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A61M 16/04 (2006.01)

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A5R RGEX

(56) Documents Cited:
GB 2393398 A
US 5669380 A
US 4978334 A
EP 0257916 A1
US 5095900 A
US 4821710 A

(58) Field of Search:
UK CL (Edition X) A5R
INT CL A61M
Other:

(54) Abstract Title: **A tracheostomy device with a carbon dioxide indicator**

(57) A tracheostomy instrument has a handle 2 with a hollow needle 22 extending with a tapered external sleeve 1. The rear end of the needle 22 opens adjacent carbon dioxide indicator 28 in the handle 2 so that, when the trachea 52 is penetrated, gas flows from the trachea along the needle onto the indicator. There may be a spring 31 in the handle 2 to pull the needle 22 rearwardly fully into the handle when a button 30 is pressed so that the sleeve can safely be pushed in further to enlarge the opening into the trachea. A handle-disconnect button 40 enables the handle 2 to be separated from the sleeve 1. The carbon dioxide indicator 28 may be a colour change indicator.

Fig.1.

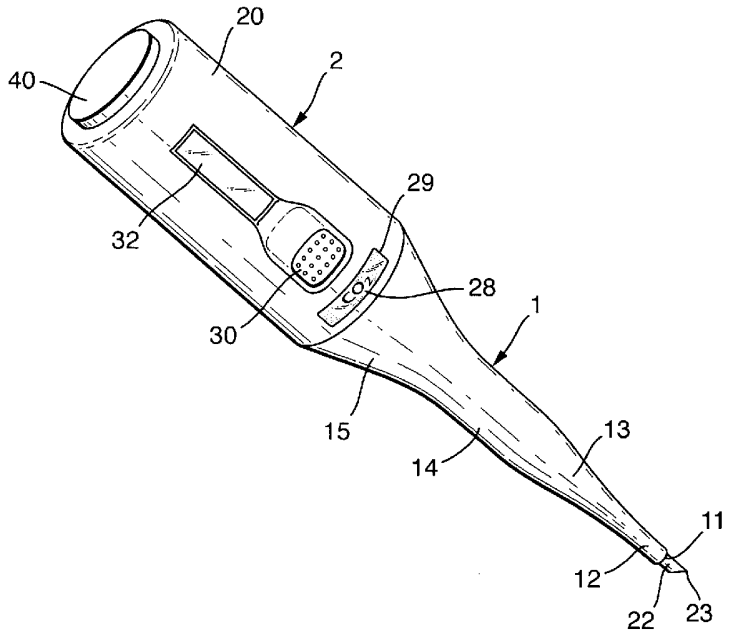

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Fig.1.

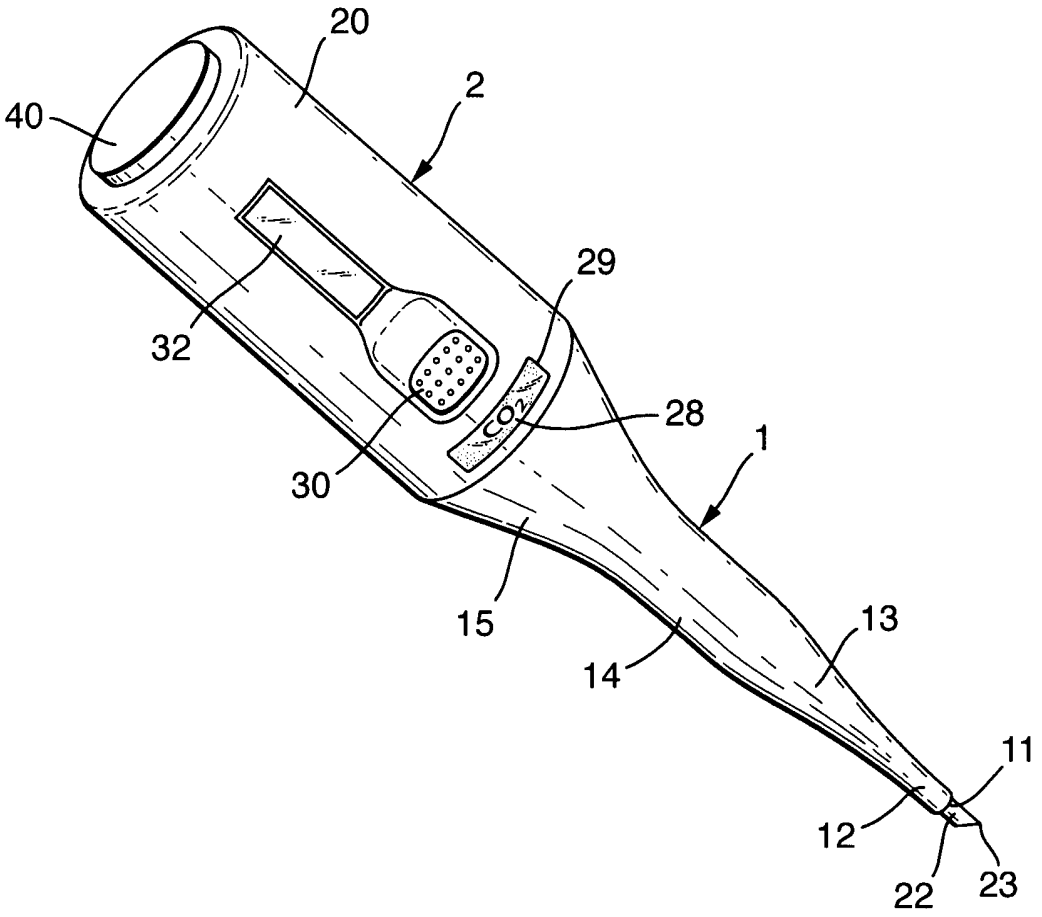


Fig.2A.

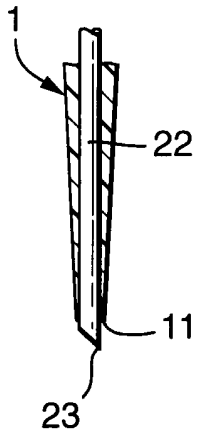


Fig.2B.

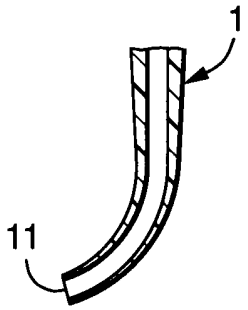


Fig.3.

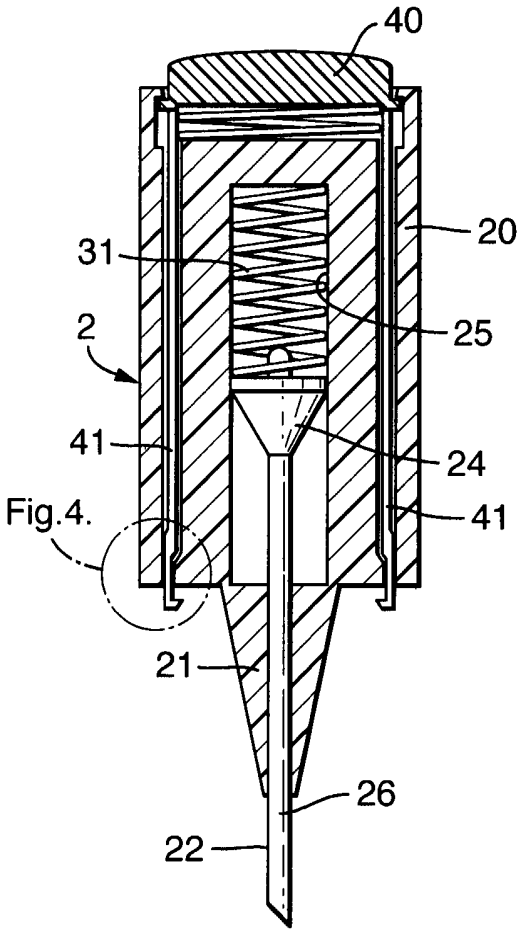


Fig.4.

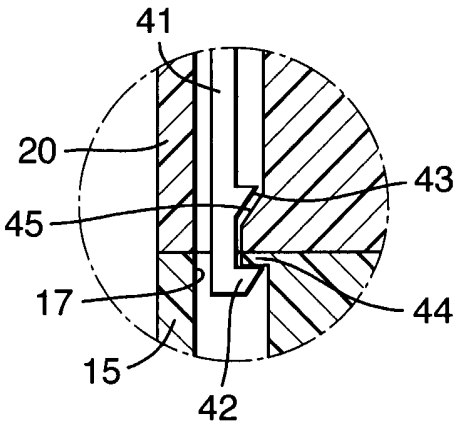


Fig.5.

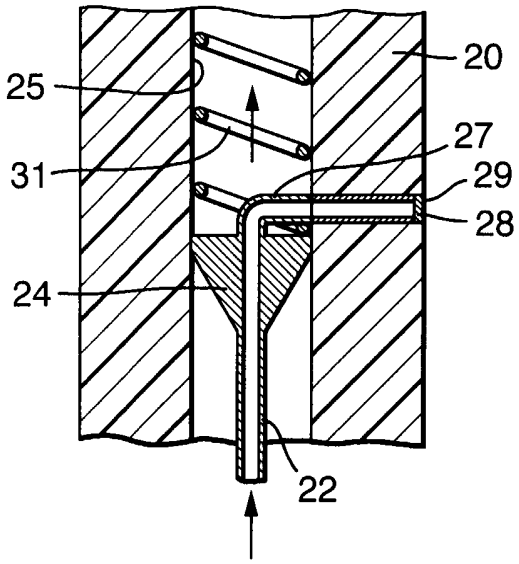


Fig.6.

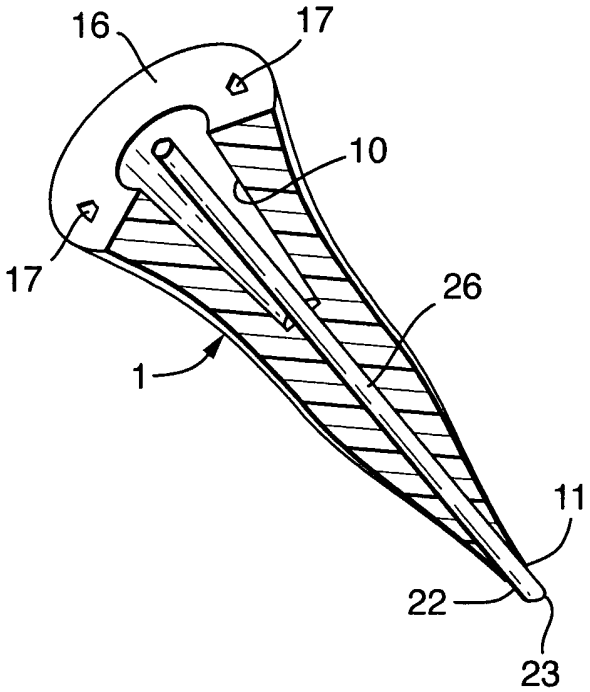


Fig.7.

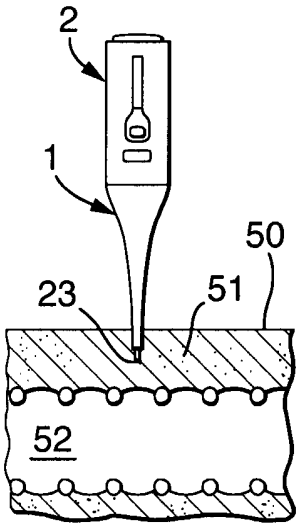


Fig.8.

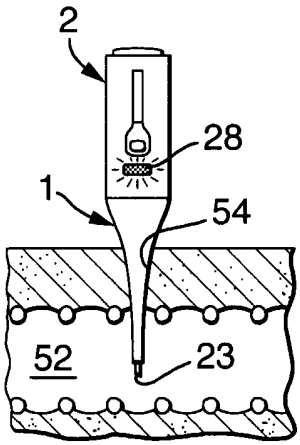


Fig.9.

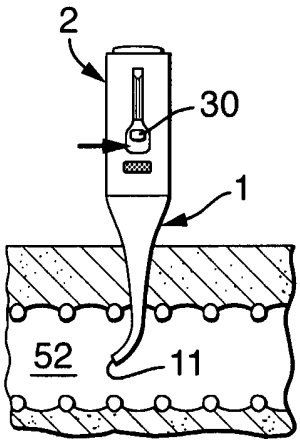


Fig.10.

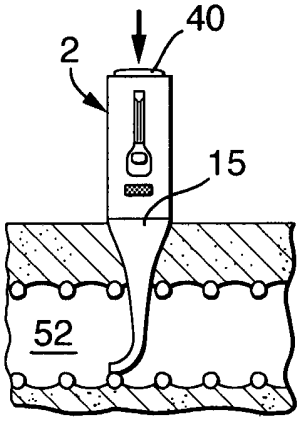


Fig.11.

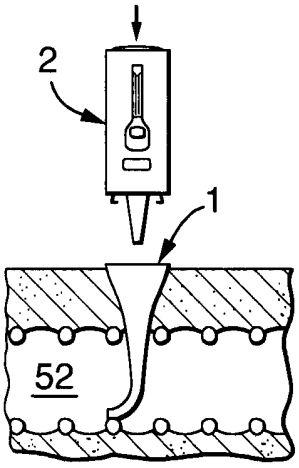


Fig.12.

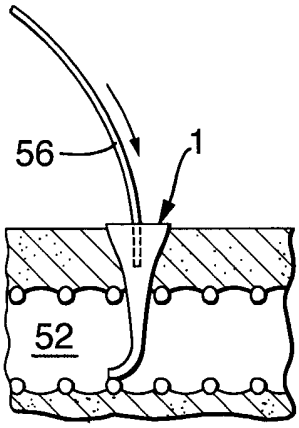


Fig.13.

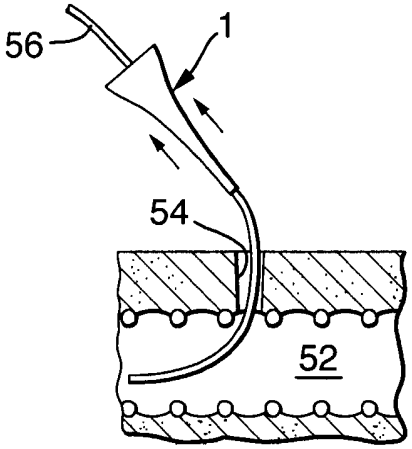


Fig.14.

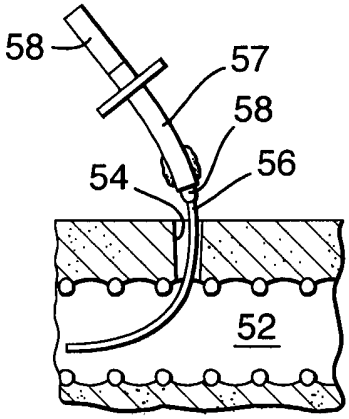
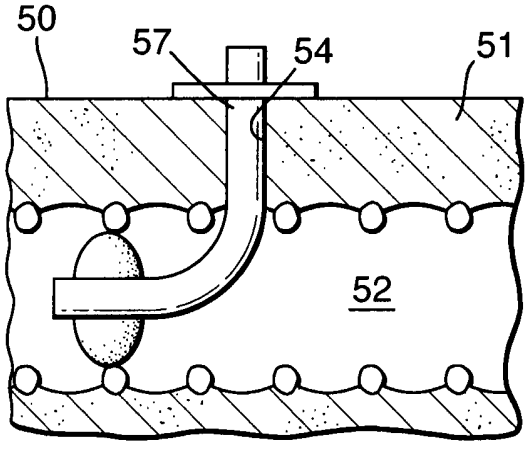


Fig.15.



TRACHEOSTOMY APPARATUS

This invention relates to tracheostomy apparatus.

Where a percutaneous or cricothyroid tracheostomy procedure is carried out it is important to know when the needle or the like has entered the trachea. One form of apparatus used for this purpose is described in GB2393398 and employs a needle with a spring-loaded rod projecting from the patient end of the needle. Entry to the trachea is detected by observing forward movement of the rod as the tip of the needle clears overlying tissue. Other techniques involve listening for the sound of air passing through a hollow needle or feeling loss of resistance to movement of a plunger in a syringe connected to a needle when the trachea is entered.

It is an object of the present invention to provide alternative tracheostomy apparatus.

According to one aspect of the present invention there is provided tracheostomy apparatus including an elongate member having a cutting tip adapted to penetrate tissue overlying the trachea, the elongate member having a gas passage extending therethrough, the handle including a carbon dioxide indicator responsive to gas flowing through the gas passage and arranged to provide an indication in response to exhaled breath in the trachea that flows through the gas passage.

The carbon dioxide indicator is preferably a visual indicator, such as a colour change indicator. The speed of response of the indicator is preferably such as to provide an

alternating response as the patient breathes. The gas passage is preferably provided at least in part by the bore of a hollow needle, the patient end of which provides the cutting tip. The elongate member may include an outer tapered sleeve within which the needle extends and the needle may be retractable relative to the sleeve to a position in which the cutting tip of the needle is concealed. The handle preferably includes resilient means arranged to retract the needle. The needle is preferably retractable to a position in which its cutting tip is located within the handle. The sleeve is preferably separable from the handle. The sleeve may have a preformed curve and be held straight by the needle while inserted in the sleeve.

According to another aspect of the present invention there is provided medico-surgical apparatus including a handle assembly and a sleeve, the handle assembly including an elongate member having a cutting tip adapted to penetrate tissue overlying a body cavity, the elongate member being arranged to be displaceable from a first position in which its cutting tip protrudes from the forward end of the sleeve member to a second position where its cutting tip is enclosed within the handle assembly, and the sleeve being removably connected with the handle assembly such that the handle assembly and the elongate member can be removed from the sleeve when the forward end of the sleeve is located in the body cavity.

The sleeve preferably has a tapering external surface adapted to dilate tissue during insertion. The apparatus may be arranged such that the sleeve cannot be separated from the handle until the needle has been retracted into the handle.

Tracheostomy apparatus according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1	is a perspective view of the assembled apparatus;
Figure 2A	illustrates the patient tip of the apparatus with the needle in place;
Figure 2B	illustrates the patient tip of the apparatus with the needle retracted;
Figure 3	is a cutaway view of the handle and needle separated from the sleeve member;
Figure 4	shows a part of the mechanism by which the handle is retained with the sleeve member;
Figure 5	is a sectional view showing a part of the handle and needle;
Figure 6	is a cutaway view of the sleeve member with the needle extended; and
Figures 7 to 15	show steps in use of the apparatus.

With reference first to Figures 1 to 6, the apparatus comprises two separable parts, namely a sleeve member 1 and a handle and needle assembly 2.

The sleeve member 1 is a moulded plastics component of circular section, which is tapered along its length and has an axial bore 10 (Figure 6). At its forward, patient end 11 it has a portion 12 with a thin wall of a constant, relatively small diameter. This continues rearwardly as a tapered portion 13, which increases in external diameter rearwardly to a third portion 14 of a larger constant diameter. The rear end portion 15 of the sleeve member 1 tapers again to a larger diameter. As shown in Figure 6, the rear end face 16 of the sleeve is flat and has two diametrically positioned locking recesses 17, the purpose of which will be explained later.

The patient end portion 12 of the sleeve member 1 has a preformed curve, as shown in Figure 2B, but is held straight by the needle when this is inserted.

The handle assembly 2 has a cylindrical housing 20 at its rear end, the external diameter of which is substantially the same as the largest part 15 of the sleeve member 1 and is shaped to be gripped comfortably and firmly by the hand. At its forward patient end, the housing 20 has a conical nose 21 of reduced diameter such that it can extend within the rear part of the bore 10 through the sleeve member 1. The handle assembly 2 contains a rigid, hollow metal needle 22, which extends axially, projecting through the nose 21 along the bore 10 of the sleeve 1 to project a short distance from its patient end tip 11. At its forward, patient end, the needle 22 has a sharp, bevelled cutting tip 23 suitable for cutting through tissue overlying the trachea. The thin wall of the forward end section 12 of the sleeve 1 ensures that there is a relatively smooth continuation between the external surface of the protruding part of the needle 22 and the exterior of the sleeve.

The rear end of the needle 22 has an enlarged head 24 of conical shape located as a sliding fit within a bore 25 along the handle 2. The bore 25 continues through the nose 21 with the shaft 26 of the needle 22 projecting along the nose. Above the head 24, the needle 22 is bent to one side to form a short lateral portion 27 (Figure 5), which extends to one side. The lateral portion 27 has an open end which aligns with a colorimetric carbon dioxide indicator 28 mounted in a small window 29 towards the lower end of the housing 20. Typically, this would be a porous material, such as paper or fabric impregnated with a chemical that undergoes a reversible colour change when exposed to carbon dioxide at levels found in exhaled breath. Such carbon dioxide indicators are used, for example, in the carbon dioxide indicator sold by Smiths Medical International Limited under the trade mark CO_2Clip. When exposed to a flow of exhaled breath from a patient, the indicator 28 changes colour to provide a visual change of exposure to exhaled breath. The speed of response may be selected to be such that the indicator 28 reverts to its normal colour between breaths so that it produces an alternating colour change. The indicator need not be a chemical colour-change indicator but could include an electrical carbon dioxide indicator and a display.

The head 24 of the needle 22 is connected to a resilient button 30 exposed on the outside of the housing 20 just above the carbon dioxide indicator 28. The button 30 has a latch member (not shown) that engages the needle head 24 to prevent rearward displacement of the needle from its fully extended position against the action of a coil spring 31 or other resilient means. The coil spring 31 extends along the bore 25 and is fixed at one end with the head 24 of the needle 22 and at its other end with the rear end of the housing 20, with the spring in tension when the needle is in its forward position. The button 30 is arranged such

that, when the user pushes it in, it releases the latch member and allows the spring 31 to pull the needle 22 along the bore 25 up into the housing 20 to a rear position. In this rear position, the sharp cutting tip 23 of the needle 22 is located to the rear of the forward end of the nose portion 21 so that the entire length of the needle is safely contained within the housing 20 preventing any risk of needle stick. A window 32 in the side of the housing 20 enables the user to check whether or not the needle 22 has been withdrawn to a safe, retracted position.

At the upper end of the housing 22 a handle-disconnect button 40 is linked to two locking arms 41 extending forwardly along the length of the housing. At its forward end, each arm 41 is shaped with an inwardly-directed locking finger 42 at its tip and a ramp formation 43 a short distance rearwardly. The forward end of each arm 42 projects a short distance beyond the forward end of the housing 20 and enters a respective one of the locking recesses 17 at the upper end of the sleeve 1. The locking fingers 42 engage under a shallow ledge 44 within the recess 17 to secure the sleeve 1 with the handle 2. The ramp formation 43 on each arm 41 aligns with a cooperating ramp formation 45 in the housing 20 such that when the button 40 is pushed in to push the locking arms 41 forwardly, the ramp on each arm slides along the respective ramp in the housing so that the forward end of the finger 42 is pushed outwardly. It can be seen that this causes the locking fingers 42 to disengage from the locking recesses 17 and enables the handle 2 to be removed from the sleeve 1. It will be appreciated that the button 40 used to disengage the handle 2 from the sleeve 1 could also be used to retract the needle 22 into the housing 20. Alternatively, the handle disengage button 40 could be prevented from being activated until the needle 22 had been retracted. Either arrangement would ensure that the handle could not be withdrawn from the sleeve with the needle in an extended position.

The method of using the apparatus will now be described, by way of example, with reference to Figures 7 to 15 of the accompanying drawings.

Initially, as shown in Figure 7, the handle 2 is assembled on the sleeve 1 and the cutting tip 23 protrudes from the end 11 of the sleeve, with the needle holding the sleeve in a straight, axial shape. The user pushes the tip 23 through the skin 50 (in some cases a preliminary scalpel cut may be made) and into the tissue 51 overlying the trachea 52. As the sleeve 1 is pushed through the tissue 51 with the needle 22, its tapering shape dilates the passage 54 through the tissue slightly. While the tip 23 of the needle 22 is being pushed through the tissue 51, its end is blocked so there is no gas flow along its bore. When the tip 23 of the needle 22 enters the trachea 52, as shown in Figure 8, a part of the gas flowing along the trachea is channelled along the bore of the needle to emerge out of the lateral portion 27 of the needle and flow onto the carbon dioxide indicator 28. When the patient exhales, the carbon dioxide content of the exhaled breath is sufficient to change the colour of the indicator 28, thereby providing a clear visual indication to the user that the trachea 52 has been entered. The user then presses the needle retract button 30 to allow the spring 31 to withdraw the needle 22 out of the sleeve 1 and fully into the housing 20, as shown in Figure 9. Because the sleeve 1 is no longer constrained by the needle 22 being within it, it is free to revert to its natural, preformed shape where its tip 11 bends caudally along the trachea 52, directed towards the bronchi. Figure 10 shows the apparatus being pushed in further, there being no risk of damage to the posterior wall of the trachea 52 because the needle 22 has been retracted and the sleeve 1 is relatively flexible and atraumatic. The apparatus is pushed in until the rear end 16 of the sleeve 1 is substantially level with the skin 50, so that the rear end portion 15 of

the sleeve further expands the passage 54 through the neck tissue 51. The next step, as shown in Figure 11, is to press the handle disconnect button 40 to release the handle 2 from the sleeve 1. The handle 2 can then be disposed of safely with the needle 1 fully enclosed within it. A flexible guide wire 56 or other flexible, elongate member is then pushed along the sleeve 1 so that one end locates inside the trachea 52 and the other end extends externally, as shown in Figure 12. The curve at the forward end 11 of the sleeve 1 helps guide the guidewire 56 caudally. The sleeve 1 can now be withdrawn along the guidewire 56, which is left in place, in the manner shown in Figure 13. The guidewire 56 is then used as a track along which a tracheostomy tube 57 and obturator 58 is slid through the dilated passage 54 through the neck tissue 51 and into the trachea 52, as shown in Figure 14. The guidewire 56 and obturator 58 are then removed to leave the tracheostomy tube 57 in position, as shown in Figure 15.

The apparatus of the present invention enables the user to penetrate the trachea and enlarge the passage into the trachea with a single unit that also provides an accurate indication of penetration and encloses the needle after use. The apparatus enables a very simple and quick procedure to be used to provide access to the trachea with a low risk of patient trauma and danger from exposed sharps.

CLAIMS

1. Tracheostomy apparatus including an elongate member having a cutting tip adapted to penetrate tissue overlying the trachea, the elongate member having a gas passage extending therethrough, wherein the handle includes a carbon dioxide indicator responsive to gas flowing through the gas passage and arranged to provide an indication in response to exhaled breath in the trachea that flows through the gas passage.

2. Tracheostomy apparatus according to Claim 1, wherein the carbon dioxide indicator includes a visual indicator.

3. Tracheostomy apparatus according to Claim 2, wherein the indicator includes a colour-change indicator.

4. Tracheostomy apparatus according to Claim 2 or 3, wherein the speed of response of the indicator is such as to provide an alternating response as the patient breathes.

5. Tracheostomy apparatus according to any one of the preceding claims, wherein the gas passage is provided at least in part by the bore of a hollow needle, the patient end of which provides the cutting tip.

6. Tracheostomy apparatus according to Claim 5, wherein the elongate member includes an outer tapered sleeve within which the needle extends, and wherein the

needle is retractable relative to the sleeve to a position where the cutting tip of the needle is concealed.

7. Tracheostomy apparatus according to Claim 6, wherein the handle includes resilient means arranged to retract the needle.

8. Tracheostomy apparatus according to Claim 6 or 7, wherein the needle is retractable to a position in which its cutting tip is located within the handle.

9. Tracheostomy apparatus according to any one of Claims 6 to 8, wherein the sleeve is separable from the handle.

10. Tracheostomy apparatus according to any one of Claims 6 to 9, wherein the sleeve has a preformed curve and is held straight by the needle while inserted in the sleeve.

11. Medico-surgical apparatus including a handle assembly and a sleeve, wherein the handle assembly includes an elongate member having a cutting tip adapted to penetrate tissue overlying a body cavity, wherein the elongate member is arranged to be displaceable from a first position in which its cutting tip protrudes from the forward end of the sleeve member to a second position where its cutting tip is enclosed within the handle assembly, and wherein the sleeve is removably connected with the handle assembly such that the handle assembly and the elongate member can be removed from the sleeve when the forward end of the sleeve is located in the body cavity.

12. Apparatus according to Claim 11, wherein the sleeve has a tapering external surface adapted to dilate tissue during insertion.

13. Apparatus according to Claim 9 or 12, wherein the apparatus is arranged such that the sleeve cannot be separated from the handle until the needle has been retracted into the handle.

14. Tracheostomy apparatus substantially as hereinbefore described with reference to the accompanying drawings.

15. Any novel and inventive feature or combination of features as hereinbefore described.

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Application No:	GB0604378.0	**Examiner:**	Mr Alex Robinson
Claims searched:	1 to 10	**Date of search:**	30 June 2006

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
Y	1 to 6	US 4821710 A (Greunwald)Whole document, note lines 66 to 68 of column 2.
Y	1 to 6	EP 0257916 A1 (Fehder) Whole document.
Y	1 to 6	US 5095900 A (Fertig) Whole document.
Y	1 to 6	US 5669380 A (Garry) Whole document.
Y	1 to 6	GB 2393398 A (Smiths Group) Whole document.
Y	1 to 6	US 4978334 A (Toye) Whole document.

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

A5R

Worldwide search of patent documents classified in the following areas of the IPC

A61M

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI.