG. **6** is a cross-sectional view of the flexible tip shown in FIG. **5**;

[0044] FIG. **7** is a detailed perspective view of the flexible tip of the intubating scope of FIG. **5** in an alternate embodiment illustrating an optional side fluid port;

[0045] FIG. **8** is a detailed perspective view of the flexible tip of the intubating scope of FIG. **2** according to another alternate embodiment of the present invention;

[0046] FIG. **9** is a cross-sectional view of the flexible tip shown in FIG. **8**;

[0047] FIG. **10** is a partial cross-sectional view of the flexible tip in an alternate embodiment;

[0048] FIG. **11** is another partial cross-sectional view of the flexible tip in an alternate embodiment;

[0049] FIG. **12** is another partial cross-sectional view of the flexible tip in an alternate embodiment; and

[0050] FIG. **13** is another partial cross-sectional view of the flexible tip in an alternate embodiment.

[0051] The drawings are not necessarily to scale, and may, in part, include exaggerated dimensions for clarity.

DETAILED DESCRIPTION OF THE INVENTION

[0052] According to various embodiments, the present invention discloses a scope, such as a scope for performing intubation of a patient's airway, which is adapted to be used with an endotracheal tube during orotracheal intubation is provided that includes a module for manipulating the intubating scope. The module includes an illumination source, an image sensor, a power source, and a viewing member. Further, an elongated semi-malleable stylet including first and second ends and at least one inner lumen therein is connected to the module at the first end thereof. Additionally, a first end of a flexible tip is connected to a second end of the stylet. The flexible tip includes first and second ends, at least one inner lumen extending from the first end to the second end, and at least one pathway extending from the first end to the second end and spaced apart from the inner lumen.

[0053] Thus, the invention according to one embodiment provides an adjustable intubating scope to facilitate orotracheal insertion of an endotracheal tube (ETT) into a patient's larynx or trachea, and provide an unobstructed view in the area in front of a lens located on the flexible tip of the intubating scope. The lens may be connected to one or a variety of different media for displaying an image of the patient's larynx or trachea or other anatomy during intubation, and may further be displayed on one of a variety of display means, described in greater detail below. The intubating scope thus provides pathways for oxygen and other fluids to continually or intermittently clear and/or cleanse the area in front of the lens.

[0054] Referring to FIG. **1**, a device according to one embodiment of the present disclosure is shown in a perspective view. The device in this embodiment comprises an ETT **4** for facilitating intubating a patient, and to ensure that the patient's airway is not closed off such that air is unable to reach the patient's lungs. The ETT **4** further comprises a shaft **8** having distal end **12** and proximal end **16** ends, a cuff **20** mounted near the distal end and a tube **24** mounted within and extending longitudinally through the shaft **8** and connected at a first end to the cuff **20**. The ETT **4** further comprises a nozzle **28** mounted to the second end of the tube **24**, a lumen **32** within the shaft **8** and a universal adaptor **36** having a lip piece **40**.

[0055] Generally, the distal end **12** of the ETT **4** is inserted orotracheally into the patient, and the universal adaptor **36** is connected to a machine, such as a ventilator, which provides air to the patient's lungs via the lumen **32**. While only a single lumen is shown, those of ordinary skill in the art will appreciate that multiple lumens can be provided to satisfy a user's specific requirements.

[0056] The cuff **20** is inflatable and is provided to form a seal with the wall of the trachea during intubation when inflated. Nozzle **28** connects the tube **24** to an inflation device (not shown). Accordingly, following insertion of the ETT **4** and when the cuff **20** is inflated with air, oxygen or other fluid, the exterior of the cuff **20** expands and contracts the interior of the patient's trachea so as to seal the trachea. Alternatively, the ETT **4** may have a pilot balloon (not shown) located under the nozzle **28** which can be manually squeezed to provide air to the cuff **20**. Preferably the ETT **4** is molded to form a single continuous piece. Alternatively, the ETT **4** may be made from separate pieces of flexible plastic that are molded and connected into the shape shown in FIG. **1**.

[0057] With reference to FIG. **2**, a perspective view of an intubating scope **44** in accordance with one embodiment of the present invention is shown ideally for use in conjunction with an ETT **4**, although the intubating scope **44** can be used in other applications as well. The intubating scope **44** generally includes a module **48** for manipulating the intubating scope **44**, a stylet **52** for carrying the majority of the length of fiber-optic bundles, fluid pathways, etc., and a flexible tip **56** that can be manipulated by the module to allow an operator to view a patient's cavity.

[0058] The module **48** is preferably of an ergonomic shape to allow the module **48** to be easily grasped by an operator, and can include finger grips (not shown) to aid in retention by the operator. The outer shell of the module **48** can be constructed of any lightweight material such as aluminum, plastics, etc.

[0059] Housed within the module **48** is one end of a fiber-optic bundle **64**, which may include illumination fibers and/or imaging fibers for allowing viewing of the patient's trachea, for example. An illumination source **77** provided proximate to a first end of the fiber-optic bundle **64** for providing illumination to a second end of the fiber-optic bundle **64** proximate to the flexible tip **56**. The illumination source **77** may be a light emitting diode, for example, although ordinary artisans will appreciate that other light sources can be utilized. Additionally housed within the module is an image sensor **81**, such as a charge-coupling device (CCD) chip, that is attached proximate to a first end of the fiber-optic bundle **64**. The image sensor **81** receives photons that are received by a lens (not shown) attached to a second end of the fiber-optic bundle **64** located in the flexible tip **56** to provide images of the area viewed by the lens. It will be appreciated that other image sensor technology, such as a complementary metal-oxide-semiconductor (CMOS) chip, are also within the scope of the present invention.

[0060] A display screen **84**, such as an LCD screen, is mounted to the module **48** and connected to the image sensor **81** via internal circuitry (not shown) to allow an operator to view the images received by the image sensor **81**. The display screen **84** can be mounted in any way known in the art, and is preferably adjustable to provide a convenient viewing orientation regardless of the position of the module. In addition, the module can include an eyepiece **42** for allowing viewing of an image received by the image sensor **81**. Additionally, an image-receiving port (not shown) may be provided in the module **48** and connected to the image sensor **81** via internal circuitry (not shown) to allow images to be transferred to an external device, such as a computer, for instance. Furthermore, a power source **46** provides power to the electrical components of the intubating scope **44**. While the power source **46** is preferably at least one battery, the power source may also be an external power source, such as a standard 120-volt AC source that would connect to the module **48** via an electrical wire and plug. An on/off switch (not shown) may be provided to control supply of power from the power source **46** to the various electrical components.

[0061] Those of ordinary skill in the art will realize that while fiber-optic bundles **64** have been described, other transmission means such as electrical wiring or similar transmission cables are within the scope of the present invention. Further, it will be recognized that if electrical wires are used, the light source could be located in the flexible tip **56** rather than the module **48**. Moreover, while the image sensor **81** is described as being located in the module **48**, ordinary artisans will appreciate that the image sensor **81** could alternatively be located in the flexible tip **56** such that images would be transferred through the stylet **52** via cables to the LCD and/or image receiving port.

[0062] Slideable along the outer surface of the stylet **52** is a connector **50** used to mate adjacent the proximal end **16** of the ETT **4** to detachably fix the intubating scope to the ETT **4**. With reference to FIG. **3**, the connector **50** includes a central bore **58** that is friction fit around and slidable along the outer surface of the stylet **52**. Additionally, the connector **50** includes cylindrical slot **68** adapted to frictionally receive the proximal end **16** of the ETT **4**. Referring now to both FIGS. **3** and **2**, in operation the connector **50** is first slid to a desired position along the outer surface of the stylet **52**. Thereafter, the flexible tip **56** is inserted longitudinally into the ETT **4** until the proximal end **16** of the ETT **4** abuts the connector **50**. Finally, the proximal end **16** is inserted into the cylindrical slot **68** of the connector **50** to detachably fix the intubating scope **44** to the ETT **4**. The connector **50** is constructed of any of various plastics, metals, etc. Alternatively, rather than utilizing a friction-fit connection, the connector **50** may utilize a fastener, such as a set-screw (not shown), that engages the proximal end **16** of the ETT **4**. Alternatively, the fastener may be a member having a cam-shaft surface that is rotated to engage the underside of the lip piece **40**.

[0063] In addition to the illumination and imaging fibers connected to the module **48**, pathways are provided for transferring various fluids from the module **48** through the stylet **52** to the flexible tip **56**. Referring now to FIGS. **2** and **4**, a first end of each pathway is an inlet **60** or other valve known in the art (i.e. threaded connection) for introducing the fluids into a pathway **62**. A second distal end of pathway **62** is connected to a port in the flexible tip **56** for allowing exit of the fluids introduced therein. Pathway **62** can be of various constructions, including tubing, conduits, ducts, etc. For instance, one or more pathways **62** can be for receiving a non-toxic solution such as lidocaine or saline for cleansing of the lens at the second distal end of the fiber-optic bundle **64** due to oropharyngeal blood or other secretions or debris in front of or on the lens as will be described below. Additionally, a pathway may be formed within the stylet **52** that runs from an inlet **60** in the module **48** to an outlet in the flexible tip **56**. The pathway may receive oxygen for removing secretions and/or displacing soft tissue atraumatically, from the area in front of the lens as described in greater detail below. While the pathways are illustrated as being mounted within the stylet **52**, it is contemplated that one or more of the pathways could be formed of a separate structure, such as a tubing structure, and run along side the stylet **52** to the flexible tip **56** and fixed to the stylet **52** via clips, adhesive, etc.

[0064] Continuing with reference to FIG. **2**, the module **48** additionally includes a lever **66** to manipulate the flexible tip **56** in an up and down direction in one plane. More specifically, at least two articulation wires (not shown) are connected to the lever **66**, run through the stylet **52**, and are mounted to the flexible tip **56**. Preferably, the articulation wires are positioned opposite each other and extend longitudinally to the flexible tip **56** so as to impart opposing flexible forces which provide the up and down motion of the flexible tip **56** upon movement of the lever in an up or down motion. However, other means may be employed to manipulate the flexible tip **56** in an up and down motion. For instance, if the flexible tip **56** is biased in either the up or down direction, then only a single wire could be utilized to overcome the bias and flex the flexible tip **56** in the opposite direction. By rotating the module, and thereby the flexible tip **56**, a user may change the plan in which the flexible tip **56** is moved relative to the axis of movement With continued reference to FIG. **2**, a junction **70** is located on the module **48** and proximate to the stylet **52** for receiving the fiber optic bundles **64**, pathway **62**, articulation wires, etc. The junction **70** is preferably rigid to allow the operator to manipulate the majority of the stylet **52** by manipulating the module **48**, although a flexible junction is also contemplated as being within the scope of the present invention. For instance, a ball and socket joint with a threaded locking pin would be useful for a difficult situation when the operator needs to change the angle between the module **48** and stylet **52**, and rigidly maintain that angle thereafter.

[0065] The stylet **52** has first end **72** and second end **74**, and is preferably constructed of a semi-malleable material, and has an internal geometry for receiving the fiber-optic bundles **64**, pathway **62**, articulation wires, etc. The material can be aluminum or other flexible metal, such as medical-grade plastic, etc. As shown in FIG. **2**, the stylet **52** has been formed into a substantially J-shaped configuration for simulating the anatomical curvature made between the tongue and soft palate when the patient is in the supine position. However, ordinary artisans will realize that numerous other shapes can be formed to accommodate individual patients. In addition, the stylet **52** and flexible tip **56** may be covered with a soft clear coating such as a thermoplastic material to protect the stylet **52** and flexible tip **56** during sterilization and from any water-soluble lubricants used to facilitate easy insertion and removal of the stylet **52** and flexible tip **56** into and out of the ETT **4**, as well as preventing trauma to the trachea caused by contact with the flexible tip **56** of the stylet **52**.

[0066] Referring now to FIG. **4**, a cross-sectional view of the stylet **52** of FIG. **2** is shown. More specifically, the stylet **52** according to this embodiment includes the inner layer **78** which forms an inner lumen **80**, and further includes an outer layer **76**, which has formed therein a pathway **62** for transporting oxygen or other gases or fluids from the module **48** to the flexible tip **56**. Preferably, the inner layer **78** and outer layer **76** of the stylet **52** are manufactured by extruding molten polymer. The pathway **62** can be formed during the manufacturing process or can be carved out of the outer layer **76** thereafter. However, it will be appreciated that tubing could be placed into the pathway **62** or otherwise formed in the outer layer **76** for carrying the oxygen or other gases or fluids from the module **48** to the flexible tip **56**.

[0067] The pathway **62** is connected at a first end to an inlet **60** in the module **48** and at a second end to a second end **54** of the stylet **52**. After forming, the inner layer **78** and outer layer **76** are laminated or adhered together, rolled and cut to form the completed stylet **52**. However, those of ordinary skill in the art will appreciate that various other manufacturing methods can be used, such as molding, welding, extruding, etc. Additionally, other materials could be used such as aluminum, copper, composites, etc. Moreover, although the fiber-optic bundles **64**, pathway **62**, inner layer **78** and outer layer **76** are in the particular orientation as shown in FIG. **4**, it will be recognized that other orientation of the bundles, pathways and wires is contemplated as being within the scope of the present invention.

[0068] Referring now to FIG. **5**, a detailed perspective view of the flexible tip **56** shown in FIG. **2** according to one alternative embodiment illustrated. The flexible tip **56** is preferably constructed to be more flexible than the stylet **52** so as to allow the flexible tip **56** to be manipulated by the lever **66** while the stylet **52** maintains its shape during orotracheal insertion. The flexible tip **56** can be constructed of soft metals, thermoplastics, medical-grade plastics, etc. Similar to the stylet **52**, the flexible tip **56** includes an outer layer **86**, an inner layer **88** and an inner lumen **80**. Additionally, the flexible tip **56** includes first end **72** and second end **74** ends and an outer layer **86**. The first end **72** of the flexible tip **56** is connected to the second end **74** of the stylet **52** by any means known in the art, such as adhesive, fusing, welding, etc. Additionally, a metal ring (not shown) can be provided at the junction of the stylet **52** and the flexible tip **56** to prevent against rupture of the flexible tip **56** from the stylet **52**. Preferably, the diameters of the outer layer **86**, inner layer **88** and inner lumen **80** are equivalent to those of the stylet **52** so as to provide continuity throughout the length of the stylet **52**.

[0069] Further, the inner lumen **80** of the stylet **52** leads directly into the inner lumen **80** of the flexible tip **56** such that both of the image sensor **81**, define a single continuous lumen extending from the module **48** to the end of the flexible tip **56**. Thus, the fiber-optic bundles **64**, pathways **62** and articulation wires **92** extend from the stylet **52** directly to the second end **74** of the flexible tip **56**. The ends of the fiber-optic bundles **64** include transparent caps, for example, to project light from the light source into the area in front of the second end of the flexible tip **56**. Moreover, one end of the fiber-optic bundle **64** includes a lens for receiving images illuminated by the light source and sending the images received to the image sensor via the fiber-optic bundle **64**. Additionally, the ends of the pathways **62** include outlet ports **94** for ejecting fluids or gases sent down the pathways **62** to the area about and/or surrounding the lens and/or transparent cap. While the ends of the fiber-optic bundles **64**, pathways **62** and articulation wires **92** are shown to be fixed right at the first end **72** of the flexible tip **56**, ordinary artisans will appreciate that the flexible tip **56** or fiber-optic bundles **64**, pathways **62** and articulation wires **92** can be constructed such that the fiber-optic bundles **64**, pathways **62** and articulation wires **92** end either before or after the first end **72** of the flexible tip **56**. Further, the ends of the fiber-optic bundles **64**, pathways **62** and articulation wires **92** can be fixed to or near the first end **72** of the flexible tip **56** in any means known in the art such as by adhesives, bonding, compression of the inner and outer layers, etc. Additionally, an end cap that fits over the fiber-optic bundles **64**, pathways **62** and articulation wires **92** that includes bores for receiving the fiber-optic bundles **64**, pathways **62** and articulation wires **92** could be utilized for fixing the fiber-optic bundles **64**, pathways **62** and articulation wires **92** to the flexible tip **56**. The end cap could be friction fitted or otherwise secured into the inner lumen **80** of the flexible tip **56** from the second end **74** of the flexible tip **56**.

[0070] With continued reference to FIGS. **5** and **6**, the outer layer **86** of the flexible tip **56** also includes a number of pathways **62** extending from the first end **72** of the flexible tip **56** to the second end **74** of the flexible tip **56**. The pathways **62** can be formed in the outer layer **86** as part of a molding process. Alternatively, the pathways **62** can be formed in the outer layer **86** after manufacturing of the outer layer **86** and before the outer layer **86** is laminated or otherwise bonded to the inner layer **88**. Each of the pathways **62** meet proximate to the second end **74** of the flexible tip **56** and radiate towards the first end **72** of the flexible tip **56** spaced around the inner lumen **80**.

[0071] In operation, the pathways **62** receive oxygen or other fluids from the pathways **62** of the stylet **52** and distribute the oxygen or other fluids to the pathways **62**. Thereafter, the fluids exit the pathways **62** proximate to the first end **72** of the flexible tip **56**. As the oxygen or fluids exit the pathways **62**, they clear debris, secretions, soft tissue, etc. from the area in front of the lens and/or transparent cap. Because the pathways **62** completely surround the lens and transparent cap, a "clean zone" is formed in front of the lens and illumination caps thus allowing the lens and image sensor to receive an unobstructed view of a particular area of the patient. While only five pathways **62** have been shown, ordinary artisans will realize that more or fewer pathways **62** can be provided

depending on a particular application of the intubating scope **44**. Further, the outlet ports **94** of the pathways **62** may comprise any number of shapes, including but not limited to semi-circular, circular, rectangular, etc., and may exit the second end **74** of the flexible tip **56** at any number of directions to provide fluid flow in a desired direction.

[0072] Preferably, the oxygen or fluid flow is directed perpendicularly or outward with respect to the second end **74** of the flexible tip **56**. Also, while pathways **62** have been formed directly in the outer layer **86** of the flexible tip **56**, it is contemplated that tubing could be mounted in the outer layer **86** of the flexible tip **56** to transport oxygen or other fluids through the stylet **52** to the area in front of and surrounding the lens and transparent cap at the second end **74** of the flexible tip **56**. To further create the clean zone, a non-toxic solution such as lidocaine or saline can be injected into the inlets **60** in the module **48**. The solution will then travel down the pathways **62** and exit from the outlet ports **94** located near the first end **72** of the flexible tip **56** thus cleaning the area on and around the lens and transparent cap.

[0073] Referring to FIG. **7**, a variation of the flexible tip of FIG. **5** is shown including at least one side fluid port **98** for transporting fluids to the outer layer **86** of the flexible tip **56** near the second end **74** of the flexible tip **56**. While only three side fluid ports **98** are illustrated for clarity, it is contemplated that each of the pathways **62** may have corresponding side fluid ports **98**. Similar to the pathways **62**, each side fluid port **98** may be formed in the outer layer **86** during the molding process or formed thereafter. Additionally, while the side fluid port **98** is shown branching from one of the pathways **62**, it is contemplated that the side fluid port **98** could begin proximate the second end **54** of the stylet **52** and then terminate at the outer layer **86** of the flexible tip **56** near the first end **72** of the flexible tip **56**.

[0074] Thus, in operation, oxygen or other fluids traveling through the stylet **52** and into the flexible tip **56** will be distributed through the pathways **62** and also the side fluid ports **98**. As a result, while the oxygen or other fluid from the pathways **62** clear debris from the area in front of the lens and transparent cap, the oxygen or other fluid from the side fluid ports **98** will clear debris approaching the lens and transparent cap from the lateral side of the second end **74** of the flexible tip **56**, thus enhancing the clean zone in front of the second end **74** of the flexible tip **56**, and allowing a greater degree of movement of the flexible tip in the cavity or orifice of the patent.

[0075] With reference to FIGS. **8** and **9**, another embodiment of the flexible tip **56** of the present invention is shown. The flexible tip **56** includes an outer layer **86**, an inner layer **88**, an inner lumen **80**, a first end **72**, and a second end **74**. Additionally, the flexible tip **56** is designed to provide a gap or space between the inner **88** and outer **86** layers for fluid flow as will be described hereinafter.

[0076] The pathway **62** of the stylet **52** carries oxygen or other fluid into the outlet ports **94** at the first end **72** of the flexible tip **56**. Situated in the outlet ports **94** and on each side of the pathway **62** as it enters the flexible tip **56** are elongated ribs **96** for directing the oxygen or other fluid from the receiving area to the second end **74** of the flexible tip **56** and for providing structural support between the inner and outer layers. Each of the elongated ribs **96** provide lateral support to the outer layer **86**, and further provide direction for distributing the oxygen or other fluid through the outlet ports **94**. Ordinary artisans will realize that more than one supporting elongated rib **96** may be provided for additional lateral support thereto.

[0077] Because of the symmetrical orientation of the elongated ribs **96**, substantially equal quantities of oxygen or other fluid will be delivered to each of the outlet ports **94**. With particular reference to the second end **74** of the flexible tip **56**, it will be recognized that the outlet ports **94** provide for the flow of oxygen or other fluid around substantially about the entire circumference of the inner lumen **80**. Thus, a clean zone is created in the area in front of the second end **74** of the flexible tip **56** for clearing debris, secretions and soft tissue away from the lens and transparent cap. Those of ordinary skill in the art will appreciate that additional elongated ribs **96** with varying orientations and/or directions within the flexible tip **56** may be further provided to direct fluid flow to a particular location. Further, it is contemplated that the previously described side fluid ports **98** may be incorporated as shown in FIG. **7** to provide fluid flow to the lateral surface of the flexible tip if desired.

[0078] Referring now to FIGS. **10**A-C and **11**, a flexible tip according to various alternative embodiments are shown. As shown in FIG. **10**A, pathways **62** running through the flexible tip are oriented in a direction to allow gas or liquid exiting the outlets to be forced at least partially across the surface of the lens and/or inner lumen. As shown in FIG. **10**B, the pathways **62** are oriented to direct and distribute gas or liquid in a somewhat radial orientation about the second end of the flexible tip, thereby providing a pushing force in both the longitudinal direction and the lateral direction with respect to the flexible tip and stylet. As shown in FIG. **10**C, the pathways are oriented to distribute gas or liquid in a helical or spiral flow-pattern, thereby providing both longitudinal and lateral force to any surrounding tissue or debris. It is to be expressly understood that while these alternate embodiments are depicted each with one type of pathway, combinations of these various alternative embodiments may be combined to provide the optimal force required for the particular application, or to provide both clearing of tissue and/or debris along with periodic cleansing of the lens. Although the drawings depict the pathways to be consistent with respect to the diameter of the pathways, in other alternative embodiments the pathways may change from a larger diameter to a smaller diameter as the pathways approach the second end of the flexible tip, thereby increasing the flow-rate of the gas or liquid therein. In yet another alternative embodiment, the pathways may change from a smaller diameter to a larger diameter as they approach the second end of the flexible tip.

[0079] Referring now to FIG. **11**, another alternative embodiment of the present disclosure is shown. In this embodiment, a single pathway **62** is shown extending from the first end of the flexible tip adjacent the inner lumen, to the second end of the flexible tip adjacent the outer surface of the flexible tip. This orientation may be desirable for providing a helical or spiral flow patterns about the surface of the lens and the second end of the flexible tip. Although only a single pathway **62** is depicted in FIG. **11**, additional pathways may be incorporated with similar or dissimilar orientations without deviating from the present inventive concepts described herein.

[0080] The outer diameter of the stylet **52** and flexible tip **56** of the intubating scope **44** may be of varying degrees to satisfy a particular application of the intubating scope **44**. For

instance, if the intubating scope **44** is used in conjunction with an ETT **4**, the outer diameter of the intubating scope **44** must be smaller than the inner diameter of the lumen **32** of the ETT **4**. However, if the intubating scope **44** is used independent of the ETT **4**, then the outer diameter of the intubating scope **44** can be any size appropriate to be placed into the cavity (i.e. larynx) of a particular patient. An initial range is contemplated to be 4.0 mm-6.5 mm. More specifically, a more preferred range is contemplated to be 4.5 mm-6.0 mm. Finally, the preferred range is 5.5 mm-6.0 mm. These ranges may vary for different applications other than insertion via the larynx, depending on the cavity or orifice of the patient.

[0081] Further, the length of the stylet **52** and flexible tip **56** can be of almost any dimension to suit a particular application of the intubating scope **44**. In general, the cope may be larger for a larger patient, or smaller for a smaller patient. For instance, an average adult male will likely require a longer stylet **52** and flexible tip **56** than will an infant child for an effective orotracheal intubation. However, if the intubating scope **44** is to be used in conjunction with an ETT **4**, the length of the stylet **52** and flexible tip **56** should not be much shorter than the length of the ETT **4** to allow the lens to effectively receive images during intubation. An initial range of the length of the stylet and flexible tip is 30.0 cm-53.0 cm. An intermediate range is contemplated as 35.0 cm-45.0 cm. Finally, a preferred range is from 38.0 cm-40.0 cm. Further, while the above ranges include both the stylet **52** and the flexible tip **56**, the flexible tip **56** alone is preferably from 3.5 cm-4.5 cm in length, as shown in FIG. **2** as length L, although may be of shorter or longer lengths to accommodate the specific application. For example, certain borescope applications may require a length in excess of 53 cm, including up to 100 cm.

[0082] Additionally, the outer and inner diameters of the ETT **4** can be of almost any dimension to accommodate a particular patient. For instance, the inner diameter of the lumen **32** of the ETT **4** must be larger than the outer diameter of the stylet **52** and flexible tip **56** of the intubating scope **44**. Additionally, the outer diameter of the ETT **4** might need to be larger or smaller depending upon the size of the airway in the patient. According to one embodiment of the present invention, the inner diameter measures within the range of 4.5 mm-10.0 mm. More preferably, the range of the inner diameter is within 5.5 mm-9.0 mm. Finally, the preferred range of the inner diameter is contemplated to be 6.5 mm-7.5 mm. The range of the outer diameter is contemplated to be 6.5 mm-15.0 mm. More preferably, the range of the outer diameter is within 8.0 mm-12.0 mm. Finally, the preferred range of the outer diameter is contemplated to be 9.5 mm-10.5 mm.

[0083] Further, the length of the ETT **4** can be of almost any dimension to allow effective oxygen flow from the mouth to the lungs of a particular patient. For instance, an average adult male will likely require a longer ETT **4** than will an infant child for an effective orotracheal intubation. An initial range of the length of the ETT **4** is 25.0 cm-45.0 cm. An intermediate range is contemplated as between 28.0 cm-38.0 cm. Finally, a preferred range is from 31.0 cm-33.0 cm.

[0084] The preferred oxygen flow rate into the inlet **60** of the stylet **52** is 5.0 L/min-10.0 L/min to allow for effective oxygen flow from the outlets near the second end **74** of the flexible tip **56**. However, those of ordinary skill in the art will appreciate other flow rates outside of this stated range may be appropriate in specific situations.

[0085] The foregoing discussion of the invention has been presented for purposes of illustration and description. The foregoing is not intended to limit the invention to the form or forms disclosed herein. In the foregoing Detailed Description for example, various features of the invention are grouped together in one or more embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed invention requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the following claims are hereby incorporated into this Detailed Description, with each claim standing on its own as a separate preferred embodiment of the invention.

[0086] As used herein, "at least one," "one or more," and "and/or" are open-ended expressions that are both conjunctive and disjunctive in operation. For example, each of the expressions "at least one of A, B and C," "at least one of A, B, or C," "one or more of A, B, and C," "one or more of A, B, or C" and "A, B, and/or C" means A alone, B alone, C alone, A and B together, A and C together, B and C together, or A, B and C together. Although certain combinations or subcombinations have been described in discrete paragraphs, it is to be expressly understood that any multiple combination of the components may be provided as reflected in the following claims.

[0087] The present invention, in various embodiments, includes components, methods, processes, systems and/or apparatus substantially as depicted and described herein, including various embodiments, subcombinations, and subsets thereof. Those of skill in the art will understand how to make and use the present invention after understanding the present disclosure. The present invention, in various embodiments, includes providing devices and processes in the absence of items not depicted and/or described herein or in various embodiments hereof, including in the absence of such items as may have been used in previous devices or processes, e.g., for improving performance, achieving ease and\or reducing cost of implementation.

[0088] The present disclosure, although relying on the description of a scope for intubating, is expressly intended to include scopes for other applications as well. For example, a Videoscope or Video Borescope is another type of scope that may include a small CCD chip embedded into the tip of the scope. The video image is relayed from the distal tip and focusable lens assembly back to the display via internal wiring. Alternatively, a traditional Borescopes relies on optical relay components to transfer the image from the tip to an eyepiece, and Fiberscopes use coherent image fiberoptics to relay the image to an eyepiece. These systems normally provide the ability to capture the images and to record those images via either live video or still photos.

What is claimed is:

1. A flexible tip for use with a scope, the flexible tip comprising:

a first end and a second end;

an outer layer and an inner layer extending longitudinally from the first end to the second end;

a lumen located within the inner layer and extending longitudinally from the first end to the second end;

the flexible tip further comprising at least four pathways exterior to the lumen located within the inner layer, each of the at least four pathways positioned in a first concen-

tric arrangement about and proximate to an outer circumference of the lumen and terminating proximate to at least one exterior surface of the outer layer for distributing fluid or gas from the first end of the flexible tip to the at least one outlet.

2. The flexible tip of claim **1**, further comprising a scope, a module for manipulating the scope, the module including an illumination source, an image sensor, a power source, and an elongated stylet including first and second ends and at least one inner lumen therein, the first end of the stylet connected to the module and the second end of the stylet connected to the first end of the flexible tip.

3. The flexible tip of claim **2**, further comprising articulation wires extending longitudinally through the flexible tip and accessible from the module to manipulate the direction of the flexible tip with respect to the longitudinal axis of the flexible tip.

4. The flexible tip of claim **1**, wherein the at least four pathways are oriented to distribute fluid or gas in both a direction substantially parallel to the longitudinal axis of the flexible tip and substantially tangential to the longitudinal axis of the flexible tip.

5. The flexible tip of claim **1**, wherein the at least four pathways are positioned in a substantially helical or spiral direction about the lumen and terminate at the second end and at an outer circumference of the outer layer of the flexible tip.

6. The flexible tip of claim **1**, wherein the at least four pathways terminate about an outer circumference of the flexible tip for ejecting a gas, liquid, fluid or other substance at a direction substantially tangential to the longitudinal axis of the flexible stylet.

7. The flexible tip of claim **2**, further comprising a display for viewing the images via the lens and the at least one second fiber for receiving images.

8. The flexible tip of claim **7**, wherein the display is selected from the group consisting of a LCD monitor, a plasma monitor, a thin film display monitor, and a high definition monitor.

9. The flexible tip of claim **2** wherein the scope is selected from the group consisting of a borescope, a colonoscope, an intubation scope, a neurosurgical scope, and a fiberscope.

10. A scope comprising:

a module having a least an illumination source, an image sensor, and a power source:

an elongated stylet having a first length with first and second ends and at least one centrally positioned inner lumen therein, the first end of the first length of the stylet proximate to the module, the first length of the elongated stylet having at least one pathway exterior to the at least one centrally positioned inner lumen;

the at least one centrally positioned inner lumen further comprising a first concentric arrangement, within the at least one inner lumen of the first length comprising at least one first fiber for illumination and at least one second fiber for receiving images;

the elongated stylet having a second length with first and second ends, the first end of the second length of the elongated stylet connected to the second end of the first length of the elongated stylet, the second end of the second length comprising a lens coupled to the at least one second fiber for receiving images, the second length of the elongated stylet having at least one centrally positioned inner lumen in communication with the at least one centrally positioned inner lumen of the first length of the elongated stylet;

the second length of the elongated stylet further comprising at least four pathways exterior to the at least one centrally positioned inner lumen of the second length of the elongated stylet, each of said at least four pathways positioned in a second concentric arrangement about and proximate to an outer circumference of the at least one centrally positioned inner lumen of the second length and terminating proximate to at least one exterior surface of the second length of the elongated stylet for distributing a gas, liquid, fluid or other substance supplied from the module through the at least one pathway of the first length and the at least four pathways of the second length.

11. The scope of claim **10**, further comprising a display coupled to the module and in communication with the lens via the imaging fibers for viewing images proximate to the second end of the second length of the elongated stylet.

12. The scope of claim **10**, further comprising articulation wires extending longitudinally through the first and second lengths of the elongated stylet, the articulation wires coupled to a lever for manipulating the direction and/or orientation of the second end of the second length of the elongated stylet.

13. The scope of claim **10** wherein the at least four pathways terminate about an outer circumference of the second length of the elongated stylet for ejecting a gas, liquid, fluid or other substance at a direction tangential to the longitudinal axis of the second length of the elongated stylet.

14. A scope comprising:

a module having a least an illumination source, an image sensor, and a power source:

an elongated stylet having a first length with first and second ends and at least one centrally positioned inner lumen therein, the first end of the first length of the stylet proximate to the module, the first length of the elongated stylet having at least one pathway exterior to the at least one centrally positioned inner lumen;

the at least one centrally positioned inner lumen further comprising a first concentric arrangement, within the at least one inner lumen of the first length comprising at least one first fiber for illumination and at least one second fiber for receiving images;

the elongated stylet having a second length with first and second ends, the first end of the second length of the elongated stylet connected to the second end of the first length of the elongated stylet, the second end of the second length comprising a lens coupled to the at least one second fiber for receiving images, the second length of the elongated stylet having at least one centrally positioned inner lumen in communication with the at least one centrally positioned inner lumen of the first length of the elongated stylet;

the second length of the elongated stylet further comprising at least four pathways exterior to the at least one centrally positioned inner lumen of the second length of the elongated stylet, each of said at least four pathways positioned in a second concentric arrangement about and proximate to an outer circumference of the at least one centrally positioned inner lumen of the second length and terminating proximate to at least one exterior surface of the second length of the elongated stylet for distributing a gas, liquid, fluid or other substance supplied from the module through the at least one pathway of the first length and the at least four pathways of the second length;

a display coupled to the module and in communication with the lens via the imaging fibers for viewing images proximate to the second end of the second length of the elongated stylet;

articulation wires extending longitudinally through the first and second lengths of the elongated stylet, the articulation wires coupled to a lever for manipulating the direction and/or orientation of the second end of the second length of the elongated stylet;

wherein the at least four pathways terminate about an outer circumference of the second length of the elongated stylet for ejecting a gas, liquid, fluid or other substance at a direction tangential to the longitudinal axis of the second length of the elongated stylet.

15. The scope of claim **14** wherein the scope is adapted to be used with an endotracheal tube during orotracheal intubation.

16. The scope of claim **14** wherein the scope is selected from the group consisting of a borescope, a colono scope, an intubation scope, a neuro surgical scope, and a fiberscope.

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专利名称(译)	管理困难途径的范围和提高其可见性的方法		
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摘要(译)

公开了一种适于在困难路径中插入，操纵和改善可视性的示波器。该范围包括至少一个用于操纵范围的模块。示波器还可包括照明源，图像传感器，电源和用于观察患者的腔或其他解剖构件的图像的观察构件。该范围可以进一步包括用于空气或流体流动以离开远侧末端的替代路径，以便最小化创伤并提高可视性。在一个实施例中，该范围旨在便于插入插管装置，该插管装置包括细长的半刚性探针，该探针包括第一和第二端以及连接到模块的至少一个内腔。另外，提供柔性尖端用于操纵示波器的一端并且在操纵困难路径时允许更大的灵活性。还公开了一种用于导航困难路径的方法。