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(71) Applicant *(for all designated States except US)*: **MONDO MEDICAL DEVICES PTY LTD** [AU/AU]; 03 Pivotal Building, Suite 2, 50 Marine Parade, Southport, Queensland 4215 (AU).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **MILLS, Karl Adrian** [AU/AU]; Unit 3, 62-64 Edward Street, Alexandra Headland, QLD 4572 (AU).

(74) Agents: **DAVIES COLLISON CAVE** et al.; Level 10, 301 Coronation Drive, Milton, QLD 4064 (AU).

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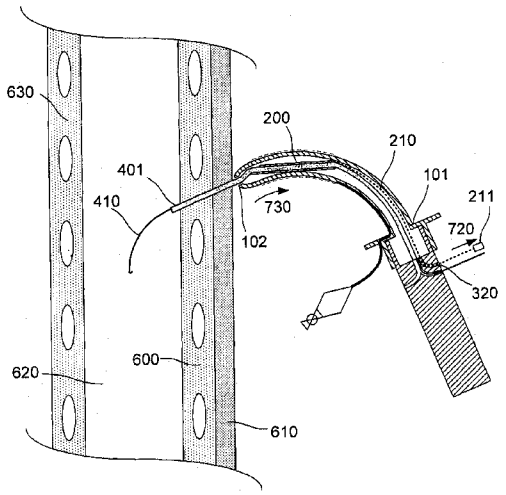

Fig. 4C

(57) Abstract: The present invention provides a device for providing an airway through a tracheal wall of a subject. The device includes a tracheal tube having an airway running from a proximal end to a distal end, a hollow needle detachably coupled to the distal end of the tracheal tube and a handle detachably connected to the proximal end of the tracheal tube. The needle is for insertion through the tracheal wall and is moveable from an extended position in which at least part of the needle extends from the distal end of the tracheal tube to a retracted position. The handle is detachably connected to the proximal end of the tracheal tube, wherein detachment of the handle from the tracheal tube allows at least the needle to be extracted from the tracheal tube, thereby allowing the tracheal tube to provide an airway through the tracheal wall.

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DEVICE AND METHOD FOR PROVIDING AN AIRWAY

Background of the Invention

The present invention relates to a device and method for providing an airway through a tracheal wall of a subject, and in particular to a device and method suitable for performing a percutaneous cricothyrotomy or percutaneous tracheostomy procedure.

Description of the Prior Art

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that the prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

Cricothyrotomy and tracheostomy procedures are surgical procedures to open an airway through a subject's cricothyroid membrane or trachea, respectively. Such procedures are used in situations when the subject's airway is obstructed or the subject is otherwise unable to breathe through their mouth or nasal passages, and are often required in emergency settings to prevent asphyxiation of the subject in those situations.

Early tracheostomy procedures were invasive and required relatively large incisions through the tracheal wall to provide a sufficiently sized opening to allow a tracheostomy tube to be inserted. Percutaneous techniques have since been developed, which require only a single small incision or needle puncture through the subject's skin and tracheal wall, and these techniques generally help to reduce trauma and post-operative complications to the subject.

Commonly used percutaneous techniques typically involve the initial use of a syringe with a needle to provide a hole through the tracheal wall. After the hole is provided, separate apparatus is typically used to prepare the hole for the eventual insertion of a tracheostomy tube which will provide the airway through the tracheal wall. Numerous separate pieces of equipment may be used in such procedures, such as guide wires, cannulas and dilators. Dilating equipment can vary from tapered dilators, for gradually dilating the hole as they are

inserted, to specially designed forceps, which can be guided into the hole and opened when in place to dilate the hole.

The use of separate pieces of medical equipment makes the procedures relatively complicated and time consuming. Furthermore, the procedures typically require a medical professional with considerable skill to operate the different pieces of equipment when performing the procedure. This can be particularly problematic in the emergency settings where such procedures are often required, as delays waiting for the attention of appropriately skilled personnel could potentially result in the loss of a life.

US-4,978,334 discloses an apparatus and method for providing a percutaneous or non-dissection passage into a body cavity or hollow viscus. A needle is attached to a syringe for insertion within the body cavity. Operation of the syringe confirms proper location of the needle within the body cavity. The needle is coaxially fitted within a dilator which is coaxially fitted within a tube. A leader portion of the dilator follows the insertion path defined by the needle to dilate the tissues for entry of the larger portions of the dilator and the tube. The needle and dilator can be slidably withdrawn to leave the tube in position. Various dilator leader structures are disclosed.

US-5,217,005 discloses a percutaneous device for performing tracheostomies or cricothyroidectomies having a hollow needle with a sharp distal end. The device includes a flexible dilator slidably positioned over the needle. The dilator includes a conical portion and an annular groove, the apex of which is positioned adjacent the distal end of the needle and the base thereby terminating at the annular groove. A flexible breathing tube is slidably positioned over the dilator for insertion into a trachea or larynx.

US-6,109,264 discloses a surgical apparatus for manipulating body tissue including a hollow needle, a bulb connected to the needle for aspirating air through an end of the needle, a flexible guide wire extending through the needle, a fitting on one end of the guide wire for permitting the guide wire to be reciprocated with the same hand that holds the instrument, from a retracted position substantially within the needle, to an extended position in which a substantial length of the guide wire extends beyond an end of the needle, an expandable dilator attached to the dilation tip for dilating a tracheal wall when the dilator is inflated, and

a tracheostomy tube detachably mounted with respect to the dilator for placement into a lumen of a trachea.

US-6,706,017 discloses an ostomy device and method for creating a stoma and implanting a canula. The ostomy device includes an elongate needle having a sharpened tip for percutaneous entry of a body forming a stoma. The needle includes a plurality of channels extending axially through the needle, and each of the plurality of channels having a distal end adjacent the needle tip. The channels permit the monitoring of the needle tip to assist in properly locating the needle within the body. A dilation device is disposed about the distal end of the needle and is insertable within the stoma. The dilation device includes a radially expandable surface to dilate the stoma for atraumatic receipt of a canula. The dilation device may include a primary dilator for dilating the stoma a first degree and a secondary dilator for dilating the stoma a second degree such that cannula may be atraumatically implanted.

US-7,036,510 discloses an apparatus and method for performing a percutaneous tracheostomy procedure utilizing dilatation means that do not require entry into the trachea by downward pressure, in order to minimize the risk of posterior tracheal trauma. In addition, the apparatus is structured to facilitate entry of the tracheostomy tube into the dilated entry site without permitting any significant shrinkage or reduction in diameter of the dilated opening.

US-7,341,061 discloses a tracheostomy system including an outer multi-layered tube, which can be expanded or allowed to contract as necessary in order to receive various sizes of cannula tubes. A dilator is used to initially insert the outer tracheostomy tube into the tracheostoma. After the initial installation dilator is removed, various sizes of dilators having a cannula mounted about them can be inserted into the outer tracheostomy tube. The multilayered tube will then expand in response to insertion of the various sizes of dilator cannula assembly being placed. When the dilator is removed the cannula tube will remain in place to maintain the desired diameter tracheostomy tube. This provides a means in which the diameter of the tube can be changed without having to actually remove and reinsert a different tube.

Summary of the Present Invention

In a first broad form the present invention seeks to provide a device for providing an airway through a tracheal wall of a subject, the device including:

a) A tracheal tube having an airway running from a proximal end to a distal end;

b) A hollow needle detachably coupled to the distal end of the tracheal tube, the needle being for insertion through the tracheal wall and being moveable from an extended position in which at least part of the needle extends from the distal end of the tracheal tube to a retracted position;

c) A handle detachably connected to the proximal end of the tracheal tube, wherein detachment of the handle from the tracheal tube allows at least the needle to be extracted from the tracheal tube, thereby allowing the tracheal tube to provide an airway through the tracheal wall.

Typically the device is configured to allow aspiration.

Typically the device includes a guide configured to extend from the distal end of the tracheal tube, thus allowing insertion of the tracheal tube through the tracheal wall to be guided by the guide.

Typically the guide passes along at least part of the airway and at least part of the needle

Typically the guide includes at least one of the following:

a) A guide wire;

b) A resilient cord; and,

c) A cannula.

Typically the guide includes a cannula having a longitudinal guide wire bore configured to allow passage of a guide wire therethrough and a longitudinal aspirate bore for allowing aspiration therethrough.

Typically the handle includes:

a) An aspirate aperture for allowing air communication between the aspirate bore of the cannula and air outside of the handle; and

b) A guide wire aperture for allowing the guide wire to pass from the guide wire bore to outside the handle.

Typically a length of the guide wire extends from the guide wire aperture, such that movement of the length of the guide wire allows a user to control an amount of the guide wire that extends from the distal end of the tracheal tube.

Typically a tip of the guide wire is configured to substantially prevent trauma to the subject during insertion.

Typically the tip of the guide wire is at least one of the following:

a) Curved;

b) Blunt;

c) Capped with a rounded end piece.

Typically the device includes a retractor wire for retracting the needle.

Typically the retractor wire is attached to the needle at a first end and passes through at least part of the tracheal tube.

Typically the handle includes a retractor aperture for allowing the retractor wire to pass from the tracheal tube to outside the handle.

Typically a length of the retractor wire extends from the retractor wire aperture, such that movement of the length of the retractor wire allows a user to control the movement of the needle from the extended position to the retracted position.

Typically the tracheal tube includes a dilator at the distal end, the dilator being for dilating a hole through the tracheal wall formed by insertion of the needle to allow insertion of the tracheal tube through the dilated hole.

Typically the tracheal tube includes a flange at the proximal end, the flange being adapted to abut against skin of the subject on the outside of the tracheal wall.

Typically the flange is for at least one of the following:

a) Preventing over-insertion of the tracheal tube;
b) Securing the tracheal tube to the subject; and,
c) Allowing the tracheal tube to be removed without the handle.

Typically the tracheal tube includes a connector at the proximal end, the connector being for connection of the tracheal tube to the handle.

Typically the connector is adapted to allow a ventilation system to be connected to the tracheal tube when the handle is detached.

Typically the connector is a universal oxygen connector.

Typically the tracheal tube includes a cuff for substantially sealing against an inner circumference of the tracheal wall.

Typically the cuff is a balloon configured to allow the tracheal tube to be inserted or removed through tracheal wall when the balloon is deflated.

Typically the balloon is connected to an inflator tube running along the tracheal tube from the balloon to the proximal end of the tracheal tube, the inflator tube allowing the balloon to be inflated so that the balloon thereby seals against the inner circumference of the tracheal wall.

Typically the inflator tube runs along a groove of the tracheal tube which runs along an outside surface of the tracheal tube from the balloon to the proximal end of the tracheal tube.

Typically the inflator tube includes an inflator fitting to allow the balloon to be inflated by at least one of the following:

a) A syringe;
b) A manual pump;
c) An automatic pump.

Typically an outer surface of the tracheal tube includes a coating for lubricating the insertion of the tracheal tube through the tracheal wall.

Typically the tracheal tube is substantially rigid and curved.

Typically the device includes at least one of the following:

a) An aspiration indicator for indicating aspiration to a user; and,

b) An optical indicator for allowing a user to visually monitor the insertion process.

Typically the needle is curved.

Typically:

a) The device includes a retractor wire for retracting the needle; and,

b) The tracheal tube includes:

i) A dilator at the distal end, the dilator being for dilating a hole through the tracheal wall formed by insertion of the needle to allow insertion of the tracheal tube through the dilated hole;

ii) An inflatable balloon for substantially sealing against an inner circumference of the tracheal wall, the balloon being configured to allow the tracheal tube to be inserted or removed through the tracheal wall when the balloon is deflated; and,

iii) A connector for allowing connection of the handle.

Typically:

a) The device includes a guide configured to extend from the distal end of the tracheal tube, thus allowing insertion of the tracheal tube through the tracheal wall to be guided by the guide, the guide including a cannula having a longitudinal guide wire bore configured to allow passage of a guide wire therethrough and a longitudinal aspirate bore for allowing aspiration therethrough; and,

b) The handle includes:

i) An aspirate aperture for allowing air communication between the aspirate bore of the cannula and air outside the handle;

ii) A guide wire aperture for allowing the guide wire to pass from the guide wire bore to outside the handle; and,

iii) A retractor wire aperture for allowing the retractor wire to pass from the tracheal tube to outside the handle, and wherein detachment of the handle from the tracheal tube allows the needle and the guide to be extracted from the tracheal tube.

Typically:

a) The needle is curved; and,

b) The handle includes:

i) An aspirate aperture for allowing air communication between the tracheal tube and air outside the handle; and,

ii) A retractor wire aperture for allowing the retractor wire to pass from the tracheal tube to outside the handle, and wherein detachment of the handle from the tracheal tube allows the needle and the guide to be extracted from the tracheal tube.

In a second broad form the present invention seeks to provide a method for providing an airway through a tracheal wall of a subject using a device including a tracheal tube having an airway running from a proximal end to a distal end, a hollow needle detachably coupled to the distal end of the tracheal tube, a guide, and a handle detachably connected to the proximal end of the tracheal tube, wherein the method includes:

a) With the needle in an extended position in which at least part of the needle extends from the distal end of the tracheal tube, inserting the needle through the tracheal wall;

b) Moving the needle to a retracted position in which the needle is positioned inside the airway and at least part of the guide extends from the distal end of the tracheal tube;

c) Inserting the tracheal tube through the tracheal wall, the insertion of the tracheal tube being guided by the guide; and,

d) Detaching the handle from the tracheal tube and extracting at least the needle from the tracheal tube, thereby allowing the tracheal tube to provide an airway through the tracheal wall.

2) In a third broad form the present invention seeks to provide a method for providing an airway through a tracheal wall of a subject using a device including a tracheal tube having an airway running from a proximal end to a distal end, a hollow needle detachably coupled to the distal end of the tracheal tube, and a handle detachably connected to the proximal end of the tracheal tube, wherein the needle is curved, and wherein the method includes:

a) With the needle in an extended position in which at least part of the needle extends from the distal end of the tracheal tube, inserting the needle through the tracheal wall;

b) Inserting the tracheal tube through the tracheal wall;

c) Moving the needle to a retracted position in which the needle is positioned inside the airway; and,

d) Detaching the handle from the tracheal tube and extracting the needle from the tracheal tube, thereby allowing the tracheal tube to provide an airway through the tracheal wall.

Brief Description of the Drawings

An example of the present invention will now be described with reference to the accompanying drawings, in which: -

Figure 1 is a schematic cross sectional view of a first example of a device for providing an airway through a tracheal wall of a subject;

Figure 2 is a flow chart outlining an example method of use of the device for providing an airway through the tracheal wall of the subject;

Figure 3A is a schematic view of a second example of the device;

Figure 3B is a cross section view across plane A-A of Figure 3A; and,

Figures 4A to 4H show schematic views of the device of Figure 3A at various stages of its use in providing an airway through the tracheal wall of the subject; and,

Figures 5A to 5D show schematic perspective, plan, side and end views of a third example of a device for providing an airway through a tracheal wall of a subject.

Detailed Description of the Preferred Embodiments

An example of a device for providing an airway through a tracheal wall of a subject will now be described with reference to Figure 1.

In this example, the device includes a tracheal tube 100 having an airway 110 running from a proximal end 101 to a distal end 102. A hollow needle 200 is detachably coupled to the distal end 102 of the tracheal tube 100, and a handle 300 is detachably connected to the proximal end 101 of the tracheal tube.

The tracheal tube 100 can be formed from bio-compatible materials such as medical grades of metal, plastic or silicone, or a combination thereof. In this example, the tracheal tube 100 is a substantially rigid curved type, such that the shape of the tracheal tube 100 is maintained throughout the procedure and after insertion. However, it will be appreciated that other types of tracheal tubes, such as flexible tubes, can be used.

The needle 200 is for insertion through the tracheal wall of the subject. Insertion of the needle 200 through the tracheal wall provides a hole (or stoma) through the tracheal wall through which the tracheal tube 100 can be inserted to provide the airway through the tracheal wall. The needle 200 is retractable, such that the needle 200 can be moved from an extended position in which at least part of the needle 200 extends from the distal end 102 of the tracheal tube 100, as illustrated in figure 1, to a retracted position in which the needle 200 is positioned at least partially inside the airway 110. The needle 200 can be retracted into the airway 110 after the hole through the tracheal wall is provided, so that when the tracheal tube 100 is inserted the needle 200 no longer extends from the tracheal tube 100, thus preventing the needle 200 from causing trauma to the subject

The device also includes a guide 400 for guiding the insertion of the tracheal tube 100 through the tracheal wall. The guide 400 is configured so that the when the needle 200 is in the retracted position at least part of the guide 400 extends from the distal end 101 of the tracheal tube 100, thus allowing insertion of the tracheal tube 100 through the tracheal wall to be guided by the guide 400.

The handle 300 can be gripped by a user and allows the user to control the insertion of the needle 200 and tracheal tube 100. In one example, the handle 300 includes a grip portion which can be contoured to allow a user to comfortably and steadily hold and manipulate the device. The handle 300 is detachable from the tracheal tube 100, and detachment of the handle 300 allows at least the needle 200 to be extracted from the tracheal tube 100. Once the needle 200 is extracted, the airway 110 of the tracheal tube 100 is able to provide an unobstructed airway through the tracheal wall.

An example method of using the device described above to provide an airway through a tracheal wall of a subject will now be described with reference to Figure 2.

As the device is for insertion into part of a subject's body, it will be appreciated that standard preparation of the subject will be necessary prior to use of the device. The following example method therefore assumes that the subject is adequately prepared as per preparations required when using other percutaneous airway access devices.

Due to the detachable/retractable needle 200 and the detachable handle 300, it will also be appreciated that the device can exist in a number of different configurations. The following example method therefore assumes that the device is provided in an initial configuration in which the needle 200 is in the extended position and the handle 300 is attached to the tracheal tube 100. In other words, the device is provided with a pre-loaded needle 200. This initial configuration is as per the configuration of the device illustrated in Figure 1. The device can be stored in this configuration so that it is ready for use without requiring any reconfiguration, which can be particularly beneficial in emergency situations.

At step 500, the needle 200, which is in the extended position, is inserted through the tracheal wall of the subject. The specific insertion point is dependent on the particular procedure to be performed by the device. In the case of a cricothyrotomy procedure, the needle 200 is inserted through the cricothyroid membrane, and in the case of a tracheostomy procedure, the needle 200 is inserted between the first and second tracheal rings. The insertion of the needle 200 can be controlled by the user by gripping the handle 300, and then manually aligning the needle 200 with the relevant part of the subject.

When the needle 200 has passed through the tracheal wall into the trachea of the subject, it is possible for aspiration to occur via the device. In one example, air communication from the subject's trachea to outside of the tracheal wall is possible through the hollow needle 200 and the airway 110 of the tracheal tube 100, via an aspirate aperture provided in the handle 300. Aspiration through the aspirate aperture can therefore be used to indicate when the needle 200 has fully passed through the tracheal wall of the subject.

At step 510, once the needle has fully passed through the tracheal wall, the needle 200 is retracted into the airway 110 of the tracheal tube 100. The part of the guide 400 which extends from the distal end 101 of the tracheal tube continues to extend through the tracheal wall when the needle 200 is retracted. The guide 400 therefore operates to prevent the hole in

the tracheal wall, which was formed by the insertion of the needle 200, from closing after retraction of the needle 200.

In one example, the device includes a retractor wire 210 for retracting needle 200. The retractor wire 210 is attached to the needle 200 at one end, and passes through the tracheal tube 100. In one particular example, the retractor wire 210 extends through a retractor aperture provided in the handle so that a user can control the retraction of the needle 200 by moving the retractor wire. The use of a retractor wire allows the needle 200 to be retracted along a curved path and thus allows the device to utilise a curved, rigid tracheal tube 100 similar to those employed in conventional tracheotomies. However, it will be appreciated that any retraction mechanism can be used.

In one example, the guide 400 is a guide wire which passes through at least part of the tracheal tube 100 and at least part of the hollow needle 200. In this case, the needle 200 is retracted over the guide wire so that the portion of the guide wire that passes through the needle 200 when in the extended state will extend from the distal end 101 of the tracheal tube 100 when the needle is retracted. Further details of an example guide will be described below. However, it will be appreciated that any guide mechanism can be used.

At step 520, the tracheal tube 100 is inserted through the tracheal wall. The insertion of the tracheal tube 100 is guided through the hole in the tracheal wall by the guide 400. It will be appreciated that guiding the insertion of the tracheal tube 100 with the guide 400 helps to simplify the insertion process, by aligning the tracheal tube 100 with the hole created by the needle 200, and thereby helps to reduce trauma to the subject compared to directly inserting the tracheal tube 100 through a hole in the tracheal wall without using a guide 400. The insertion of the tracheal tube 100 can be controlled by the user by gripping and moving the handle 300 in the appropriate directions.

In one example, the tracheal tube 100 includes a dilator 140 at the distal end 102, for dilating the hole through the tracheal wall as the tracheal tube 100 is inserted. For example, the dilator 140 can be provided as a tapered end of the tracheal tube 100, so that the diameter of the tracheal tube 100 passing into the hole in the tracheal wall increases as the tracheal tube 100 is inserted, thus gradually dilating the hole during insertion. In one example, the dilator 140

extends from the distal end 102 of the tracheal tube 100 by a length selected to allow the taper in the diameter of the dilator 140 to be sufficiently gradual so that trauma to the subject during insertion of the tracheal tube 100 is substantially reduced.

The outer surface of the tracheal tube 100 and/or the dilator 140 can be provided with a coating for lubricating the insertion of the tracheal tube 100 through the tracheal wall. Such a coating can include a biologically compatible substance that, when wet, becomes slippery and therefore helps to allow the tracheal tube 100 to be easily passed through the tracheal wall. For example, the tracheal tube 100 can have a hydrophilic coating, such as "PHOTO-LINK" coating material commercially available from SurModics, Inc., which can be activated by being dipped into sterile saline or water. Once hydrated, the coating on the tracheal tube 100 is made very slippery without the need for additional lubricants. Alternatively, the outer surface of the tracheal tube 100 and/or the dilator can be coated with a low friction material such as polytetrafluoroethylene (commonly known as "TEFLON^{TM}") or the like. However, it will be appreciated that any suitable coating can be used.

In any event, a coating such as those described above will help to reduce the force required during the insertion of the tracheal tube 100 through the tracheal wall.

The tracheal tube 100 is inserted through the hole in the tracheal wall until a sufficient length of tracheal tube 100 has been inserted. In one example, the tracheal tube 100 includes a flange 120 at the proximal end. The flange 120 can have numerous uses, but in particular, the flange 120 can be used to control the insertion length of the tracheal tube 100, thus helping to prevent over-insertion. In addition, the flange 120 can be used to secure the tracheal tube 100 to the skin of the subject once fully inserted, by way of tape or sutures, for example. The flange 120 can also assist the eventual removal of the tracheal tube 100.

Furthermore, the flange 120 can provide the point of connection between the tracheal tube 100 and the handle 300. This facilitates the use of connection fittings with sizes other than the diameter of the tracheal tube 100. Accordingly, in one example the flange 120 includes a tracheal tube connector 130, which is configured to connect with an appropriately configured handle connector 310 provided on the handle 300.

In another example, the tracheal tube connector 130 is a standard connector of the type typically used for medial oxygen systems, such as a 15mm or 22mm tapered connector conforming to one of the following, or similar standards: AS2496 (1981), BS3849, ANSIZ-79.6 (1975) and ISO5356-1. It will be appreciated that in this example, the handle connector 310 will be similarly configured to comply with the same standards.

At step 530, following insertion of the tracheal tube 100, the handle 300 is detached from the tracheal tube 100. The particular means of detaching the handle 300 is dependent on the type of connection used. In one example, the connection is a twist fit connection, so that the handle 300 is detached by rotation about a longitudinal axis. In another example, the connection is a friction fit connection, allowing the handle 300 to be detached by pulling the handle away from the flange 120 whilst simultaneously applying pressure to the flange 120 to prevent movement of the tracheal tube 100. However, it will be appreciated that other connections and detachment mechanisms may be used. In any event, detachment of the handle 300 allows at least the needle 200 to be extracted from the tracheal tube 100.

At step 540, the needle 200 is extracted such that the needle 200 is no longer positioned in the airway 110. This therefore allows the tracheal tube 100 to provide the airway 110 through the tracheal wall without the needle 200 obstructing the airway 110.

Extraction of the needle 200 can be performed using the same mechanism as the retraction of the needle in step 510. In one example, in which the device includes the retractor wire 210, the needle 200 can be extracted by extracting the retractor wire 210 and the needle 200 along with it. In one example, the guide 400 can also be extracted from the tracheal tube 100 after the handle 300 is detached. This further prevents the guide 400 from obstructing the airway 110. However, this is not essential.

In another example, the handle 300 is configured so that the needle 200 and guide 400 are extracted when the handle 300 is removed after being detached. In this example, the removal of all potential obstructions from the airway 110 can be simply performed in a single step as the handle 300 is removed.

It will be appreciated that the above described example device and method of use allow an airway to be provided through the tracheal wall of the subject using a single device. This is in direct contrast with conventional methods of providing access to the subject's trachea, which typically require separate apparatus for performing different parts of the procedure. For example, many conventional methods require the use of a scalpel or a syringe with a needle to form an opening through the tracheal wall, after which one or more further devices are used to dilate the opening before a tracheostomy tube or the like is finally able to be inserted.

It will also be appreciated that the inclusion of a detachable needle 200 allows the device to be provided in a configuration that is ready for use whilst allowing the needle to be retracted and extracted from the device. For example, a user is able to grip the ready-for-use device by the handle 300 and quickly initiate the procedure. The user can easily control the insertion of the needle 200 and tracheal tube 100 via the handle 300 with one hand, with the other hand available for operating retraction mechanisms and the like. When the insertion is complete, the user can then remove the handle 300 and extract at least the needle 200 from the airway 110. It will be appreciated that it is possible for the user to maintain a grip on the handle 300 throughout the entire procedure.

The above described device therefore provides a convenient and simplified way of providing an airway through the tracheal wall of the subject. This is of particular benefit for providing emergency access to the trachea, as the device may be used quickly and without the need for separate items of medical equipment.

A second example device for providing an airway through a tracheal wall of a subject will now be described with reference to Figures 3A and 3B. Features similar to those of the example device described above with respect to Figures 1 and 2 have been assigned correspondingly similar reference numerals.

Figures 3A shows the example device, which includes the tracheal tube 100, needle 200, and handle 300 as described above with respect to Figure 1 and 2. However, in this example, the guide 400 includes a cannula 401. Figure 3B shows a cross section across the tracheal tube 100 at plane A-A as indicated on Figure 3A, allowing the internal configuration of the cannula to be seen.

The cannula 401 is a tube with a split cross section providing the cannula 401 with a longitudinal guide wire bore 403, configured to allow passage of a guide wire 410 therethrough, and a longitudinal aspirate bore 404, for allowing aspiration therethrough. The provision of two separate bores 403, 404 in the cannula 401 allows the guide wire 410 to be moved in its own guide wire bore 403 without obstructing the aspirate bore 404 and compromising aspiration. Accordingly, aspiration is allowed throughout the insertion process.

In this example, the guide wire bore 403 and the aspirate bore 404 are separated along the length of the cannula 401 by an internal membrane 402. However, it will be appreciated that different cannula configurations can be used. For example, the guide wire bore 403 can be provided as a cylindrical bore with a diameter slightly larger than the guide wire 410 to allow movement of the guide wire 410. This would allow the aspirate bore 404 to occupy a greater cross sectional area of the cannula, thus allowing increased airflow when compared to a cannula configuration providing equally sized guide wire and aspirate bores 403, 404.

The cannula 401 passes along the tracheal tube 100 and at least part of the needle 200, and when the needle 200 is retracted, the needle 200 is moved along the outside of the cannula 401 into the airway 110. The cannula 401 is made from a compliant material to allow the portion passing through the needle 200 to be straightened.

The guide wire 410 passes along the length of the guide wire bore 403 of the cannula 401. The guide wire 410 is able to be moved through the cannula 401 to adjust a length of the guide wire that extends from the distal end 102 of the tracheal tube 100.

In this example, the cannula 401 passes from the proximal end 101 of the tracheal tube 100 towards the handle 300 and is fixed to the handle 300 at one end. The handle 300 includes an aspirate aperture 340 for allowing air communication between the aspirate bore 404 of the cannula 40 and the air outside of the handle 300, and a guide wire aperture 330 for allowing the guide wire 410 to pass from the guide wire bore 403 to outside the handle 300.

A length of the guide wire 410 extends outside of the handle 300, via the guide wire aperture 330, so that this is accessible to the user. This allows the user to move the length of the guide wire 410 to control the amount of the guide wire 410 that extends from the distal end 102 of

the tracheal tube 100. In this example, the user can feed an additional length of guide wire 410 into the aperture so that the guide wire 410 extends from the distal end 102 of the tracheal tube 100 by a similar length.

The handle 300 also includes a retractor aperture 320 for allowing the retractor wire 210 to pass from the tracheal tube 100 to outside the handle 300. This allows a length of the retractor wire 210 to extend outside of the handle 300 so that it is accessible by the user, thereby allowing the user to move the length of the retractor wire 210 to control the retraction of the needle 200. In this example, the user can pull a length of retractor wire 210 through the retractor aperture 320 so that the needle 200 is retracted by a distance corresponding to that length. In this example, the end of the retractor wire 210 protruding from the retractor aperture 320 is connected to a pull tab 211 in order to simplify pulling the retractor wire 210, and additionally preventing the end of the retractor wire 210 from inadvertently withdrawing into the retractor aperture 320.

It will be appreciated that the ability to manipulate the guide wire 410 and the retractor wire 210 allows the user to control parts of the device located inside the subject's body from outside of the subject's body.

The needle 200 is detachably connected to the distal end 102 of the tracheal tube 100. When the needle 200 is in the extended configuration in which it extends from the distal end 102 of the tracheal tube 100, the detachable connection is typically configured to allow the needle 200 to penetrate the tracheal wall of the subject without inadvertently retracting, whilst allowing the needle 200 to be retracted when the user pulls on the retractor wire 210. Such a detachable connection can be achieved in a number of ways.

In one example the needle base 202 is attached to the tracheal tube 100 using a frangible connection which is configured to remain intact during the insertion of the needle 200 through the tracheal wall, but is broken when the retractor wire 210 is pulled. For example, the frangible connection may be a plastic material with a tearable portion around the circumference of the needle base 202, such that when the retractor wire 210 is pulled the tearable portion is torn and the connection is broken, allowing retraction of the needle 200. It

will be appreciated that configurations similar to those used in pill jars with seals which may be torn by a pull tab could be adapted to provide the frangible connection in such cases.

In another example, the needle base 202 is attached to the tracheal tube 100 using a connection which includes a latch, configured such that the connection is secure during insertion of the needle 200, but when the retractor wire 210 is pulled the latch is released and the needle base 202 is allowed to move, subsequently allowing retraction of the needle 200.

The skilled person will appreciate that numerous other means for providing the detachable connection between the needle 200 and the tracheal tube 100 are possible, such as friction fits, or the like.

The tracheal tube 100 can optionally include a cuff which can be used to seal against an inner circumference of the tracheal wall when the tracheal tube 100 has been inserted. The use of a cuffed tracheal tube is not essential, but the cuff helps to prevent fluids from passing the cuff, and also helps to ensure that the subject's breathing takes place entirely via the tracheal tube 100.

In this example, the cuff is a balloon 150 which is collapsed against the outer surface of the tracheal tube 100 when in a deflated state, in order to allow the tracheal tube 100 to be easily inserted or removed despite the presence of the balloon 150. The balloon 150 can be inflated so that the balloon 150 volume expands to contact the inner surface of the tracheal wall about its circumference, so as to lightly seal the subject's trachea about the tracheal tube 100. The balloon 150 is typically of a high-volume low-pressure type, and this helps to minimise pressure related effects on the tracheal mucosa.

The balloon 150 is connected to an inflator tube 151 which runs along the outside of the tracheal tube 100 from the balloon 150 to the proximal end 101 of the tracheal tube 100, and allows the balloon 150 to be inflated. In this example, the inflator tube 151 runs along a groove 105 formed along the outside of the tracheal tube 100, so that the inflator tube 151 does not result in an additional protrusion from the tracheal tube 100, and therefore does not substantially affect the insertion of the tracheal tube 100 through the tracheal wall. Figure 3B shows cross sectional details of the configuration of the groove 105 and inflator tube 151.

In this example, the inflator tube 151 passes through the flange 120, so that the inflator tube 151 can be accessed by a user when the tracheal tube 100 is inserted. A pilot balloon 152 and valve 153 are provided to assist in the inflation of the cuff balloon 150. Inflation can be performed manually by injecting air through the valve 153 using an air-filled syringe. The inflated volume of the balloon 150 can be controlled by monitoring the volume of air supplied to the balloon 150 via the syringe.

The pressure in the pilot balloon 152 will be equal to the pressure in the cuff balloon 150 and this can be used to determine whether the cuff balloon 150 is sufficiently inflated. In addition, the user can feel the back-pressure resisting further compression of the syringe plunger and use this as another indicator of the degree of inflation of the cuff balloon 150. Once the cuff balloon 150 is inflated, the syringe can be removed and escape of air from the cuff balloon 152 will be prevented by the valve 153.

It will be appreciated that numerous alternative methods of inflating the balloon 150 are possible, including the use of a manual pump or an automatic pump. Furthermore, means can be provided to regulate the pressure in the balloon, such as valve arrangements that allow excess pressure to be released, and such means would further help to prevent pressure related trauma to the trachea.

In this example, the inflator tube 151, pilot balloon 152 and valve 153 are retained with the tracheal tube 100 after the handle 300 is removed. This allows monitoring and adjustments of the cuff balloon 150 whilst the tracheal tube 100 is providing the airway through the tracheal wall of the subject.

A detailed example outlining the steps involved in providing an airway through the tracheal wall of a subject, using the device described above with reference to Figures 3A and 3B, will now be described with reference to Figures 4A to 4H.

As was the case for the example method described with reference to Figure 2, it is assumed that the device is provided with the needle 200 extended and the handle 300 attached to the tracheal tube 100 at the start of the procedure, and that the patient has been adequately prepared for the procedure. Additionally, the cuff balloon 150 should be deflated with the

cannula tube 401 passing along the inside of the needle 200 such that an end of the cannula tube 401 is located near the tip of the needle 200, with the guide wire 410 running through the cannula tube 401. In other words, in this example the device is provided with a pre-loaded needle 200 and guide 400. This initial configuration is as per the configuration of the device illustrated in Figure 3A, with the cuff balloon 150 deflated. The device can be stored in this configuration so that it is ready for use without requiring any reconfiguration, which can be particularly beneficial in emergency situations.

With reference to Figure 4A, the procedure begins by penetrating the subject's skin 610 with the needle 200 and inserting the needle 200 through the tracheal wall 600 until the needle passes completely through the tracheal wall 600 such that the tip 201 of the needle 200 is positioned inside the subject's trachea 620. As per the method previously describe with reference to Figure 2, the insertion point is dependent on the particular procedure. For example the needle 200 may be inserted through the cricothyroid membrane for a cricothyrotomy, or between the first and second tracheal rings for a tracheostomy.

Once the needle tip 201 enters the trachea 620, air is allowed to flow through the aspirate bore 404 of the cannula 401 and the aspirate aperture 340 of the handle 300. A continuous aspiration path is therefore provided, thus allowing the subject to aspirate throughout the procedure. Additionally, a user is able to detect the commencement of aspiration through the aspirate bore 404 and use this to provide an indication that the needle 200 has successfully passed through the tracheal wall 600. This confirms that the needle 200 has been inserted by a sufficient length and allows the user to stop inserting the needle 200 before it penetrates the far wall 630 of the trachea 630.

There are numerous ways that the user can detect aspiration. For example, the user can place a finger over the aspirate aperture 340 and detect a puff of air that will typically indicate the commencement of aspiration, or the user can observe the aspirate aperture 340 to detect a mist of vapour expelled from the aspirate aperture at the commencement of aspiration. In another example, the aspirate aperture 340 is configured to allow a fluid filled syringe to be connected thereto, with the appearance of bubbles in the fluid in the syringe being indicative of aspiration.

Alternatively and/or additionally, the handle 300 can include an aspiration indicator for indicating that aspiration is taking place. For example, the handle 300 can include a clear aspiration window (not shown) which allows the user to see through the handle 300 to a portion of the aspirate aperture 340 inside the handle 300. In one example, the user can detect aspiration via the window by observing the appearance of a mist of vapour in the window which can indicate commencement of aspiration.

The aspiration window can include a visual indicator that aspiration is taking place. In one example, the indicator can be provided mechanically, such as by way of threads installed in the aperture, which move with the flow of air. In another example, the indicator may be provided using a substance in the window which changes colour when the presence of oxygen or exhaled carbon dioxide is detected. If the colour of the window reverts back to clear then this would indicate that the flow of air is impeded.

In another example, the handle 300 may include sensors for detecting and indicating airflow or the presence of oxygen or exhaled carbon dioxide. In these cases, the sensors can provide a signal that causes an indicator to be provided to the user, such as a light turning on or a sound being emitted when aspiration is detected.

It will be appreciated that the use of an aspiration indicator can be helpful in allowing the user to control the insertion of the needle 200 through the tracheal wall 600, and to monitor aspiration once it has commenced. However it will be appreciated that an aspiration indicator is not essential.

The device can also include an optical indicator (not shown) to allow the user to visually monitor the insertion process.

In one example, the device includes an optical fibre which allows light to be transmitted from one end of the optical fibre to the other end of the optical fibre. For example, the optical fibre can be provided as an additional element of the guide 400, such that the optical fibre passes from the handle 300, along the airway 110, and through the needle 200. The handle 300 can include an additional viewing window (not shown) allowing the user to view the light from a distal end of the optical fibre, wherein changes in the colour observed by the user in the

viewing window are indicative of the position of the distal end of the optical fibre inside the subject. A separate light source may also be included in the device at the distal end of the optical fibre to illuminate the surrounding tissue. This may be provided, for example, by a second optical fibre with a light source at its proximal end, such that the light is transmitted to the distal end of the second optical fibre to provide a light source inside the subject during insertion.

In another example, a bundle of a plurality of optical fibres can be used, and a proximal end of the bundle of optical fibres can be fitted with a viewing lens to allow an image to be observed by the user that is indicative of the position of the distal end of the bundle of optical fibres. It will be appreciated that this is similar to the functionality of an endoscope, and accordingly, similar imaging techniques can be used, such as the use of an optical detector, or camera, allowing the inside of the trachea to be imaged. This allows the operator to view the positioning of the tracheal tube 100, for example on a video display, thereby allowing the user to confirm the tracheal tube 100 has passed through the tracheal wall 600.

In any event, the guide 400 can be adapted to allow the use of an optical indicator as described above. In one example, the cannula 401 includes an additional optical bore (not shown) for allowing passage of one or more optical fibres therethrough. However, in another example, the cannula 401 is configured as described above with reference to Figure 3B, but with one or more optical fibres provided in place of a guide wire 410. Alternatively, the guide wire 410 can be configured to include one or more optical fibres running along it, such that the guide wire 410 includes an optical indicator.

It will be appreciated that the use of an optical indicator can be helpful in providing visual feedback to the user during the procedure, in particular allowing the user to monitor the insertion of the needle 200 and the subsequent insertion of the tracheal tube 100. However, it will be appreciated that an optical indicator is not essential.

With reference to Figure 4B, the next step involves feeding an additional length of the guide wire 410 through the guide wire aperture 340 in the direction indicated by arrow 700. This causes a corresponding length of guide wire 410 to extend from the end of the cannula 401 and out of the needle tip 201 into the subject's trachea 620, in the direction indicated by arrow

710. This additional length of the guide wire 410 helps to guide the later insertion of the tracheal tube 100 into the subject's trachea 620.

In this example, the guide wire tip 411 is curved back on itself to help to prevent the guide wire tip 411 from causing trauma to the inner tracheal wall during the procedure. Alternatively and/or additionally, the guide wire tip 411 may be rounded or blunt, or capped with an end piece configured to minimise the risk of trauma.

With reference to Figure 4C, after the guide wire 410 is fed into the subject's trachea the needle 200 is retracted into the airway 110 of the tracheal tube 100. The user controls the retraction of the needle by pulling the pull tab 211 end of the retractor wire 210, thus pulling the retractor wire 210 through the retractor aperture 320 in the direction indicated by arrow 720.

As the retractor wire 210 is pulled through the retractor aperture 320, the needle 200 is correspondingly retracted into the airway 110 of the tracheal tube 100 in the direction indicated by arrow 730. In this example, the needle 200 is retracted until the entire length of the needle 200 is inside the airway 110. However, in other examples, the needle 200 is retracted so that the needle 200 is drawn further along the airway 110, and when fully retracted the needle 200 may be positioned at the proximal end 101 of the tracheal tube 100, or within a recess in the handle 300, itself.

In another example, the retractor wire 210 may include a stopper (not shown) fixed at a point along the retractor wire 210 inside the airway 110. The stopper has a diameter larger than the diameter of the retractor aperture 320. The retractor wire 210 is pulled through the retractor aperture 320, and when the stopper reaches the retractor aperture 320 the stopper will not be able to pass through the retractor aperture 320 and will thus prevent the retractor wire 210 from being pulled any further. The stopper helps to control the amount of retraction of the needle 200, and also helps to indicate when the needle 200 has been sufficiently retracted such that it no longer extends from the distal end 201 of the tracheal tube 100.

In any event, after retraction is complete, the needle 200 no longer extends from the distal end 102 of the tracheal tube 100, and therefore is no longer able to penetrate any part of the

subject. This helps to ensure that the needle 200 will not cause any trauma to the inner tracheal wall during the rest of the insertion procedure, throughout which the needle 200 is retained in the retracted position.

It will be appreciated that the needle 200 is retracted over the cannula 401 and guide wire 410 passing therethrough, such that the cannula 401 and guide wire 410 remain in the same respective positions as the needle 200 is moved through the airway 110. As a result, as the needle 200 is retracted from the hole it has formed in the tracheal wall 600 and skin 610, the cannula 401 is left to pass through the hole such that the hole is not allowed to close once the needle 200 is retracted. The passage of the cannula 401 through the hole allows aspiration to continue through the aspirate bore 404, and also allows the subsequent insertion of the tracheal tube 100 to be guided by the cannula 401 and the guide wire 410. It will be appreciated that if no guide 400 was provided, the hole would close after the needle was retracted and insertion of the tracheal tube 100 through the closed hole would be difficult and potentially traumatic to the subject.

With reference to Figure 4D, following retraction of the needle 200, the distal end 102 of the tracheal tube 100 is inserted through the skin 610 and the tracheal wall 600. It should be noted that the lengths of the retractor wire 210 and guide wire 410 extending from the retractor aperture 320 and guide wire aperture 330 are not shown in Figures 4D to 4H, for clarity reasons. The insertion of the tracheal tube 100 is guided by the cannula 401 such that the tracheal tube 100 follows the cannula 401 through the hole in the subject's skin 610 and tracheal wall 600. The user is able to control the insertion by appropriate manipulation of the device via the handle 300.

The dilator 140 at the distal end 102 of the tracheal tube 100 is provided to help to dilate the hole as the tracheal tube 100 is inserted. In this example, the extremity of the dilator 140 at the distal end 102 has a diameter slightly larger than the outer diameter of the needle 200, and the diameter increases away from the distal end 102 until the full diameter of the tracheal tube 100 is provided. This gradual increase of diameter allows the dilator 140 to gradually dilate the hole during insertion of the tracheal tube 100, and helps to minimise any trauma associated with inserting the tracheal tube 100 through the hole left by the needle 200.

As discussed above, the outer surface of the tracheal tube 100 can be coated with a lubricating material to also allow for easier insertion.

The insertion of the tracheal tube 100 continues until it is fully inserted, as shown in Figure 4E. The depth of insertion is controlled by the flange 120 at the proximal end 101 of the tracheal tube 100, which abuts against the skin 610 of the subject when the tracheal tube 100 is fully inserted. As discussed above, the flange 120 also allows the tracheal tube 100 to be secured to the skin 610 of the subject, by an adhesive, tape or sutures, for example. In addition, the flange 120 can be used to ensure the appropriate orientation of the tracheal tube 100 in the subject's trachea 620, by providing an indication of the orientation to the user, as the actual orientation of the tracheal tube 100 itself can not be readily observed by the user. In general, the tracheal tube 100 is in a proper orientation when the distal end 102 passes through the approximate centre of the trachea 620 towards the subject's lungs, without contacting the tracheal wall 600.

Following full insertion of the tracheal tube 100, the cuff balloon 150 can be inflated as shown in Figure 4F. As discussed above with reference to Figures 3A and 3B, inflation of the cuff balloon 150 takes place via the inflator tube 151 which passes along a groove in the outside of the tracheal tube 100. The pilot balloon 152 and valve 153 located outside of the subject's body can therefore be used to inflate the cuff balloon. In this example, an air-filled syringe is inserted into the valve 153 and compression of the syringe provides air to inflate the cuff balloon 150. The volume of air provided can be controlled by directly adjusting the amount of compression of the syringe. The pressure can be monitored via the pilot balloon 152 which will be inflated with the same pressure as the cuff balloon 150. The cuff balloon 150 is inflated so as to just contact the tracheal wall 600 so that a seal is provided about the circumference of the tracheal wall 600 without providing excessive pressure against the tracheal wall 600 which can be a cause of trauma to the subject. The degree of inflation of the cuff balloon 150 can also be adjusted at a later time as required using the same methods.

Once the cuff balloon 150 makes a seal against the subject's tracheal wall 600, passage of fluids and airflow past the cuff balloon 150 is prevented, however the subject is able to

continue to breathe through the device via the aspirate bore 404 and the aspirate aperture 340 in the handle 300.

In addition to its sealing function, the cuff balloon 150 also gently helps to keep the tracheal tube located inside the subject's trachea 620 without contacting the tracheal wall 600. Should the patient move in a way that changes the shape of the tracheal wall 600 in relation to the tracheal tube 100, the cuff balloon 150 will help to hold the tracheal tube in position without trauma to the tracheal wall 600.

It should be noted that the use of the cuff balloon 150 is optional, but it is generally of assistance to the procedure.

Once the cuff balloon 150 is inflated, handle 300 and the equipment passing through the airway 110 including the retracted needle 200, cannula 401, guide wire 410 can be removed.

In one example, the detachable connection between the handle 300 and the tracheal tube 100 is configured so that the handle 300 is rotated anti-clockwise about its longitudinal axis to disconnect the handle 300 from the tracheal tube 100. This turning action would not normally occur during the previous insertion steps and therefore inadvertent disconnection of the handle 300 during insertion is prevented. However, it will be appreciated that numerous types of connectors can be used for allowing the handle 300 to be detached by the user, whilst preventing inadvertent detachment during insertion. The type of connectors 130, 310 used in the device will result in corresponding modification of the detachment operation.

Once the handle 300 is detached, the handle 400 can moved away from the tracheal tube 100 as shown in Figure 4G. In this example, the handle 300 is configured so that when it is moved away from the tracheal tube 100 as indicated by arrow 740, the needle 200, cannula 401 and guide wire 410 are extracted from the airway 110. However, in other examples the handle 300 may be first removed and then the other equipment can be extracted separately.

In one example, the handle 300 is configured so that the retractor wire 210, cannula 401 and guide wire 410 are pulled together with the handle 300. The handle 300 can include a mechanism that prevents the cannula 401 and wires 210, 410 from moving relative to the handle 300 as the handle 300 is moved, thus ensuring that they, and the needle 200 attached

to the retractor wire 210, are extracted from the airway 110. For example, the mechanism can be provided as a lever that is operated by the user and facilitates clamping of the wires 210, 410 so that they can no longer pass freely through the retractor and guide wire apertures.

After the handle 300 is removed and the needle 200, cannula 401, and guide wire 410 are extracted from the airway, only the tracheal tube 100 and cuff balloon 150 are left in the subject's trachea, as shown in Figure 4H. This is the final inserted configuration of the device, and an unobstructed airway is now provided through the tracheal wall 600, allowing the subject to breathe freely therethrough.

After an airway through the tracheal wall 600 is provided, the tracheal tube 100 may be optionally connected to a ventilation system to provide a direct air or oxygen source to the subject. In this example, the connector 130 is a standard connector which is compatible with standard ventilation system tubing, such that the ventilation system can be easily connected to the tracheal tube 100. After the ventilation system is attached and pressurised, a final adjustment of the cuff balloon 150 inflation is typically performed using the method described above for the initial inflation of the balloon, in order to ensure an adequate seal is provided in the subjects trachea 620, which assists the subject to comfortably breathe through the tracheal tube 100. The balloon inflation equipment, namely the pilot balloon 152 and valve 153 is typically left in place, however in other examples tracheal tube 100 can be configured so that this equipment can also be removed or re-attached as required.

As discussed above, the flange 120 can be secured to the subject to hold the tracheal tube 100 in place. When the tracheal tube 100 is no longer needed, the flange 120 can also be used to facilitate removal of the tracheal tube 100, after the cuff balloon 150 is deflated.

Some variations in the order of the steps outlined above are possible without changing the overall operation of the device. For example, the additional length of the guide wire 410 may be extended into the trachea 620 after the needle 200 is retracted, or the cuff balloon 150 can be inflated after the handle 300 is detached.

A third example of a device for providing an airway through a tracheal wall of a subject will now be described with reference to Figures 5A to 5D. For the purpose of this example similar reference numerals are used to refer to similar features.

In this example, the device includes a tracheal tube 100 having an airway 110, running from a proximal end 101 to a distal end 102, the distal end including a dilator 140. A hollow needle 200, having a tip 201, is detachably coupled to the distal end 102 of the tracheal tube 100. The tracheal tube 100 includes a flange 120, which is coupled to a handle 300 via a tracheal tube connector, configured to connect with an appropriately configured handle connector 310 provided on the handle 300.

The handle 300 includes a first portion 301 defining an aspirate aperture 340, which is in fluid communication with the airway 110, allowing airflow therethrough. The handle also includes a second handle portion 302 housing a retractor wire 210, and tab 211, held in position via a retractor guide 303. As in previous examples, the retractor wire 210 is attached to the needle 200 at one end, allowing this to be retracted into the airway 110. However, in this example, the retractor wire 210 also functions as a guide 400 as will be explained in more detail below.

In this example, a balloon 150 is provided on an outside of the tracheal tube 100, with the balloon 150 being connected via an inflator tube 151 to a pilot balloon 152, to allow the balloon 150 to be inflated.

In use, operation of the third example device is substantially similar to that of the first and second example devices described above. Accordingly, in use, the needle tip 201 is inserted into the into the subject's trachea. At this point, the subject is able to breathe via the aspirate aperture 340.

The retractor wire 210 is then depressed, by pushing the tab 211, causing the retractor wire 210 to extend into the subject's trachea, thereby acting as a guide in a manner similar to that described above with respect to the guide wire of the previous examples. Following this, the needle 200 can be pushed further into the subject's trachea, along the guide, as in previous examples, allowing the dilator 400 to dilate the trachea so that the tracheal tube 100 can be

inserted. At this point, the needle 200 can be retracted by pulling out the retractor wire 210, so that the tracheal tube 100 can then be fully inserted into the subject's trachea.

Following this, the handle 300 can be decoupled from the tracheal tube, and removed, allowing the needle 200 to be removed from the airway 110, so that the tracheal tube 100 to act as an airway for the subject.

Accordingly, it will be appreciated that in one example the retractor wire 210 can act to both retract the needle 200 and provide a guide for insertion of the needle. However, this is not essential, and in an alternative example, the retractor wire 210 can be replaced with a guide 400, with retraction of the needle 200 being achieved by having the needle 200 coupled to the handle 300, so that the needle 200 is retracted as the handle 300 is decoupled from the tracheal tube 100.

In the above described example, the needle 200 has a curved configuration which is similar to the curvature of the tracheal tube 100. This facilitates the insertion of the needle 200 into the subject, and in particular prevents unwanted penetration of the tracheal wall.

As a result of this configuration, in a further example the requirement for a separate guide can be eliminated, with the needle itself acting as the guide to thereby ensure that the device is inserted into the subject's trachea.

It will be appreciated that a device in accordance with the above described examples facilitates a simplified method of providing an airway through the tracheal wall of a subject. By simplifying the procedure and reducing the required equipment to a single device, it is feasible that users could operate the device to perform cricothyrotomy or tracheostomy procedures with minimal training, thus allowing the device to be used in emergency scenarios by personnel other than qualified medical professionals. For example, this device could be provided to emergency response personnel or the like, in a ready-for-use configuration.

Persons skilled in the art will appreciate that numerous variations and modifications will become apparent. All such variations and modifications which become apparent to persons skilled in the art, should be considered to fall within the spirit and scope that the invention broadly appearing before described.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1) A device for providing an airway through a tracheal wall of a subject, the device including:
   a) A tracheal tube having an airway running from a proximal end to a distal end;
   b) A hollow needle detachably coupled to the distal end of the tracheal tube, the needle being for insertion through the tracheal wall and being moveable from an extended position in which at least part of the needle extends from the distal end of the tracheal tube to a retracted position;
   c) A handle detachably connected to the proximal end of the tracheal tube, wherein detachment of the handle from the tracheal tube allows at least the needle to be extracted from the tracheal tube, thereby allowing the tracheal tube to provide an airway through the tracheal wall.
2) A device according to claim 1, wherein the device is configured to allow aspiration.
3) A device according to claim 1 or claim 2, wherein the device includes a guide configured to extend from the distal end of the tracheal tube, thus allowing insertion of the tracheal tube through the tracheal wall to be guided by the guide.
4) A device according to claim 3, wherein the guide passes along at least part of the airway and at least part of the needle
5) A device according to claim 3 or claim 4, wherein the guide includes at least one of the following:
   a) A guide wire;
   b) A resilient cord; and,
   c) A cannula.
6) A device according to claim 4 or claim 5, wherein the guide includes a cannula having a longitudinal guide wire bore configured to allow passage of a guide wire therethrough and a longitudinal aspirate bore for allowing aspiration therethrough.
7) A device according to claim 6, wherein the handle includes:
   a) An aspirate aperture for allowing air communication between the aspirate bore of the cannula and air outside of the handle; and

b) A guide wire aperture for allowing the guide wire to pass from the guide wire bore to outside the handle.

8) A device according to claim 7, wherein a length of the guide wire extends from the guide wire aperture, such that movement of the length of the guide wire allows a user to control an amount of the guide wire that extends from the distal end of the tracheal tube.

9) A device according to any one of claims 6 to 8, wherein a tip of the guide wire is configured to substantially prevent trauma to the subject during insertion.

10) A device according to claim 9, wherein the tip of the guide wire is at least one of the following:

a) Curved;

b) Blunt;

c) Capped with a rounded end piece.

11) A device according to any one of claims 1 to 10, wherein the device includes a retractor wire for retracting the needle.

12) A device according to claim 11, wherein the retractor wire is attached to the needle at a first end and passes through at least part of the tracheal tube.

13) A device according to claim 12, wherein the handle includes a retractor aperture for allowing the retractor wire to pass from the tracheal tube to outside the handle.

14) A device according to claim 13, wherein a length of the retractor wire extends from the retractor wire aperture, such that movement of the length of the retractor wire allows a user to control the movement of the needle from the extended position to the retracted position.

15) A device according to any one of claims 1 to 14, wherein the tracheal tube includes a dilator at the distal end, the dilator being for dilating a hole through the tracheal wall formed by insertion of the needle to allow insertion of the tracheal tube through the dilated hole.

16) A device according to any one of claims 1 to 15, wherein the tracheal tube includes a flange at the proximal end, the flange being adapted to abut against skin of the subject on the outside of the tracheal wall.

17) A device according to claim 16, wherein the flange is for at least one of the following:

a) Preventing over-insertion of the tracheal tube;

b) Securing the tracheal tube to the subject; and,

c) Allowing the tracheal tube to be removed without the handle.

18) A device according to any one of claims 1 to 17, wherein the tracheal tube includes a connector at the proximal end, the connector being for connection of the tracheal tube to the handle.

19) A device according to claim 18, wherein the connector is adapted to allow a ventilation system to be connected to the tracheal tube when the handle is detached.

20) A device according to claim 19, wherein the connector is a universal oxygen connector.

21) A device according to any one of claims 1 to 20, wherein the tracheal tube includes a cuff for substantially sealing against an inner circumference of the tracheal wall.

22) A device according to claim 21, wherein the cuff is a balloon configured to allow the tracheal tube to be inserted or removed through tracheal wall when the balloon is deflated.

23) A device according to claim 22, wherein the balloon is connected to an inflator tube running along the tracheal tube from the balloon to the proximal end of the tracheal tube, the inflator tube allowing the balloon to be inflated so that the balloon thereby seals against the inner circumference of the tracheal wall.

24) A device according to claim 23, wherein the inflator tube runs along a groove of the tracheal tube which runs along an outside surface of the tracheal tube from the balloon to the proximal end of the tracheal tube.

25) A device according to claim 23 or claim 24, wherein the inflator tube includes an inflator fitting to allow the balloon to be inflated by at least one of the following:

a) A syringe;

b) A manual pump;

c) An automatic pump.

26) A device according to any one of claims 1 to 25, wherein an outer surface of the tracheal tube includes a coating for lubricating the insertion of the tracheal tube through the tracheal wall.

27) A device according to any one of claims 1 to 26, wherein the tracheal tube is substantially rigid and curved.

28) A device according to any one of claims 1 to 27, wherein the device includes at least one of the following:

a) An aspiration indicator for indicating aspiration to a user; and,

b) An optical indicator for allowing a user to visually monitor the insertion process.

29) A device according to any one of claims 1 to 28, wherein the needle is curved.

30) A device according to any one of claims 1 to 29, wherein:

a) The device includes a retractor wire for retracting the needle; and,

b) The tracheal tube includes:

i) A dilator at the distal end, the dilator being for dilating a hole through the tracheal wall formed by insertion of the needle to allow insertion of the tracheal tube through the dilated hole;

ii) An inflatable balloon for substantially sealing against an inner circumference of the tracheal wall, the balloon being configured to allow the tracheal tube to be inserted or removed through the tracheal wall when the balloon is deflated; and,

iii) A connector for allowing connection of the handle.

31) A device according to claim 30, wherein:

a) The device includes a guide configured to extend from the distal end of the tracheal tube, thus allowing insertion of the tracheal tube through the tracheal wall to be guided by the guide, the guide including a cannula having a longitudinal guide wire bore configured to allow passage of a guide wire therethrough and a longitudinal aspirate bore for allowing aspiration therethrough; and,

b) The handle includes:

i) An aspirate aperture for allowing air communication between the aspirate bore of the cannula and air outside the handle;

ii) A guide wire aperture for allowing the guide wire to pass from the guide wire bore to outside the handle; and,

iii) A retractor wire aperture for allowing the retractor wire to pass from the tracheal tube to outside the handle, and wherein detachment of the handle from the tracheal tube allows the needle and the guide to be extracted from the tracheal tube.

32) A device according to claim 30, wherein:

a) The needle is curved; and,

b) The handle includes:

i) An aspirate aperture for allowing air communication between the tracheal tube and air outside the handle; and,

ii) A retractor wire aperture for allowing the retractor wire to pass from the tracheal tube to outside the handle, and wherein detachment of the handle from the tracheal tube allows the needle and the guide to be extracted from the tracheal tube.

33) A method for providing an airway through a tracheal wall of a subject using a device including a tracheal tube having an airway running from a proximal end to a distal end, a hollow needle detachably coupled to the distal end of the tracheal tube, a guide, and a handle detachably connected to the proximal end of the tracheal tube, wherein the method includes:

a) With the needle in an extended position in which at least part of the needle extends from the distal end of the tracheal tube, inserting the needle through the tracheal wall;

b) Moving the needle to a retracted position in which the needle is positioned inside the airway and at least part of the guide extends from the distal end of the tracheal tube;

c) Inserting the tracheal tube through the tracheal wall, the insertion of the tracheal tube being guided by the guide; and,

d) Detaching the handle from the tracheal tube and extracting at least the needle from the tracheal tube, thereby allowing the tracheal tube to provide an airway through the tracheal wall.

34) A method for providing an airway through a tracheal wall of a subject using a device including a tracheal tube having an airway running from a proximal end to a distal end, a hollow needle detachably coupled to the distal end of the tracheal tube, and a handle detachably connected to the proximal end of the tracheal tube, wherein the needle is curved, and wherein the method includes:

a) With the needle in an extended position in which at least part of the needle extends from the distal end of the tracheal tube, inserting the needle through the tracheal wall;

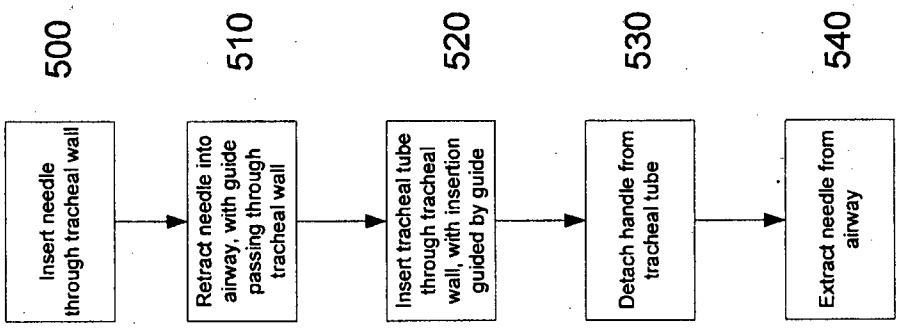
b) Inserting the tracheal tube through the tracheal wall;

c) Moving the needle to a retracted position in which the needle is positioned inside the airway; and,

d) Detaching the handle from the tracheal tube and extracting the needle from the tracheal tube, thereby allowing the tracheal tube to provide an airway through the tracheal wall.

35) A device and a method for providing an airway through a tracheal wall of a subject, substantially as hereinbefore described.

36) A device and a method for providing an airway through a tracheal wall of a subject, substantially as hereinbefore described and illustrated with reference to the accompanying drawings.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Insert needle through tracheal wall
510
Retract needle into airway, with guide passing through tracheal wall
520
Insert tracheal tube through tracheal wall, with insertion guided by guide
530
Detach handle from tracheal tube
540
Extract needle from airway

Fig. 2

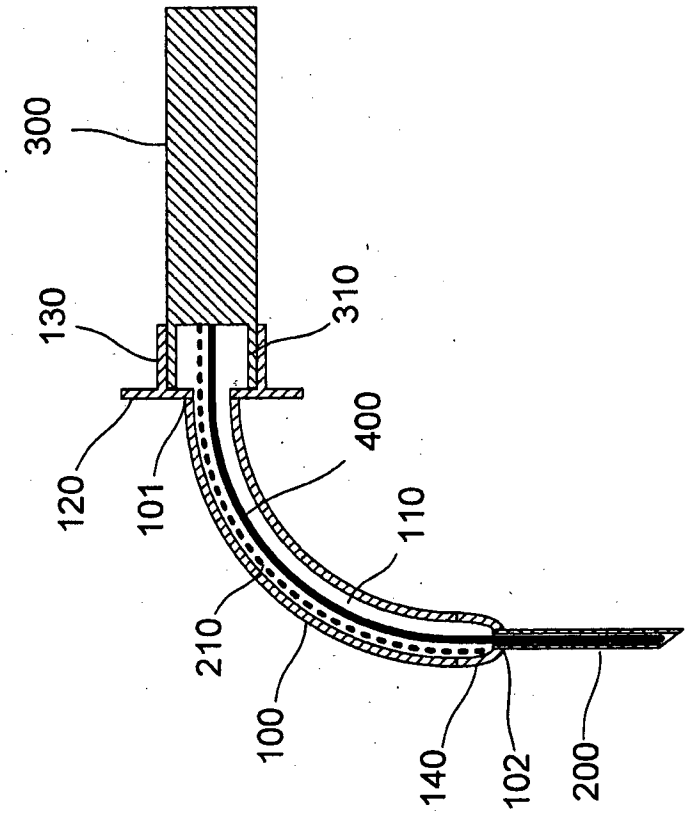
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Fig. 1

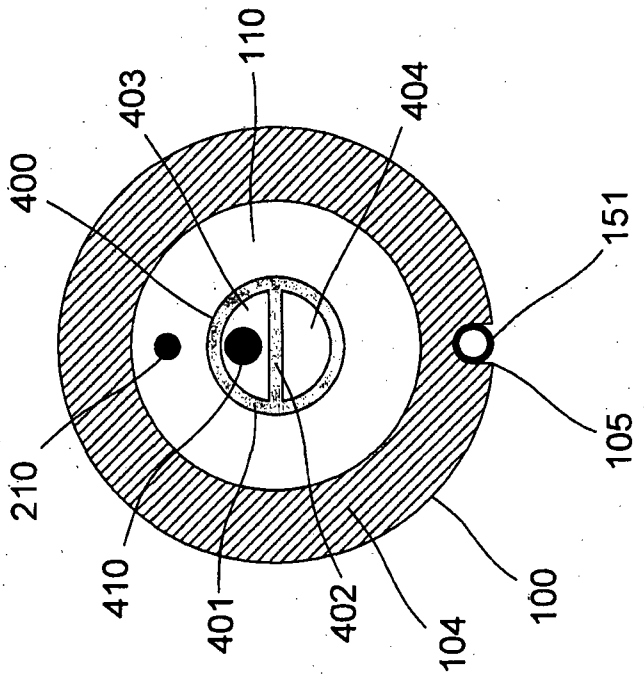
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Fig. 3B

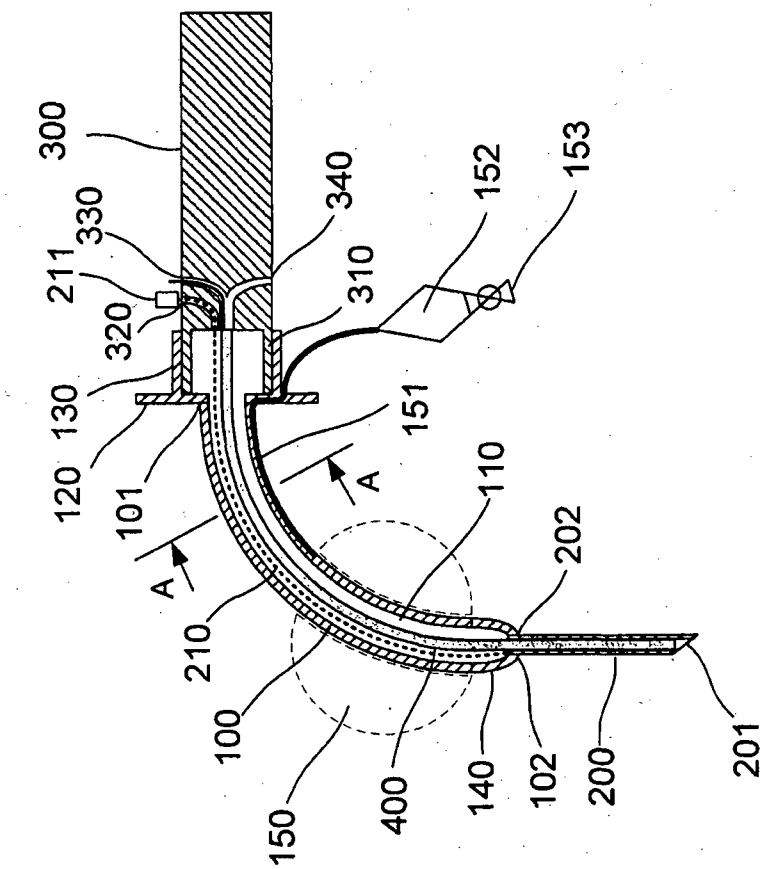
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Fig. 3A

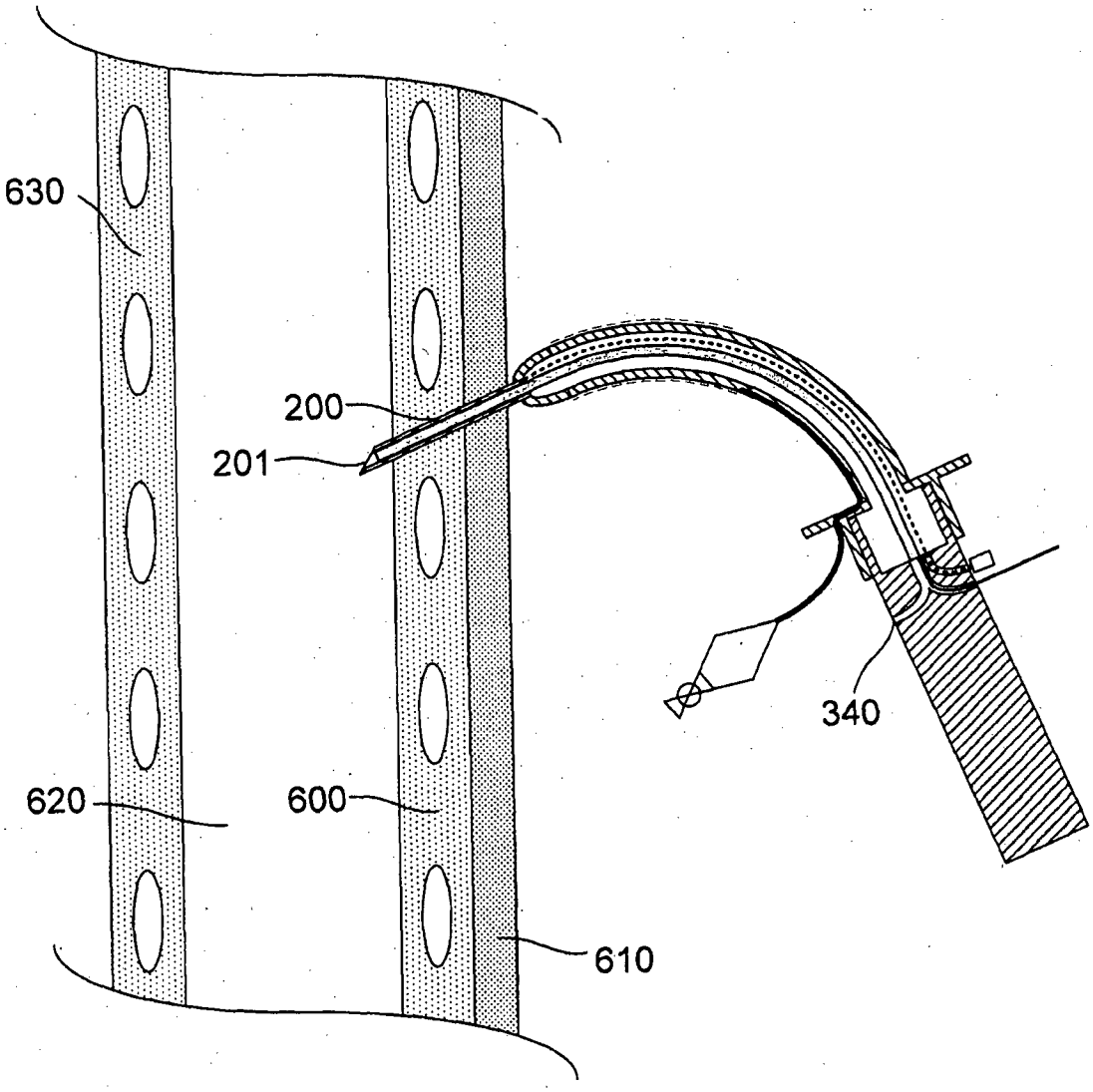

Fig. 4A

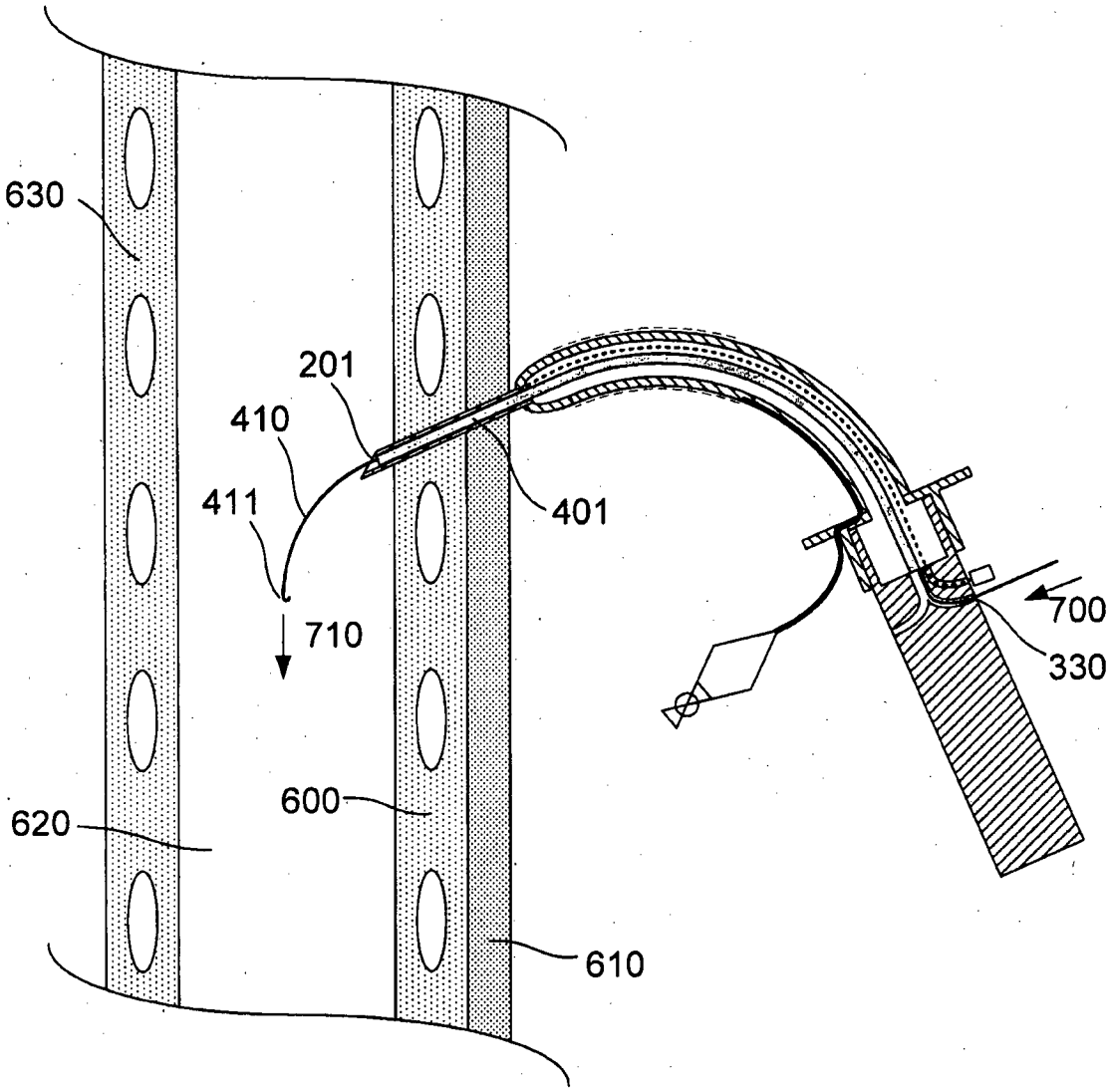

Fig. 4B

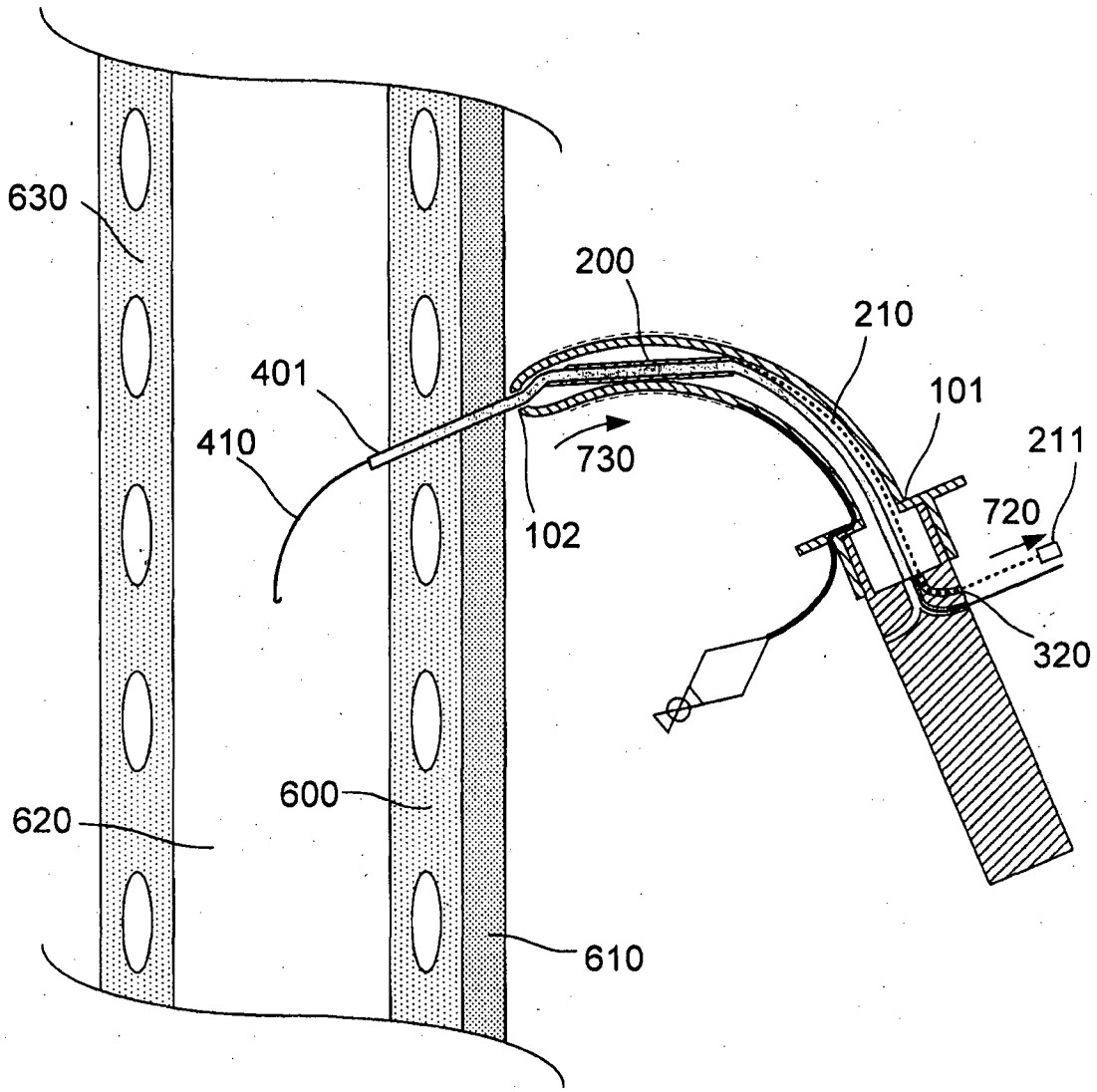

Fig. 4C

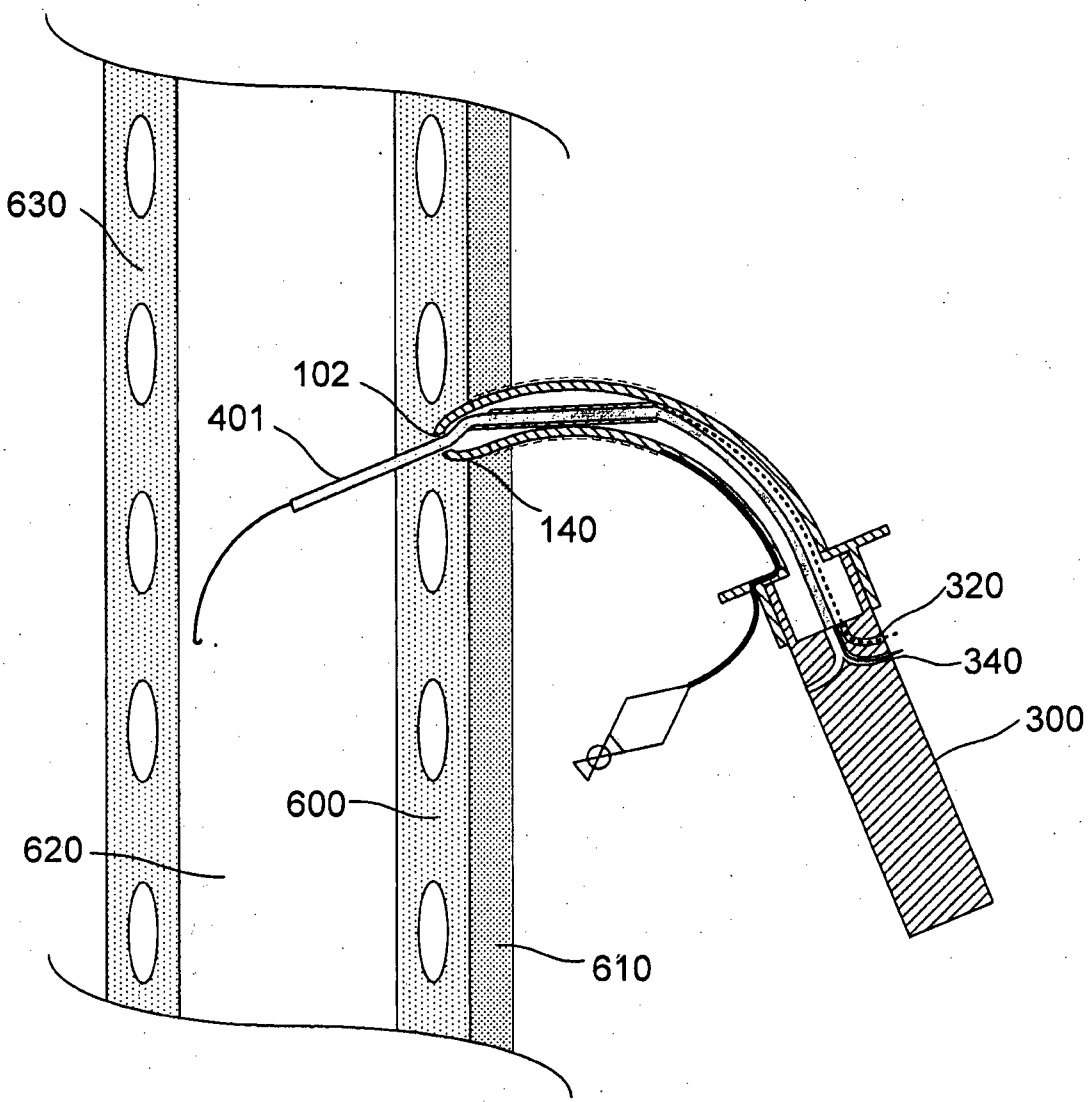

Fig. 4D

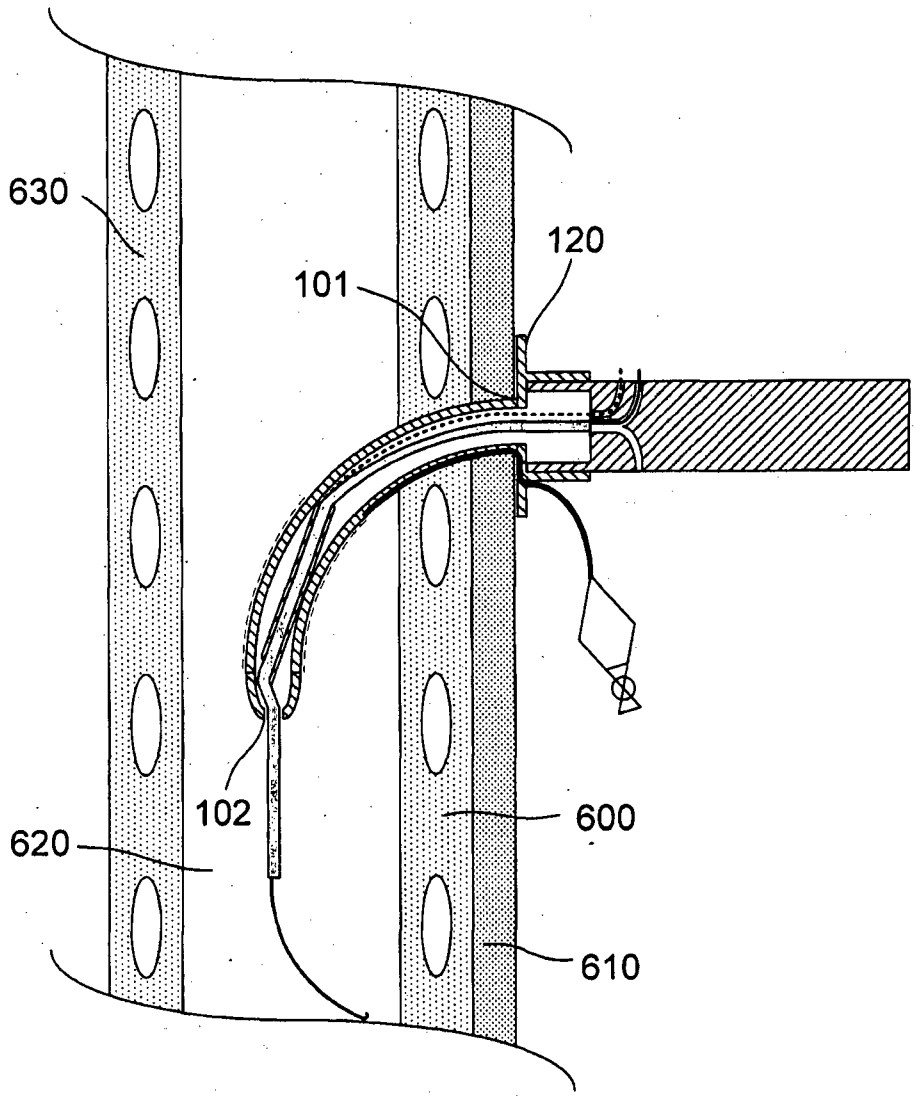

Fig. 4E

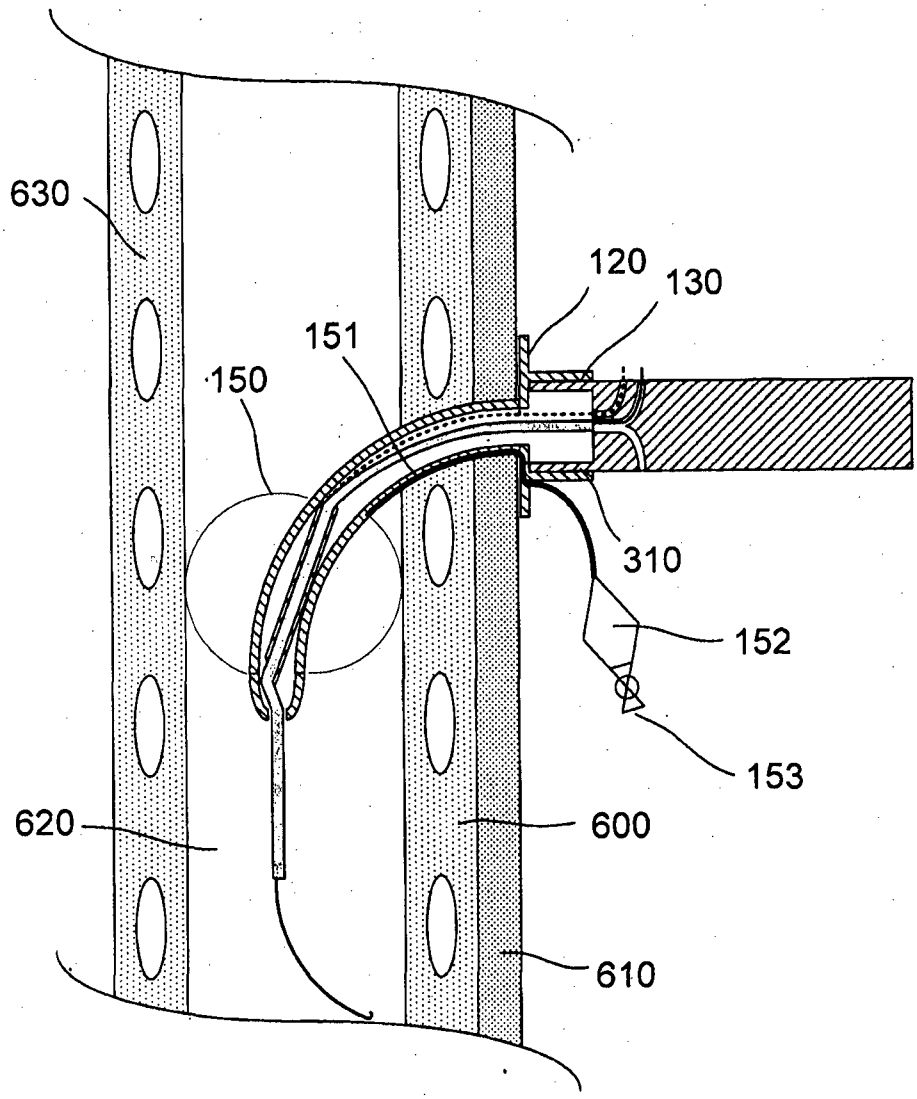

Fig. 4F

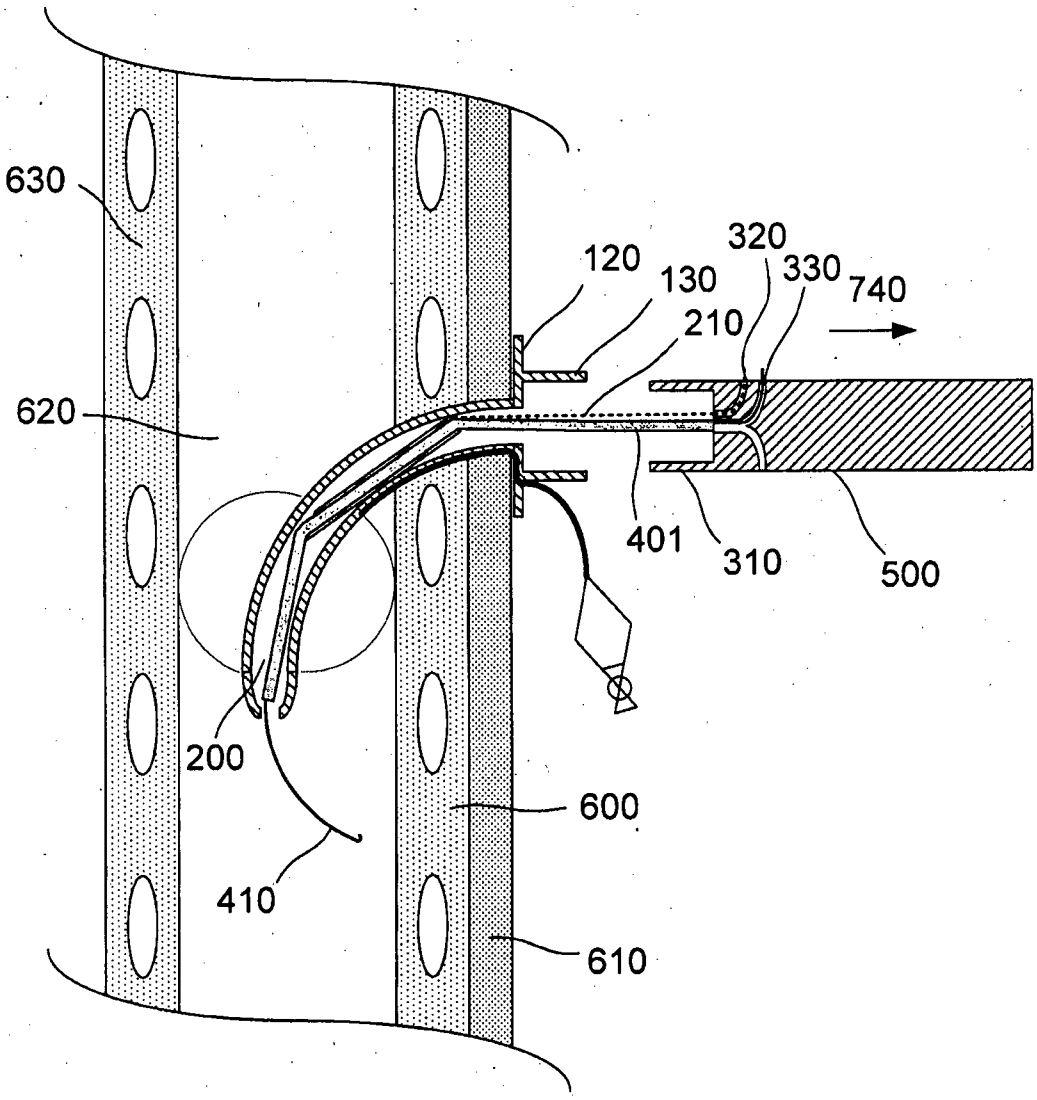

Fig. 4G

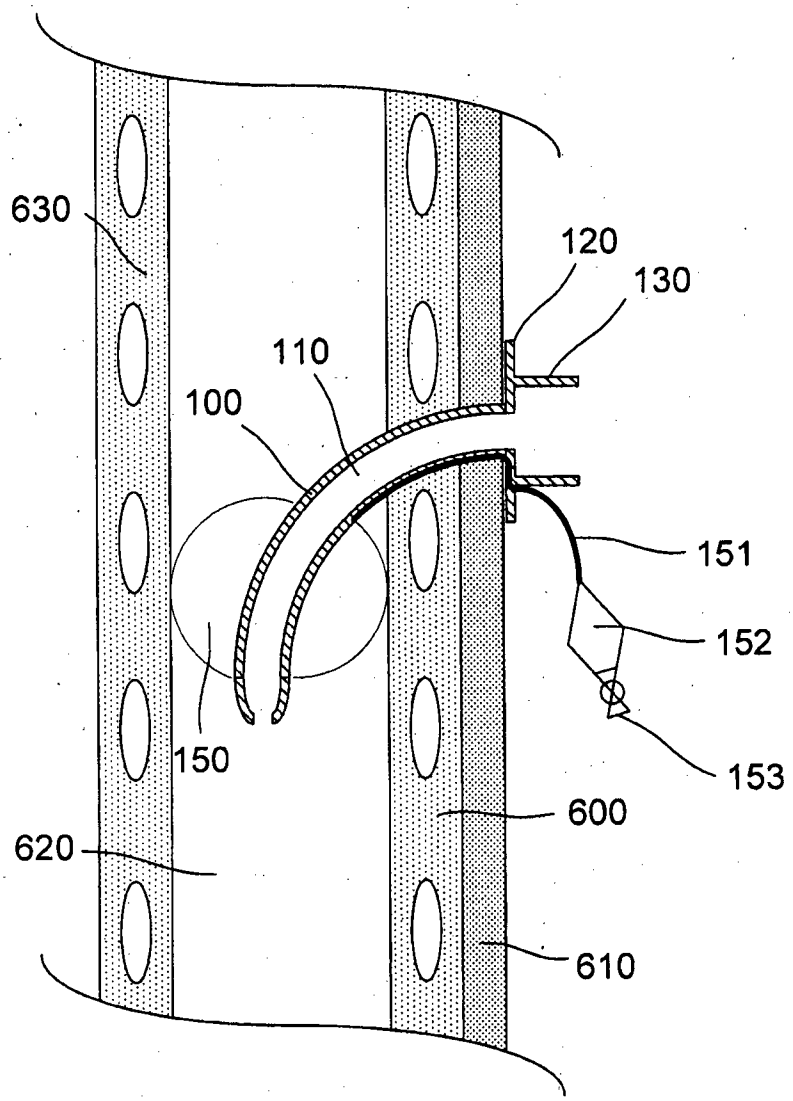

Fig. 4H

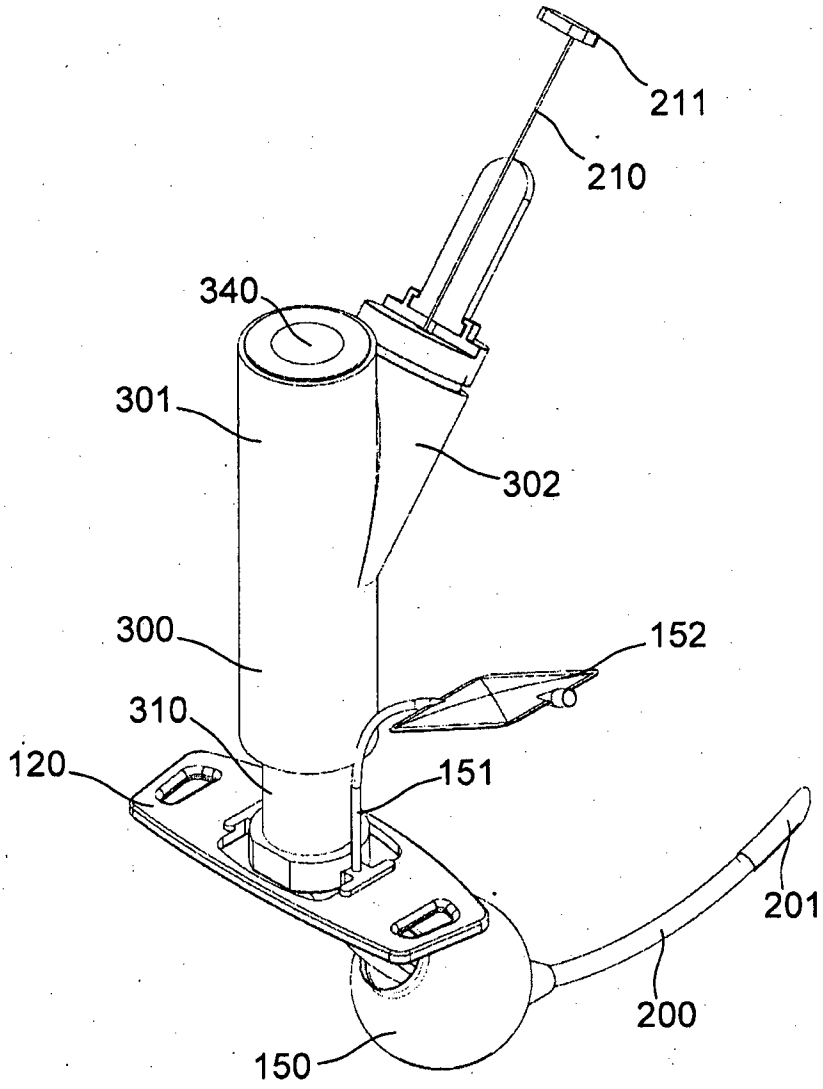

Fig. 5A

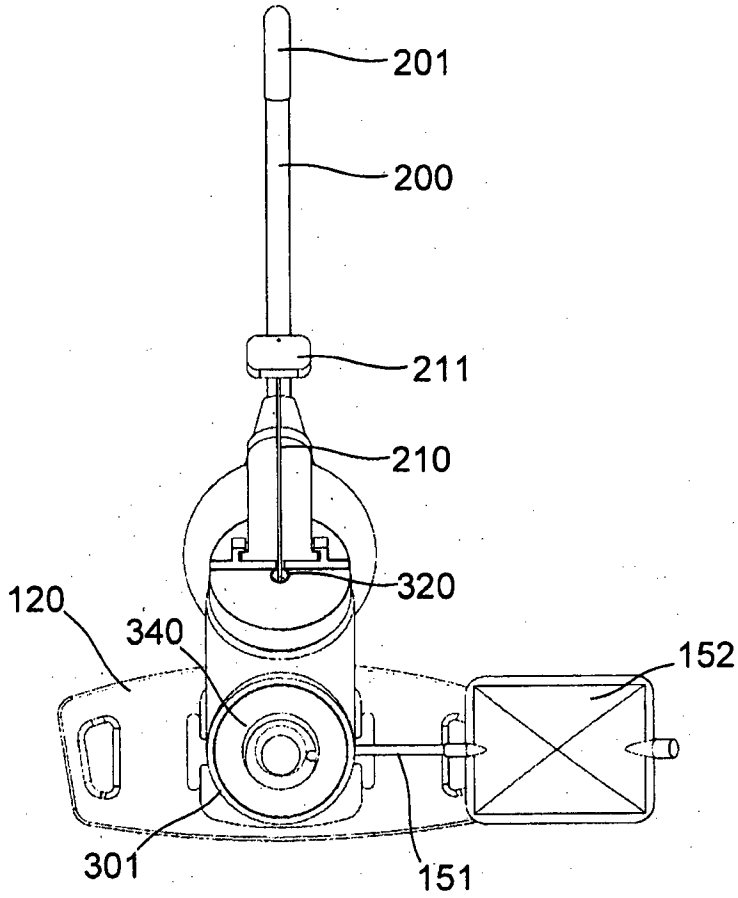

Fig. 5B

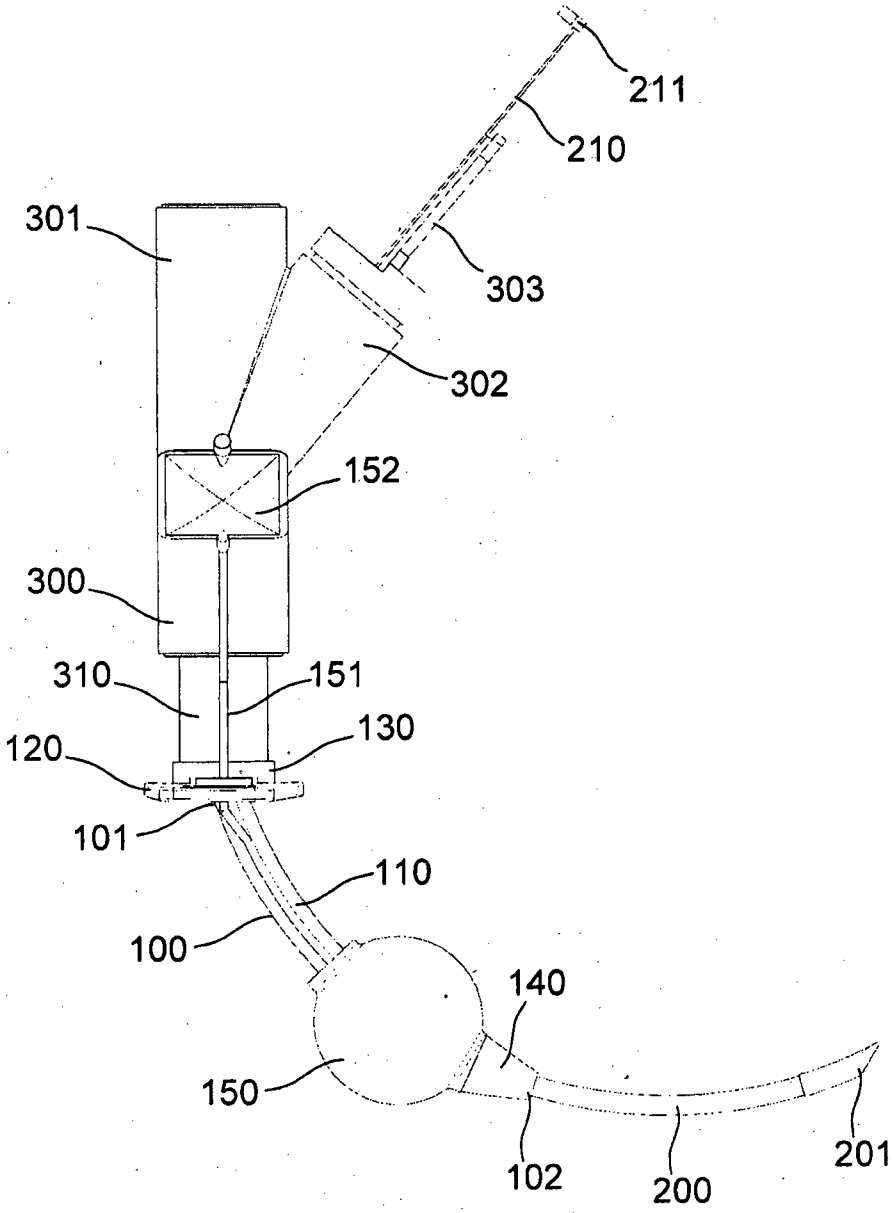
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Fig. 5C

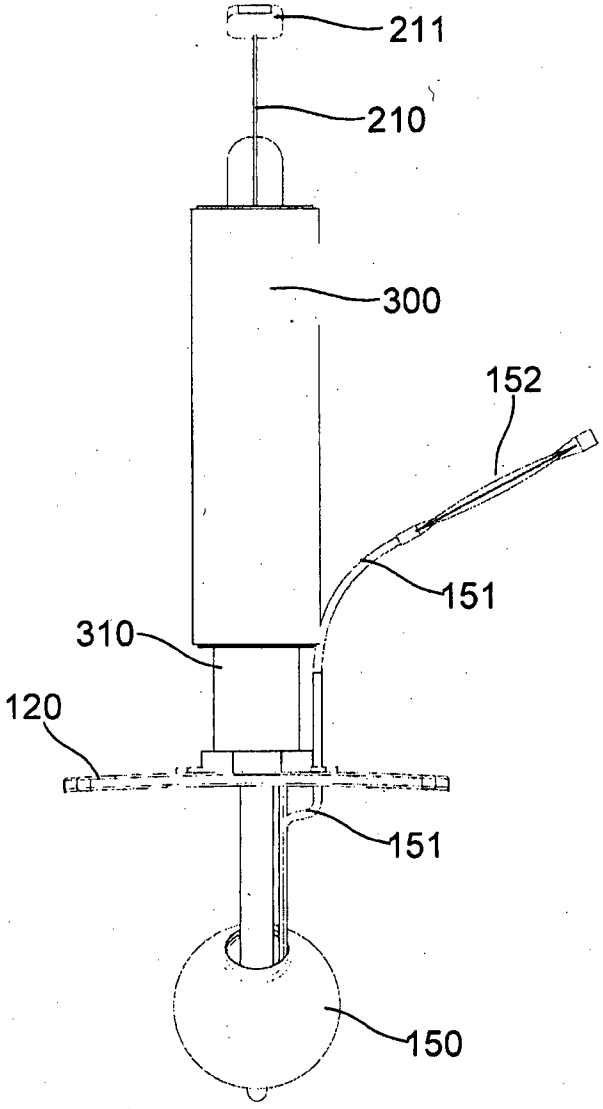

Fig. 5D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2011/000199

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/04 (2006.01)

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)

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)
WPI EPODOC; A61M/IC/EC, A61M 16/IC/EC, A61M 25/06E3B/EC, A61B 17/34 trache cricothy emergency handle grip extension butt remove detach disconnect separate needle cannula puncture trocar retract withdraw extend
EPODOC; A61M16/04E A61M16/04E8, A61M 16/04M,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 2887259 Y (LIU) 11 April 2007 Figures and English language abstract	1-8, 11-25, 27, 29, 30-34
Y		7-10, 15, 21-25, 26, 28
Y	Figures	11-14, 30-32
X	US 4488545 A (SHEN) 18 December 1984 Column 3 lines 43 to 67, column 4 lines 23 to 52, column 5 lines 2 to 57, column 6 lines 2 to 31, figures	1-8, 15-25, 27-29, 33, 34
Y		1-33

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 May 2011	23 MAY 2011
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer **MATTHEW FORWARD** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6283 2606

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2011/000199

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: **35 and 36**
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
These claims do not comply with Rule 6.2(a) because they rely on references to the description and/or drawings.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2011/000199

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2007/006055 A2 (VASCULAR PATHWAYS INC.) 11 January 2007 Page 10, 2nd paragraph Figure 2 Figures 4A and page 8	1-33 3-6 9-10
Y	US 5944732 A (RAULERSON et al) 31 August 1999 Column 6 lines 52 to 56, column 7 lines 32 to 43, figures 8 and 11	1-8, 11-25, 28-32
Y	WO 1999/038548 A2 (VARGAS) 5 August 1999 Page 11 lines 15 to 19 Figures 6, 7 and 8 Page 14 line 25 to page 15 line 9	2, 7, 15, 21,-25 28
Y	WO 2006/125006 A2 (APMED SOLUTIONS, INC.) 23 November 2006 Paragraph 0007, paragraph 0058 and figures 18 to 20 Paragraphs 0065 to 0069 and 0072	2, 7, 28
Y	US 2006/0124134 A1 (WOOD) 15 June 2006 Figure 2 Paragraph 0029, figures 6 to 8	3-6, 33 15, 21-25
Y	US 5217005 A (WEINSTEIN) 8 June 1993 Figures 4 to 6 Column 3 lines 34 to 43 Column 4 lines 23 to 26, column 7 lines 6 to 17	3-6, 33 15, 21-25 26
Y	US 7036510 B2 (ZGODA et al) 2 May 2006 Figures 1 and 5 Column 4 lines 17 to 50	7-8, 15, 21-25 26
Y	WO 2005/094926 A1 (COOK CRITICAL CARE INCORPORATED) 13 October 2005 Figure 20	9-10
Y	CN 201299631 Y (SHENZHEN BAGAN PEOPLES HOSPITAL) 2 September 2009 English abstract and Figure 1	11-14, 30-32
A	SU 1409242 A1 (VINNITSA MEDICAL INSTITUTE) Figure	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2011/000199

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CN 2067129 U (PANG) 12 December 1990	1, 33, 34
A	WO 2008/034872 A1 (GUERRA) 27 March 2008 Entire document	1, 33, 34

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2011/000199

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
CN	2887259	NONE					
US	4488545	NONE					
WO	2007006055	AU	2006264300	AU	2007269530	CN	101242868
		EP	1907042	EP	2037985	US	2008300574
		US	2010094310	WO	2008005618		
US	5944732	NONE					
WO	9938548	NONE					
WO	2006125006	CN	101163517	EP	1881860	US	2006260616
		US	7556042	US	2006260617		
US	2006124134	EP	1824567	US	7341061	WO	2006065554
US	5217005	NONE					
US	7036510	US	2004255954				
WO	2005094926	AU	2005228989	CA	2561339	EP	1727581
		US	2006081260				
CN	201299631	NONE					
SU	1409242	NONE					
CN	2067129U	NONE					
WO	2008034872	CA	2664238	EP	2063943	IT	GO20060001U
		IT	GO20060002	US	2010012130		

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX