Title: TRACHEAL INTUBATION DEVICE

Abstract: A device for tracheal intubation is provided which includes an endotracheal tube, and a detachable inflatable sleeve fixed to an end of the tube, the inflatable sleeve having an array of magnetic field-responsive members disposed on an inner surface thereof. The device also includes a hand-held magnet which is used to attract the inflatable sleeve, thereby permitting manipulation of the position of the end of the tube. By direction of the hand-held magnet in the vicinity of the end of the tube, the tracheal intubation device permits placement of an endotracheal tube in the trachea without the necessity of direct visualization, hence providing a novel approach to resolving difficult intubations.
TRACHEAL INTUBATION DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS
This application claims the benefit of the priority of U.S. Provisional Application 61/175,575, filed May 5, 2009, the contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Field of the Invention
[001] The present invention relates generally to devices for the endotracheal intubation of an animal. More particularly, it relates to a device for guiding the placement of an endotracheal tube during the intubation of a human.

Description of the Background Art

[002] Tracheal intubation refers to the placement of a flexible tube (an endotracheal tube) into the trachea of the body to protect the patient's airway and provide a means of mechanical ventilation. The most common tracheal intubation is orotracheal intubation where, with the assistance of a laryngoscope, the endotracheal tube is passed through the mouth, larynx, and vocal cords, into the trachea. However, proper intubation is difficult to achieve due to the complex anatomical arrangement in which the pharynx splits anteriorly into the trachea and posteriorly into esophagus, and due to the fact that the endotracheal tube tends to travel posteriorly toward the esophagus during insertion. Thus, orotracheal intubation using conventional methods and devices requires extensive training and experience to be performed successfully, and is typically performed by otolaryngologists or anesthesiologists.

[003] During conventional orotracheal intubation, a laryngoscope is inserted into the mouth and used to position the lower jaw so as to obtain a view of the vocal folds and the glottis, which is the space between the vocal cords. Once these structures are visualized, the endotracheal tube is threaded through the glottis and into the trachea. However, under certain circumstances, such as
traumatic injury to the cervical spine or suspected injury to the cervical spine, movement of the patient or the patient's head, neck or lower jaw is contraindicated. In other circumstances the neck may not be able to be manipulated at all, due to patient conditions such as rheumatoid arthritis or ankylosing spondylitis. In addition, patients presenting with preexisting abnormalities, such as, but not limited to, anatomical abnormalities of the neck or jaw; abnormally large tongue; anatomical abnormalities of the lips or palate; arthritic cervical spine or temporomandibular joint; inelastic scar tissue of the face, neck or mouth; burns of the face, mouth, or throat; tumors or inflammation of the pharynx, larynx, trachea, esophagus, tonsils, uvula, retropharyngeal space, or vocal chords; crush injuries to the larynx; jaw fractures; facial fractures; thyroid disease; spatial deviation of the epiglottis, vocal cords or trachea from the midline of the body; microglossia; foreign body in the airway; caustic injections; and allergic reactions, make visualization of the key anatomical structures difficult or impossible, resulting in challenges to achieving tracheal intubation.

**SUMMARY**

[004] A device for tracheal intubation is provided which includes an endotracheal tube, and a detachable inflatable sleeve fixed to an end of the tube. The detachable inflatable sleeve includes an array of magnetic field-responsive members disposed on an inner surface thereof. The device also includes a hand-held magnet which is used to attract the inflatable sleeve, thereby permitting manipulation of the position of the end of the tube. By direction of the hand-held magnet in the vicinity of the end of the tube, the tracheal intubation device permits placement of an endotracheal tube in the trachea without the necessity of direct visualization, hence providing a novel approach to resolving difficult intubations.

[005] In some aspects, a tracheal intubation device for placement of an elongate flexible tube into the trachea is provided. The device includes the elongate flexible tube, an inflatable member fixed to an end of the tube, and a magnetic field-responsive member disposed on the inflatable member.
[006] The device may include one or more of the following features: The magnetic field-responsive member is disposed on an interior surface of the inflatable member. The magnetic field-responsive member is embedded in a wall of the inflatable member. The magnetic field-responsive member includes an array of magnetic field-responsive members. The array is arranged so that when the inflatable member is inflated, a periphery of the array defines a diamond shape. The array is arranged so that when the inflatable member is deflated, a periphery of the array defines a line. The inflatable member includes a pressure sensor. The intubation device further includes a remote magnet configured to provide a magnetic field when the guide is placed in the vicinity of the end of the tube. The inflatable member is attached to an outer surface of the tube. The inflatable member is detachable from the end of the tube. The tube is pre-formed to curve along its longitudinal axis, and the magnetic field-responsive member is disposed on a portion of the inflatable member that corresponds to a concave part of the tube. The inflatable member expands asymmetrically with respect to a diameter of the tube. The inflatable member is transparent.

[007] In some aspects, a method of intubating an airway of an animal is provided. The method includes the following method steps: Providing an intubation device, the device including an elongate flexible tube with an inflatable member fixed to an end of the tube, a magnetic field-responsive member disposed on a side of the inflatable member, and a guide magnet. Inserting the end of the tube into the animal’s oropharynx. Inflating the inflatable member when the end of the tube is disposed in a posterior portion of the oropharynx. Placing the guide magnet on an external anterior surface of the animal’s throat to attract the magnetic field-responsive member, whereby the inflatable member and tube are drawn to an anterior portion of the trachea. Deflating the inflatable member. Moving the guide magnet along the throat in an inferior direction with respect to the mouth whereby the tube is drawn into the trachea through the attractive forces between the magnetic field-responsive member and the guide magnet.

[008] The method may further include one or more of the following steps:
Performing the step of inflating the inflatable member when the end of the tube is disposed in a posterior portion of the oropharynx at a location corresponding to the animal’s epiglottis. Using the guide magnet to guide the inflatable member and tube through the vocal cords to a location inferior to the vocal cords. Removing the inflatable member from the trachea while leaving the tube within the trachea.

[009] In some aspects, an intubation kit is provided which includes at least one inflatable sleeve configured to detachably connect to an endotracheal tube, the at least one inflatable sleeve having one or more magnetic field-responsive members disposed thereon, and a guide magnet. The intubation kit may further include at least one endotracheal tube.

[010] In some aspects, an inflatable member is provided which includes an elongate tubular body portion, a gas supply tube connected to an end of the body portion and configured to supply gas to an interior space of the body portion, and a magnetic field-responsive member disposed on the body portion.

[011] The inflatable member may include one or more of the following features: An inner diameter of the body portion is sized to fit on an exterior surface of an endotracheal tube. The elongate tubular body comprises a generally cylindrical inner compartment, and a generally cylindrical outer compartment surrounding the inner compartment, the inner and outer compartments being individually inflatable. The magnetic field responsive member is disposed on an inner surface of an outer wall of the outer compartment.

[012] Among other advantages, the inventive tracheal intubation device permits placement of an endotracheal tube in trachea without the necessity of direct visualization, hence providing a novel approach to resolving difficult intubations.

[013] Moreover, the method described here to provide tracheal intubation can
be extended to provide one lung ventilation, also achieved without direct visualization.

[014] As a further advantage, the tracheal intubation device can be used to easily achieve tracheal intubation regardless of variations in anatomy and medical condition. The device can be used for all intubations, regardless of patient age or physical condition. Moreover, since it can be done without visualization, it is much easier to achieve intubation using the device than by conventional intubation devices and methods. The simplicity of the method of using the device makes it very easy to be used by anyone with minimum base of medical knowledge. Thus the intubation device can be used by non-specialist physicians and even physician extender personnel, such as physician assistants and respiratory therapists.

[015] Modes for carrying out the present invention are explained below by reference to an embodiment of the present invention shown in the attached drawings. The above-mentioned object, other objects, characteristics and advantages of the present invention will become apparent from the detailed description of the embodiment of the invention presented below in conjunction with the attached drawings.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[016] Fig. 1 is a perspective view of an inflated tracheal intubation device.

[017] Fig. 2 is a perspective view of an inflated guide sleeve of the tracheal intubation device of Fig. 1.

[018] Fig. 3 is a view of the end of the tracheal intubation device of Fig. 1 as seen in the direction of arrow A of Fig. 1.

[019] Fig. 4 is a sectional view of the tracheal intubation device as seen along line 4—4 of Fig. 3.

[020] Fig. 5 is a cross-sectional view of another embodiment of the tracheal intubation device.

[021] Fig. 6 is a view of the end of the tracheal intubation device of Fig. 1 in an uninflated state.

[022] Fig. 7 is a cross-sectional view of the tracheal intubation device as seen
along line 7—7 of Fig. 6.

[023] Fig. 8. is a view of the end of another embodiment of the tracheal intubation device as seen in the direction of arrow A of Fig. 1.

[024] Fig. 9. is a view of the end of another embodiment of the tracheal intubation device as seen in the direction of arrow A of Fig. 1.

[025] Fig. 10 is a sectional view of the hand-held magnet.

[026] Fig. 11 is a sectional view of a patient’s head and neck illustrating introduction of the device of Fig. 1 into the oropharynx of the patient.

[027] Fig. 12 is a sectional view of a patient’s head and neck illustrating inflation first chamber of the guide sleeve.

[028] Fig. 13 is a sectional view of a patient’s head and neck illustrating providing the hand-held magnet.

[029] Fig. 14 is a sectional view of a patient’s head and neck illustrating deflation of first chamber of the guide sleeve.

[030] Fig. 15 is a sectional view of a patient’s head and neck illustrating using the hand-held magnet to position the endotracheal tube.

[031] Fig. 16 is a sectional view of a patient’s head and neck illustrating withdrawal of the guide sleeve from the patient while the endotracheal tube remains in place.

[032] Fig. 17 is a perspective view of another embodiment of an inflated tracheal intubation device.

[033] Fig. 18 is a perspective view of still another embodiment of an inflated tracheal intubation device.

**DETAILED DESCRIPTION**

[034] Referring now to Fig. 1, the tracheal intubation device 25 includes an endotracheal tube 50, a guide sleeve 100, and a hand-held magnet 180. In use, the endotracheal tube 50 is received within, and extends through, an interior of the guide sleeve 100 so that the guide sleeve 100 surrounds, and is positioned adjacent to the leading end 52, of the endotracheal tube 50. As discussed further below, the guide sleeve 100 is responsive to the magnetic field provided by the hand-held magnet 180.

[035] The endotracheal tube 50 is an oral, un-cuffed, single-lumen plastic
tube pre-formed to curve along its longitudinal axis 66. The leading (insertion) end 52 of the endotracheal tube 50 is tapered, and the trailing end 54 includes a connector 64 to permit connection of the endotracheal tube 50 to a air supply source such as an amбу bag or ventilation device (not shown). Due to its curvature, the endotracheal tube 50 includes an outer surface 56 which has a concave portion 70 extending between the leading and trailing ends 52, 54, and has a convex portion 68 that is opposed to the concave portion 70. Although not illustrated here, the endotracheal tube 50 includes a numbered scale imprinted on its outer surface 56 to permit the user to easily determine the depth of insertion of the leading end 52 of the tube 50 during intubation.

[036] The guide sleeve 100 (shown in detail in Fig. 2) is disposed on the outer surface 56 of the endotracheal tube at a location closely adjacent to (e.g. within about 1 cm of) the leading end 52 of the tube 50. The guide sleeve 100 includes a substantially transparent, inflatable member 102 having a generally cylindrically tubular shape including an outer wall 114 and an inner wall 130 extending between opposed end walls 104, 106.

[037] The guide sleeve further includes an intermediate wall 120 disposed between the outer and inner walls 114, 130 that divides the interior space into two coaxial, tubular chambers. That is, an outer chamber 118 is formed between the outer wall 114 and the intermediate wall 120, and an inner chamber 122 is formed between the intermediate wall 120 and the inner wall 130. The outer and inner chambers 118, 122 are individually controllable with respect to introduction, maintenance, and release of air therewithin. In particular, inflation and deflation of the outer chamber 118 is achieved by directing air flow within an air supply tube 108 fixed to the end wall 106 of the guide sleeve 100. Similarly, inflation and deflation of the inner chamber 122 is achieved by directing air flow within an air supply tube 108 fixed to the end wall 106 of the guide sleeve 100. Each air supply tube 108, 109 includes a bulb portion 110 which can be palpated by a user to determine the air pressure within the respective chambers 108, 112. In addition, each air supply tube includes a connector 112 for connecting to an air source, such as a
The outer chamber 118 is used in cooperation with the hand-held magnet 180 to guide the position of the leading end 52 of the endotracheal tube 50, and the inner chamber 122 is used to fix the guide sleeve 100 to the endotracheal tube 50. To this end, the guide sleeve 100 is constructed so the outer chamber 118 is holds a greater volume of air than the inner chamber 122. In addition, the guide sleeve 100 is constructed so that when air is introduced into the outer chamber 118, the outer chamber 118 expands outwardly relative to the intermediate wall 120, and when air is introduced into the inner chamber 122, the second chamber expands inwardly relative to the intermediate wall 120.

In use, the endotracheal tube 50 is received within, and extends through, an interior space 140 defined by the inner wall 130 so that the uninflated guide sleeve 100 surrounds and is positioned adjacent to the leading end 52 of the endotracheal tube 50. The guide sleeve 100 is assembled on the endotracheal tube 50 in the uninflated state. The intermediate wall 120 and inner wall 130 have an uninflated diameter that is greater than the outer diameter of the endotracheal tube 50, allowing the endotracheal tube 50 to be easily received within the interior space 140. Once the guide sleeve 100 is positioned adjacent to an end of the endotracheal tube 50, the inner chamber 122 is inflated. Air pressure within the inner chamber 122 urges the inner wall 130 radially inward until the tube-facing surface 132 of the inner wall 130 is pressed firmly against the outer surface 56 of the endotracheal tube 50. In the inflated state, the inner chamber 122 serves to fix the guide sleeve 100 to the endotracheal tube 50. Because the inner chamber 122 is inflated to accommodate the outer diameter of the endotracheal tube 50, the guide sleeve 100 can be fixed to an endotracheal tubes 50 of any outer diameter, including both pediatric and adult sized endotracheal tubes 50. In addition, the guide sleeve 100 can be easily detached from the endotracheal tube 50 by deflating the inner chamber 122.
[040] Referring also now to Fig. 4, which is a cross-sectional view of the endotracheal tube 50 and guide sleeve 100, it can be seen that the guide sleeve 100 is shaped so that when it is inflated, it is asymmetric with respect to a plane P1. The plane P1 is transverse to both the plane of the cross-section, and to a plane P2 in which the longitudinal axis 66 of the endotracheal tube 50 lies. The guide sleeve 100 is shaped so that most of the inflated volume is located on the side of the endotracheal tube 50 corresponding to its concave portion 70. When the endotracheal tube 50 is inserted into the pharynx (throat) of a patient, this portion of the guide sleeve 100 is disposed facing an anterior portion of the pharynx. The advantages of this configuration will be described below.

[041] The guide sleeve 100 further includes magnetic field-responsive material disposed within the outer chamber 118, on the outer wall 114 thereof. More specifically, an array 152 of magnetic spheres 150 are disposed on the inward-facing surface 116 of the outer wall 114. The array 152 is located on the surface 116 on a side 115 of the outer wall 114 facing the concave portion 77 of the endotracheal tube 50, that is, at a location where the plane P2 intercepts the outer wall 114. Alternatively, the array may be embedded in the outer wall 114 at this location (Fig. 5). In any case, when the guide sleeve 100 is inflated, the array 152 is spaced apart from the inner wall 130 by a distance corresponding to the sum of the thicknesses of the outer and inner chambers 118, 122.

[042] By placing the magnetic spheres 150 within the guide sleeve 100, the magnetic spheres 150 are protected from exposure to body fluids and excretions. In addition, the outer wall 114 effectively serves as cushioning buffer between the magnetic spheres 150 and the interior surfaces of the pharynx, reducing possibility of irritation or injury. Finally, such placement of the spheres 150 within the guide sleeve 100 serves as a safeguard against any possibility of detachment and loss of the magnetic spheres 150 in the patient during use.
[043] In the embodiment shown in Figs. 3-7, the inflated guide sleeve 100 includes the magnetic spheres 150 arranged such that a periphery of the array 152 defines a diamond shape, and the magnetic spheres 150 are distributed so as to spaced apart from each other within that periphery. This arrangement serves to concentrate the spheres both along a line generally corresponding to a longitudinal axis 105 of the guide sleeve 100, and also along a second line transverse to that axis. When the guide sleeve 100 is disposed on the endotracheal tube 50 inserted in the trachea, the longitudinal axis 105 of the guide sleeve 105 is generally aligned with an axis of the trachea. By distributing the magnetic spheres 150 along the line corresponding to the longitudinal axis 105, the guide sleeve 100 will be affected by a magnetic field provided on the exterior of the patient’s body along a midline of the neck. In addition, by also distributing the magnetic spheres 150 on each side of the longitudinal axis 105, the guide sleeve 100 will still be affected by a magnetic field provided on the exterior of the body along a midline of the neck even when used in patients having anatomical anomalies such as a lateral tracheal deviation.

[044] Moreover, when the guide sleeve 100 is in an uninflated state, the array 152 contracts inward so that the periphery of the array generally falls along a line that is substantially parallel to the longitudinal axis 105 of the guide sleeve 100 (Figs. 6-7). This can be accomplished either through the elastic properties of the outer wall 114, or by the folding properties of the outer wall 114.

[045] In the embodiment illustrated in Figs. 3-7, the magnetic responsive member includes one or more small spherical magnets. For example, the magnets can consist of Neodymium (also referred to as NIB or NdFeB) magnets, which are the strongest of the rare earth magnets and are permanent. The grade of neodymium magnets is generally measured in units millions of Gauss Oersted (MGOe). Generally speaking, the higher the grade, the stronger the magnet. Here, for example, each spherical magnet consist of a grade N42 Neodymium magnet, and thus has a Maximum Energy Product of 42 MGOe. Use of neodymium magnets is advantageous due to its general
durability. Specifically, if a neodymium magnet is not overheated or physically damaged, it will lose less than 1% of its strength over 10 years.

[046] In use, guide sleeve 100 is assembled to the endotracheal tube 50 and is used to guide the endotracheal tube 50 into the trachea through cooperation of the magnetic spheres 150 within the guide sleeve 100 and the hand-held magnet 180, which provides a magnetic field and is positioned externally of the patient. That is, the position of the guide sleeve 100, and thus the end of the endotracheal tube 50, is controllable through the hand-held magnet 180 due to the attraction force between the array 152 and the hand-held magnet 180.

[047] Referring to Figs. 1 and 10, the hand-held magnet 180 is a generally rectangular N42 or N52 Neodymium magnet 182 that is disposed within a pliable coating 186. The coating 186 is fixed to at least one side 188 of the magnet 182 corresponding to a pole of the magnet, and is detached from an opposed side 190 thereof. An elastic material such as a gel is disposed within the coating 186 at a location corresponding to the opposed side 190, forming a partially compressible pad 184 on the side of the magnet 182. The pad 184 is configured, for example through shape and material selection, to permit a partial compression thereof when a compressive force is applied to the hand-held magnet 180. For example, the pad 184 has a thickness $t_1$ when no compressive force is applied thereto, and when a compressive force $F$ is applied to the pad 184, such as when a user grips the hand-held magnet 180 and pushes the magnet 180 against a surface with the pad 184 disposed between the magnet 182 and the surface, the pad 184 partially compresses to a thickness of $t_2$, where $t_1 > t_2 > 0$.

[048] Because the strength of the magnetic field provided by the magnet 182 generally decreases with distance from the magnet 182, the strength of the magnetic field imposed by the user can be adjusted by changing the compression force $F$ applied to the hand-held magnet 180. For example, an adult may require a greater magnetic field to be able to affect a guide sleeve 100 disposed in the throat due to relatively larger anatomical structures. In
this case, a user can apply a larger compressive force when using the hand
held magnet 180, whereby the gel pad 184 would be compressed to be
relatively thin. In contrast, when used with a child, a relatively lesser
magnetic field is required due to the smaller anatomical structures of a child,
whereby the user would apply little or no compressive force F to the hand-held
magnet 180.

[049] The method of using the tracheal intubation device 25 will now be
described with reference to Figures 11-16.

[050] In using the intubation device 25, the patient P can be placed in any
position including a supine position. The guide sleeve 100 is assembled onto
the endotracheal tube 50 so that the side 115 is disposed on a side of the
endotracheal tube 50 corresponding to the concave portion 77, and an end 104
of the guide sleeve 100 is approximately 1 cm from the leading end 52 of the
endotracheal tube 50. The inner chamber 122 is inflated sufficiently to secure
the guide sleeve 100 to the endotracheal tube 50, while the outer chamber 118
remains uninflated. Alternatively, the endotracheal tube 50 can be provided
with the guide sleeve 100 preassembled thereon.

[051] Referring to Fig. 11, the assembled endotracheal tube 50 and guide
sleeve 100 are inserted into the oropharynx 6 of patient P, passing the
vallecula 15 and then the epiglottis 16.

[052] When the leading end 52 of the endotracheal tube 50 is positioned in
the posterior oropharynx adjacent to the epiglottis 16, advancement of the
endotracheal tube 50 is temporarily halted while outer chamber 118 of the
guide sleeve 100 is inflated (Fig. 12). By inflating the outer chamber 118, the
array 152 is caused move close to the anterior surface of the patient’s body. In
addition, the outer wall 114 of the guide sleeve 100 expands outward against
the epiglottis 16, pushing the epiglottis 16 anteriorly within the pharynx
(throat) 10, and opening the pathway into the trachea 12.

[053] Referring to Fig. 13, the hand-held magnet 180 is placed on the skin of
the patient’s neck at a location corresponding to the cricothyroid cartilage, which is an anatomical landmark associated with, and next to, the juncture of the trachea 12 and the esophagus 14. The endotracheal tube 50 remains halted to allow magnetic attraction to occur between the hand-held magnet 180 and the guide sleeve’s magnet array 152. The magnetic attraction between the hand-held magnet and the magnet array 152 results in the guide sleeve 100, and thus the leading end 52 of the endotracheal tube 50 being drawn to an anterior portion of the trachea 12.

[054] As the attraction occurs, the outer chamber 118 of the guide sleeve 100 is deflated (Fig. 14), and with the aid of the hand-held magnet 180, the leading end 52 of the endotracheal tube 50 is pulled through the trachea 12. By using the attractive force, inferiorly-directed movement (ie, relative to the mouth) of the hand-held magnet 180 is used to guide the leading end 52 of the endotracheal tube 50 through the vocal cords 18 and beyond them (Fig. 15). By this technique, no visualization of the vocal cords is needed to achieve placement of the endotracheal tube 50 in the trachea 12 and to avoid a misdirection into the esophagus 14. In addition, the numbering conventionally provided on the endotracheal tube 50 as seen outside the mouth allows the user know the exact distance of the leading end 52 from the incisive teeth or the lips. .

[055] As the hand-held magnet 180 is advanced inferiorly, the guide sleeve 100, and thus also the endotracheal tube 50, is pulled and advanced through the pharynx. For selective one lung intubation/ventilation, the endotracheal tube 50 is advanced still further inferiorly and then laterally to draw the endotracheal tube 50 into a bronchi of one lung.

[056] When the desired position of the endotracheal tube 50 has been achieved, then the hand held magnet 180 is withdrawn from the vicinity of the patient. In addition, the inner chamber 122 is deflated by opening the valve 112 and releasing the air from the inner chamber 122. Finally, since in its deflated state the guide sleeve is no longer fixed to the endotracheal tube 50, the guide sleeve is withdrawn from the trachea and out of the mouth by pulling.
gently on the air tube 108 (Fig. 16).

[057] Referring now to Fig. 17, another embodiment of the guide sleeve 200 is shown which is adapted for use with a conventional cuffed endotracheal tube 250. The guide sleeve 200 of Fig. 17 is substantially the same as the guide sleeve 100 shown in Figure 1, except that the inflatable member 202 is formed without an intermediate wall 120, whereby the inflatable member 202 has a single air chamber 218 corresponding to the outer chamber 118. In this embodiment, inflation of the cuff 260 of the endotracheal tube 250 is used to secure the guide sleeve 200 to the endotracheal tube 250.

[058] When the guide sleeve 200 is used with the cuffed endotracheal tube 250, the tube-facing surface of the guide sleeve 200 may be formed having a property which provides a relatively high coefficient of friction so as to reduce likelihood of slippage of the guide sleeve 200 relative to the endotracheal tube 250.

[059] Referring now to Fig. 18, another embodiment of the device is shown. In this embodiment, a single lumen, cuffed endotracheal tube 350 is provided in which magnetic field responsive material is disposed within the inflatable cuff 360 of the endotracheal tube 350, whereby a guide sleeve is not required. More specifically, magnetic spheres 150 are disposed on an inner surface of, or embedded within, the cuff wall 365.

[060] The description above includes one possible configuration for deploying magnets within the guide sleeve 100. However, there are other alternatives to employing an array of spherical magnets as the magnetic-field responsive material. The magnetic field-responsive material may include magnets having a shape other than spherical, including but not limited to ovoid (not shown), rectangular (not shown) or disk-shaped (not shown). The magnetic field responsive material may be a ferric metal rather than a magnet. The magnetic field-responsive material may be in the form of a single thin sheet or filament. The array or thin sheet of magnetic responsive material may have a peripheral shape that is a diamond, oval (Fig. 9), or cross having a long
axis thereof aligned with the longitudinal axis of the guide sleeve 100. The filament may be arranged in the form of a serpentine or spiral (Fig. 8). The thin sheet or filament may be fixed to the inward facing surface 116 of the outer wall 114, or alternatively may be embedded within the outer wall 114.

[061] The device 25 is disclosed herein with respect to a single lumen endotracheal tube 50. However, a double lumen endotracheal tube could also be used.

[062] While the device 25 has been described herein and is particularly suitable for the endotracheal intubation of a human patient, it may also be adapted and used in the intubation of nonhuman subjects, such as in veterinary medical practice.

[063] The device and method described herein provide the following advantages:

a. Use of a magnetic field generated externally of a patient by a hand-held magnet 180, in cooperation with magnetic field responsive members 150 mounted to an endotracheal tube 50 in the pharynx of a patient, to guide the position of the end of the endotracheal tube without the need for direct visualization of the patient anatomy.

b. Use of an inflatable guide sleeve 100 to bring the magnetic field responsive members 150 closer to the hand held magnet 180, facilitating the attraction between the hand held magnet and the guide sleeve 100.

c. Placement of the magnetic field responsive members 150 inside the outer layer of the guide sleeve 100, protecting them from the oropharyngeal secretions and the obstacles in the pharynx, and preventing them from falling into the trachea.

d. Use of an inflatable hollow cylinder (guide sleeve 100) detachably connected to an external surface of the endotracheal tube 50. The guide sleeve 100 is external to the endotracheal tube 50 and thus serves as an external guide for the
endotracheal intubation, providing better manipulation and guidance of the endotracheal tube 50. The external placement of the guide sleeve 100 permits the unimpeded use of the internal airway of the endotracheal tube 50. Moreover, when deflated, the guide sleeve 100 occupies very little space which permits the introduction of the endotracheal tube 50 to the trachea. When deflated, it also can be easily detached from the endotracheal tube 50 and retrieved.

[064] A selected illustrative embodiment of the invention is described above in some detail. It should be understood that only structures considered necessary for clarifying the present invention have been described herein. Other conventional structures, and those of ancillary and auxiliary components of the system, are assumed to be known and understood by those skilled in the art. Moreover, while a working example of the present invention has been described above, the present invention is not limited to the working example described above, but various design alterations may be carried out without departing from the present invention as set forth in the claims.
What is claimed is,

1. A tracheal intubation device for placement of an elongate flexible tube into the trachea, the device comprising:
   the elongate flexible tube,
   an inflatable member fixed to an end of the tube; and
   a magnetic field-responsive member disposed on the inflatable member.

2. The tracheal intubation device of claim 1, wherein the magnetic field-responsive member is disposed on an interior surface of the inflatable member.

3. The tracheal intubation device of claim 1, wherein the magnetic field-responsive member is embedded in a wall of the inflatable member.

4. The tracheal intubation device of claim 1, wherein the magnetic field-responsive member includes an array of magnetic field-responsive members.

5. The tracheal intubation device of claim 4, wherein the array is arranged so that when the inflatable member is inflated, a periphery of the array defines a diamond shape.

6. The tracheal intubation device of claim 4, wherein the array is arranged so that when the inflatable member is deflated, a periphery of the array defines a line.

7. The tracheal intubation device of claim 1, wherein the inflatable member includes a pressure sensor.

8. The tracheal intubation device of claim 1, wherein the intubation device further includes a remote magnet configured to provide a magnetic field when the guide is placed in the vicinity of the end of the tube.
9. The tracheal intubation device of claim 1, wherein the inflatable member is attached to an outer surface of the tube.

10. The tracheal intubation device of claim 1, wherein the inflatable member is detachable from the end of the tube.

11. The tracheal intubation device of claim 1, wherein the tube is pre-formed to curve along its longitudinal axis, and the magnetic field-responsive member is disposed on a portion of the inflatable member that corresponds to a concave part of the tube.

12. The tracheal intubation device of claim 1, wherein the inflatable member expands asymmetrically with respect to a diameter of the tube.

13. The tracheal intubation device of claim 1, wherein the inflatable member is transparent.

14. A method of intubating an airway of an animal, the method comprising the following method steps:

    providing an intubation device, the device including
    an elongate flexible tube,
    an inflatable member fixed to an end of the tube;
    a magnetic field-responsive member disposed on a side of the inflatable member; and
    a guide magnet,

    inserting the end of the tube into the animal’s oropharynx,
    inflating the inflatable member when the end of the tube is disposed in a posterior portion of the oropharynx,
    placing the guide magnet on an external anterior surface of the animal’s throat to attract the magnetic field-responsive member, whereby the inflatable member and tube are drawn to an anterior portion of the trachea,
    deflating the inflatable member; and
    moving the guide magnet along the throat in an inferior direction with respect to the mouth whereby the tube is drawn into the trachea through the
attractive forces between the magnetic field-responsive member and the guide magnet.

15. The method of claim 14, further including performing the step of inflating the inflatable member when the end of the tube is disposed in a posterior portion of the oropharynx at a location corresponding to the animal's epiglottis.

16. The method of claim 14, further including using the guide magnet to guide the inflatable member and tube through the vocal cords to a location inferior to the vocal cords.

17. The method of claim 14, further including the method step of removing the inflatable member from the trachea while leaving the tube within the trachea.

18. An intubation kit comprising:
   at least one inflatable sleeve configured to detachably connect to an endotracheal tube, the at least one inflatable sleeve having one or more magnetic field-responsive members disposed thereon; and
   a guide magnet.

19. The intubation kit of claim 18, further comprising at least one endotracheal tube.

20. An inflatable member comprising:
   an elongate tubular body portion;
   a gas supply tube connected to an end of the body portion and configured to supply gas to an interior space of the body portion; and
   a magnetic field-responsive member disposed on the body portion.
21. The inflatable member of claim 20 wherein an inner diameter of the body portion is sized to fit on an exterior surface of an endotracheal tube.

22. The inflatable member of claim 20 wherein the elongate tubular body comprises a generally cylindrical inner compartment, and a generally cylindrical outer compartment surrounding the inner compartment, the inner and outer compartments being individually inflatable.

23. The inflatable member of claim 22 wherein the magnetic field responsive member is disposed on an inner surface of an outer wall of the outer compartment.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
   IPC(8) - A61M 25/10 (2010.01)
   USPC - 128/207.14
   According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
   Minimum documentation searched (classification system followed by classification symbols)
   IPC(8) - A61M 16/04, 25/01, 25/10 (2010.01)
   USPC - 128/200.26, 207.14-207.15; 600/12, 585

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

   Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
   USPTO EAST System (US, USPG-PUB, EPO, DERWENT), MicroPatent, IP.com, DialogPro

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 4,063,581 A (MCKENNA) 20 December 1977 (20.12.1977) entire document</td>
<td>1-6, 8-9, 20-21</td>
</tr>
<tr>
<td></td>
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<td>7, 10-19, 22-23</td>
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Further documents are listed in the continuation of Box C.

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Date of the actual completion of the international search
14 June 2010

Date of mailing of the international search report
28 JUN 2010

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